# International Drug Control and Access to Controlled Medicines in Brazil:

# Changes and Tensions in International Regimes

# (2009-2019)

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Submitted to Swansea University in fulfilment of the requirements for the degree of Doctor of Philosophy

**Swansea University**

**2022**

Summary

Millions of people suffering pain are faced with barriers that prevent them from alleviating unbearable symptoms. This situation is of humanitarian concern and as such raises several key questions: What causes this situation? To what extent and in which ways does the international drug control system contribute to this problem? What is the role of transnational advocacy networks in this process? In answering these questions this study analyzes tensions created by the intersection between the international drug control and human rights regimes. It is focused on the behavior of States that, in the attempt to comply with drug control obligations, undermine the protection of the right to health in the area of access to opioids for pain treatment. To discuss this broad tension in a comprehensive manner, this thesis identifies three relevant levels: Tensions between (1) national sovereignty and States' international commitments; (2) systematic institutional tensions between the World Health Organizations and the International Narcotics Control Board, and (3) tensions between adequate access to medicines and efforts to eliminate illicit markets. Based on field work interviews, this thesis examines problems faced by patients and practitioners at the national level to trace the reasons for the lack of adequate access to analgesic opioids in Brazil, which is the object of a case study. The analysis covers the period between 2009 - when The Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem was adopted at the Commission on Narcotic Drugs - and 2019, the target date to review achievements of the previous ten years.

DECLARATIONS AND STATEMENTS

DECLARATION

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

Signed [redacted] (candidate)

Date: 21 June 2022

STATEMENT 1

This thesis is the result of my own investigations, except where otherwise stated. Other sources are acknowledged by footnotes giving explicit references. A bibliography is appended.

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Date: 21 June 2022

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I hereby give consent for my thesis, if accepted, to be available for photocopying and for inter-library loan, and for the title and summary to be made available to outside organisations.

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Date: 21 June 2022

**Introduction** ..... **13**

1. Context and definitions ..... 13

2. Research questions ..... 17

3. Case Study: Brazil ..... 21

4. Tensions between drug control and human rights regimes ..... 22

5. Outline of chapters ..... 28

**Chapter 1** ..... **31**

**Themes addressed, theoretical approach and methods** ..... **31**

1. Introduction ..... 31

2. Levels of tensions ..... 32

2.1. National sovereignty and international commitments ..... 32

2.2. International drug control and human rights ..... 39

2.3. Intra-regime complexity ..... 45

2.4. Access to medicines and illicit markets ..... 49

3. Methods used and data collection ..... 51

3.1. First part: historical antecedents ..... 53

3.2. Second part: Tensions involving the international drug control regime 55

3.3. Third part: single case study about access to opioids in Brazil ..... 58

4. Research ethics ..... 62

5. Conclusion ..... 63

**Chapter 2** ..... **64**

**The foundations of the international drug control regime and the demonization of opium** ..... **64**

1. Introduction ..... 64

2. Drug treaties pre-United Nations and the demonization of opium ..... 66

2.1. Antecedents of the Shanghai Commission ..... 66
2.2. Origins of Prohibitionism ..... 70
3. Drug control treaties and access to controlled medicines ..... 76
3.1. Medical and scientific use of drugs - 1909 ..... 76
3.2. The prohibited substances - 1912 ..... 79
3.3. Estimating medical use -1925 ..... 82
3.4. Schedules and limited manufacture -1931 ..... 85
3.5. Penal sanctions for drug trafficking - 1936 ..... 91
4. Conclusion ..... 95
**Chapter 3 ..... 97**
**The expansion of prohibitionism in the international drug control regime since 1945 ..... 97**
1. Introduction ..... 97
2. The expansion of prohibition in the international drug control regime ..... 98
3. The 1953 Opium Protocol ..... 100
3.1. Anslinger's strategy and methods ..... 101
3.2. US Foreign Policy and the Single Convention ..... 106
4. The Single Convention 1961: health and drug control ..... 110
4.1. Purposes of the Convention ..... 110
4.2. Health Concerns in the Single Convention 1961 ..... 114
4.3. INCB's composition and the power of embargo ..... 120
4.4. Scheduling system ..... 127
4.5. Control and prohibitionism ..... 129
5. New treaties post Single Convention ..... 133
6. Conclusion ..... 134
**Chapter 4 ..... 138**

**The emerging issue of access to controlled medicines in the international drug control regime (2009-2013) ..... 138**

1. Introduction ..... 138

2. The context before the 2009 Political Declaration ..... 140

2.1. The HIV-AIDS Epidemic in the 1980s and 1990 ..... 140

2.2. Tensions between the INCB and WHO ..... 146

2.2.1. The Access to Controlled Medicines Programme ..... 146

2.2.2. Harm Reduction in Switzerland ..... 150

2.2.3. Ketamine ..... 152

3. Human rights meet drug control: The 2009 Political Declaration ..... 157

3.1. Preparing for changes in the regime ..... 163

4. Conclusion ..... 168

**Chapter 5 ..... 170**

**Changes in international drug control regime and tensions with the human rights regime (2014-2019) ..... 170**

1. Introduction ..... 170

2. 2014 Joint Ministerial Statement and access to medicines ..... 172

3. UNGASS, INCB and changes in the regime ..... 174

4. Ketamine, tramadol and civil society ..... 180

5. UNGASS, civil society and tensions between regimes ..... 183

5.1. Drafting Process ..... 184

5.2. The Outcome document and controlled medicines ..... 189

5.3. The Outcome document and human rights ..... 191

6. The post UNGASS period ..... 195

7. UN bodies adapting to changes in the regime ..... 198

8. The 2019 Political Declaration ..... 200

9. Conclusion ..... 202

**Chapter 6 ..... 205**

**Case Study: The international drug control regime, Brazilian drug policy and access to opioids in Brazil ..... 205**

1. Introduction ..... 205

2. Endogenous Prohibitionism ..... 206

3. Brazilian drug control and international drug treaties ..... 212

4. Estado Novo's dictatorship and the adoption of Executive Order 891/1938 on drug policy ..... 215

4.1. Scarcity of opioids in Brazil during the Second World War ..... 219

5. The Cold War and the legislation reforms in the civil-military dictatorship (1964-1985) ..... 222

6. The democratic period and shifts in drug policy ..... 226

6.1 Harm reduction in Brazil ..... 229

7. Conclusion ..... 234

**Chapter 7 ..... 237**

**Brazil: consequences of a prohibitionist approach on access to opioids ..... 237**

1. Introduction ..... 237

2. Data on access to opioids in Brazil ..... 240

3. Opioids provided by the Brazilian Unique Health System (SUS) ..... 246

3.1. Onerous Regulatory Framework ..... 247

3.2. Gaps in the education of health care professionals ..... 252

3.3. Corruption and poor management ..... 259

4. Drug trafficking, militias and access to medicines in Brazil ..... 260

5. Difficulties to find medicines in commercial pharmacies ..... 265

6. Gaps and barriers in a complex health system ..... 267

7. Primary Health Care (PHC) and access to opioids ..... 269

8. Local Cultural Attitudes ..... 275

9. Logistics of opioids in the Amazon region ..... 278

10. Conclusion ..... 280

**Conclusion of the dissertation ..... 282**

**Appendices ..... 290**

**Glossary ..... 300**

**Bibliography ..... 301**

**Acknowledgements**

The PhD journey is like climbing a mountain. Keeping the pace is important to reach the peak, despite steep stretches with many rocks and the view of the abyss. I would like to thank my supervisors Prof. David Bewley-Taylor and Dr. Luca Trenta for the invaluable guidance and endless patience to teach me how to organize my thoughts and motivating me in different phases of this work.

My deepest gratitude goes to Martin Matter, who supported me all the way, in different manners and all the time. I thank him for sharing his life and immense knowledge with me and our daughters, Olívia and Clarissa.

Special thanks go to Dr. Katherine Pettus, who believed in me and, with generosity, introduced me to the universe of access to controlled medicines and showed me the importance of palliative care.

I am thankful to Elizabeth Mattfeld for all she thought me during the period we worked together.

I am also grateful to family and friends who assisted me in different ways to conclude this work.

Without them this work would not exist.

I am grateful for this journey.

**List of illustrations and tables**

*Figure 1*- BRAZIL, States and capitals, p. 239.

*Figure 2* - Average consumption of opioid analgesics in South America, 2001-2003, 2007-2009 and 2011-2013, p. 241.

*Figure 3* - Opioid consumption in Brazil in Morphine Equivalence, p. 242.

*Figure 4* - Opioid consumption in Germany in Morphine Equivalence, p. 243.

**Abbreviations**

ACMP -Access to Controlled Medicines Programme

ANVISA – Brazilian Health Regulatory Agency

CND - Commission on Narcotic Drugs

CND – Commission on Narcotic Drugs

CNFE – Standing Committee of Narcotics Control/Conselho Nacional de Fiscalização de Entorpecentes

DND – Division on Narcotic Drugs

DSB – Drug Supervisory Board

ECOSOC- Economic and Social Council

FBN - Federal Bureau of Narcotics

IAHPC – International Association for Hospice and Palliative Care

ICESCR -International Covenant on Economic Social and Cultural Rights

IDCR – International Drug Control Regime

IDCS – International Drug control system

IDU – Injection Drug User

INCB - International Narcotics Control Board

MoH – Ministry of Health

OAC - Opium Advisory Committee

OHCHR - Human Rights Office of the High Commissioner

OPB - Opium Control Board

PCOB – Permanent Control of Opium Board

PHC - Primary Health Care

SUS – Unique Health System/Sistema Único de Saúde

UNODC – United Nations Office for Drugs and Crime

WHA – World Health Assembly

WHO - World Health Organization

S-DDD – Defined daily doses for statistical purposes

# Introduction

## 1. Context and definitions

The adequate use of controlled medicines such as those controlled under the international drug treaties is essential to health. Drugs used to treat moderate to severe pain include non-opioids, opioids and adjuvant medicines, but opioids are the main pillar of treatment of chronic pain management.

Despite the universally recognized indispensability of narcotic drugs in treating pain in medical settings, moderate to severe pain is often under-treated, which is an enormous problem worldwide. Over eighty per cent (84.25%) of the world's population lacks adequate access to opioid medications for pain control. Australia, Canada, New Zealand, the United States, and several European countries accounted for more than 90% of the global consumption of opioid analgesics while Low-and-Middle-Income Countries (LMICs) consumed only 10% of global opioids.[1] Millions of people suffering pain are faced with barriers that prevent them from alleviating unbearable symptoms. This situation is obviously of humanitarian concern.

This dissertation seeks to explore the reasons behind of the lack of adequate access to opioids, by examining to what extent the international drug control system plays a role on this situation. This dissertation highlights the tensions and frictions between international drug control and access to medicines. To illustrate these tensions, the dissertation adopts a case study to show how international drug control affects access to opioids in Brazil. This country was chosen for an in-depth analysis because according to the International Narcotics Control Board, Brazil has an adequate consumption of opioids, in comparison to other States.[2] But in fact, there are still several barriers present at the national level that lead to a low consumption of opioids

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[1] Stephen R. Connor, *Atlas of Palliative Care* , ed. by Stephen R. Connor, 2nd edn (London: Worldwide Hospice Palliative Care Alliance, WHO, 2020) , second edition, London, 2020, p. 34.

< http://www.thewhpca.org/resources/global-atlas-on-end-of-life-care> > [Accessed 31 May 22].

[2] International Narcotics Control Board (INCB), Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes, Indispensable, adequately available and not unduly restricted,(E/INCB/2015/1/Supp.1)(New York: UN, 2016)

https://www.incb.org/documents/Publications/AnnualReports/AR2015/English/Supplement-AR15_availability_English.pdf [accessed 31 May 2022], p. 7.

among the Brazilian population using the public health system. Approximately 75% of the Brazilian population rely solely on the public health system.[3]

It is necessary at this point to include an important note on definitions. While sometimes confused, the related categories of opiates and opioids are distinct. Opioids are defined by the United Nations Office on Drugs and Crime (UNODC) as 'a generic term that refers both to opiates and their synthetic analogues (mainly prescription and pharmaceutical opioids) and compounds synthesized in the body.' Meanwhile, again according to the UNODC, opiates are a 'subset of opioids comprising various products derived from the opium poppy plant, including opium, morphine and heroin.'[4]

Opiates and most opioids are internationally controlled medicines classified under the scheduling system of the Single Convention on Narcotic Drugs of 1961 (as amended by the 1972 Protocol), according to their propensity to cause dependence. International drug control is established by the system formed by Single Convention, the Convention on Psychotropic Substances of 1971 and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. This treaty framework can be regarded as an international drug control regime. As Ethan Nadelmann notes, the vast majority of states count themselves as members of the global drug prohibition regime.[5] Three core bodies operate within this regime, the International Narcotics Control Board (INCB or Board), the CND and the World Health Organization (WHO) and state governments. Stephen Krasner defines regimes as "sets of implicit or explicit principles, norms, rules and decision-making procedures around which actors' expectations converge in a given area of international relations."[6]

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[3] IBGE, *Tabela 7573 – Pessoas que tinham algum plano de saúde médico*, (Rio de Janeiro: IBGE, 2022 https://sidra.ibge.gov.br/tabela/7573#resultado [Accessed 13 June 2022].

[4] United Nations Office for Drugs and Crime, *World Drug Report, Booklet 3 Depressants, 2019*, (Vienna: UN 2019), https://wdr.unodc.org/wdr2019/prelaunch/WDR19_Booklet_3_DEPRESSANTS.pdf , [accessed 31 May 2022] p.51.

[5] Ethan Nadelmann, Global Prohibition Regimes, *International Organization* 44. 4 (1990), 479-526 (p. 503)

<http://www.jstor.org/stable/2706851 > [Accessed 31 May 2022].

[6] Stephen Krasner, 'Structural Causes and Regime Consequences: regimes as intervening variables', *International Organization*, 36.2 *International Regimes* (1982), 185-205 (p.186)

<https://pos-graduacao.uepb.edu.br/ppgri/files/2016/02/Krasner-Structural-Causes-and-Regime-Consequencies-Regime-as-Intervening-Variables.pdf> [Accessed 31 May 2022] .

In this dissertation, the overarching theory of constructivism is used to examine norm dynamics.

Within the international system norms are codified through treaties and conventions.[7] According to Martha Finnemore and Kathryn Sikkink, norms have a life cycle that includes norm emergence, norm cascade - when norm leaders socialize other states to become norm followers - and norm internalization.[8] Scholars also observed that norms sometimes degenerate. As Diana Panke and Ulrich Petersohn note, the necessary condition for the degeneration of a norm is that some actors experience mismatch between their preferences, beliefs or identities and develop an interest in violating a norm.[9]

The Commission on Narcotic Drugs (CND) was established by the Economic and Social Council (ECOSOC) in 1946 to assist the ECOSOC in supervising the application of the international drug control treaties. CND reviews and analyzes the global drug situation, considering supply and demand reduction. It takes action through resolutions and decisions and decides on the control of substances under the three drug control conventions.[10] CND is the policy making body within the UN system on drug control issues. It supervises the application of international control treaties and acts as the governing body of UNODC since 1991.[11] CND has the specific authority pursuant to the Single Convention to add, remove and transfer drugs among the treaty's four schedules of controlled substances.[12]Any changes to drug scheduling[13] under the

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[7] Diana Panke and Ulrich Petersohn, 'Why international norms disappear sometimes?' *European Journal of International Relations* 18.4 (2011), pp. 719-742 ( p. 721)

https://journals.sagepub.com/doi/pdf/10.1177/1354066111407690 [Accessed 17 June 2022].

[8] Martha Finnemore and Kathryn Sikkink, 'International Norm Dynamics and Political Change', 52.4 (1998) pp. 887-917 (p.895) < https://pos-graduacao.uepb.edu.br/ppgri/files/2016/02/Finnemore-and-Sikkink.-International-Norm-Dynamics-and-Political-Change-1.pdf> [Acessed 31 May 2022].

[9] Panke and Petersohn, p. 734.

[10] United Nations on Narcotic Drugs (UNODC,) *United Nations Commission on Narcotic Drugs (CND)* , para. 2-4 of 13, <https://www.unodc.org/unodc/en/commissions/CND/index.html > [Accessed 31 May 2022].

[11] UNODC, *CND*, para. 1-13.

[12] World Health Organization (WHO), *Expert Committee on Drug Dependence (ECDD)*, para. 1 of 1. <https://www.who.int/groups/who-expert-committee-on-drug-dependence/about> [Accessed 31 May 2022].

[13] Scheduling a substance means to include it in international control, under the drug conventions, according to its potential of dependence. The schedules vary according to the degree of risk of dependence. A substance can be removed from international control or move from one schedule to another. Rules and procedures on how to schedule a substance depend on what is established by each convention. More on scheduling procedures in: UNODC, *Scheduling Procedures under the International Drug Control Conventions*, (Vienna: United Nations 2020)

Single Convention must be made in accordance with the findings and recommendations of the WHO's Expert Committee on Drug Dependence (ECDD), which has the mandate to review substances and make recommendations to CND, according to evidence of their dependence and therapeutic applications.[14] The United Nations Office on Drugs and Crime (UNDOC), of which the INCB's secretariat is a part, supports member states to implement drug control conventions to ensuring access to controlled substances for medical purposes[15].

The INCB has a twofold mandate. 1. Regarding the licit manufacture of, trafficking, and use of drugs, the INCB's mandate is to ensure, in cooperation with governments, that supplies of drugs are available for medical and scientific uses and that diversion of drugs from licit sources into illicit channels does not occur. 2. Regarding the illicit manufacture of, trafficking, and use of drugs, the INCB's mandate is to identify weaknesses in national and international drug control systems, and to correct such situations.[16]Article 9 of the Single Convention establishes the INCB as the lead organ of the regime with authority to implement the treaty together with States parties and provides the aims of the Convention.[17] They are expressed in paragraph 4, which reads that the INCB, in collaboration with States, shall "limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes to ensure their availability for such purposes (…) and prevent illicit cultivation, production and manufacture of, and illicit trafficking in and use of drugs."[18] Article 14 of the Single Convention, Measures by the Board to ensure the execution of provisions of the Single Convention, the INCB is granted the power to ask for explanations from governments that are endangering the aims of the Convention.[19]

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<https://www.unodc.org/documents/commissions/CND/Scheduling_Resource_Material/19-11955_Drug_Conventions_eBook_2.pdf>[Accessed 17 June 2022], p. 2.

[14] WHO, Expert Committee on Drug Dependence, para 1.

[15]UNODC, *UNODC work is based in five areas of activity* <https://www.unodc.org/images/about-unodc/activity-areas_1100x1251px.jpg> [Accessed 31 May 2022].

[16] International Narcotics Control Board (INCB), *Mandate and functions*, paras. 1-9 of 14, <https://www.incb.org/incb/en/about/mandate-functions.html.> [Accessed 31 May 2022].

[17] Allyn L. Taylor, *Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs*, (Georgetown University Law Center 2008) 556-570 (p. 560). <http://scholarship.law.georgetown.edu/oispapers/6.> [Accessed 31 May 2022].

18 United Nations Treaty Collection (UNTC), *Single Convention on Narcotic Drugs 1961 as Amended by The Protocol Amending the Single Conventions 1961*, Treaty Series, vol 976 No. 14152 (New York: United Nations 1961) pp.105-292 https://treaties.un.org/doc/Publication/UNTS/Volume%20976/volume-976-I-14152-English.pdf [Accessed 17 June 2022].

[19] UNTC, *Single Convention 1961 as Amended*, vol 976 No. 14152, (p.114).

Substances used as medicines, such as opioids, are included in the international drug conventions' schedules and are internationally controlled because while their adequate use is essential to health, they may provoke health consequences in case of misuse and abuse. These substances also appear on the World Health Organization's Model List of Essential Medicines. That is to say they are deemed indispensable for the treatment of medical conditions. As opioids such as morphine and codeine are on the WHO list of essential medicines, States must provide these medications as part of their core obligations under the right to health, expressed in the Charter of the United Nations, the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights. As such, they must ensure that they are both available in adequate quantities and physically and financially accessible for those who need them.[20] Although States have international obligations both under the international drug control regime and the human rights regime, regarding access to medicines, most of the countries fail to comply with them.

## 2. Research questions

The problem of the tensions and frictions between the international drug control regime and access to controlled medicines will be analyzed in four dimensions. First, the dissertation explores the dilemma presented in the aims of the convention of ensuring availability of medicines while preventing their diversion, and their implications for the global lack of access to opioids. The second dimension refers to the responsibility and roles of the INCB, UNODC, Member States and WHO to ensuring the availability of morphine and other opioids. The third dimension refers to Member States that failed to meet their obligations in the international drug control system, and in doing so also failed to meet their obligations within the human rights regime, regarding the right to health. The fourth dimension refers to other factors alongside with the international drug control system that hinders access to medicines. These are weak healthcare system, lack of clinical education and training of health

[20] Diederik Lohman, D., Rebecca Schleifer, R. & Joseph Amon, J.J. Access to pain treatment as a human right. *BMC Med* **8,** 8 (2010), p. 6 https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-8-8#citeas [Accessed 31 May 2022] .

care professionals for pain management and palliative care, drug laws and medicine's restrictive national legislation, problems in procurement[21] and high prices.[22]

The aim of this dissertation is to understand the degree to which the international drug control system influences the lack of adequate access to opioids. In doing so, the dissertation also highlights how the international drug control regime may, in certain cases, drive domestic policy choices and is, in turn, influenced by unique cultural, social and economic factors from within each State. This work analyzes the reasons why, in some states, the access to opioids is inadequate, how and to what extent the international drug control system affects access to these medicines. Therefore, this work focuses on changes, shifts, and tensions in the international drug control system, highlighting aspects of the right to health between 2009 and 2019.

To understand the reasons why some countries currently face lack of adequate access to opioids, this research seeks to answer the following questions:

1. How and why have historical antecedents led to the lack of access to opioids for medical purposes in some countries?
2. How has the issue of access to medicines achieved increased importance within the international drug control system?
3. How and why have drug related health issues generated tensions within the international drug control system and with the human rights system?
4. What are the antecedents that led to the low consumption of opioids in Brazil?
5. What are the barriers to access to opioids in Brazil today and how do patients circumvent difficulties, even though the country is considered to have adequate access to opioids, according to the INCB?

This research can be divided in three parts:

1. The history of the drug control system to analyze how the use of opium and its derivates, such as morphine became restricted, covered in chapters 2 and 3.

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[21] INCB, *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes, Indispensable, adequately available and not unduly restricted* (E/INCB/2015/1 Supp.1) (Vienna: United Nations, 2015), p. 29.

[22] Global Commission on Drug Policy (GCDP), *The Negative Impact of Drug Control on Public Health- The Global Crisis of Avoidable Pain*, (2015), p.13 < http://www.globalcommissionondrugs.org/reports-files/18102015/GCODP-THE-NEGATIVE-IMPACT-OF-DRUG-CONTROL-ON-PUBLIC-HEALTH-EN.pdf> [Accessed 31 May 2022]

2. The tensions within the international drug control system, regarding access to opioids between 2009 and 2019, covered in chapters 4 and 5.
3. A single case study is carried out to establish the causes of the lack of access to opioids for pain treatment in Brazil, covered in chapters 6 and 7.

The main argument of this work is that the goal of controlling potential abuse and diversion of drugs should not hamper the availability and use of opioids for pain treatment and palliative care. The lack of availability of opioids in some countries is a problem aggravated by unduly strict regulations, which can be linked to the UN Conventions.[23] They reduce possibilities for medical improvements related to avoidable pain and other symptoms for patients in need.[24]

This dissertation contributes to show how prohibitionism has been entrenched in the international drug control system and at the national level, affecting access to controlled medicines. It makes the following original contribution to knowledge:

1) At the international level, the analysis of the development of international drug control regime is carried out through the lens of the issue of access to controlled medicines. It includes in-depth analysis of two volumes of the Official records of the negotiation of the Single Convention 1961. This shows that the system prioritized drug control through law enforcement to prevent diversion of substances but neglected the importance of the availability of controlled substances for the treatment of pain.

2) At the national level, timely research shows the reasons behind the current situation of low access to opioids in Brazil, by examining the development of the national drug control and identifying its influence on the low consumption of opioids in the country. It also examines real problems faced by patients and practitioners at the national level to trace the causes of the lack of adequate availability analgesic opioids in Brazil. One of the main original contributions of the thesis is the collection and analysis of data from interviews that show how health care professionals and patients circumvent barriers to obtain medicines, even if they must resort to drug traffickers. Interviews covered all Brazilian regions and some of them were conducted with health care

[23]GCDP, *The Negative Impact of Drug Control on Public Health*, p. 5.

[24] Anne Line Breteville-Jensen, et. Al. *Unintended Consequences of Drug Control Policies*, 2017, p. 24. (Pompidou Group, Council of Europe, 2017)

<https://rm.coe.int/costs-and-unitended-consequences-of-drug-control-policies/16807701a9> [Accessed 31 May 2022]

professionals working in areas not reached by the State. These are places hard to be accessed either because they are remote areas like the Amazon region or because of security issues and constant imminence of armed conflict, due to the presence of drug traffickers and militias, in Rio de Janeiro. Interviews were semi-structured and snowball sampling was used as a technique to recruit interviewees. Semi-structured interviews have the purpose of obtaining descriptions of the life world of the interviewees to interpret the meaning of a described phenomenon.[25] As it is noted by Chaim Noy, in the snowball sampling procedure the researcher accesses informants through contact information that is provided by other informants.[26] Nevertheless, in this work, data collection was not limited to single sampling cluster of interviewees.

3) The analysis of the elements of the right to health in the Single Convention, shows that States' obligations under the international drug control and human rights regimes have implications for the access of opioids for pain treatment. In doing this analysis, I contribute to the debate on reforms on the international drug control regime, proposing Allyn Taylor's interpretation[27] of Article 14 of the Single Convention, with views to advance the aims of the Convention, by improving access to controlled medicines.

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[25] Svend Brinkmann, 'Unstructured and Semi-structured Interviews' pp. 424-456 (p. 437), in: The Oxford Handbook of Qualitative Research, edited by Patricia Levy, Second Edition (New York: Oxford University Press 2014, 2020), Ebook.

<https://books.google.ch/books?hl=en&lr=&id=n771DwAAQBAJ&oi=fnd&pg=PA424&dq=semi+structured+interview+in+social+sciences&ots=nQLtlSsv8A&sig=Xb3Wn3kiqNXpzUKMQJ-pTJgv1Hs#v=onepage&q=semi%20structured%20interview%20in%20social%20sciences&f=false> [Accessed 17 June 2022]

[26] Chaim Noy, 'Sampling Knowledge: The Hermeneutics of Snowball Sampling in Qualitative Research', International Journal of Social Research Methodology, 11:4, 327-344, p. 330. (2008) https://www.tandfonline.com/doi/pdf/10.1080/13645570701401305?needAccess=true [Accessed 17 June 2022]

[27] Allyn Taylor L., 'Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs', The Journal of Law, Medicine & Ethics, 35.4 (2007), 556–70 (p.566-567)
https://oneill.law.georgetown.edu/publications/addressing-the-global-tragedy-of-needless-pain-rethinking-the-united-nations-single-convention-on-narcotic-drugs/ [Accessed 13 June 2022]

## 3. Case Study: Brazil

Brazil was chosen as a case study because it has a universal health coverage system, a constitution that recognizes the right to health and its opioid consumption is considered "adequate" by the INCB. Despite that, access on opioids is still low in comparison with other countries with adequate consumption of opioids, such as Germany. This tendency appears also in the Global Drug Policy Index[28] and in the assessment conducted by the European Association for Palliative Care[29], both in 2021.

According to the INCB, Brazil has a consumption of approximately 365 S-DDDs per million inhabitants per day which is considered by the Board as adequate[30], while Germany has 25,273 S-DDDs[31]. S-DDDs are defined daily doses for statistical purposes, a technical unit of measurement, created by the INCB, useful to ascertain the degree of over prescription and under prescription of opioids in each country. It is not a recommended prescription dose.[32] Consumption under 100 S-DDDs is considered very inadequate, between 100 and 200 S-DDDs is considered inadequate.[33] The case study seeks to show that even if Brazil is among countries with adequate consumption of opioids, undertreated pain is the reality of many patients that rely on the public health system.

Also, according to the Global Drug Policy Index, from November 2021, Brazil occupies the last position in the ranking of 30 researched states from all the regions in the world, based on data of 2020. The index measures how drug policies align with many of the key UN recommendations on how to design and implement drug policies in accordance with UN principles of health, human rights and development, using 75 indicators, that run across 5 dimensions: availability of international controlled substances for pain relief, development, funding availability and coverage of harm

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[28] International Drug Policy Consortium (IDPC) *Global Drug Policy Index 2021,* pp.1-87, (p.6) http://fileserver.idpc.net/library/2021-10-GDPI-Analytical-Report-Pages-EN.pdf[Accessed 31 May 2022]

[29] Some specialists do not agree with methodology used in this study. In: Eric. A. Finkelstein et. Al, A cross-country comparison expert assessments on the quality of death and dying in 2021. *Journal of Symptoms and Pain Management* (2022) 66:4 pp.419-429, (p. 4).

<https://www.jpsmjournal.com/article/S0885-3924(21)00673-4/fulltext> [Accessed 31 May 2022]

[30] INCB, *Narcotic Drugs 2014, Estimated World Requirements for 2015*, (E/INCB/2014/2) (New York: United Nations, 2015), p. 242

[31] (E/INCB/2014/2), p. 237.

[32] (E/INCB/2015/Suppl.1) p. 6.

[33] (E/INCB/2015/Suppl.1) p.17.

reduction interventions, proportionality of criminal justice responses to drugs and the absence of extreme sentencing and responses to drugs such as death sentence.[34] Brazil's profile in the index show that there is a policy prioritization of availability and accessibility of controlled medicines for the relief of pain and suffering beyond the average, but a low de facto availability of controlled medicines for pain treatment.[35]

According to a cross-country comparison of assessments on the quality of death and dying in 2021, conducted by the European Association for Palliative Care, Brazil occupies position 79/81 in the ranking. Experts from 81 countries participated on a survey including questions about 13 indicators. Managed pain and discomfort were considered the most important indicator to determine the quality of death and dying.[36]

## 4. Tensions between drug control and human rights regimes

The main tension examined in this dissertation emerges from the intersection between the international drug control and the human rights regimes. As noted by Kal Raustiala and David Victor these two regimes form a regime complex, which is an array of partially overlapping and hierarchical institutions governing a particular issue area. [37] The international drug control regime intersects with the international human rights regime through the right to health forming a regime complex. Karen Alter and Raustiala showed that regime complexes can generate regime complexity, which emerge because of the co-existence of rule density and regime complexes. [38]

In this dissertation the issue of access to opioids is examined both by the perspectives of human rights, particularly the right to health, and international drug control. The

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[34]IDPC, *Global Drug Policy Index 2021*, p. 6.

[35]IDPC, *Global Drug Policy Index 2021*, p. 61.

[36] Finkelstein et. Al, p. 4.

[37] Kal Raustiala and David Victor, "The Regime Complex for Plant Genetic Resources." *International Organization*, 58. 2, 2004, pp. 277–309, 8 p. 279) <http://www.jstor.org/stable/3877859> [Accessed 6 Jun. 2022]

[37] Karen Alter & Raustiala, The Rise of International Regime Complexity, *Annual Review of Law and Social Sciences*, 2018, UCLA School of Law, Public Law Research Paper n. 17-47

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3085043 [Accessed 6 Jun. 2022].

[38] Karen Alter & Kal Raustiala, The Rise of International Regime Complexity, *Annual Review of Law and Social Sciences*, 2018, UCLA School of Law, Public Law Research Paper n. 17-47

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3085043 [Accessed 6 Jun. 2022]

increased importance of human rights also generated intra-regime complexity within the international drug control regime, due to the overlapping of mandates of its UN bodies and different views on some drug control issues and human rights among them.

This is especially apt since, the UNODC recognized in 2008 that, in international drug control "public health was displaced into the background, more honoured in lip service and rhetoric, but less in actual practice".[39] At the same time, a huge black market of drugs has been created and attempts of law enforcement response, consumed a huge number of resources.[40]

The human rights regime was built upon The Charter of the United Nations, signed in 1945. It reaffirms "faith in fundamental human rights, in the dignity and worth of the human person, the equal rights of men and women and of nations large and small." [41]Also, in Article 1, it highlights the achievement of 'international cooperation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedom.'[42] As Jack Donnelly notes there was a gradual strengthening of international human rights regimes after 1945. If the regime's norms are important or appealing enough for states to commit themselves to them, then it is difficult to argue against promoting their further spread and implementation. However, implementation involves a major qualitative jump that most states resist.[43] National commitment is the single most important contributor to a strong regime.[44]

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[39] Commission on Narcotic Drugs (CND), Fifty-First Session, *Making Drug Control fit for Purpose: Building on the UNGASS decade*, Report by the Executive Director of the United Nations Office on Drugs and Crime as a Contribution to the Review of the Twentieth Special Session of the General Assembly, (4E/CN.7/2008/CRP.17), (2008), p. 10.

<https://www.unodc.org/documents/commissions/CND/CND_Sessions/CND_51/1_CRPs/E-CN7> [Accessed 31 May 2022].

[40] (4E/CN.7/2008/CRP.17), p. 10.

[41] International Drug Policy Consortium (IDPC) and Global Drug Policy Observatory (GDPO), *International Narcotics Control Board on Human Rights: A critique of the Report for 2019*, (2020), p. 17.

http://fileserver.idpc.net/library/INCB_HR_2019.pdf, [Accessed 31 May 2022]

[42] IDPC and GDPO, *International Narcotics Control Board on Human Rights*: *A critique of the Report for 2019*, (2020), p. 17.

[43] Jack Donnelly, *Universal Human Rights in Theory and Practice*, (Ithaca: Cornell University Press 2013), p. 192.

[44] Donnelly, p. 194.

With the creation of Commission on Human Rights and the Commission of Narcotic Drugs (CND), in 1946, both systems began to develop in parallel. The Commission on Human Rights was replaced by the Human Rights Council, which has the mandate of the Commission on Human Rights to examine, monitor and publicly report on human rights situations in specific countries and human rights violations worldwide.[45]

In the realm of drug control, the 1961 the Single Convention replaced previous drug control treaties. The elements of human rights are present in its preamble, which expresses those states are concerned with *the health and welfare of mankind*[46] The Convention also recognized *that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that* ***adequate provision must be made to ensure the availability of narcotic drugs***.[47]

The first legally binding human rights instrument was the International Covenant on Economic Social and Cultural Rights (ICESCR) signed by most UN states in 1966 and entered into force in 1976. [48]It expresses the right to health in Article 12, which states that everyone has the right to "the enjoyment of the highest attainable standard of physical and mental health" and the obligation of States "**for the provision of essential drugs**" in Article 12.2, such as opioids.[49]

The interpretation of this article was explained in further details in Comment 14, on the Right to the Highest Attainable Standard of Health, issued by the Committee on Economic, Social and Cultural Rights (CESCR), the treaty's monitoring body[50] of the ICESCR. Comment 14 expresses that States Parties to international agreements such as the ICESCR must carry out progressive realization of the right to health, a continuing obligation to move forward 'as expeditiously and effectively as possible towards the full realization of the right to health'.[51]

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[45]Human Rights Office of the High Commissioner (OHCHR), *United Nations Human Rights Council* (OHCHR), para. 1 of 23.<https://www.ohchr.org/en/hr-bodies/hrc/about-council>[Accessed 31 May 2022]

[46]UNTC, *Single Convention 1961 as Amended* , vol 976 No. 14152 , p.116.

[47] UNTC, v *Single Convention 1961 as Amended* ol 976 No. 14152 , p. 116.

[48] IDPC and GDPO, International Narcotics Control Board on Human Rights, p. 17.

[49] Office of the High Commissioner for Human Rights (OHCHR), *CESCR General Comment no. 14: The Right to the Highest Attainable Standard of Health (art. 12),* adopted at the Twentieth-second session of the Economical Social and Cultural Rights, (E/C. 12/2000/4) 2000, para. 17. <https://www.refworld.org/pdfid/4538838d0.pdf> [Accessed 31 May 2022]

[50] CESCR was established by ECOSOC in 1985

[51] (E/C. 12/2000/4), paras. 30 and 31.

As Allyn Taylor noted, the link between pain medicines and human rights was first made by the General Assembly in 2004 in a resolution[52] on access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria. It recognized that access to medication is a full element to achieving the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, thus the right to health. As such, States should adopt legislation to safeguard and promote effective access to palliative pharmaceutical products, which includes opioids.[53] A similar resolution[54] on access to medication in the context of pandemics such as HIV/Aids, Tuberculosis and Malaria was adopted in 2003 by the Human Rights Commission.[55] Taylor developed an interpretation of Article 14 of the Single Convention, showing that the INCB could implement this Article as a tool to advance the availability of opioids, thus making States and UN bodies to protect the right to health.

Comparing the development of both the international drug control and human rights regimes over the decades, the two regimes evolved in isolation from one another, "as if they exist in parallel universes"[56], as noted in 2008 by the Special Rapporteur on the Right to Health, Paul Hunt.[57]The idea that restrictive drug control policies had an impact on human rights was not common in the UN system, which had shown a remarkable indifference to examining the engagement between the two regimes. This shows that that drug control bodies, at the UN in Vienna were not interested in human rights, and UN drug bodies in Geneva had no interest in drug control.[58] In 2008, the first resolution ever on human rights was adopted at CND, which opened a political space for cooperation on human rights across the UN system, including with the human

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[52] United Nations General Assembly (UNGA), *Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria, (*A/RES/58/179), (New York: UN 2004) pp. 1-5, (p.4)<https://digitallibrary.un.org/record/509354?ln=en>[Accessed 10 june 2022]

[53] Taylor, p. 565.

[54] Office of the High Commissioner for Human Rights (OHCHR), *Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria*, (E/CN4./RES/2003/29) (Geneva: UN 2003) pp. 1-5<https://ap.ohchr.org/documents/alldocs.aspx?doc_id=4980>>[Accessed 10 june 2022]

[55] Taylor, p. 565.

[56] His comment was motivated by a visit to Sweden, where he criticized the government's failure to provide harm reduction programs for people who used drugs, on the basis that this constituted an infringement to the right to health. In: Julie Hannah and Rick Lines, 'Drug control and human rights: parallel universes, universal paralllels' in: *Research Handbook on International Drug Policy,* ed. by David Bewley-Taylor, Khalid Tinasti, (Cheltenhan, UK, Northampton, MA, USA, Edward Elgar Publishing 2020), pp 225-247, (p. 225).

[57]Hannah and Lines, p.225.

[58] Hannah and Lines, p. 225.

rights regime in Geneva. Prior to that, discussions on human rights were almost unthinkable in UN drug control fora.[59]

Today both the international drug control system and the human rights system recognize the right to health.[60] Moreover, the growing appreciation in recent years of human rights, particularly the right to health, in the realm of international drug control is a key reason to examine points of intersection between these two systems. To be sure, the issue gained more traction in 2016, when countries agreed their commitment to improving access to controlled substances for medical and scientific purposes, through an operational recommendation from the Outcome Document of the 2016 United Nations General Assembly Special Session on the World Drug Problem (UNGASS).[61]

The following chapters will explore the reasons behind the lack of adequate access to opioids in many countries and, from the perspective of human rights, in particular the right to health, and the extent to which the international drug control system has an impact on this situation. In doing so, additional factors of impact, other than the influence of the international drug control system will also be analyzed. Consequently, this work will discuss tensions created by the intersection between the drug control and the human rights regimes. It focuses on understanding the behavior of States that, in the attempt to comply with drug control obligations, have the potential to undermine the protection to the right to health regarding access to opioids for pain treatment.

To discuss this tension in a comprehensive manner, it will be examined in four levels: (1) tensions between national sovereignty and states' international commitments; (2) systematic institutional tensions between the World Health Organizations and the International Narcotics Control Board; and (3) tensions between adequate access to medicines and efforts to eliminate illicit markets. (4) The role of advocacy networks in these three levels of tensions. The analysis focuses on the period between 2009 and 2019. It explores changes and progresses on drug policy achieved within this period, regarding access to opioids and the friction between the international drug control and

[59] Hannah and Lines, p. 227.

[60] (E/C. 12/2000/4), paragraph 9.

[61] UNODC, *Outcome Document of the 2016 United Nations General Assembly Special Session on the World Drug Problem: Our joint commitment to effectively addressing and countering the World Drug Problem,* (New York: United Nations 2016), pp.1-26 <https://www.unodc.org/documents/postungass2016/outcome/V1603301-E.pdf> [Accessed 31 May 2022].

human rights regimes. This time frame starts when a new interest on the human rights impacts of drug control was emerging at UNODC and CND.[62] In this period, a slow but steady shift occurred in the engagement between the drug control and human rights. In 2009 the Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem was adopted at CND. This document reviewed the commitments made by members States at UNGASS in 1998 and evaluate achievements. The 2009 Political Declaration set out 2019 as the target date for States to eliminate or reduce significantly and measurably illicit drug supply and demand, mentioning explicitly opium poppy, the diversion and trafficking of precursors and money laundering.[63]

In 2009, UNODC acknowledged the failure of war on drugs, recognizing that there were too many people in prison, too few in health services. A huge criminal black market had been developed and few resources for prevention, treatment and rehabilitation were available.[64] It was the moment of an important shift in the drug control debate. The increasing the importance of health, began to occupy a more significant space and involve WHO on the discussions that were earlier focused on control and law enforcement, restricted to CND in Vienna. In 2015, the INCB published a report listing the barriers that produce impediments to the availability of controlled medicines such as opioids. The related survey carried out by the body identified the following barriers: a lack of training, fear of addiction, problems in sourcing, fear of diversion, limited financial resources, trade control measures, cultural attitudes, and fear of prosecution or sanction.[65]The INCB seemed to believe that States were responsible for existing barriers to the availability of opioids , without reflecting about the body's responsibility on this issue.

In 2019, the High-Level Segment of 62nd CND took place in Vienna. It was planned with the objective of reviewing improvements made in the world drug problem in the

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[62] Hannah and Lines, p. 228.

[63] UNODC, *Political Declaration and Plan of Action 2009 on international cooperation towards an integrated and balanced strategy to counter the World Drug Problem* (New York: UN 2009),

<https://www.unodc.org/documents/drug-prevention-and-treatment/High-level_segment_Commission_on_Narcotic_Drugs_11- 12_March_2209.pdf>[Accessed 31 May 2022], ), p.14.

[64] Antonio Maria da Costa, *The 51st Session of the Commission of Narcotic Drugs speech at 51st , UNODC Executive Director Antonio Maria da Costa*, (Vienna: 2008) https://www.unodc.org/unodc/en/about-unodc/speeches/2008-03-10.html [Accessed 31 May 2022]

[65] (E/INCB/2015/Supp.1), p. 18.

previous ten years. In this CND session the Commission adopted the Ministerial Declaration on Strengthening our actions, at the national, regional and international levels to accelerate the implementation of our joint commitments to address and counter the worlds problem.[66] In this document states "reiterate their resolve (…) to ensure access to and the availability of controlled drugs for the relieve of pain and suffering"[67]. In 2019, a UN common position on drug policy was published, which is the first inter-agency articulation of a shared commitments to strengthening human rights and placing people in the center of drug policy and practice, instead of substances. The document was developed with collaboration of Member States, civil society, WHO, UNODC, UNAIDS, and United Nations Human Rights Office of the High Commissioner (OHCHR).[68]

After presenting the key problems and questions of this dissertation, the next section presents the plan of chapters.

## 5. Outline of chapters

The objective of chapter 1 is to explore the theoretical approach and methods used for this research. The constructivist theory and scholarships on norm dynamics, regime complexes and regime complexity are used to examine three levels of tensions: First, between national sovereignty and states' international commitments; second, the systematic institutional tensions between the regimes of international human rights and the international drug control. In addition, tensions within the international drug control system, notably between the INCB and WHO. Third, the chapter explores the tension between adequate access to medicines and efforts to eliminate illicit markets.

Chapter 2 examines the history of the international drug control conventions to show how opium and its derivates were demonized. The chapter identifies political tensions and market related changes that led to each new hard law instrument in the period between 1909, when the Shanghai Commission and the UN foundation in 1945. Rather than a broad-brush historical overview, the chapter will offer an original perspective

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[66] UNODC, CND, *2019 Ministerial Declaration on Strengthening our actions, at the national, regional and international levels to accelerate the implementation of our joint commitments to address and counter the worlds problem* (Vienna: United Nations, 2019), https://www.unodc.org/documents/commissions/CND/2019/19-06699_E_ebook.pdf [Accessed 31 May 2022]

[67] UNODC, *2019 Ministerial Declaration on Strengthening our actions*, p.3.

[68] Hannah and Lines, p. 241

by focusing particularly on the regime's imperative to ensure access to controlled medicines under the international treaties.

Chapter 3 examines the increased prohibitionist approach in the drug control regime, largely driven by the US after the creation of the UN system, and the tension between sovereignty and states' international commitments, to show how prohibitionist norms were exported worldwide. Drug treaties between 1945 and 1972 are analyzed and a unique forensic analysis of Single Convention's drafting process is carried out. It shows the discussions that shaped the Convention, regarding the Preamble, quasi-medical use of substances, the role of WHO and the power of the INCB. This analysis also shows the element of health in the international drug control regime and its implications for the access to the use of opioids in the following decades.

Chapter 4 analyzes the context of international drug policy and the AIDS epidemic pre-2009. It also explores the period between 2009 - when the concern with health in the international drug control regime began to attract attention, and 2013 - when important changes occurred in the regime, particularly because of the increasing importance of human rights. This chapter highlights the systemic tensions between the INCB and WHO, as well as tensions between the international drug control and human rights regimes. This is the period when the issue of availability of controlled medicines began to gain traction in international fora, governments were adopting non punitive drug policies and regulating the cannabis market.

Chapter 5 continues the analysis on tension initiated in Chapter 4 looking at changes in the regime between 2014 and 2019. In this period the issue of access to controlled medicines gained traction and culminated with the inclusion of an operational paragraph on this topic in the UNGASS Outcome document in 2016.

Chapters 6 and 7 cover a case study about access to controlled medicines in Brazil to establish the reasons behind the lack of adequate access of opioids in the country. Chapter 6 examines the development of drug legislation in Brazil and implications for access to controlled medicines in the country. The chapter explores the influence of three main factors: the international drug control regime, the US-Brazilian relations and Brazilian endogenous prohibitionism. In Chapter 7 the current situation of access to opioids in the country is analyzed, showing the consequences of the prohibitionist approach of the international drug control regime and how it interplays with Brazilian

drug policy and regulations of opioids in the health system. In doing so, the tension between access to medicines and the control of illicit markets at the national level is discussed. Also, this chapter shows how patients circumvent barriers to have access to medicines, which sometimes and discusses aspects of the Brazilian culture that have implications for the low consumption of opioids.

The conclusion will recapitulate the work carried out and draw together its main points.

# Chapter 1

# Themes addressed, theoretical approach and methods

## 1. Introduction

To analyze the causes of the lack of adequate access internationally controlled medicines such as opioids and the extent to which the international drug control system has an impact on this issue, the contribution of this dissertation is primarily empirical, conducted with a bottom-up or inductive approach. It relies on existing theoretical work to better organize and understand the friction between the international drug control and human rights regimes at different levels. In this chapter, the theoretical approach to address the three levels of tension and methods used for this dissertation will be discussed.

That said, the issue area necessitates a degree of engagement with international relations theory in regard to the key concepts of norms, rules and identities and approaches that consider not only the state as an agent or actor, but also transnational organizations and international organizations.[69] Constructivism is consequently the selected theoretical approach because it considers that the dimension of human action includes knowledge and reality and they depend on our interpretation.[70] Also, constructivists are concerned on how norms are developed, the relation between structures and agents, how agents have an impact on structures and how they are altered and produced. Moreover, constructivism seeks to understand how interactions and context influence identities – which are specific understandings about oneself.[71] It sees individuals and states as social beings enmeshed in an interactive normative context, which influence who they are and how they see each other.[72]

This work examines how norms change within regimes and the importance of non-state actors and ideas in shaping identities and interests. Neo realism and neo liberalism are not especially useful theories, because they tend to believe that identities and

[69] Mark V. Kauppi and Paul R. Viotti, *International Relations Theory*, 6th edn. (Rowman & Littlefield, Lanham, Boulder, New York, London, 2020), Kindle edition, p.143.

[70] Kauppi and Viotti, p.143.

[71] Kauppi and Viotti, p. 155.

[72] Kauppi and Viotti, p. 146.

interests are givens.[73] Constructivists on the other hand believe that normative or ideational factors or structure are more important than material structures such as population size, weapons systems, manufacturing outputs or geographical factors.[74] The neorealist perspective such as Kenneth Waltz' is not appropriate for the analysis proposed in this dissertation since it argues that material capabilities have a decisive impact on outcomes unmediated by ideas.[75] Moreover, neoliberalists such as Keohane, understand the importance of ideas, but still consider material interests important to explain the conduct of states in international relations.[76]

In the next sections the three levels of tensions are explored in more detail. To examine the tensions between national sovereignty and states' international commitments and between adequate access to medicines and efforts to eliminate illicit markets, under a constructivist approach, the scholarship on norm dynamics is applied. The systematic institutional tensions between the regimes of international human rights and the international drug control are examined from the constructivist perspective of regime complexes and regime complexity. In addition, tensions within the international drug control system, notably between the INCB and WHO are analyzed from the perspective of "intra-regime complexity", which is a contribution to the debate of international regime complexity.

## 2. Levels of tensions

### 2.1. National sovereignty and international commitments

The role of the US in the development of the international drug control system increased with time and was particularly strong in the Cold War, which contributed to shape the international drug control system as it is today. In exploring this tension there are two aspects to be analyzed. First, how states lost sovereignty through the adherence of the drug control regime. In doing so, it will be explored how local norms are diffused in a way that they can be exported worldwide. This is crucial to understand how the US contributed to diffusion of a prohibitionist approach in the international drug control regime, and crucially how it affected access to opioids for pain treatment.

[73] Kauppi and Viotti, p. 144.

[74] Kauppi and Viotti, p. 147.

[75] Kauppi and Viotti, p. 148.

[76] Kauppi and Viotti, p.148.

Second, how the norm shift emerged with the growing importance of human rights obligations, particularly the right to health.

To understand how norms change and to analyze the first aspect proposed in this section, it is useful to begin with the theory of three-stage norm cycle, developed by Martha Finnemore and Kathryn Sikkink, which are norm emergence, norm legitimization and internalization.[77] The emergence of norm building, the first stage of the norm cycle. It is characterized by the persuasion of local actors such as norm entrepreneurs, which attempt to convince a critical mass of states to embrace new norms.[78] According to Ethan Nadelmann, norm entrepreneurs mobilize popular opinion and political support within their host country and abroad, they stimulate and assist in the creation of like-minded organizations in other countries through proselytism. Their efforts are often directed toward persuading foreign audiences, especially foreign elites, that a particular prohibition regime reflects a widely shared or a universal moral sense, rather than the peculiar moral code of one society.[79]Moral views and moral arguments held by governments or states to influence national and foreign policies stem from the political influence of domestic and transnational moral entrepreneurs.[80] Moral entrepreneurs have a crucial role on the process of emerging norms because they shape moral views of diverse societies, imposing their norms on international regimes.[81]

The second stage of the norms cycle, according to Finnemore and Sikkink is the legitimization period, in which norms must become institutionalized in specific sets of international rules and organizations.[82] That is called the tipping point, when norm entrepreneurs convince states to adopt new norms and reach the stage of norm cascade. At this second stage of the norm cycle, more countries begin to adopt new norms more rapidly even without domestic pressure for such change. Countries respond to a kind of peer pressure possibly motivated by legitimation conformity and esteem.[83] The third

[77] Finnemore and Sikkink, p. 895.

[78] Finnemore and Sikkink, p. 895.

[79] Nadelmann, p. 482.

[80] Nadelmann, p. 483.

[81] Nadelmann, p. 484.

[82] Finnemore and Sikkink, p. 900.

[83] Finnemore and Sikkink, p. 902.

stage of a norm is reached when they become so widely accepted that they are internalized by actors and achieve a "taken for granted" quality that conformance with the norm is almost automatic, and that is how they become extremely powerful. Precisely because they are not controversial, these norms are not on the centerpiece of political debate.[84]

Amitav Acharya's work on norm change is also useful to examine norm diffusion, regarding the international drug control system. He analyzes two waves of scholarships on norm changes.[85] In examining the first wave, he acknowledges Nadelmann's work on constructivism, and the concept of "moral proselytism" and how norms evolve from the local level to global regimes. In this regard, the resistance to cosmopolitan or universal norms such as the ban on chemical weapons, protection of whales and promotion of human rights are considered illegitimate and immoral, making a distinction between what is good and what is evil. [86]

As Nadelmann notes, norms exist not only in the conventions and treaties of international law, but also in the implicit rules and patterns that govern the behavior of state and non-state actors and in the moral principles embraced by individuals. And laws are patterns of behavior. Those who conform to a particular norm, they do it because it is seen to be just, or coincide with their other interests, because they fear the consequences of disobeying the norm or because it is a habit.[87] It is true that international regimes tend to reflect economic and political interests, but moral and emotional factors, religious beliefs, humanitarian sentiments, faith in universalism, compassion, conscience, paternalism fear, prejudice and compulsion to proselytize can transform norms into regimes.[88] According to Nadelmann, the global drug enforcement regime reflected the desire and capacity of the United States to impose their drug-related norms on the rest of the world because he perceives norm diffusion as teaching process, which differentiates what is good and what is evil. It was the case in drug control regime, as it will be discussed in the following chapters. Although it is an

[84] Finnemore and Sikkink, p. 904.

[85] Amitav Acharya, *Rethinking Power, Institutions and Ideas, Whose IR*? (New York, Routledge 2014) p. 184, Kindle edition

[86] Acharya, *Rethinking Power* p. 185.

[87] Nadelmann, 1990, p. 480.

[88] Nadelmann, , p. 480.

important analysis of the of how norms spread, it downplays the participation of local actors.[89]

This strategy of moral entrepreneurs, which is key to spread norms, is observed on the initial period of the drug control system.[90] US norm entrepreneurs introduced the idea of drug prohibition and acted through organizational platforms such as religious networks and press, resulting in the realization of the Shanghai Commission in 1909. Since then, the international drug control system evolved, showing an increasing loss of states' sovereignty, justified by a moral judgement that drugs were dangerous. Moral entrepreneurs transformed a home government's national interest into transnational and universal objective, rather a peculiar moral code of one particular society, by persuading foreign audience.[91]

In this regard, the role of norm entrepreneurs was motivated by a social purpose: 'to fight against the evil of drugs. As Martha Finnemore notes, one of the mechanisms of collective change of social purposes occurs through international institutions and law. [92]Once persuasion has happened the fact that the new understanding was signed as a treaty, facilitated by agents such a powerful state, it is embedded as a structure of law. This is crucial for social change because it becomes institutionalized.[93]

Examining drugs treaties between the Shanghai Commission in 1909 and the Single Convention 1961, as states parties to the international drug control system adopted drug treaties, they were gradually affected by a loss of sovereignty. International drug treaties started limiting opium use for medical purposes in 1909 and increased restrictions until the adoption of the Single Convention in 1961.

In 1912 with the Hague Convention[94], the restriction of opium use only for medical purposes was extended to opium, heroine, morphine cocaine and Indian hemp,

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[89] Acharya *Rethinking Power*, p. 185

[90] Acharya, *Rethinking Power*, p. 185

[91] Nadelmann, p. 482

[92] Other mechanisms, according to Finnemore are coercion, profession and epistemic communities and social movements. In: Finemmore, p. 149.

[93] Finnemore, p. 146.

[94] United Nations Treaty Collection (UNTC), *The Hague Convention 1912*, Treaty Series, vol. 8, No. 222 (The Hague: League of Nations,1912), p.28

phttps://treaties.un.org/pages/ViewDetailsIV.aspx?src=TREATY&mtdsg_no=VI-2&chapter=6&Temp=mtdsg4&clang=_en [Accessed 31 May 2022], p. 28.

commonly known as cannabis. In 1925, the Geneva International Opium Convention (Geneva Convention)[95] fixed estimates of drugs needed for medical purposes, even for states not parties to the Geneva Convention and regulated distribution through the creation of an international control body, the Permanent Central Opium Board (PCOB). This body had the power to determine, the quantity of drugs manufactured each year, based on information of imports and exports provided by countries. The obligations that earlier were domestic turned into international since 1925. In 1931, as the name explains, The Convention for Limiting the Manufacture and Regulating the Distribution Narcotic Drugs,[96] established how much opioids could be processed in each member state, for medical and scientific needs, and scheduled substances according to their propensity to cause addiction. It also established which drugs had therapeutical properties and which had not. In 1936, the Convention for the Suppression on the Illicit Traffic in Dangerous Drugs increased restrictions to the extreme of criminalizing cultivation, production, manufacture and distribution, with penal sanctions to drug trafficking.[97] In 1961, restrictions remained in the Single Convention.[98] The PCOB became the INCB and was granted the power to make recommendations to states that put in danger the aims of the convention. Considering that states had freedom to decide or to allow the use of any substance prior to 1909, in 1961, the parties to the Single Convention had a stricter margin to establish drug policies due to their obligations within the international drug control system.

The hegemonic position of the US, particularly after 1945, was crucial for exporting drug control norms and turning it practically universal in 1961. Restrictive norms

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[95] The United Nations Treaty Collection (UNTC), *The International Opium Convention (Geneva Convention)*, Treaty Series, Vol 81 No. 1845 (Geneva: League of Nations 1925)

https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-6-a&chapter=6&clang=_en [Accessed 31 May 2022], page 3, Article 6.

[96] United Nations Treaty Collection, *Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs*, *Treaty Series*, Vol 139 No 3219 (Geneva: League of Nations 1931)

https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-8-a&chapter=6&clang=_en [Accessed 31 May 2022] pp.5-7-.

[97] United Nations Treaty Collections ,(UNTC*) Convention for the Suppression of the Illicit Traffic on Dangerous Drugs*, Treaty Series, Vol 198 No 4648. (Geneva: League of Nations 1936)

https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-11&chapter=6&clang=_en [Accessed 31 May 2022]

[98] United Nations Treaty Collection (UNTC), *Single Convention on Narcotic Drugs 1961 as Amended by The Protocol Amending the Single Conventions 1961, Treaty Series*, vol 976 No. 14152 (New York: United Nations 1961) pp.105-292 https://treaties.un.org/doc/Publication/UNTS/Volume%20976/volume-976-I-14152-English.pdf [Accessed 31 May 2022]

continued to affect the sovereignty of member states. As Finnemore notes, states use their power and influence all the time to try to shape the actions of other states, using leverage in trade, making alliances, among other ways, to make other states behave the way they desire and these measures can seriously compromise the autonomy and control of target states, specially weak ones, even if these deals are not seen as interventions.[99] To explore the tension between sovereignty and states' international commitments, it is important to observe Finnemore's view that the policy of one state can compromise the sovereignty of another state, constituting an intervention. This is the term used by Finnemore for compromises of sovereignty by other states that are exceptional in some way, yet lines that differentiates and constitute these exceptions are not always clear and have varied over time.[100] As an example, the US had the capacity to intervene in other states, through the international drug control regime, and they were exceptional in having the desire and capacity to impose prohibition and evolve a national construct into an international one, globalizing prohibition.[101] It happened probably because in the Cold War the United States felt the political need to invest significant resources in coalition building and working through the UN, giving great importance to multilateralism.[102]And such, strong multilateralism norms reflect particular US notions about political legitimacy. As Finnemore notes, it was not just an overwhelming concentration of power, but the fact is that "the power was American".[103]In this normative context, the Single Convention was negotiated and the understandings about drug control were exported to other states through UN bodies and following drug conventions from 1972 and 1988. According to Finnemore, "in the Cold War it is the peculiar social purpose of *Americans*, and the success of Americans at both exporting these notions to other powerful states and institutionalizing them in international organizations and treaties, that has been important for establishing these multilateralism norms that now shape contemporary world politics and intervention

[99] Finnemore, p. 11.

[100] Finnemore, p. 11.

[101] James Windle 'How the East Influenced Drug Prohibition', *The International History Review*, 35:5, 1185-1199 (p. 1194) https://www.tandfonline.com/doi/abs/10.1080/07075332.2013.820769 [Accessed 31 May 2022]

[102] Finnemore, p.122.

[103] Finnemore, p. 8.

[103] Finnemore, *p.123.*

behavior."[104]Analyzing the international drug control regime it is possible to note that it was shaped and became strong during the Cold War when the system of sphere of influence allowed strong states such as the US to "decouple certain aspects of the internal behavior of states from assessments of the external threat they posed". It happened because the internal organization of states mattered greatly on a capitalist-communist dimension. As such, at this point, once states were situated within a sphere, the way they treated their citizens was considered a domestic matter and any interference from other states was considered a significant violation of sovereignty.[105] But it changed after the end of the Cold War, with the increasing importance of human rights, which made States no longer dissociate external and internal assessments of violent behavior to the degree they did when the concern of great powers was to keep other states under their sphere of influence after 1945.[106]

The Single Convention 1961 was adopted and interpreted by States within the normative context ruling at that time. The purpose of the treaty stated in its Preamble begins with "The Parties, concerned **with health and welfare of mankind"** [107] an continues (…) Conscious of their duty to prevent and combat this **evi**l, (…)"[108], which refers to addiction to drugs. The term evil stems from the times of the Shanghai Commission in 1909,[109] and was also used in the Harrison Act in 1914, which established the US strategy towards the prohibition of narcotic drugs[110], and was repeated 21 times in the negotiations of the Single Convention, as it will be mentioned in chapter 1. This illustrates what Finnemore notes about current multilateralism, which "legitimizes action by signaling broad support for actor's goals."[111] Having that said, throughout the development of the international drug control system, the dominant narrative was that in order to achieve health and welfare of mankind, people

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[104] Finnemore, p.123.

[104] Finnemore, p.127.

[105] Finnemore, p. 127.

[106] Finnemore, p. 127.

[107] UN TC *Single Convention 1961 as Amended*, Vol. 976 No.14152, p.106, emphasis added.

[108] UN TC *Single Convention 1961 as Amended* Vol. 976 No. 1452, p. 106, emphasis added.

[109] David R. Bewley-Taylor, *The United States and International Drug Control*, (1909-1997) (London: Continuun, 1999), p. 20

[110]David R. Bewley-Taylor, *International Drug Control, Consensus Fractured,* (Cambridge: Cambridge University Press, 2012), p.26.

[111] Finnemore, p. 78.

should be isolated from drugs because they are "evil", even if they can be used for medical purposes. In the Cold War, since the US had the support of states under their sphere of influence, the prohibitionist approach on drug control was exported successfully and became entrenched in other states and in drug control UN bodies, notably the INCB. Within this context, some states supporting US approach, parties to the international drug control regime were Latin American dictatorships, like Brazil. Keeping states reliable allies under the sphere of influence was a crucial concern for the US.

### 2.2.International drug control and human rights

The analysis of the second aspect proposed in this section refers to the norm shift that occurred in the international drug control system since the HIV epidemics in the 1990s. With the increasing importance of human rights, particularly the right to health, harm reduction initiatives undertook by civil society in various countries challenged drug control norms, opened the opportunity to push for access to medicines and to connect the international drug control and the human rights regime.

As a consequence of the growing importance of human rights in world politics, here process of norm diffusion is discussed, regarding how and why harm reduction initiatives challenged the norms of the international drug control system after the Cold War, creating new international commitments to States under the international human rights law. In the theory of norms change this is what Acharya calls norm subsidiarity, a tool to study norm dynamics, which he defines as "process whereby local actors create rules with a view to preserve their autonomy from dominance, neglect, violation, or abuse by more powerful central actors."[112] Norms subsidiarity is a process of norm diffusion that can be perceived as a response from local agents to transnational norms or a higher authority. The outcomes of this response can be challenging/resisting or supportive/subordinative to transnational norms. When the response is challenging existing norms, it implies a desire of non-intervention by a higher authority, which is allowed to perform only those tasks that cannot be performed al a more immediate or local level.[113] The outcome analyzed here is the

[112] Acharya, *Rethinking Power*, p. 217

[113] Amitav Acharya, *Constructing Global Order, Agency and Change in World Politics* (Cambridge: Cambridge University Press 2018) p. 48, Kindle Edition

challenge of norms in the international drug control regime that stem from harm reduction initiatives in the 1990s.

With the shift in world politics after the end of the Cold War, states that abused citizens in massive or systematic ways started to be seen as security threats because the flows of refugees and social tensions that such policies create are destabilizing and because aggressive behavior is and indicator that a state can behave aggressively externally.[114] Since then, states were concerned with the risk of creating a security threat and have its reputation affected in multilateral fora, because sovereignty could only be respected where human rights were valued.[115] Since security could not be said to exist internationally without human rights protections, what earlier used to be perceived as simple atrocities, since the 1990s could be understood as threats to international peace.[116]

Consequently, in the realm of drug control, in 1990s the HIV-AIDS epidemic became a global problem and a security threat with the disease spreading worldwide among injecting drug users. The response came with harm reduction initiatives from civil society and later were integrated in domestic policies, for instance in Switzerland, EU countries and in Brazil in the 2000s. These initiatives protected human rights of drug users, particularly the right to health and at the same time began to challenge norms and reshape the international drug control system.

The attempts to curb the HIV/AIDS epidemic through harm reduction policies gave a new impulse to the health approach in the drug control regime and opened space for the debate on rights of drug users, both for dependence treatment and pain treatment within the human rights regime. According to the International Harm Reduction Association (IHRA), harm reduction refers to policies, programmes and practices that aim primarily to reduce the adverse, health, social and economic consequences of the use of illegal psychoactive drugs without necessarily reducing drug consumption.[117]

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[114] Finnemore, p. 127.

[115] The link between human rights abuses and threats to regional peace and security has its origins in the antiapartheid campaign and became institutionalized in international institutions, especially at the UN, and in foreign policies in a variety of powerful states by 1990s. In: Finnemore p. 127.

[116] Finnemore, p. 128.

[117] Bewley-Taylor, *International Drug Control*, p. 37.

Although they are cost effective and have a high impact in individual and community health, harm reduction approaches such as the use of opioid substitution therapy (OST), methadone maintenance therapy (MMT),[118] needle and syringe programmes. In consumer countries such as the US, harm reduction can be seen as tolerant non punitive policies to the possession of drugs and a Trojan horse for a dramatic shift in paradigm that would lead to the legalization of drugs.[119] However, harm reduction lowers the risks of spreading HIV and hepatitis C, reduces and even eliminate illicit opiate use, criminal activity, unemployment rates and shows good levels of retention in treatment,[120]

According to Finnemore, the normative context is important here because it shapes the conception of interests and gives purposes and meaning to actions. It shapes the rights and duties states believe they have to one another. It shapes the goals they value and the means they believe are effective to obtain those goals and the political costs and benefits attached to different choices.[121]

The discussion on harm reduction in drug control fora opened space for increased participation of non-governmental organizations and media worldwide, as it is stated in the 1998 UNGASS Political Declaration.[122] This opened the opportunity to call attention for the importance of ensuring the availability of opioids for pain treatment. At this point, putting people in the center of drug policies, instead of substances, challenged the previous principle that isolating people from drugs was a 'concern with health and welfare of mankind' as it is stated in the Preamble of the Single Convention. As a result of this process a new principle emerged, which reaffirms that isolating people from drugs is not always a solution to protect human rights of drug users and patients in need of pain treatment. In the 2000s, NGOs networks were formed calling for modern and more pragmatic ideas against the outdated drug control regime and was actively engaged in the UN debates in 2003, 2009 and 2014 and 2016. In 2006 the

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[118] Bewley-Taylor, *International Drug Control* , p. 41.

[119] Bewley-Taylor, *International Drug Control*, p. 38.

[120] Bewley-Taylor, *International Drug Control*, p. 38.

[121] Finnemore, p. 55.

[122] Jamie Bridge, Christopher Hallam, Marie Nougier, Miguel H. Cangas, Martin Jelsma, Tom Blickman and David Bewley-Taylor, *Edging forward: how the UN's language on drugs has advanced since 1990,* IDPC, (Transnational Institute TNI, Global Drug Policy Observatory GDPO 2017)

http://fileserver.idpc.net/library/Edging-Forward_FINAL.pdf [Accessed 31 May 2022] p.10.

International Drug Policy Consortium, IDPC, was created, which included also organizations that advocate for adequate access to pain medicines and palliative care such as IAHPC International Association for Hospice and Palliative Care, IAHPC and the World Hospice and Palliative Care Alliance, WHPCA.[123]

The Commission on Narcotic Drugs operates through consensus, according to functional Rules of Procedures of the Functioning Commissions of the Economic and Social Council, ECOSOC[124]When new principles emerged, some states and UN bodies such as the INCB showed resistance to harm reduction initiatives, regulations of cannabis markets, and legalization of cannabis in some countries. The INCB was interested in maintaining the status quo. Other states and bodies such as WHO, fully embraced the idea of a human right and health-based approach, which led to what David Bewley-Taylor called "a consensus fractured".[125]

At this point it is important to make a distinction between two aspects of tensions that were noted as the norms of the international drug control system began to be challenged. First, drawing on the theory of regime complexes and international regime complexity, it analyzes the engagement between the international drug control regime and human rights regime. The second aspect analyzes the tensions within the international drug control regime. Here these tensions referred as "intra-regime complexity" involve the INCB, WHO, UNODC and CND. In both cases, there were implications for access to controlled medicines. According to Kal Raustiala and David Victor, regime complexes are "an array of partially overlapping and hierarchical institutions governing a particular issue area."[126]Karen Alter and Kal Raustiala introduced the concept of international regime complexity, which "refers to international political systems of global governance that emerge because of the co-existence of rule density and regime complexes."[127]This concept refers to the

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[123] Bridge Et. Al. p. 11

[124] UN, *Rules of Procedures of the Functioning Commissions of the ECOSOC* (E/5975/Rev.1) (New York: UN 1983) (Rule 57). https://digitallibrary.un.org/record/50230?ln=en [Accessed 31 May 2022]

[125] David Bewley-Taylor, *International Drug Control*, p. 333

[126] Kal Raustiala and David Victor, "The Regime Complex for Plant Genetic Resources." International Organization, 58. 2, 2004, pp. 277–309, 8 p. 279) <http://www.jstor.org/stable/3877859> [Accessed 6 Jun. 2022], p. 279.

[127] Karen Alter & Raustiala, The Rise of International Regime Complexity, *Annual Review of Law and Social Sciences*, 2018, UCLA School of Law, Public Law Research Paper n. 17-47

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3085043 [Accessed 6 Jun. 2022].

miscellany of agreements and rules that intersect with regard to a particular issue or set of issues and how they shape the politics of international cooperation.[128] As Karen Alter and Sophie Meunier note, rule complexity exist also in the domestic realm, but it is the lack of hierarchy that distinguishes *international* regime complexity.[129]

Here it is argued that the international human rights regime and the international drug control regime constitute a regime complex. As global problems increasingly overlap and intersect generating regime complexes, new international and cooperative efforts often fit into preexisting agreements and institutions.[130] In a dense regime complex legal consistency among rules, treaties and agreements is a challenge because there are often conflicts among overlapping rules in the international legal system, which has no formal hierarchy of treaty rules.[131] That is the reason why, regimes and rules developed in one forum frequently implicate or even challenge regimes and rules developed in other fora.[132]Among multiple international fora, actors are expected to choose the most suitable forum, according to their interests, a process called forum shopping.[133]

The international drug control regime and the human rights regime constitute a regime complex because they have a component of connection, or intersection, which is the right to health. The drug control regime began to be developed in 1909. As such, the human rights regime emerged decades later, among other previous existing rules and agreements, as it is typical in regime complexes. Today, the human rights regime has nine global treaties, two regional treaties and monitoring organ other treaties were added to regime. The right to health is expressed in human rights treaties protecting women, children and adolescents, migrants and persons living with HIV and AIDS.

When the International Covenant on Economic Social and Cultural Rights (ICESCR) entered into force in 1976,[134] including states' obligations "for the provision of essential

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[128] Alter & Raustiala, p.2.

[129] Karen Alter and Sophie Meunier, 'The Politics of International Regime Complexity', *Perspectives on Politics*, (2009), 7.1, 13-24 (p. 13) < https://www.cambridge.org/core/journals/perspectives-on-politics/article/abs/politics-of-international-regime-complexity/37B14B427A95988E48D9F5D3CDB13403#> [Accessed 6 Jun. 2022].

[130] Alter and Raustiala, p.10.

[131] Raustiala and Victor, p.300.

[132] Raustiala and Victor, p.295.

[133] Raustiala and Victor, p.299.

[134] IDPC, GDPO, *International Narcotics Control Board on Human Rights: A critique of the Report for 2019*, December 2020. http://fileserver.idpc.net/library/INCB_HR_2019.pdf > p.17[Accessed 6 Jun. 2022],.

drugs" such as opioids, in Article 12.2 [135], the international drug control regime already had a sophisticated structure. At this point, Single Convention 1961, amended in 1972 had clearly established that one of aims of the convention was to ensure the availability of drugs for pain treatment. The conflict emerges when rules and norms regarding the other aim of the convention - prevent the diversion of drugs - are implemented, in a manner that hampers access the availability of drugs for medical and scientific use.

After discussing what constitutes a regime complex and how this concept applies to the study of the drug control and human rights regimes, here it is discussed how the dynamics occurring in overlapping regimes shape policy choices.

The overlapping of these two regimes involves clusters of international legal agreements and create rule density. Alter and Raustiala note that in regime complexity it matters to understand what occurs when a policy space gets occupied by another institution in the complex.[136] Analyzing the international drug control system through the lens of regime complexity provides a way understand how a series of elemental institutions and regime complexes mutually affect each other.[137]

Although the international human rights regime and the international drug control regime have points of intersection, during decades they operated in "parallel universes"[138] However, since the HIV-AIDS epidemic the importance of human rights, particularly the right to health has become increasingly important, also in the realm of drug control. As harm reduction appeared as an alternative to curb the spread of the epidemics in many countries, and the use of opioids in in substitution therapies were adopted, the international drug control regime was challenged by human rights norms. The complexity generated by the intersection of the two regimes opened space for increased discussions on access to opioids for pain treatments and for dependance treatment, generating choices from Member States. In the period pre-UNGASS 2016,

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[135] UN Economic and Social Council (ECOSOC), *General Comment no. 14: The Right to the Highest Attainable Standard of Health (art. 12)* (E/C.12/2000/4) (Geneva: UN Committee on Economic and Social and Cultural Rights 2000), paragraph 17.< https://www.refworld.org/docid/4538838d0.html>[Accessed 6 Jun. 2022].

[136] Alter and Raustiala, p.18.

[137] Alter and Raustiala, p.18.

[138] Paul Hunt, *Human Rights, Health and Harm Reduction, States' Amnesia and parallel universes,* International Human Rights Association (2008) <https://www.hri.global/contents/550> [Accessed 6 Jun. 2022], p. 9.

there was pressure from states adopting harm reduction and civil society engagement to make the international drug control regime to engage more significantly with human rights norms and principles, regarding drugs. Despite the resistance of some states to human rights, a policy space earlier strictly dominated by control and law enforcement was opened. As a result, the Outcome Document adopted at UNGASS 2016 included one operational paragraph on access to controlled medicines and one on human rights.

### 2.3.Intra-regime complexity

The second aspect analyzed in this section is the "intra-regime complexity", which examines the tensions within the international drug control regime, involving the INCB, WHO, UNODC, CND and drug control conventions, created throughout its development. Several drug conventions were replaced with the adoption of the Single Convention in 1961. The conventions on psychotropics in 1971 and precursors, in 1988 were added to the system. The scope of power of the INCB has been a topic in the discussions about embargo in the negotiations of the Single Convention.[139] With the creation of UNODC, the regime gained more new mandates, that together with the role of WHO, made the interaction of these bodies, often complicated, when they claim for the authority on issues. Today, all these bodies compete for greater visibility and extra funding.

The overlapping functions of bodies illustrate tensions emerged, generating "intra regime complexity". It means that the increasing number of bodies, treaties are entangled, leading to overlapping mandates. This makes it difficult for states and other actors to understand which body is responsible for each function within the regime. This complexity mutually affects bodies in the system and choices of Member States, regarding access to controlled medicines for pain treatment. As the issue of access to medicines gained importance, it attracted some funding to UN bodies, requiring coordinated action within the international drug control system.

Alter and Meunier note that in international regime complexity, where organizations are competing, actors lack an incentive to coordinate their efforts generating inefficiencies, repetitive efforts, turf battles. Moreover, uncoordinated efforts can lead

[139] United Nations, *United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs*: *official records : Volume 1 : summary records of plenary meetings*, (E/CONF/34/24) (New York : UN, 1964) pp. xxix-2918 < https://digitallibrary.un.org/record/720279?ln=en> [Accessed 31 May 2022], p. 11.

to achievements by one organization that is later erased or undermined.[140] This is also valid for "intra-regime complexity" in which cooperation or competition can occur between actors. As example, the growing interest in access to medicines particularly since 2014, also attracted the INCB's engagement in activities to improve access to opioids, increasing competition for funds with WHO and UNODC. In 2018, in The Memorandum of Understanding between WHO and UNODC, both agencies agreed to collaborate to improve access to controlled medicines.[141] In practice, the discussion about how to use the contributions made by states parties can create tensions between bodies, requiring states and UN bodies to navigate through complexity, which can cause confusion.

Within the realm of international drug control, the issue of ketamine shows clearly how both the INCB and WHO were claiming authority to decide about the scheduling of Ketamine. It is an anesthetic medication widely used for essential surgery in many Lower and Middle-income countries, prompting the ECDD (WHO) to declare that placing it under control would precipitate a global health crisis.[142] According to WHO's mandate, the body, through its Expert Committee on Drug Dependence, has the authority to recommend the scheduling of a substance. The INCB flagged up the issue of abuse of ketamine in Southeast Asia in its reports in 2004[143], 2005[144], 2006[145], 2007[146],

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[140] Alter and Meunier, 2009, p.19.

[141] WHO, *Memorandum of Understanding between WHO and UNODC, 2018*, Article III, paragraph 3.1.3 https://cdn.who.int/media/docs/default-source/controlled-substances/mou-who-unodc.pdf?sfvrsn=612bced9_2&download=true Accessed 6 Jun. 2022].

[142] Katherine Pettus, 'Access to Internationally Controlled Medicines' in: *Collapse of the Global Order on Drugs, From UNGASS 2016 to Review 2019*, edited by Axel Klein and Blaine Stothard, (UK: Emerald Publishing 2018) Limited, UK. p. 89.

[143] International Narcotics Control Board (INCB), *Report of the International Narcotics Control Board for 2004* (E/INCB/2004/1) (New York: United Nations 2005) pp. 58-59.

https://www.incb.org/documents/Publications/AnnualReports/AR2004/AR_04_English.pdf [Accessed 6 Jun. 2022].

[144] INCB, *Report of the International Narcotics Control Board for 2005* (E/INCB/2005/1) (New York: United Nations 2006), p.66. https://www.incb.org/documents/Publications/AnnualReports/AR2005/AR_05_English.pdf [Accessed 6 Jun. 2022].

[145] INCB *Report of the International Narcotics Control Board for 2006* (E/INCB/2006/1) (New York: United Nations 2007), p.31 https://www.incb.org/documents/Publications/AnnualReports/AR2006/AR_06_English.pdf [Accessed 6 Jun. 2022]

[146] INCB, *Report of the International Narcotics Control Board for 2007* (E/INCB/2007/1) (New York: United Nations 2008), p.38

https://www.incb.org/incb/en/publications/annual-reports/annual-report-2007.html , [Accessed 6 Jun. 2022].

2008[147], 2010[148], 2011[149] and 2012[150]. In the annual report of 2012, it was stated that if this medicine was under control only in national legislations, it would not be enough to enable law enforcement. In 2006 CND passed a resolution calling upon States to "consider the use of Ketamine by placing it on the list of substances controlled under their national legislation."[151]

In 2014, China proposed to schedule ketamine, which would leave low- and middle-income countries in serious difficulties to have access to these medicines, where there are no other alternatives. WHO reviewed ketamine in repeated occasions in 2006, 2012 and 2014 and have never recommended the scheduling of this substances in the 1971 Convention on Psychotropic Substances.[152] Although ketamine is not an opioid, and for this reason could not be scheduled under the 1961 Convention, this example illustrates relevant participation of civil society, involved in the protection of the right to health within a situation that is generated and sustained by intra-regime complexity. In 2015, the pressure scheduling ketamine also created the opportunity of intense participation of civil society at CND to influence countries' decisions on the voting to include or not the substance on the schedule.

Margaret Keck and Kathryn Sikkink further developed the concept of transnational network in the seminal book *Activists beyond Borders*. Transnational advocacy networks are organized to promote causes, principled ideas and norms.[153] They begin

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147 INCB, *Report of the International Narcotics Control Board for 2008* (E/INCB/2008/1), (New York: United Nations 2009), p. 45

https://www.incb.org/incb/en/publications/annual-reports/annual-report-2008.html [Accessed 6 Jun. 2022].

148 INCB, *Report of the International Narcotics Control Board for 2010* (E/INCB/2010/) (New York: United Nations 2011), p.85

https://www.incb.org/incb/en/publications/annual-reports/annual-report-2010.html [Accessed 6 Jun. 2022].

149 INCB, *Report of the International Narcotics Control Board for 2011* (E/INCB/2011/1) (New York: United Nations 2012, p. 73

https://www.incb.org/incb/en/publications/annual-reports/annual-report-2011.html [Accessed 6 Jun. 2022].

150 INCB, *Report of the International Narcotics Control Board for 2012* (E/INCB/2012/1) (New York: United Nations 2012), p.45

https://www.incb.org/incb/en/publications/annual-reports/annual-report-2012.htm [Accessed 6 Jun. 2022].

151 United Nations Commission on Narcotic Drugs CND, 'Listing of Ketamine as a controlled substance,' CND 49/6, *Report on the 49th Session*, (E/CN.7/2006/10) (Vienna: UN, 2005, 2006).

p. 28. https://www.incb.org/documents/Psychotropics/Resolutions/CND_Res-49-6.pdf [Accessed 12 June 2022].

152 Jason Nickerson, The Commission on Narcotic Drugs' attempt to restrict Ketamine. *Lancet 2015* https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)60490-1/fulltext [Accessed 12 June 2022]

153 Margaret Keck and Kathryn Sikkink, *Activists beyond borders, advocacy networks in international politics*, (Ithaca: Cornell University Press 1998), Kindle edition Location 268.

with an issue creation and agenda setting, influence discursive positions of states and international organizations, policy change and "target actors", which can be states, international organizations, private actors or influence state behaviour.[154] It is important to note that transnational advocacy networks one of the strategies used by transnational advocacy networks is the boomerang pattern. When the channels between the government and its domestic actors are blocked, domestic networks bypass their state and directly search out international allies to try to bring pressure on their state from outside.[155]

The role of civil society in "intra-regime complexity" is not always the only force to give impulse for increased engagement of member states. They can also be mobilized by states to reach common objectives and vice-versa. As an example, in 2015, the delegation of Switzerland at CND warned the International Committee of the Red Cross in Geneva that ketamine was about to be scheduled and the organization contacted ministries of health in various countries and other NGOs. In an advocacy effort, diplomats and NGO representatives sent an alert to their counterparts in Vienna to vote against the scheduling of ketamine, challenging China, CND and INCB efforts to schedule this medicine.[156] This is not a commonly used anesthetic in Switzerland, but this delegation defended the importance of the use of ketamine in other countries and the authority of WHO for this recommendation for humanitarian reasons. The INCB challenged WHO's decision, but WHO role in the case of ketamine was in accordance with its mandate, while the INCB attempted to exceed its own mandate, claiming authority on the issue. The "intra regime complexity" makes it harder to other stakeholders in the regime to locate responsibility and accountability for decisions and procedures.

This section showed that as international drug control regime became more sophisticated, it became more complex. This generates an overlapping of mandates and functions that lead to a confusion among states and non-sate actors to understand each bodies' responsibilities, which can affect the functioning of the regime through duplication of efforts and waste of funds.

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[154] Keck and Sikkink, 1998, Location 559.

[155] Keck and Sikkink, 1998, Location 330.

[156] Participation on a meeting involving the delegation of Switzerland and Norway, representatives of NGOs in Vienna, in early March 2015.

### 2.4.Access to medicines and illicit markets

The third level of tension refers to the behavior of Brazil within the international drug control system, regarding access to opioids, to understand how international norms influence domestic policies and if domestic behaviors have an impact on the creation and maintenance of international norms. As Viotti and Kaupi note, "Norms are generally accepted values that define standards of appropriate behavior for agents (actors) with a given identity."[157]

It could be argued that the 'hegemonic' position of the United State, especially after 1945 has contributed to create a prohibitionist approach to drug use, which led to a low consumption of opioids in Brazil today because the state was under the sphere of influence of the US in the Cold War. Although constructivists acknowledge the importance of ideas of norms change, they share different views about how and why occurs. [158]

Both for Alexander Wendt[159], Ikeberry and Kupchan,[160] power played an important role on norms change. According to the theory of hegemonic socialization, Ikenberry and Kupchan, believe that a hegemonic state can exercise power through material incentives and by altering *substantive beliefs* of leaders of other nations belonging to the elite[161], while Wendt believes that norms change because "the structures of human association are determined primarily by shared ideas rather than material forces".[162] Other scholars such as Finnemore and Sikkink, "show that consent of a materially powerful state is not a necessary condition for norm cascades."[163]Also, as it was already discussed in this introduction, early constructivist works such as Nadelmann's, emphasized the role of proselytism and norm entrepreneurs in the process of norms change.[164] Acharya challenges these previous constructivist works noting that ideas and norms constitute an important tool for the agency of weaker actors in world politics

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[157] Viotti and Kauppi, p.153.

[158] Acharya, *Constructing Global Order*, p. 40.

[159] Acharya, *Constructing Global Order*, p. 41.

[160] Acharya, *Constructing Global Order*, p. 37.

[161] John Ilkenberry and Charles Kupchan, Socialization and Hegemonic Power, *International Organizatio*n, Summer 1990, 44.3 (The MIT Press,1990), pp. 283-315 (p. 286) https://www.jstor.org/stable/2706778?seq=1 [Accessed 6 June 2022].

[162] Viotti and Kauppi, p. 161.

[163] Acharya, *Constructing Global* Order, p.40.

[164] For instance, in Nadelmann, p. 483.

and a good deal of this agency happens at the local level, signifying the agency of norm takers-rather than the norm-givers.[165]

In developing a second wave on norms change, Acharya discusses the concept of norm localization as one form of norm diffusion. He notes that in some process of norm diffusion domestic political and cultural variables condition the reception of new global norms in a way that international and domestic norms produce a cultural match.[166]This congruence of foreign ideas with local beliefs and practices norms called by Acharya of 'localization'.[167] It starts with a reinterpretation and re-representation of the outside norm and may include a more complex process of reconstitution to make an outside norm congruent with a pre-existing local normative order.[168]

Acharya's concept of norm localization is useful to understand how the international norms and domestic drug control in Brazil became a perfect match. He notes that the localization process occurs in three acts. First, ideas are not imposed through force. Instead, local actors proactively seek out foreign ideas that they find morally appealing or politically empowering.[169] Second, foreign ideas are used as frame to express local beliefs and practices. In this case, the name and structure of the foreign idea remains the same, its contents are infused with local beliefs and practices, thus, validating then and making them relevant in a broader context.[170]The third act of localization involves changing the formal shape and content of foreign ideas on the basis of the recipient's own prior beliefs and practices, in a way that they are congruent with local beliefs, and which may enhance the prestige of the borrower.[171]

While the US exported the idea of prohibitionism worldwide, Brazil not only developed its own domestic 'home grown' prohibitionism, but also supported the prohibitionist approach of the international drug control system built up with US efforts. Members of the Brazilian elite, such as politicians, professionals of the health and justice system were norm entrepreneurs "pursuing a universal moral agenda, but

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[165] Acharya, *Constructing Global Order*, p. 41.

[166] Acharya, *Rethinking Power*, p. 185.

[167] Acharya, *Constructing Global Order* , p.42.

[168] Acharya, *Rethinking Power*, p.186.

[169] Acharya, *Constructing Global Order*, p. 43.

[170] Acharya, *Constructing Global Order* , p. 44.

[171] Acharya, *Construction Global Order*, p. 44.

also insider proponents seeking to legitimize a local identity."[172]Moreover, the endogenous prohibitionist ideas present in local Brazilian beliefs and practices found congruence in international drug control norms. According to Acharya, it could also involve pruning part of foreign ideas that do not match with local beliefs, keeping only those that are desirable to produce a good fit.[173]

As the norms of the international drug control system were absorbed by the Brazilian health and justice system, there was a congruence between principles from both levels. The international obligation of ensuring the availability of medicines for pain treatment was, neglected, thus pruned from beliefs and practices in Brazil, leading to a low consumption of opioids in the country, which prevailed for decades without questioning. This occurs probably because norms can be regarded as path dependent and internalized, they are usually not controversial and that is the reason why they are often not the center piece of political debate.[174]In the case of Brazil the machinery of drug control, affected the access to controlled medicines such as opioids and at the same time failed on the efforts to eliminate illicit markets. Health and justice institutions are often not even aware that the consumption of opioids in the country is inadequate, because the valid norms regarding these drugs view them as dangerous.

Today, the low consumption of opioids in Brazil reflects the automatization of the norm that drugs are dangerous, even if they serve to treat a common symptom like pain. Both patients are afraid to take, and physicians to prescribe them, fearing to suffer sanctions in case non-compliance with excessive rules and regulations currently in force.

## 3. Methods used and data collection

To answer the proposed questions, empirical research with qualitative analysis was carried out. Data collection for each part of this research required different methods: document- based research, participant observation and elite interviews with key informants. Different methods were used in the three parts of this research: 1.

[172] Acharya, *Constructing Global Order* , p. 43.

[173] Acharya, *Constructing Global Order*, p.45.

[174] Finnemore and Sikkink, p.904.

Historical antecedents; 2. Tensions involving the international drug control regime. 3. Single case study about access to opioids in Brazil.

Apart from desktop research of secondary sources, in depth analysis of the official records of the negotiations of the Single Convention 1961 and document-based research of documents produced by UN bodies were the primary sources used to analyze how the issue of access to controlled medicines, particularly, has been approached throughout a variety of UN documents.

Extensive participant observation was carried out particularly at the Commission on Narcotic Drugs (CND) meetings attended personally between 2015 and 2020 and in 2021, online. CND is the governing body of UNODC and meets every year, usually in March in Vienna at the Vienna International Center (VIC), to consider and adopt resolutions and decisions. The agenda has two distinct segments: a normative segment for discharging treaty-based and normative functions; and an operational segment for exercising the role as the governing body of UNODC.[175] Intersessional meetings happen during the year and in December a reconvened session considers budgetary and administrative matters.[176] CND meetings are the occasion where UN officers, delegations of states and NGOs are together. It is not just where decisions and negotiations take place, but it is also where alliances are formed, informal meetings take place, networks are expanded, knowledge is exchanged, and strategies are set among all actors. Participant observation permitted to see how drug policy is executed in practice by the UN bodies involved with drug policy and shows perspectives that cannot be always perceived through the analysis of documents and records of meetings.

I had access to the setting and context since I was living in Vienna between 2014 and 2017 and I was accredited at UNODC as a journalist. Firstly, I took part in CND main sessions, intersessionals and reconvened sessions and took part in press conferences at UNODC in Vienna took part of UNGASS 2016, in New York, World Health Assembly and other meetings at WHO in Geneva.

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[175] UNODC, *United Nations Commission on Narcotic Drugs* <https://www.unodc.org/unodc/en/commissions/CND/index.html>[Accessed 6 June 2022].

[176] UNODC, *United Nations Commission on Narcotic Drugs.*

From September 2016 to March 2017, I was selected for an internship for six months at the Prevention, Treatment and Rehabilitation Section of the Health Branch at UNODC, where I had the opportunity to work at the The Joint Global Programme on "Access to Controlled Drugs for Medical Purposes While Preventing Diversion and Abuse" (also known as GLOK67) is the result of the cooperation between UNODC, the World Health Organization (WHO) and the Union for International Cancer Control (UICC). I took part on the daily routine of UNODC and participated on expert groups meetings on access to controlled medicines, particularly on opioids, at UNODC and WHO. In this setting, as a participant observer, I had the opportunity to conduct formal and informal interviews with diplomats, NGOs, UNODC and WHO officers (See Appendix 4)

In 2018 I began to represent a civil society organization, the International Association for Hospice and Palliative Care (IAHPC) in international meetings and became a member of the Civil Society Task Force of the Vienna NGO Committee on the preparation for the High-Level Segment in 2019 and since 2021I became a board member of the Vienna NGO Committee.

As research advanced semi-structured and elite interviews with key informants were used specially to collect data for the single case study about Brazil, to explore unique aspects of access to opioids that were never approached until today. In the following sections more details about how and why these methods were used will be clarified.

### 3.1.First part: historical antecedents

Document based research was used to answer all questions proposed. In the first part of research, to analyze the historical antecedents that led to the lack of access to opioids I examined the UN documents related to drug control, in particular to the Single Convention. As Christopher Lamont notes, official documents can give an insight into a particular organization, and in fact it is rare to have full access to an organization's official records.[177] In the case of the negotiation of the Single Convention it was possible because it took place in 1961 and the access to the documents was provided by UNODC's library.

[177] Christopher Lamont, *Research Methods in International Relations*, 2015, (Los Angeles: Sage, 2015) p.80, Kindle Edition.

It can be highlighted that the analysis of the Official records of the United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs, Volume 1[178]and 2[179] were not explored in detail in the literature about the Single Convention so far. In this work, the official records were examined in depth to identify the main concerns of states negotiating the Single Convention. As such, the discourse of delegates present at the plenary meetings was analyzed and word counting was used to assess the relevance of control and health issues. As Robert Weber notes "the most frequent appearing words reflect the great concerns".[180] But this kind of content analysis have limitations. For instance, one problem with simple counting and sorting of words is that these procedures lose the context in while the word occur[181]. And one word may be used in a variety of contexts or may have more than one meaning, so that word frequencies may suggest far greater uniformity in usage than actually exists. It questions the validity of inferences from word-frequency data.[182] In this research, there are certain cases in which word counting and sorting lead to relevant discussions that took place in the drafting process of the Convention.

Other primary sources analyzed were the drug control conventions between 1909 and 1972 and the Official records of the United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs, Volume 1-: Summary Records of Plenary Meetings and Volume 2, Preparatory Documents, Amendments, and Miscellaneous Papers, Proceedings of Committees, Final Act, Single Convention and Schedules, Resolutions are analyzed. Other documents used are Protocol amending the Single

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[178] United Nations, *United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs*, New York, 24 January - 25 March 1961 : official records : Volume 1 : summary records of plenary meetings, (E/CONF/34/24) New York : UN, 1964 pp. xxix-2918

< https://digitallibrary.un.org/record/720279?ln=en> [Accessed 31 May 2022].

[179] United Nations, *United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs*, Official Records, Volume 2, Preparatory Documents, Amendments, and Miscellaneous Papers, Proceedings of Committees, Final Act, Single Convention, Schedules and Resolutions, New York, 24 January-25 March1961Volume 2, 1961 (E/CONF/34/24/add.1)(New York: United Nations 1964) pp. 1-316.

https://digitallibrary.un.org/record/1297315?ln=en [Accessed 31 May 2022].

[180] Robert Weber, *Techniques of Content Analysis in Basic content analysis*, (1990, 2011, Sage publications) <https://methods.sagepub.com/book/basic-content-analysis/n3.xml?fromsearch=true> p. 9. [Accessed 31 May 2022].

[181] Leonard Bickman, and Debra Rog, (editors) *Handbook of Applied Social Research Methods*, Sage Publications, 1998 p. 521

https://www.semanticscholar.org/paper/The-SAGE-Handbook-of-Applied-Social-Research-Bickman-Rog/e6bc6aa220a5f390db005276c9e5f08df5048977 [Accessed 31 May 2022].

[182] Weber, p. 9.

Convention on Narcotic Drugs on Narcotic Drugs 1961[183], from 1972, and the Commentary on the Protocol the Single Convention on Narcotics Drugs 1961[184], international human rights law documents and conventions. Other limitations of document-based research, even when complete access is possible, are that the documents only give a glimpse into those items that were recorded into an organization's institutional memory. There are many aspects of social interaction that remain invisible to the researcher about how a certain outcome came about or how a decision-making process worked.[185]

### 3.2. Second part: Tensions involving the international drug control regime

The second part of research was divided in two periods: The first period between 2009-2013, starts with Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem was adopted at CND. It finishes in 2013 with the announcements of shifts that occurred in the second period. The second period (2014-2019) shows significant changes regarding the increasing importance access to opioids since 2014 and ends in 2019, which was the target date set out by the Political Declaration in 2009 for States to eliminate or reduce significantly and measurably illicit drug supply and demand, mentioning explicitly opium poppy.[186] In 2019, the High-Level Segment of 62nd CND, reviewed improvements made in the world drug problem in the previous ten years and adopted the Ministerial Declaration[187], in which states "reiterate their resolve (…) to ensure access to and the availability of controlled medicines for the relieve of pain and suffering"[188].

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[183] United Nations, Treaty Collection (UNTC), *Protocol Amending the Single Convention on Narcotic Drugs 1961*, vol. 976, No. 14151 (Geneva: United Nations 1972)

https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=VI-17&chapter=6&clang=_en [Accessed 31 May 2022]

[184] United Nations, *Commentary on the Protocol amending the Single Convention on Narcotics Drugs 1961*, (E/CN.7/588) (Geneva: United Nations 1972)

https://www.unodc.org/documents/treaties/organized_crime/Drug%20Convention/Commentary_on_the_protocol_1961.pdf [Accessed 31 May 2022]

[185] Lamont, p. 82

[186] UNODC, *Political Declaration and Plan of Action, 2009*.

[187] UNODC, *Ministerial Declaration Strengthening our actions*.

[188] UNODC, *Ministerial Declaration Strengthening our actions*.

In the first period (2009-2013) the research methods used were document-based research of primary sources such as INCB reports, World Drug Reports from UNODC, UN resolutions, World Health Assembly resolutions and press releases. They were useful to analyze how the issue of access to medicines created space in the drug policy agenda in the international drug control system and built the basis for further developments in the following research period. The limitation of this method was, as mentioned above, the lack of information of social interaction that resulted on the content of documents examined.

The same UN documents researched in the previous period researched continued to be analyzed in the period between 2014 and 2019. But in this period, participant observation was added as a useful method to understand how the issue of access to medicines increased its importance within the international drug control system and how and why drug related health issues generated tensions within the international drug control regime and with the human rights regime. According to Kathleen DeWelt and Billie DeWelt, participant observation is a way to collect data in naturalistic settings by ethnographers who observe and take part in the common activity of people being studied. [189] It is the systematic descriptions of events, behaviors and artifacts in the social setting chosen for study. It enables the researcher to describe the situations using the five senses providing a written photograph of the situation under study.[190]

The process of primary data collection included one to one conversation, having the Vienna International Center, as the main setting. As mentioned above, both in the role of journalist, intern at UNODC. I observed CND meetings, took part at the UNODC routine and the interaction of the section of Prevention Treatment and Rehabilitation with other UN bodies such as INCB and WHO. As an NGO representative I interacted with civil society delegations, experts in drug policy and states' delegations.

Key elements of participant observation were carried out in this research such as living in the context for an extended period, actively participating in a wide range of daily routine and extraordinary activities with people who are true participants in the context, using both tacit and explicit information in analysis and using everyday

[189] Kathleen Musante DeWalt and Billlie DeWalt, *Participant Observation: a Guide for Field Workers*. (2010-12-16, Altamira Press). p. 13.

[190] Barbara Kawulich, Participant Observation as a Data Collection Method, *Forum Qualitative Social Research*, 6.2, Art. 43, May 2005. P. 2. <https://www.qualitative-research.net/index.php/fqs/article/view/466>

conversation as an interview technique.[191] Participant observation particularly encourages the continual reassessment of initial research questions and hypothesis as new insights occur. They are a result of increasing familiarity with the context.[192] The advantage of participant observations is that it facilitates the development of new research questions or hypotheses.[193]

Participant observation was done while I was playing these different roles and allowed me to collect data such as notes and conduct formal and informal interviews, which provided a more sophisticated understanding on the participation of civil society in the international drug control system.

Although I had access to the "physical" field of research, the Vienna International Center, where the Commission on Narcotic Drugs meetings take place, and to WHO, the challenge was to acknowledge the processes going on at the same time during the meetings and between them. I had the opportunity to see many important discussions on the main topics, fights to include or remove words in resolutions, that are sometimes the basis for further developments and shifts in drug policy. These discussions show tensions within the system and among countries, the role of civil society, and how groups of stakeholders perceive each other. Moreover, it is a challenge to surgically select what was important for this work looking to the issue of access to opioids sometimes as an UNODC intern or as a civil society advocate, but always as a researcher.

Like other research methods, participant observation has also limitations. In doing so, the researcher is inevitably biased to a certain degree. Gender, class, ethnicity, age and appearance play a role on the information that is collected and its interpretation, because these aspects have an impact on the acceptance of the researcher in the community researched.[194] In addition, in each new role one is inevitably naïve. It takes some time and some experience to extract relevant information from sources and to understand what is behind their actions. As Lamont explains, getting access to an individual for interviews or to official documents require some form of relationship

[191] Kathleen Musante DeWalt and Billlie DeWalt, p. 15.

[192] DeWalt and DeWalt, p.23.

[193] Kawulich, p. 6.

[194] Kawulich, p.7.

with those working with, or, for an organization or group that is under study.[195] Another kind of limitation may occur when interviewees see the researcher as a representative of the organization and not as a researcher.[196] A feeling of being excluded at some point of the research process can occur, which can be motivated by a lack of trust or a community discomfort. But it is important to recognize what that exclusion means to the research process.[197] In order to collect information as a participant observer, it was necessary to build trust with informants to obtain relevant information, which is a process that, in certain cases, took years. The experience as a civil society representative allowed me to acknowledge an extra layer of interactions that can be neither perceived by the analysis of documents and statements, nor in the interviews. That is how civil society participation within the international drug control system gained a more relevant space in this work. It would not be possible to understand this perspective in an adequate manner without my participation as a representative of this group.

### 3.3.Third part: single case study about access to opioids in Brazil

The case study refers to the last part of the research. After examining the international drug control system and tensions at the international level, a case study was selected to examine the impact of the international system at the country level, or in other words, if there was no international drug control system, would the access to opioids be adequate in Brazil? This case study analyzes the antecedents that led to the low consumption of opioids in Brazil. It also seeks to establish the causes of barriers to access to opioids in Brazil today and how patients circumvent difficulties.

According to Lamont, case studies are defined as in-depth studies of a single unit or historical episode to explain or understand other units or episodes.[198] For Thomas Pepinsky, a single-country study means, simply, a study that uses empirical data exclusively from one country. This kind of study is not defined by methodology or

[195] Lamont, p. 145.

[196] Lamont, p. 146.

[197] Lamont, p. 146.

[198] Lamont, p. 130.

size of the sample.[199] The new style of a single-country research implies a shift in focus from national politics and macropolitical processes to local politics, individual beliefs, and micro-level causal processes.[200]

The criticism to single-case studies is that they may lack internal validity because researchers, among other difficulties have limited time to develop substantive expertise or political intuition about a certain state. Contemporary single-country research is criticized for being insufficiently attentive to national political and social conditions relative to its methodological and theoretical contributions.[201]But Pepinsky adds that contemporary single-country research has a greater emphasis on empirical research on well-identified causal questions than on a theoretically informed analysis of national political systems or aggregate political phenomena.[202]

The single case study aims to understand what these two sets of data mean in practical terms for health care professionals and patients, in the case of Brazil, to figure as a country that has an adequate consumption of opioids and have a low de facto availability of controlled medicines for the relief of pain and suffering.

To clarify that, this case study analyzes the antecedents that led to the low consumption of opioids in Brazil. It also seeks to examine the barriers to access to opioids in Brazil today and how patients circumvent difficulties, even though the country is considered to have adequate access to opioids, according to the INCB. The decision to research a single case study, instead of comparing a group of countries was made because the analysis of the data collected made it possible to understand (in depth) where Brazil stands, regarding access to opioids. As John Gerring[203] and Lamont[204] observe, the in-depth analysis of a single unit is useful in elucidating causal mechanisms. While comparing different countries would provide information about the same variables in each country, it would fail to provide insights about unique local aspects that have an impact on access to opioids, which are distinct of those related to the impact of the

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[199] Thomas Pepinsky, "The Return of the Single-Country Study", *Annual Review of Political Science*, 2019. 22:187-2003, p. 188. https://tompepinsky.files.wordpress.com/2019/05/arps2019.pdf [Accessed 6 June 2022]

[200] Pepinsky, p. 200.

[201] Pepinsky, p. 200.

[202] Pepinsky, p. 201.

[203] John Gerring,"What Is a Case Study and What Is It Good For?" *The American Political Science Review*, 98. 2, (2004), pp. 341–54. (p.349) http://www.jstor.org/stable/4145316 [Accessed 6 Jun. 2022]

[204] Lamont, p. 131.

international drug control system. As Gerring explains "Cross-unit variation, (…) is often mute with respect to causal mechanisms"[205]The limitation of a single case study is the lack of comparison to other countries. The collection of original data is more difficult in a cross unit-analysis than in a case study analysis, since it involves greater expense, greater difficulties in identifying and coding cases, learning foreign languages and so forth. [206]Since the case study research was conducted mostly during the Covid 19 pandemic, not only financial resources were limited, but also face to face interviews in other countries that would serve for comparison.

In the single case study, to explore the causal mechanisms that lead to the lack of access to opioids in Brazil. I used the process-tracing analysis of the data collected. This tool allows the understanding of how variables interact which each other and trace the sequence of events that brought about the outcome that is being explained. Process-tracing allows the researcher to explore what causal mechanisms brought about a particular outcome. And thus provide a deeper explanatory insight for the reader.[207]

The methods used for the research about Brazil were document-based research and semi-structured interviews with key informants. Apart from the literature available on drug policy in Brazil, primary sources such as Brazilian drug laws and ordinances, as well as guidelines published by the Brazilian Ministry of Health were examined.

For the sample of key informants, I used the snowball sampling strategy. The advantage of this strategy is to quickly reach out relevant key informants in a relatively short period of time. The drawback is the risk of being locked into a particular social or professional network.[208]Firstly I contacted seasoned palliative care specialists in Brazil, which indicated further relevant interviewees. However, I was not limited to the contacts originated from my first interviews and searched for informants from different professional networks, based on desktop research suggestions by informants I contacted during CND meetings in Vienna or at WHO, in Geneva.

As the goal of process tracing is to obtain information about well-defined and specific events and processes, the most appropriate sample are those that had the most

[205] Gerring, p. 349.

[206] Gerring, p. 353.

[207] Lamont p. 135.

[208] Lamont, p. 147.

involvement with the processes of interest. In elite interviews the aim is to draw a sample that includes the most important political players who are participating in the events being studied.[209]Elite interviews as the name explains is made with someone that was chosen because of who they are and the position they occupy.[210]Although elite interviews compensate the weaknesses of archival documents, because important processes lack documentary evidence, they also have limitations. While interviews can compensate distortions in written sources, interviewees misrepresent their own positions questioning the reliability of their statements. As politicians may inflate their participation in events, civil servants are prone to under-represent their role in political decision-making. Also, when interviewees are subject to lapses of memory when the event of interest has taken place years earlier.[211] Elite interviews are distinct from intensive interviews, thus not suitable for this single case study, which uses process tracing as a strategy of analysis. Intensive interviews a are made with ordinary persons to understand what they think or feel about ideas of a certain issue area, where they express ambivalence, passion, incoherence, certainty, what connections they make. Basically, they serve to understand how interviewees frame their views and are chosen randomly.[212]

The interviews with informants contacted after desk research, but not chosen randomly. This is the case for officers from the Brazilian Ministry of Health and Justice. Key informants were palliative care physicians, pain specialists, oncologists and family doctors, anesthesiologist, working both in the private and public sectors, from all Brazilian regions. A few had experiences with health care management. Nurses, pharmacists and experts in pharmacology, a psychologist specialized in palliative care, community leaders and NGO personnel were also interviewed. I also contacted officers from the Brazilian Ministry of Health and Ministry of Justice, an

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[209] Oisín Tansey, 'Process Tracing and Elite Interviewing: A case for Non-probability Sampling', *Political Science and Politics*, (American Political Science Association, 2007), .40.4 pp. 765-772.

https://www.cambridge.org/core/journals/ps-political-science-and-politics/article/abs/process-tracing-and-elite-interviewing-a-case-for-nonprobability-sampling/8EE25765F4BF94599E7FBD996CBFDE74 [Accessed 6 June 2022], p.765.

[210] Hochschild JL. *Conducting Intensive and Elite Interviews*, Workshop on Interdisciplinary Standards for Systematic Qualitative Research, (Harvard University, 2009).

https://scholar.harvard.edu/jlhochschild/publications/conducting-intensive-interviews-and-elite-interviews [Accessed 6 June 2022]

[211] Tansey, p.767.

[212] Hochschild JL.

opioid researcher from Fundação Oswaldo Cruz, which is connected to the Brazilian Ministry of Health. To assess the validity of data collected on interviews, I used the strategy of triangulation with quantitative data available, although scarce, on access to medicines in Brazil and official documents.

The interviews for the case study were done mostly by video conference, due to the Covid 19 pandemic, and I was given permission for recording in all cases. In a few cases, due to technical limitations and circumstances in which the interview occurred, it was not possible to record, but the interviews were registered in notes. I was familiar with Brazilian health system structure and the institutions interviewees belonged. I knew well regional differences in Brazil, which facilitated the understanding of collected data. The material obtained are in the format of audio files and notes and organized in topics such as bureaucracy, poor distribution, gaps in the health system, education of health care professionals, opioids in primary health care, local cultural attitudes. Interviews for the case study were conducted in Portuguese, which required translation work. The terms that had no correspondent in English were explained in the text.

## 4. Research ethics

Although I took different roles during the participant observation period, there was no conflict between them, and the interviewees agreed to give information. As Lamont notes, particularly in International Relations, certain research ethics practices such as securing an interview consent may not be in all cases, the most appropriate course of action.[213]Sometimes, formalities such a written informed consent are viewed with distrust.[214] In this work, both formal and informal conducted interviews could only take place after having developed a certain degree of trust with the interviewees.

I went through the process of ethics approval at Swansea University, and I was granted ethical clearance. This allowed me to carry out the interviews as a participant observer in Vienna and Geneva and for the case study about Brazil. This research was self-funded. It caused no harm to participants and did not involve children or vulnerable adults.

[213] Lamont, p. 49.

[214] Lamont, p. 151.

## 5. Conclusion

This chapter discussed how this dissertation is organized, its themes and methods used in this work. This dissertation is divided in three parts: historical antecedents of the current international drug control regime, changes in in the regime focusing on the period between 2009 and 2019, and the case study about Brazil. The themes approached in this dissertation encompass three levels of tensions. First, the tension between national sovereignty and states' international commitments; second the tension between the international human rights and the international drug control regimes. Tensions within the international drug control regime, between WHO and the INCB will also be analyzed. Third, the tension between adequate access of internationally controlled medicines and control of illicit drug markets. The overarching theory to analyze the proposed themes is constructivism. From this perspective, the theory of norm dynamics will be used to discuss the changes occurred in the international drug control regime that led to the increased importance of the issues of access to controlled medicines in drug control fora. The theory of regime complexes and regime complexity will be also used to show the friction between the international drug control regime and human rights regime. The idea intra-regime complexity will be used to discuss the tensions between WHO and the INCB, within the international drug control regime.

Methods used in this work are the analysis of secondary and primary sources such as the official records of the negotiations of the Single Convention, and participant observation at the Commission of Narcotic Drugs and its intersessionals, as member of civil society organizations and as an intern at UNODC. Elite interviews were used mostly in the case study.

# Chapter 2

# The foundations of the international drug control regime and the demonization of opium

## 1. Introduction

This chapter presents the history of the international drug control conventions, to identify the political tensions and market related changes that led to each new hard law instrument and treaty bodies that, today, correspond to the International Narcotics Control Board (INCB), the Commission on Narcotic Drugs (CND) and, albeit often marginalized, the World Health Organization (WHO). Rather than a broad-brush historical overview, the chapter will offer an original perspective by focusing particularly on the regime's imperative to ensure access to controlled medicines under the international treaties.

As mentioned in the introduction, some controlled medicines, classified under the scheduling system of the drug control conventions also appear on the WHO's Model List of Essential Medicines, and are indispensable for the treatment of medical conditions. This work focuses specifically on one class of controlled and essential medicines, opioids, and the tensions emerged on the conflicting requirements of ensuring access for medical and scientific purposes and preventing their diversion and non-medical use. Other substances scheduled under the drug control conventions with traditional use (such as coca leaf) and medical use (such as cannabis) are not discussed in depth here.

With this in mind, this chapter explores, in a systematic manner, how the international drug control system approaches the medical use of opioids. This analysis covers the period between 1909, when the Shanghai Commission, the first multilateral forum on drugs, restricted the licit use the use of opium only to medical purposes and analyzes all the following drug treaties adopted until 1945, when the UN was founded.

As will be discussed, building upon the outcomes of the Shanghai Commission, the first legally binding international drug control treaty from the pre-United Nations period was the Hague Convention of 1912. In 1920, with the establishment of the League of Nations, emerged the League Health Committee, responsible to advise in

medical matters. In 1925, under the Geneva Opium Convention, drug control was expanded and included not only opium and morphine, but also heroin and cocaine.[215] The Health Committee later devised a scheduling system with two different groups of substances, under the 1931 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs. The substances were classified according to their propensity to cause dependence, and morphine was included in the group of most addictive substances. The chapter will demonstrate how concern over opium leakage into the newly created illicit market drove increased restrictions and sophistication of control measures. Indeed, in the Convention of 1936 for the Suppression of the Illicit Traffic in Dangerous Drugs, personal use was criminalized under penal sanctions.

The period between the Shanghai Convention in 1909 and the founding of the United Nations in 1945 was focused on preventing the leakage of opium produced for medical and scientific purposes into the illicit market. Discussions on a definition of drug addiction and on its treatment were dominated by practices carried out in the United States but remained controversial and unconclusive. The assumptions that drug addiction was a cause of violence and drug abuse a practice by social minorities were present both in US's domestic narratives and within the League of Nations.

While a multilateral endeavor developed, initiatives to create new treaties were largely led by the United States, aiming to increase the level of control. US diplomats were in many ways influenced by moralistic and religious groups at home to promote the prohibition of drug use, except for medical use. However, since the beginning of the international drug control regime's development, discussions to define what constituted medical use of a substance, or if self-medication would be acceptable as medical use, or even, what would be characterized as drug abuse were scarce. Among different countries these concepts were understood in different ways, particularly where traditional medicine played an important role.

In the light of this historical overview, this chapter it aims to explain how historical antecedents led to the lack of access to licit opioids for medical purposes occurring

[215] UNTC, *International Opium Convention (Geneva Convention)*, Treaty Series, Vol 81 No. 1845, p. 6

today and why a health approach of the international drug control regime (IDCR) has been put aside.

To answer these questions and clarify the fundamental characters of the regime, this chapter will explore the demonization of opium and the origins of drug prohibition in the international drug control regime. Therefore, the chapter begins with the antecedents of the Shanghai Commission, discusses the origins of prohibitionism and the drug control treaties of 1909, 1912, 1931, 1936 and their implications for the issue of access of controlled medicines, such as opioids.

## 2. Drug treaties pre-United Nations and the demonization of opium

This section will discuss how opium and other substances, as a result of excessive control, have been demonized by government authorities and their representatives, under the influence of moralistic religious and conservative groups. Their actions limited, even if indirectly, the use of opioids for medical purposes and it has not changed considerably until today. This contributed ultimately to the lack of adequate access to opioids for pain treatment in many parts of the world.

The demonization of opium will be discussed in this section by examining: the antecedents of the Shanghai Commission and the development of the international drug control regime under the League of Nations.

The world drug problem was internationally discussed for the first time in 1909, at the Shanghai Opium Commission. At that time their objective was to develop some form of international control on opium trade.[216]

### 2.1. Antecedents of the Shanghai Commission

The Shanghai Commission, initiated by the US, was a combination of three aspects such as the British opium trade with China, the role of American moral entrepreneurs

[216] David R.Bewley-Taylor, *The United States and International Drug Control*, (1909-1997) (London :Continuun, 1999), p.22.

in Asia and the relations between United States and China. The combination of these factors led to the beginning of multilateral drug control system.

In the 19th century the British government was strongly interested in the opium trade, as British traders sold opium produced in British India to China. Until then, in China, opium was a rather exclusive symbol of wealth and power, used among friends and business partners.[217] It was also available as a medication, recognized by medical professionals as a cure for many conditions, including pain, fevers, dysentery, rheuma, plague and cholera, among others.[218] Opium houses provided accommodation and meals for poor workers, in need of a temporary home also used to silence hunger like coca in Peru and Bolivia.[219]

However, as Frank Dikötter and others note, on the turn of the 19th century, "control over opium meant control over trade and ultimately, control over society".[220] The use of opium spread throughout Chinese society, was consumed by the imperial clan, workers, merchants, officials, women, nuns and monks. Opium trade was such a good business for the British, that they went to war twice, when the Chinese wanted to ban the flow of opium brought by the British in China.[221]

While the demonization of opium in China was affecting its relations with Britain, interested in continuing to sell opium to China, Americans took advantage of this situation. In fact, US-China relations were shaken because Chinese migrants were seen as a threat to the purity of the American society and to white labor.[222] The reason was that opium smoking made them commonly associated with prostitution, addiction, gambling and all sorts of vices that would undermine American society. [223] Consequently, the first opium law was passed in San Francisco, in 1875, prohibiting

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[217] Frank Dikötter , Lars Lamaann and Zhou Xun *Narcotic Culture, a History of Drugs in China*, (Chicago: Chicago University Press 2002) p. 325.

[218] Dikötter, 2002, p. 324.

[219] Dikötter, Laamann, Zhou Xun, Narcotic Culture, A Social History of Drug Consumption in China, *British Journal of Criminology* (2002), 42, 317-336. ( p. 324) < https://www.semanticscholar.org/paper/Narcotic-Culture.-A-Social-History-of-Drug-in-China-Dikötter-Laamann/74c7596fb55e984a1f7ddeea4e318995f42298a3> [Accessed 7 June 2022]

[220] Dikötter et al, p. 321.

[221] Opium Wars (1839-1842) and (1856-1860).

[222] Bewley-Taylor, David R. *The United States and International Drug Control*, p. 17.

[223] Richard Davenport-Hines, *The pursuit of oblivion*, (Phoenix 2001), location 2249, Kindle edition.

[223] Nadelmann, p. 506.

opium smoking and targeting Chinese immigrants and white people acting in ways perceived to be deviant behavior.[224] Also, American from upper and middle class were acquiring Chinese migrant's habits, which "provoked high anxieties to protect their youngsters from addiction."[225] At that time also, American civil society groups made pressure to restrict the use of opium. Their influence in earlier periods "was minimal, but very influential"[226]. Evangelical networks were responsible for demonizing both industrialized products and raw material to produce drugs, including those to treat pain, used by doctors and traditional healers.[227] US moral entrepreneurs played an important role in advocating sobriety, which resulted in the enactment of federal and state legislation prohibiting opiates, cocaine, alcohol, and cigarettes. They convinced the American elite that lower classes were vulnerable to drug abuse, a problem that would affect economic productivity.[228]

As Jensen and Gerber note, the American elite's views on opium were an example of what happens with states that ignored certain social pressing issues such as poverty, crime, and inequality of life chances. It is much better and politically safer to attack the useful enemy as defined by Christie and Bruun in 1991. They usually consider that problems that become official social problems are those defined as leaders by powerful groups. Such enemies are usually dangerous, satanic and inhuman, at least for the leaders. To assume the responsibility in the fight against the enemy, one must feel secure. Criticism comes later. Good enemies always stay alive, there are victories, but not permanent peace. The enemy is sufficiently defined so that it can be fought, but sufficiently ambiguous so it can be suspected behind every bush.[229]As an example of a good enemy, the fight against opium use was useful to justify other issues facing the US government.

As such, the tension between the United States and China culminated when the American Congress decided to exclude Chinese labor force through the *Chinese*

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[224] Nadelmann, p. 506.

[225] Davenport-Hines, location 2296.

[226] Katherine Pettus, Katherine, 'Improving Access to Internationally Controlled Medicines in the Post- UNGASS Agenda 2030 Framework in: *Collapse of the Global Order: From UNGASS 2016 to Review 2019*, 85-100, edited by Axel Klein, Blayne Stothard, pp. 85-100 (UK: Emerald Publishing Limited, 2018), p. 86.

[227] Pettus, p. 90

[228] Nadelmann, p. 506

[229] Jurg Gerber and Eric L. Jensen (editors), *Drug War American Style, the internationalization of failed policy and its alternatives*, (New York: Garland 2001/ Routledge, 2013), p.8. Kindle edition

*Exclusion Act* signed by Roosevelt and, as a response, China embargoed American products in China, provoking a commercial disaster.[230] This was the scene just before the organization of the Shanghai Commission. But the impetus for a multilateral approach came from United States, when their missionaries returned from the Far East and were joined by various economic and political groups in the US against opium.[231] Those are who Ethan Nadelmann called "moral entrepreneurs".[232] Nadelmann's work on diffusion of norms showed that that moral proselytism, made by moral entrepreneurs played an important role in the initial stages of the development of the international drug control regime."[233] European and American Christian missionaries mobilized popular opinion, political support in in their home and host countries, transforming a national interest with the home government into transnational and universal objective, rather a peculiar moral code of one particular society, by persuading foreign audience.[234]

The role of moral entrepreneurs like Bishop Charles Brent, Episcopal Bishop in the Philippines[235] and Hamilton Wright, physician with political connections was to convince president Theodor Roosevelt to organize an international conference to help the Chinese on the fight against opium.[236] The initiative resulted in the Shanghai Commission, and was supported by American governor in the Philippines, William Howard Taft, who suggested that helping the Chinese to reform opium norms, would soften the tensions provoked by American trade policies in China[237] and would result in a less favorable relation between China and Britain.[238]

The Shanghai Commission, in 1909 was the beginning as international drug control regime, which, according to Nadelmann, is a "global prohibition regime" influenced by the morality and self-interest of American and British missionaries, who acted as

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[230] Antonio Escohotado, *História General de las Drogas, II, de la prohibición a nuestros días*, (Madrid: La Emboscadura 1998/2018), p. 31.

[231] Nadelmann, p. 504.

[232] Nadelmann, p.482.

[233] Nadelmann, p. 503.

[234] Nadelmann, p. 482.

[235] From 1898 to 1912, the Philippines were occupied the US after the war US-American War, during the expansion period of US territories, that included Cuba and Puerto Rico.

[236] Escohotado, p. 31.

[237] Escohotado, p. 32.

[238] Nadelmann, p. 507.

moral entrepreneurs that lived and worked in China in the 19th.[239] According to Martha Finnemore and Kathryn Sikkink, the Shanghai Commission illustrates the first stage of norms cycle, which is norm emergence and whose characteristic is the persuasion by norm entrepreneurs. They attempt to convince a critical mass of states (norm leaders) to embrace new norms.[240]

### 2.2. Origins of Prohibitionism

According to Ethan Nadelmann, the international drug control regime is a "international prohibition regime", which reflects not only economic and political interests but moral and emotional factors, involving religious beliefs, humanitarian sentiments, faith in universalism, compassion, conscience, paternalism, fear, prejudice and compulsion to proselytize.[241] He notes that moral entrepreneurs were driven by the morality of United States and Western Europe and moral entrepreneurs, able to mobilize popular and political support for drug prohibition.[242] Although their role was crucial on prohibition, the idea that prohibitionism was created and developed in the US, was challenged by James Windle, in his article "How the East Influenced Drug Prohibition" in which he discusses that Americans learnt about prohibition in the Far East.[243] Also, Isaac Campos in the book *Home Grown*[244]argues that the idea that cannabis was dangerous was brought from Mexico to the US. Although Campos focuses his book on cannabis, his insights on prohibition are useful to examine its origins. In his article, Windle disagrees with Nadelmann about the origins of prohibition as an American invention but reinforces Nadelmann's argument on the desire and capacity of the US to export prohibitionism to other parts of the world.

As he points out, for Nadelmann:

*The nature of the global drug control regime reflected the predominance of the United States and Europe in*

[239] Nadelmann, p. 480.

[240] Finnemore and Sikkink, p. 895.

[241] Nadelmann, p. 480.

[242] James Windle. "How the East Influenced Drug Prohibition." *The International History Review*, 35. 5, (Taylor and Francis2013) pp. 1185–99 (p.1185)http://www.jstor.org/stable/24701256. [Accessed 10 Jun. 2022]

[243] Windle. p. 1185.

[244] Isaac Campos, *Home Grown Marijuana and the Origins of Mexico's War on Drugs,* (Chapel Hill: the University of North Carolina Press 2012)

> *establishing global norms concerning the selection and appropriate uses of psychoactive substances. Some Asian states, for instance, might have opted for a different global regime that legitimized the use of opium [however] … the global drug enforcement regime reflected the desire and capacity of the United States to impose its drug-related norms on the rest of the world.*[245]

Also, Bewley-Taylor's book *The United States and International Drug Control, 1909-1997*,[246] shows a precise account, under an international relations perspective, of the influence of the US on shaping the fundamental character of the international drug control system.

Here, it is accepted that the US would also encourage other nations to place faith in a prohibitive policy[247] and was successful in exporting this idea worldwide. But it is argued that although it is true that the US was successful in imposing a prohibitionist approach to other countries, the US should not be solely blamed for the demonization of drugs and its consequent issues on access to medicines. These ideas found rather an echo that gained force in some countries, than a new concept coming from the US. This argument is based on works of Windle and Campos, showed, later in 2013 and 2012, respectively, that local prohibitions were originated in different parts of the world, such as Far East[248], Mexico[249], South Africa[250], and in Brazil[251], prior to international controls.

Countries where prohibitionism flourished, had already a prohibitionist legislation and groups of physicians and pharmacists that took advantage of prohibitionism to guarantee their self-interests or bureaucratic survival of institutions they worked for. These countries also had elites interested to prohibit drug use, usually with the excuse

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[245] Nadelmann, p. 511.

[246] Bewley-Taylor, *The United States and International Drug Control*, p. 33.

[247] Bewley-Taylor, *The United States and International Drug Control* p. 33

[248] Windle, p. 1189

[249] Campos, p. 203

[250] Campos, p.19

[251] Carlos Eduardo Martins Torcato, *A história das drogas e sua proibição no Brasil: da Colônia à República*, (unpublished doctoral thesis, Faculdade de Filosofia, Letras e Ciências Humanas (FFLCH), Universidade de São Paulo – USP, 2016), p. 164.

https://teses.usp.br/teses/disponiveis/8/8138/tde-05102016-165617/publico/2016_CarlosEduardoMartinsTorcato_VCorr.pdf [Accessed 7 June 2022]

that it was associated to criminality, to control certain social groups such as African Americans, immigrants or indigenous, among others. Their scientific discourse was not based in scientific evidence but was supported by the police and justice system in the first half of the 20th century. It is important to note that the category of health professionals is not always prohibitionist, because drugs are used for medical purposes. But they claim for the power to decide which medicines, how much of a medicine should be used and who is allowed to use a medicine and for how long.

In a more nuanced perspective, James Windle, argues that the United States undoubtedly wanted global prohibition, but it does not mean that the US national prohibition was an American construct. On the contrary, he explains that US prohibitionism was learnt from missionaries that were in Asian countries, where opium prohibition occurred much earlier.[252]

Windle argues that the opium prohibition in the US was a result of the influence of moral entrepreneurs, such as missionaries, that, together with the medical industry, interested in securing their professions and profits, lobbied for opium prohibition and against self-medication and home remedies.

The development of new drugs, such as morphine and heroin, was considered revolutionary. They were produced and distributed by Europeans with enthusiasm of medical professionals and pharmaceutical companies, that gained power through the organization of powerful association of physicians and pharmacists. [253] Americans were not only interested in restricting drug exports to the US. They were strongly interested in monopolizing public's access to medicines and advice to substances.[254] Even in the period of maximum opium prohibition, in 1894-1895, paradox group of catholic and protestant missionaries and Chinese modern reformers accepted the use of morphine, as an anti-opium medicine but it was obtained only under prescription.[255]

Despite all the anxiety of American upper class provoked by opium smoking, the first federal responses came only in 1890, although with significant loopholes. The first prohibition law was passed in the Philippines, in 1905, where missionaries had strong

[252] Windle, p. 1185.

[253] Windle, p.1188.

[254] Nadelmann, p. 505.

[255] Dikkötter, Lamaann and Xun, p. 148.

influence. However, the United States had no domestic prohibition law on opium smoking until 1909, when Shanghai Commission took place. Domestic distribution of opium had no restrictions until 1914, when the Harrison Narcotics Act was passed.[256]

Windle shows that opium prohibition in the US came much later than in other countries in Asia.[257] In Thailand, opium consumption and trade was prohibited in 1360.[258], lasted for almost 500 years, and included death penalty for offenders in 1811 and 1839, for trafficking. [259]

In Japan, opium for non-medicinal use was prohibited between 1600 and 1867, during the Edo period and continued during the Meiji period (1868 -1912). In Viet Nan, opium was prohibited in 1665, when the eradication of opium crops and stores was called. Consumption and distribution were punished with exile, and opium smuggling, with death penalty in the first half of 1800s. [260]In Burma, during the Kombaung Dinasty, all intoxicants and stimulants were prohibited during the reign of King Bodapaya between 1781 and 1819, who made consumption a capital offence.

In China, despite records of medicinal use of opium in the eighth century, the prohibition of sale and distribution of smoking opium dates back from 1729 by Emperor Yongzheng. Punishments included death penalty for merchants and opium den-operators, but it was not enough to curb the increased demand and consequently, greater quantities of opium exports by Western merchants. In response to that, in 1780 China prohibited the importing of opium for non-medicinal purposes, but distribution continued because the definition of medicinal use was vague.[261] In the 19th century, Emperor Daouguang, from the Qing dynasty (1820-1850), considered opium the cause of military weakness and harmful to people for being a waste of money, particularly for those in the workforce. For moral reformers, opium was a source of corruption,

[256] Windle, p. 1187.

[257] In fact, Budhist societies prohibited opium before the opium trade in Eastern countries based on the assumption that it affected monk's concentration and elites followed their religious leader's prohibitions. In: Windle, 2013, p. 1189.

[258] Windle, p. 1189.

[259] Windle, p.1189.

[260] Windle, p. 1190.

[261] Windle, p. 1191.

and it became the scapegoat for political and economic problems faced by the court and demonized for its association with the West.[262]

These examples of prohibition and demonization of opium show that the difficulty in drawing a line to separate medical from non-medical use was already present in the 18th century and remains until today as it will be discussed in this dissertation.

The value of Windle's work is to show how the views about opium changed while Western missionaries were in China in the 19th century. Moral entrepreneurs initially collaborated with opium trade, since they built schools, orphanages and hospitals and used opium as a medicine, according to the norms of Chinese doctors. Other missionaries even travelled to China in ships carrying opium to China, traded drugs as a means of funding their mission and or supplied addicts as a condition that they attended prayer meetings and were perceived as Westerners that were selling drugs to Chinese.[263] But missionaries, that usually came from Western countries where opium use was tolerated, realized that in fact opium traders were hindering their work on proselytizing and began to blame opium use as the cause for their failure to convert Chinese. Consequently, as Windle well observes "it is possible that many individual perceptions of opium were changed by experiences in China and the interactions with Chinese prohibitionists", and from other Asian countries.[264]

Mexico is another example of a country that adopted prohibitionism particularly on cannabis earlier than the US. According to Isaac Campos, it was actually Mexico that influenced the US regarding cannabis use. Although this thesis is not focused on cannabis, the case of Mexico is another example to show that prohibitionism was not simply constructed in the United States but was rather a local reality in other countries, including in Latin America. In Mexico, cannabis was nation-wide prohibited in 1920 considered it a threat for the well-being of an entire nation. But Since 1870 medical and legal scholars began to describe the effects of substance use as madness or idiotism. [265] Later, the belief was that cannabis use would lead to crime and violence. It was similar to the idea "drinking was road to crime", a concept based on the theories

[262] Dikötter, Lammann and Xun, p. 321.

[263] Windle, p. 1192.

[264] Windle, p. 1192.

[265] Campos, p.83.

of public hygiene.[266]At the end of the 19th century marijuana began to be perceived as an especially pernicious drug because it was associated with a class of people considered to be dangerous, degenerated, and criminal – which was deeply rooted in social and racial prejudice with support of scientific discourse.[267]

It was a useful argument for Mexican elites to justify the miserable condition of indigenous peoples, that were migrating to Mexico City, and validate strong social hierarchies that used to rule life in the country. [268]

Again, corporativism among pharmacists and physicians increased their interest in securing their professions, in Mexico's first sanitary code in 1891. It included provisions that medicinal substances could only be dispensed by authorized pharmacists and prescribed by physicians, thus lobbying for stricter controls. The problem is that poisonous and dangerous drugs were gradually being recognized as recreational drugs and in Mexico, the list of these drugs included opium, morphine, and cannabis. These provisions show how Mexican legislation on drugs was ahead of its time, considering that they were discussed internationally before the Hague Convention, in 1912.[269]

Campos argues that Mexican ideas formed a foundation for the development of ideas that marijuana caused crime violence and madness[270] in the United States and these ideas crossed the border most significantly through the press. In 1895, the Mexican Herald[271] began to be published in English and they owned a franchise of the news agency Associated Press in Mexico City. As a result, the American press started to pick stories on what was happening in the streets of Mexico City, with all the details on crimes and insanities committed by the Mexican lower class.[272]Although Mexican

[266] Campos, p.105.

[267] Campos, p. 119.

[268] Campos, p. 129.

[269] Campos, p. 193.

[270] It is argued by Campos the idea that marijuana caused madness was imported from Egypt and India. In: Campos, p.204.

[271] Examples of headlines from Mexican newspapers: "Marijuana mind destroyer is grown San Antonio?" "Madness in Plants", "Smoking that Maddens", "Dangerous Mexican Weeds", "Evil Mexican Plants that drive you insane" In: Campos, p. 21.

[272] Campos, p.206.

played an important role in the prohibition of marijuana, in the US they usually appear as victims of American prejudice.

In fact, in the analysis of Campos, Americans used stereotypes of irresponsibility and violence against Mexicans, the same way Mexican elites treated their own lower classes: with racism.[273] A similar situation occurred in Brazil, where race issues also played a role in prohibitionism.

The cases of prohibition examined so far were clearly domestic affairs, but as it will be shown throughout this chapter, the United States was the country that had the desire and, critically, capacity to impose prohibition and evolve a national concept into an international one, whereas none of the countries discussed above did, and although they did not construct prohibition, they globalized its prohibitionist policies and counter-narcotic measures.[274] The following sections will show how the drugs, particularly opium continued to be demonized, in the international drug control system.

## 3. Drug control treaties and access to controlled medicines

In this section it will be discussed how the international drug control regime began to develop a framework to differentiate what was medical, thus licit, and non-medical illicit use of opium, at the Shanghai Commission. This the bone of contention of the system and the source of the three levels of tensions analyzed in this dissertation.

### 3.1. Medical and scientific use of drugs - 1909

The strained US-China relations combined with the efforts of American moral entrepreneurs in Asia led President Theodor Roosevelt to initiate the Shanghai Commission to negotiate a new set of rules for opium control.[275] In February 1st, 1909, the 38 delegates from 13 countries assembled in the Palace Hotel Shanghai were greeted by a telegram sent by Roosevelt: “I extend to the Commissioners today

[273] Campos, p. 223.

[274] Windle, p.1194.

[275] States represented at the Shanghai Commission: United States of America, Austria-Hungary, China, France, Germany, United Kingdom, Italy, Japan, Netherlands, Persia, Portugal, Russia and Siam. In: UNODC, The Shanghai Opium Commission. https://www.unodc.org/unodc/en/data-and-analysis/bulletin/bulletin_1959-01-01_1_page006.html [Accessed 10 June 2022]

assembled my good wishes and conviction that their labours will be of the greatest importance towards the general suppression of the opium evil throughout the world."[276] As it will be discussed in this thesis, countries failed to effectively suppress the opium "evil". But the term remained on the core of other drug treaties and evolved to be the "drug evil consensus".[277]

The US made pressure for prohibition, interested in restricting the licit use of opium to medical and scientific in terms of purposes, as defined in terms of western science.[278] Britain wanted to protect the Indian Opium trade, but the discussions were focused on China's domestic situation on opium use. Other colonial powers present at the Commission refused the idea, advocating for quasi-medical use of opium and mentioning the difficulty in prohibiting the use of opium without an alternative.[279] As Kettil Bruun and others observe "the proposal to discuss medical matters was narrowly defeated."[280].There was an initiative to appoint a committee to discuss medical use of opium, which was blocked by the British, claiming that delegates lacked the expertise on the subject. But there were four qualified physicians among the delegates, who could easily have formed a committee to discuss medical perspectives.[281]

The meeting did not result in a drug control treaty, but the Commission adopted nine resolutions that served as recommendations to countries. One of them was "on the problem of morphine and an injunction to take drastic to measures control its use."[282] As such, since the Shanghai Commission the use of morphine was associated to a great danger in an international document as one of the resolutions of the Shanghai Commission states:

*5. That the International Opium Commission*

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[276] Helena Barop, "Building the «Opium Evil» Consensus – The International Opium Commission of Shanghai." Journal of Modern European History / *Zeitschrift Für Moderne Europäische Geschichte / Revue d'histoire Européenne Contemporaine*, vol. 13, no. 1, (JSTOR 2015), pp. 115–37, p. 115

https://www.jstor.org/stable/26266168 [Accessed 10 June 2022]

[277] Barop, p.115

[278] William B. Mc Callister, *Drug Diplomacy in the Twentieth Century an international history*, (London and New York: Routledge 2000) p. 29.

[279] Mc Callister, p. 29.

[280] Kettil Bruun, Lynn Pan, Ingemar Rexed, *The Gentlemen's Club, International Control of Drugs and Alcohol*, The University of Chicago Press, Chicago and London, 1975. p. 11.

[281]Barop, p. 133.

[282] Bruun, Pan and Rexed, p. 11.

> *finds that the unrestricted manufacture, sale and distribution of morphine already constitute a grave danger, and that the morphine habit shows signs of spreading: the International Opium Commission, therefore, desires to urge strongly on all governments that it is highly important that drastic measures should be taken by each government in its own territories and possessions to control the manufacture, sale and distribution of this drug, and also of such other derivatives of opium as may appear on scientific inquiry to be liable to similar abuse and productive of like ill effects.*[283]

Although Americans believed that opium prohibition should be accomplished as soon as possible, except for medical purposes, this proposal was rejected by most of the countries and particularly by Great Britain. According to Bishop Charles Brent[284] of American representative at the Shanghai Commission, it was not possible to reach an agreement that their use other than medical was evil and immoral.[285]

The notion that non-medical use of opium was evil, and for this reason needed to be prohibited, resulted in a tendency to fight drug problems with law enforcement measures.[286] With the resolutions agreed at the Shanghai Commission, a core dilemma emerged because of the dualist nature of drugs. They can be beneficial if used appropriately or they can cause harm to those who abuse of them. The challenge, as noted by Buxton, was "how to construct a framework that could reconcile conflicting

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[283] UNODC, *The Shanghai Opium Commission*, pp- 45-46, (p.45) https://www.unodc.org/unodc/en/data-and-analysis/bulletin/bulletin_1959-01-01_1_page006.html,

[284] Charles Henry Brent was a missionary bishop from the Episcopal Church at the Philippines between 1902-1918. He served President Theodor Roosevelt's interests in "freeing the colony from perceived opium smoking". In: Bewley-Taylor, *The United States and International Drug Control* , p.20.

[285] Bewley-Taylor, *The United States and the International Drug Control*, p.20.

[286] Barop, 115.

interests, ensure an adequate global supply of medical drugs and alter patterns of individual behavior"[287]This question remains to this day.

Since the end of the Shanghai Commission, the US continued to lobby in favor of a new conference aiming to reach stricter international controls, while reinforcing domestic control objectives.

### 3.2. The prohibited substances - 1912

In 1912, the Hague Convention[288], extended the restriction of opium use only for medical purposes to heroine, morphine, cocaine and Indian hemp, commonly known as cannabis.[289] It also instituted a system of licensing, record keeping and international reporting on the production, despite the lack of administrative structure to apply these measures was created but it was not said on how these principles should be put into practice.[290]The treaty entered into force in 1919 .

The International Opium Convention in The Hague (The Hague Convention 1912) also called the Convention on the Suppression of Abuse of Opium, entered into force in 1919. It was the first legally binding instrument of international drug control, but states obligations referred to the domestic sphere of each government.[291]As such, implications for the sovereignty of member states to this convention were still relatively weak, in comparison to treaties that were about to come. (See Appendix 2)

With the Hague Convention, the idea of restricting opium to medical and scientific purposes gained further recognition. In this regard, the US was clearly willing to make progress in international drug control driven by moral motivation, but it had not the same importance in global politics as colonial powers such as France, Great Britain,

[287] Julia Buxton, pp.38-39.

[288] UNTC, *The Hague Convention 1912, Treaty Series*, vol. 8, No. 222

[289] Bewley-Taylor, *The United States and International Drug Control*, p. 24

[290] Bewley-Taylor, *The United States and International Drug Control*, p. 24.

[291] Bruun, Pan and Rexed. p. 12.

Portugal and the Netherlands. These countries limited radical proposals made by the US.[292]

When the negotiations were concluded, the International Opium Convention its Preamble highlighted a health concern as it states:

> *(…) resolved to pursue progressive suppression of the abuse of opium, morphine, cocaine as well as drugs prepared or derived from these substances giving rise (…) to analogous abuses (…)*[293]

As Rick Lines notes, the progressive suppression of abuse is referred in the preamble as a "humanitarian effort"[294], (Appendix 1) adding for the first time an element of human rights to drug treaties.[295]This treaty included provisions, in Article 14, to control the manufacture importation, sale and exportation of medicinal opium, morphine, cocaine and their respective salts, all preparations containing more than 0, 2% of morphine or 0,1% of cocaine, heroin and its salts and preparations containing more than 0,1% of heroin. Article 14, paragraph d) stated that to the laws and regulations would apply to every new derivative of morphine, cocaine, their respective salts or any other alkaloid of opium, which after scientific investigations would give rise to similar abuse or injurious effects.[296] This paragraph had already anticipated that other substances that were not even yet developed, would be automatically subject to international control if provoked abuse or similar effects to the drugs subject to control under the Hague Convention. The first attempt to control cannabis was initiated in the conference for the Hague Convention, initiated by Italy, and supported by Americans.[297] As such, this Article included the rudimentary principles of the scheduling system and the work of the Expert Committee on Drug Dependence, as it will be discussed later in this chapter.

US international efforts on drug prohibition sounded unreasonable without a domestic regulation on the issue. The first federal law on drug regulations was the Harrison Act,

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[292] Bewley-Taylor, *The United States and International Drug Control*, p. 25.

[293] UNTC, *Geneva Opium Convention*, Treaty Series, Vol 81 No. 1845, p.2

[294] UNTC, *International Opium Convention* (Geneva Convention) Treaty Series, Vol 81 No. 1845, p.2

[295] Rick Lines, Deliver us from evil? -The Single Convention on Narcotic Drugs, 50 years on. *International Journal on Human Rights and Drug Policy*, vol 1 (2010) International Centre on Human Rights and Drug Policy, p. 6.

[296] UNTC, *The Hague Convention 1912*, Treaty Series, vol. 8, No. 222.

[297] Bruun, Pan and Rexed, p. 12

passed in 1914, to justify their position internationally. This law required the registration and imposed a special tax for those "who produce, import, manufacture, compound, deal in, dispense, sell, distribute, or give away opium or coca leaves, their salts, derivatives, or preparations."[298] Medical use was allowed since preparations had less than 2 grams of opium or one fourth of morphine in one fluid ounce.[299] The Act set the tone for American drug legislation, leading the federal policy to consider drug use as a law enforcement problem, instead of a medical issue,[300] which lasted for decades and powerfully shaped drug prohibition regimes in many countries.[301] At that time, although the use of narcotic drugs was not seen with the same urgency that the alcohol use, laws such as the Harrison Act was considered a 'routine slap at the moral evil' and the non-medical use of drugs was a menace both physically and morally to society.[302]

With the outbreak of the First World War the mobilization of efforts devoted to drug control were suspended, but the war gave an impulse to the creation of what would be an international organization. The League of Nations was the result of President's Woodrow Wilson formalized attempt to create an international body designed to mediate disputes with permanent structures and a Charter[303] and to manage more efficiently political, financial, economic and social issues. As such, the international opium control was placed under the custody of the League of Nations, founded in1920, in Geneva.

The Americans were initially not closely involved in the work of the League of Nations because the US Senate did not approve the Covenant of the League in 1919 and 1920. There was a fear that the League would be an organization where countries would be

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[298] *Harrison Narcotics Tax Act, 1914*. https://www.druglibrary.org/schaffer/history/e1910/harrisonact.htm, para 6of 25

[299] *Harrison Narcotics Tax Act*, 1914. https://www.druglibrary.org/schaffer/history/e1910/harrisonact.ht, para 8 of 25.

[300] Bewley-Taylor, *The United States and International Drug Control*, p. 25

[301] Nadelmann, p. 512.

[302] Bewley-Taylor, *The United States and International Drug Control*, p. 26.

[303] Susan Carruthers, International History 1900-1945, T*he Globalization of World Politics*, in T*he Globalization of World Politics* , ed. by Steve Smith and John Baylis Baylis (Oxford, :1997 Oxford University Press), pp. 49-70 (p. 54)

influenced by the Bolshevism. Consequently, the United States were outside of the official body responsible for the international opium control.[304]

In 1920, the League of Nations created the Advisory Committee on the Traffic in Opium and Other Dangerous Drugs, or just Opium Advisory Committee (OAC)[305], dominated by colonial powers. The OAC, in turn, created the Opium Control Board (OPB) supported by the Opium and Social Questions Section. The OAC was essentially what the Commission on Narcotic Drugs (CND) is today, and it was the body under the League of Nations that centralized the administration of drug control. Its mandate was to "report upon measures taken by governments to carry out the obligations of the Convention, and upon distribution and consumption"[306] of substances controlled by the Conventions. Therefore, the OAC requested information about imports, exports, re-exports, consumption, and reserve stocks. Since a great quantity of manufactured drugs were sold for non-medical purposes in many countries, the drug problem became apparent.[307] The League of Nations also created the League Health Committee, in 1922, which took responsibility for advising on medical matters. [308] it was what the World Health Organization is today. [309]

### 3.3. Estimating medical use -1925

As the negotiations for the Geneva Convention were taking place in 1924 e 1925, the US started a relative approximation with the League. The idea of the US delegation was proposing a new treaty, with emphasis in transnational control, instead of only domestic control provided by the Hague Convention. Therefore, the Americans, that had heroin domestically prohibited, proposed to ban the drug worldwide.[310]In 1924,

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[304] Bewley-Taylor, *The United States and the International, Drug Control* p. 27.

[305][305] UNODC, *Illicit Traffic in Opium*, 1953, pp. 24-29

https://www.unodc.org/unodc/en/data-and-analysis/bulletin/bulletin_1953-01-01_3_page009.html# [Accessed 10 June 2022]

[306] UNODC, *Illicit Traffic in Opium*, 1953, pp. 24-29

https://www.unodc.org/unodc/en/data-and-analysis/bulletin/bulletin_1953-01-01_3_page009.html# [Accessed 10 June 2022]

[307] Mc Callister, p.47.

[308] McAllister, p.44.

[309] Another international health authority was the International Health Office in Paris, created in 1908.

[310] Bewley-Taylor, *The United States and International Drug Control*, p. 30.

Stephen Porter, chief American representative at Geneva and the chairman of the House of Representatives on Foreign Affairs, believed that "heroin addicts spring from sin and crime"[311]. He came with Bishop Brent to Geneva proposing the limitation of coca leaves and the elimination of opium smoking in the Far East. These ideas were brought to the League's conferences suggesting a moral superiority of the Americans vis a vis other delegations and little knowledge of about the work of the League. [312] Porter demanded the limitation of raw material production for non-medical use of drugs, but this rigid position was not accepted by other states' delegations. As a response, the American delegation walked out from the conference.[313]Bishop Brent, regretted the reaction of League's members and seized this opportunity to demonize drug use saying that "Christ and religion are brought under reproach and put open shame".[314]

In the negotiations of the Geneva Opium Convention, in 1924, the Egyptian delegate, Mohammed el Guindy claimed that 'illicit use of hashish is the principal cause of most of the cases of insanity occurring in Egypt.[315] With the support of the US, the Egyptian delegate persuaded other states' representatives at the international opium conference, who lacked knowledge on cannabis and were there mostly to discuss opium issues, to include cannabis in the list of banished drugs in 1925.[316]

The Egyptian delegate's views about cannabis were similar to those commonly repeated in Mexico, that influenced American moral entrepreneurs. As it will be discussed in Chapter 6, the same ideas were part of the common sense of Brazilian authorities, in the same period.

Despite American efforts lobbying on drug control, there was not much success there were different views among members of the League of Nations. China, France, Great

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[311] Bewley-Taylor, *The United States and International Drug Control*, p. 31.

[312] Bewley-Taylor, *The United States and International Drug Control*, p. 30.

[313] Bewley-Taylor, *The United States and International Drug Control*, p. 39.

[314] Bewley-Taylor, *The United States and International Drug Control* , p. 31.

[315] James Mills, 'Science, Diplomacy and Cannabis, the Evidence Base and the International Drugs Regulatory System, 1924-1961'. In: *Governing the Global Drug Wars*. (London: LSE Ideas, 2012. Available at: <https://www.lse.ac.uk/ideas/Assets/Documents/reports/LSE-IDEAS-Governing-the-Global-Drug-Wars.pdf>[Accessed 10 June 2022]

[316] James H., Mills, *Cannabis Britannica : Empire, Trade, and Prohibition, 1800-1928* (Oxford ;: Oxford University Press, 2003),

https://books.google.ch/books?id=gMhaD7iuF8gC&pg=PA1&hl=de&source=gbs_toc_r&cad=2#v=onepage&q&f=falsep. 11 [Accessed 10 June 2022], p. 11.

Britain, Japan, Portugal and Spain had different views about the non-medical use of opium because in these countries the use of opium was permitted under certain government restrictions on production, transportation and use. The "old opium bloc" formed by European colonial powers and drug manufacturing drugs also resisted to the American attempts of limiting opium production.[317]

The League also tried to discuss and define health-related questions to define an abuse and how it was supposed to occur, and even, what was the aim of the work undertaken by members states.[318] Therefore, a Mixed Sub Committee was created with medical experts from the League Health Committee and non-physician members from OAC. The work of the Sub Committee discussed the quasi-medical use of substances, defended by the non-medical members while physicians were more concerned with the effects of drugs for health, including iatrogenic addiction.[319]This Sub Committee's work was not successful. In this process, answers regarding reasons why people use drugs and how to prevent abuse and social factors that affected drug taking and other etiological issues were not seriously taken into consideration.[320]As a result, instead of the development of a better understanding of a social-medical question such as the one of limits of acceptable drug use, in the international fora, views about drug users became increasingly pessimistic, although medical questions never disappeared entirely.[321] The League and other organizations focused on health and welfare preferred to work punctual projects such as the search for a magical solution: a non-addictive, but potent analgesic.[322]

The Geneva Opium Convention[323]adopted in 1925 included the control of cannabis. raw opium and coca, the distribution of heroin, morphine and cocaine.[324] It established that States had fixed estimates and regulated distribution through the creation of an international control body, the Permanent Central Opium Board (PCOB), which had the power to determine, the quantity of drugs manufactured each year, based on

[317] Bewley-Taylor, *The United States and International Drug Control*, p. 29.

[318] Mc Callister, p. 47.

[319] McCallister, p. 48.

[320] McCallister, p. 49.

[321] Mc Callister, p. 49.

[322] Mc Callister, p. 49.

[323] League of Nations, *International Opium Convention (Geneva Convention*) Treaty Series, Vol 81 No. 1845

[324] League of Nations, *International Opium Convention (Geneva Convention*) Treaty Series, Vol 81 No. 1845 .

information of imports and exports provided by countries. It established procedures to add new drugs to the list of controlled substances, although the procedure on how to do it was not clearly defined.[325]The attempts to reduce illicit trade through the 1925 International Opium Convention were not strong enough to reduce manufacturing of drugs since they were shipped through non-signatory countries of the Drug Conventions. Also, regarding sovereignty it is a significant interference to have an international body defining the quantity of a product a state is allowed to manufacture.[326] If this product is a medicine, and the system becomes excessively focused on increasing restrictions, it has implications for lack of access to these medicines, as it will be discussed in the next sessions. Since the League of Nations era an important question for OAC lied on defining parameters of legitimate demand (or demand for medical use). But this turned to be a sensitive task because manufacturing countries and colonial powers had no interest on having parameters precisely calculated.[327] Consequently, the dilemma on the dual obligations of the Conventions remained on how to construct a framework to limit the manufacture of cocaine, heroin and morphine and limit their distribution and at the same time ensuring their legitimate use.

### 3.4.Schedules and limited manufacture -1931

In the period between the two World Wars, little attention was given to drug addiction. The League of Nations' Health Committee was concerned with nutrition, due to the famine in Russia, epidemiology and contagious diseases such as typhus, cholera, smallpox and typhus, diphtheria, tetanus and tuberculosis, and the development of vaccines to treat these diseases in Africa, Eastern Mediterranean, Far East and the Soviet Union.[328]

At that time, although the overlap between health and drug issues did not attract much attention at the League of Nations. The concerns with abuse mentioned in one of the resolutions adopted in the Shanghai Commission and in the preamble of the 1912 and

[325] Mc Callister, p. 76.

[326] Mc Callister, p. 77.

[327] Mc Callister, p. 47.

[328] League of Nations, *European Health Conference*, (Lausanne: League of Nations 1922) p. 11, https://archive.org/details/europeanhealthco00euro/page/n7/mode/2up) [Accessed10 June 2022]

1925 drug treaties, show that the element of human rights, was present also in Geneva Convention. As Rick Lines notes, human rights related language also appears in this treaty of 1925, as it states in the preamble:

> *Confident that this humanitarian effort will meet with the unanimous adhesion of the nations concerned, (…)*[329]

The humanitarian effort refers to suppression of contraband trade and abuse, keeping the same terms inserted in the previous treaty. (See Appendix1)

Regarding drugs, the League of Nations had also a section on Social Questions and Opium Traffic, whose chief was Dame Rachel Crowdy, British citizen. She gave a statement to members states in 1927, on the importance of the issues of the limitation of opium production or the control of manufactures. In her statement she announced what she considered a great progress: India was reducing her export of opium by ten per cent. She also celebrated the space given by the press to inform about big seizures and the establishment of opium committees [330]

At the same time, in the US, increased moralist anti-drug campaigns principles that inspired the model of alcohol prohibition law in that country between 1920 and 1933. One of the most articulated influencers was Richmond Hobson. He was the founder of International Narcotics Defense Association and the World Conference on Narcotic Education and spread the idea that narcotics prompted crime in newspapers, radio and schoolbooks in the US.[331] As a consequence, the dominating notion about drugs in the US in the 1920's was that drug abuse could be stopped by restricting drug production. Furthermore, the attempts to change behavior patterns included harsher fines and longer prison sentences for drug use.[332] Xenophobic ideas spread the belief the drug addiction came out of Asia and soon the same accusations target other foreigner and minority groups in the US.[333] Hobson used to organize what he called educational events to demonize the use of substances. He used the space given by the National Broadcasting Company, in 1928 to talk about heroin addicts, who he called "the living

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[329] League of Nations, *International Opium Convention (Geneva Convention*) Treaty Series, Vol 81 No. 1845

[330] Rachel E. Crowdy *Journal of the Royal Institute of International Affairs*, Vol. 6, No. 3 (Oxford, Oxford University Press on behalf of the Royal Institute of International Affairs 1927), pp. 153-169, p. 154: Oxford <:https://www.jstor.org/stable/3014842>[Accessed: 13-02-2020]

[331] Bewley-Taylor, *The United States and International Drug Control* p. 36

[332] Bewley-Taylor, *The United States and International Drug Control*, p. 37.

[333] Bewley-Taylor, *The United States and International Drug Control*, p. 36.

deads".[334] At the occasion, he made the following remark to close the second Narcotic Education Week, an event to create national awareness about heroin addicts:[335]

> *To get this heroin supply the addict will not only advocate public policies against the public welfare, but will lie, steal, rob, and if necessary, commit murder. Heroin addiction can be likened to a contagion. Suppose it were announced that there were more than a million lepers among our people. Think what a shock the announcement would produce! Yet drug addiction is far more incurable than leprosy, far more tragic to its victims, and is spreading like a moral and physical scourge.*[336]

As such, Hobson not only put drug dependents as the cause of violence but also referred to addiction as a contagious disease less curable than leprosy and affirmed that they were incubators and carriers of the streptococcus, pneumococcus, the germ of flu, of tuberculosis, and other diseases.[337] His messages were replicated by other civil society lay groups such as National Tuberculosis Association founded in 1904; the National Committee for Mental Hygiene, 1909), the White Cross, Inc. and these groups had their chapters in different US states.[338]

It is important to note that there were physicians against the use of narcotics but there were also those who understood the importance of maintenance therapies for the treatment of drug addiction. They believed that the cause of drug addiction was not a vicious habit, but rather a disease without moral stigma.[339] It suggests that because of the Harrison Act, medical doctors, druggists and drug manufacturers were the most important target of prohibitionists in the US government.[340]

The combination of moralist anti-drug campaigns, the concerns with infectious diseases both at the League of Nations and at the domestic level in various countries and the beliefs that drug abuse could be curbed with restrictions on drug production

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[334] His messages were replicated by other civil society lay groups such as National Tuberculosis Association founded in 1904; the National Committee for Mental Hygiene, 1909): The White Cross, Inc. and these groups had their chapters in different US states. In: David F Musto. *The American Disease* (Oxford: Oxford University Press 1973, 1987, 1999), p. 191Kindle Edition.

[335] Musto, *The American Disease*, p. 191

[336] Musto, *The American Disease* p.191

[337] Musto, *The American Disease*, p. 191.

[338] His messages were replicated by other civil society lay groups such as National Tuberculosis Association founded in 1904; the National Committee for Mental Hygiene, 1909): The White Cross, Inc. and these groups had their chapters in different US states. Musto, p. 192

[339] Musto, *The American Disease*, p. 196.

[340] Musto, *The American Disease*, p. 195.

created the widespread idea that if states adopted drug prohibition, they would eliminate drug dependence, infectious diseases, crime and violence as if they were one single problem.

This was the context at the occasion of the negotiations of the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, adopted in 1931. As a result of the internal campaigns, the US continued to insist in stricter drug controls at the international level internationally.

The American strategy at the League of Nations, in Geneva, was led the by Harry Anslinger, a government official who served as the first commissioner of the US Treasury's Federal Bureau of Narcotics (FBN). This is currently the DEA, the US Drug Enforcement Agency. The US objective was to increase influence abroad through multilateralism.[341]Anslinger led also the anti-drug campaign within the US and supporter of prohibition, the criminalization of drugs and was very influential in the international drug control circles from 1930-62 as an American representative at OAC.[342] After the walk out from the negotiations of the Geneva Convention the State Department believed that Anslinger would be able improve US relations with the League even if the cost would be a softened approach in comparison to the demands from 1924.[343]

Despite the more realistic approach, the American notion that drug abuse within the US could be curbed by production restrictions throughout the rest of the world became irreversibly established in international law.[344]This illustrates the first stages of the norms cycle. According to Finnemore and Sikkink, after norm entrepreneurs have persuaded a critical mass of states to become norm leaders and adopt new norms, it can be said that the norm reaches a threshold.[345] As it was already discussed, the work of American moral entrepreneurs such as Bishop Brent, in Asia and Richmond Hobson at the domestic level, resulted in a widespread idea that drugs have their production stopped because they were the reason of most social problems faced by the US in that period. When a norm reaches the threshold, or tipping point, a norm begins the stage

[341] Bewley-Taylor, *The United States and International Drug Control*, p. 35.

[342] Mc Callister, p. 89

[343] Bewley-Taylor, *The United States and International Drug Control*, p. 39

[344] Bewley-Taylor, *The United States and International Drug Control*, p. 39

[345] Finnemore and Sikkink, p. 901

of norm cascade, in which more countries begin to adopt new norms more rapidly and even without domestic pressure for such change.[346] The norms present at that time were reflected in the new drug treaty in 1931.

The concerns of states negotiating the Convention Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs were supply control and the reduction of illicit market to eliminate the excess of controlled substances produced, that were destined to medical use. Consequently, to tackle these concerns, the convention established the system of schedules and kept the system of estimates established in the 1925 Geneva Convention, which introduced the framework for the Single Convention thirty years later. [347]

The system of estimates was compulsory, and its objective was to limit the global manufacture of drugs necessary for medical and scientific purposes and prevent their leakage into illicit market. It limited manufactures of opiates to the amounts to meet medical and scientific needs of three drugs seen as 'dangerous' by the US: morphine, diacetylmorphine (heroin) and cocaine, both for convention's signatories and non-signatories.[348] To administer the system, the convention established the Drug Supervisory Board (DSB), which is an important characteristic of the control framework. Therefore, each country had to submit estimates four times a year on the quantities needed for medical and scientific needs, for conversion, for reserve stocks and for government stocks, which could assess the drug trade situation in each country and consequently develop an indirect power over the global drug trade.[349] The treaty also and granted to the PCOB the power to place an embargo on the export of drugs exceeding their estimates.[350]The DSB and the PCOB merged later, in 1961, established by the Single Convention, to form what the INCB is today.

Prior to the 1931 Convention, each state decided, based to recognized scientific research if a drug would be controlled. substances were classified according to their 'addictive propensity', as determined by representatives, medical experts,

[346] Finnemore and Sikkink, p. 901

[347] Bruun, Pan and Rexed., p.15

[348] Bruun,Pan and Rexed, p. 14

[349] A Century of International Drug Control, *World Drug Report*, 2009, p.56.

[350] David Bewley Taylor and Martin Jelsma (2012) 'Regime Change:Re-visiting the 1961 Single Convention on Narcotic Drugs, *International Journal of Drug Policy 23*, p.74.

pharmaceutical companies and research community.[351] With the introduction of the scheduling system by the Limitation Convention, the Health Committee of the League of Nations was assigned to decide which substances should be controlled and how strictly.[352]

Within this context, the German pharmaceutical industry became the leader in the manufacturing of codeine and the German delegates argued in the debates that lead to the Limitation Convention, that codeine was safer the opium, heroin and cocaine. However, more control would result in more difficulties to commercialize drugs because substances out of schedule had the possibility of gaining a bigger market share. The system of schedules classified substances according to the principle of similarity which means that substances controlled were of opium and morphine, cocaine and cannabis. Following the principle of similarity drugs that had morphine-like, cocaine-like or cannabis-like effect could be scheduled in two groups: Group 1, which include morphine, heroin and cocaine and their salts and Group 2, comprising codeine and ethyl morphine, and their salts. The second group was exempted from some of the more onerous regulatory and reporting requirements applied to the first.[353]

Concerns were raised when new categories of drugs emerged, such as psychotropics. Their effects were different from those caused by drugs listed in existing schedules, but they also had propensity to cause addiction. For this reason, a question emerged on how to have new medicines controlled. Western countries with pharmaceutical industries, made pressure to place new medicines out of the scheduling system, which provoked later, in 1971 discussions about the amendment of the 1961 Single Convention[354] and the negotiation of the Psychotropics Convention with a different and less stringent scheduling system. It was believed that a potent drug to treat pain and substitute narcotics such as morphine without causing addiction would be developed. While waiting for such a drug, psychotropics received less restrictions because it would be difficult for pharmaceutical industry to make profit with a strictly controlled medicine. However, such medicine has not been developed until today. Instead,

[351] McAllister, p.100.

[352] Christopher Hallam, Dave Bewley -Taylor and Martin Jelsma, Scheduling in the international drug control system, *Series on Legislative Reform of Drug Policies* no. 25, June 2014 p.4

[353][353] Hallam, Bewley -Taylor Jelsma, Scheduling in the international drug control system, *Series on Legislative Reform of Drug Policie*s no. 25, 2014 p.3

[354] Mc Allister, p. 231.

despite states' efforts to create a control system to limit drug use for medical purposes and at the same prevent their diversion, an illicit drug market emerged.

As Arnold Taylor notes, the US returned gradually to international cooperation until just before the Second World War, when it became again an active partner in the world campaign to limit the use of narcotics for medical needs.[355] The US were moderately successful in the endeavor of increasing international drug control. Since the system's inception the US believed that an effective way to deal with the problem was to limit growing plants from which narcotics are derived, however the importance of these agricultural production, particularly in Persia and Turkey, stood in the way of American attempts for agreements.[356] William O. Walker III, agrees with this view presented by Arnold Taylor in his book *Opium and Foreign Policy: The Anglo American search for order in Asia 1912-1954*, regarding that Americans failed to understand the economic and cultural basis for narcotics in Asian societies and argues that the goal of suppression of opium, that led to the 1936 Convention of the Suppression of Opium was subordinated and subverted to America's perceived security needs.[357]

### 3.5.Penal sanctions for drug trafficking - 1936

A response to concerns with the growing illicit market came with initiative of International Criminal Police Organization (INTERPOL) to create a new treaty that called for harsher punitive measures for drug traffickers. In the negotiations of the Convention of 1936 for the Suppression of Illicit Traffic in Dangerous Drugs the US proposed to "criminalize all non-medical production and distribution and perhaps individual use as well".[358] These provisions were objected by several delegations and

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[355] David Musto F. review of *American diplomacy and the narcotics traffic, 1900-1939: A study in international humanitarian reform* by Arnold H. Taylor The Journal of American History, vol. 63, no. 1, 1976, pp. 160–61. (p. 161). <https://www.jstor.org/stable/1909051?seq=2JSTOR>, [Accessed 11 Jun. 2022]

[356] Paul Varg, review of *American diplomacy and the narcotics traffic 1900-1939: a Study in international humanitarian reform*, by Arnold Taylor Pacific Historical Review, 39, 4 (1970), p. 555, University of California Press, p. 555. <https://www.jstor.org/stable/3637819?seq=1<[Accessed 11 Jun. 2022]

[357] Noel H. Pugasch, review of, *Opium and Foreign Policy: The Anglo-American search for Order in Asia 1912-1954*, by William O. Walker III, The American Historical Review 98, I (1993) Historical Chapel Hill, University of North Carolina Press, p. 142

<https://academic.oup.com/ahr/article-abstract/98/1/142/60857?redirectedFrom=fulltext&login=false>[Accessed 11 Jun. 2022]

[358] Mc Allister, p. 123

the result was that the treaty neither satisfied pro-control delegations nor other member states that did not want more obligations. As a result, the 1936 Convention, entered into force in 1939, had a low uptake and reached less than 40 ratifications.[359] Despite the relative rejection, the Convention for the Suppression on the Illicit Traffic in Dangerous Drugs this treaty was a turning point in the international drug control regime. [360] Previous conventions were related to legitimate drug activities, but 1936, for the first time, trafficking-related activities were considered an international crime and subject to penal sanctions. [361] This is clearly stated in Article 2:

> *Each of the High Contracting Parties agrees to make the necessary legislative provisions for severely punishing, particularly by imprisonment or other penalties of deprivation of liberty, the following acts—namely: The manufacture, conversion, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale, delivery on any terms whatsoever, brokage, despatch, in transit, transport, importation and exportation of narcotic drugs contrary to the provision of the said Convention.*[362]

As Neil Boister observes, suppression conventions are law enforcement instruments, and their main purpose is the suppression of crime. For this reason, they are highly invasive.[363] According Boister, this kind of treaty is created when there is concern with offences which include transnational elements, because acting alone they are unable to suppress them.[364]

The low acceptance of this treaty can be explained by the three reasons. First, the League had no power to discipline states in non-compliance with the system; second, the US had not the same geopolitical prominence that it achieved after 1945; third, dominant European nations were reluctant to waive national sovereignty over

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[359] Mc Allister, p. 123

[360] The first 13 states that signed and ratified the treaty were Belgium, Brazil, Canada, China, Colombia, Egypt, France, Greece, Guatemala, Haiti, India, Romania and Turkey. In: Bewley Taylor, *The creation, Spread and Impact of Global Drug Prohibitions (1909-1998)*p. 14

[361] Bruun, Pan and Rexed., p. 15.

[362] UNTC, *Convention of 1936 for the Suppression of Illicit Traffic in Dangerous Drugs,* Treaty Series, Vol 198 No 4648

[363] Neil Boister, 'Human Rights Protections in the Suppression Conventions', Human Rights Law Review, 2.2 (2002), 199–227, p. 217

https://academic.oup.com/hrlr/article-abstract/2/2/199/591400?redirectedFrom=fulltext [Accessed 6 June 2022].

[364] Boister, p.216.

domestic drug control and renounce profit obtained with opium monopolies, because it was not a consensus that states should cooperate on criminalizing production, distribution and use of drugs.[365]

The control of illicit traffic became more difficult the League's work was disrupted because of the Second World War and treaties' provisions could not be normally enforced. Resources from the US became scarce due to the economic depression and during the Second World and the international control could not rely on the collaboration of Germany Italy and Japan.[366] The Health Committee was merged with Drug Control, Social and Cultural Questions in 1939, due to financial reasons. In 1940, the effective collaboration in health and other fields was suspended.

With the creation of the systems of schedules and estimates, states had their sovereignty one more time affected by two organs of the League of Nations. The DSB, fixing estimates and limiting the manufacture of drugs for medical purposes and the PCOB with the power of placing an embargo on countries exceeding estimates. As the drug control system had limitations of resources, the administration of the estimates' system had to rely on the information about internal control of substances provided by each state to know the quantity of substances traded.[367]

The creation of a separate and autonomous health organization had been discussed for many years, but there was competition between the League's Health Committee and the Officine International de Hygiene Publique (OIHP) and resistance of some health authorities. The American surgeon Hugh Cunning, one of the most enthusiastic campaigners against the creation of the World Health Organization (WHO), was the director of the Pan American Sanitary Bureau (PASB).[368] During the International Health Conference, that took place in New York in 1946, to frame the constitution of WHO, Cunning seized on the opportunity to warn other delegates, also members of the PASB, participating in the working dinner, that the presence of representatives of Eastern countries implied that the new organization would be a communist

[365] Mc Allister, p. 123.

[366] McAllister, p. 124.

[367] David Bewley-Taylor, and Martin Jelsma, 'Regime Change: Re-Visiting the 1961 Single Convention on Narcotic Drugs', *The International Journal of Drug Policy*, 23.1 (2011), 72–81, (p. 74)

[368] The Pan American Sanitary Bureau(PASB) today corresponds to the Pan American Health Organization (PAHO).

instrument.[369]With the foundation of WHO, the OIHP and the League's Health Committee were absorbed by the new body. This fact illustrates how intra-regime complexity undermines the role of bodies in carrying out their mandates. The competition among bodies such as the OIHP and the League Health Committee resulted in marginalization of the Health Committee and this was the body with a mandate to discuss medical matters, including drug abuse. Moreover, attempts to undermine the creation of WHO came from its own American regional branch, which suggests that US priorities within the international system, were not related to health issues.

As the operation of the League of nations became complicated in Geneva because of the war, the Americans invited the Permanent Central Opium Board (PCOB) and the Drug Supervisory Board to move to Washington in 1941. This was an important shift because it would create opportunities for the US to increase their influence in the international drug control.[370] The political, financial and military support given by US president Franklin Roosevelt to European's countries fighting the fascist coalition increased reliance by Britain and France on the Americans. This changed the isolationist mindset of the Americans and fostered their internationalist spirit. This situation changed the balance of power as it used to be in the League of Nations and their drug control apparatus and put the US in a position of prominence in the field of international drug control.[371]

The question on how to control the licit market also became an important concern, particularly for opium manufacturing countries interested in expanding their markets and controlling the production of raw material at sources. [372]

The demand for morphine and agricultural cultivation of poppy increased, driving research on new drugs and alternative methods to extract morphine from the poppy straw. The increased need for pain medicines was a challenge for the US' prohibitionist

[369] Howard-Jones, Norman & World Health Organization. (1978). *International public health between the two world wars: the organizational problems* (World Health Organization 1978),

https://apps.who.int/iris/handle/10665/39249 [Accessed 11 Jun. 2022], p. 78.

[370] Bewley-Taylor, *The United States and International Drug Control*, p. 43.

[371] Bewley-Taylor, *The United States and International Drug Control* , p. 44.

[372] Mc Callister, p.141.

approach. But despite the need for a larger opium production, opium controls became more stringent after the war.

Within this context, the 1940's, the pharmaceutical drug market was gaining a new shape.[373] Manufacturers of traditional analgesics such as morphine feared new competitors in the illicit market and in the licit market, with the development of synthetic drugs such as pethidine and methadone. This new class of synthetic narcotics was not covered by the extant treaties. [374]

As it will be discussed in the following chapter, despite the American pressure, the development of international control was slow during the period pre-UN system. A significant change occurred in 1945, when the US became the hegemonic power in the international politics.

## 4. Conclusion

This chapter showed how the demonization of opium throughout the development of the international drug control system before 1945 restricted the use of opium and its derivates, such as morphine. Despite the use of opium as a medicine to treat pain and other symptoms, its prohibition occurred even before the creation of the international drug control system in Japan, Burma, Thailand, Vietnam and China prior to the creation of the international drug control system in 1909, with the Shanghai Commission. Prohibition was commonly established according to the interests of the elites, in different countries, with views to social control. This challenged the idea that prohibition was an American construct. In fact, moral entrepreneurs that played an important role on the demonization of opium at the beginning of the 20th century learned that in the Far East and imported this belief to the US. The demonization of drug use was useful to control social groups associating drug use to danger, madness, degeneration and criminality, thus turning it into a threat to society. The discourse of prohibition was rather based in moral assumptions than in scientific evidence, however ideas of social and racial prejudice were supported by a scientific discourse.

[373] As Mc Allister describes A new and less expensive method to extract morphine directly from the poppy straw developed in Hungary. Pethidine and methadone – synthetic opioids were produced in Germany for the first time in the late 1930's, In: Mc Allister, p. 126.

[374] Mc Callister, p. 156.

As it was analyzed throughout the chapter, although the United States had not invented prohibition, it had the desire and capacity to impose prohibition and evolve a national construct into an international one. The US globalized prohibition. Other prohibitionist countries such as Mexico and Brazil had no geopolitical power to export prohibitionism worldwide. The US influence was limited in the period pre-United Nations, because of their relatively weak importance in geopolitics. However, constant attempts in restricting drug use only for medical purposes, and encouraging increased enforcement measures regarding drug control, contributed to shape the international drug control regime. It occurred gradually. Each treaty contributed to transform opioids such as morphine in a "dangerous"medicine. The system of reporting was established in 1912. In 1925 the treaty fixed estimates and regulated distribution. In 1931 the scheduling system was created and the limits for production were settled. In 1936 the convention criminalized cultivation, production, manufacture and distribution of drugs, establishing penal sanctions for these actions, except for medical purposes. But in fact, criminalization contributed to the marginalization of controlled medicines.

The health approach in the international drug control regime was put aside in several occasions. At the Shanghai Commission, despite the presence of qualified physicians, the medical use of opium failed to be discussed. In the League of Nations, the Mixed Sub Committee involving members of OAC, and Health Committee was formed to discuss health effects of drugs but was not successful. The League preferred to work on punctual projects. Later, in the transition from the League to the UN, WHO was regarded as a communist body. As such, the INCB had a more prominent role in the international drug control system, than international health bodies.

This showed that the priority of the regime was law enforcement to prevent the leakage of drugs in the market, that were not produced for medical purposes. Even though medical use of drugs has been always permitted, the boundaries between medical and non-medical use were never clearly defined. As a result, medical use has been always implying a risk for prescribers, patients and those in charge of establishing regulatory measures.

# Chapter 3

# The expansion of prohibitionism in the international drug control regime since 1945

## 1. Introduction

After the end of the Second World War, the United Nations was founded in 1945. The League of Nations' responsibilities were transferred to the UN in 1946, as established by the Protocol of Lake Success, signed in 1946. The organs' functions in the new organization were determined by the Economic and Social Council (ECOSOC). Some of these instruments, including those of international drug control were of a technical and non-political character, according to the ideals of the organization.[375]Therefore, the Commission on Narcotic Drugs (CND), replaced OAC (Opium Advisory Committee) and CND began to report directly to the newly created ECOSOC (Economic and Social Council).[376] The PCOB (Permanent Central Opium Board) and DSB (Drug Supervisory Board) continued responsible for national estimates and administration of treaties, respectively.[377] Advocates for stringent controls preferred to put WHO aside and have an independent organization that would comprise economic, medical, social, cultural and agricultural factors considerations on drugs. They feared that if drug control were integrated within a larger health or social-issues organization, doctors would pursue lenient schemes.[378]

As the United States occupied a new and prominent position in the international community, playing an important role in the newly founded United Nations, in 1945, they influenced the work of technical bodies from the League of Nations, which assumed a new political character in the UN era. In the late 1940's the US generated pressure to draft a new treaty capable to substitute all the previous conventions, but

[375] Bewley-Taylor, *The United States and International Drug Control*, p 57.

[376] The ECOSOC was established by the UN Charter.

[377] Mc Allister, p. 154.

[378] Mc Allister, p. 153.

with more stringent provisions, regarding the use of opium, its derivates and other substances.[379]

Against this context, this chapter examines the increased prohibitionist approach in the drug control regime, largely driven by the US after the creation of the UN system, and the tension between sovereignty and states' international commitments, under the constructivist theory of norm diffusion to show how prohibitionist norms were exported worldwide.

A unique forensic analysis of the conference's records for the adoption of Single Convention's will show that despite the concern with the development of a complex and sophisticated control system, the health element was always present in the international drug control regime. This chapter provides an original analysis of the Single Convention's negotiations, which discusses the roles of WHO and INCB in the process, the meaning of health and well-being at that time and the implications for the access to the licit use of opioids in the following decades.

## 2. The expansion of prohibition in the international drug control regime

With the development of new synthetic substances in the market and the creation of WHO in the late 1940's, the international drug control regime became confused with the number of treaties, documents regulations and bodies involved in drug control. In the initial period of the Cold War, countries were interested in controlling the opium production at sources, fearing a lack of pain medicines for the case of a future war. After the two World Wars, some countries increased concerns with stockpiling opium for medical purposes to treat wounded soldiers. [380]But the more opium was necessary, the more it became restricted by drug treaties.

This section discusses the transition from the League of Nations to the United Nations and how the US took advantage of its prominent geopolitical position to use the international drug control system to reach wider foreign policy objectives. In doing so, it exported prohibitionism worldwide, restricting opium production and impacting access to controlled pain medicines, such as opioids, particularly morphine for pain

[379] Mc Callister, p. 172.

[380] Bruun, Pan and Rexed, p. 16.

treatment. Exporting prohibition had implications that affected the economy of opium producing countries and benefitted industrialized countries with flourishing pharmaceutical industry. This became clear in the negotiations of a Single Convention to substitute the set of previous treaties. States formed groups, according to their political support either for western or eastern bloc.

At the UN, it was established that CND and other drug control bodies would report to ECOSOC. But the International Synthetics Protocol international protocol, signed in 1948, in Paris gave to WHO the authority to decide which substances would go under control according to the recommendation of the ECDD (Expert Committee on Drug Dependence from WHO). The importance of this document was to bring to control substances like synthetic opioids. Article I of the Paris Protocol stated that if the WHO found a drug to be "capable of producing addiction or of conversion into a product capable of producing addiction," it would decide how to classify it within the international drug control structure, which suggested that other treaties would be necessary.[381]As Bruun and others note, apart from role WHO played in the development of international drug policy through the ECDD – evaluating substances for their placement on the scheduling lists, the agency "increased the emphasis upon treatment as a preventive form of control."[382]

At that time, at CND, key players were the US, supported by manufacturing countries (particularly Canada, UK and France) and producing countries (Iran, India, Turkey and Yugoslavia). Latin American countries and opium producing countries were interested in receiving development aid, in exchange for reducing or eliminating their drug production. This sets the scene for the drug treaties in the UN era.

In this context, there are two relevant aspects to be examined. First, Anslinger worked to keep the importance of the Federal Bureau of Narcotics (FBN), both domestically and in the international drug control regime. To achieve these objectives he, representing the US government at the UN, proposed a new treaty, which would be

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[381] United Nations Treaty, Collection, (UNTC) *Protocol Bringing under International Control Drugs Outside the Scope of the Convention of 13 July 1931 for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, as amended by the Protocol signed at Lake Success*, New York, on 11 December 1946, UN Treaty Series, vol 44, No 688, (Paris: UN, 1948)

https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-13&chapter=6&clang=_en

[Accessed 21 June, 2022], p. 3.

[382] Bruun, Pan and Rexed, p.16.

the Single Convention. Second, at that time, the dominant narrative within the US was that drug problems were caused by foreigners that contaminated Americans with drugs, following Richmond Hobson's strategy.[383] However, the US foreign policy in this period used power to export the idea of prohibitionism, only when increasing control matched wider objectives of the State Department such as deterring communism and keeping countries under their sphere of influence.[384] In the following section, the drafting process of the new treaty will be discussed and then examples on how the US Department approached issues involving drug control in this period will be explored.

The objectives of Anslinger for the treaty were substituting all the previous drug treaties by one strongly stringent single convention. The Single Convention was an US initiative, presented to the CND in 1948.[385] The Chinese proposed the creation of an interim agreement as an immediate measure to limit opium production. The proposal was accepted at CND, which resulted on the 1953 Opium Protocol, despite the objections of the British, Canadian and American delegations, who wished to concentrate on the draft of a long-term project to serve as the basis of negotiations.[386] The Protocol was never adopted but showed the highest level of prohibitionism in the international drug control regime and was the basis for the negotiation of the Single Convention.

## 3. The 1953 Opium Protocol

Within the drafting period of the Single Convention, Anslinger exploited political issues at CND to keep the relevance of his post at the FBN and in international drug control fora. Within the US, in the 1950's there were oppositions to the FBN's policies and practices, rumors of corruption and despite draconian legislation enacted at FBN's insistence, drug use was rising.[387] Moreover, the support of the State Department was

[383] Edward Jay Epstein, *Agency of fear, Opiates and Political Power in America*, (New York: Verso 1977) p. 81.

[384] Bewley-Taylor, *The United States and International Drug Control*, p. 129.

[385] Mc Callister, p. 172.

[386] Mc Callister, p. 172.

[387] Mc Allister, p. 190.

not always certain, such as in the occasion that the Division on Narcotic Drugs (DND) moved from New York to Geneva.[388]

In 1953-54, Gilbert Yates, the new chief of Division on Narcotic Drug and Dag Hammarskjöld, UN secretary General between 1953-1961 managed to move the Division on Narcotic Drugs (DND)[389] from New York to Geneva, to strengthen the agency's position within the UN. Anslinger realized that he was trying to bring the PCOB and DSB into DND and put them under the UN's influence. The UN's control apparatus was in Washington since 1945 and Anslinger had a good relationship with Secretary General Trigve Lie, who was pro-American, but with his successor the Swede Dag Hammarskjöldthe relationship was poor.[390]

Anslinger had supporters such as The Women's Christian Temperance Union and the American Drug Manufacturers, who believed that in Geneva, the DND would be inefficient. They argued that the body would receive more influence from European countries, which were soft on the communist's regime in China and on narcotics control, or that countries' representatives would not be able to attend meetings so easily as in Washington. As an attempt to revert the move from drug control bodies to Geneva, Anslinger threatened to cut funding for DND.[391] The consequences would be serious for foreign policy. From the one hand if the Soviet Union kept their contributions to the UN, they would increase their influence. On the other hand, for US enemies, it would look like the US was blackjacking the world. [392] Consequently, at this time, Anslinger had no support from the State Department, which preferred to protect their image vis a vis the Soviet Union, at the expense of what he perceived to be effective international drug control. [393]

### 3.1.Anslinger's strategy and methods

As Anslinger needed support to draw a treaty with strong restrictions for the production, with reporting crop plants and yields, buying and storing securely opium

[388] Bewley-Taylor, *The United States and International Drug Control*, p. 115.

[389] The Division on Narcotic Drugs oversaw the preparatory process of the conferences.

[390] Bewley-Taylor, *The United States and International Drug Control*, p. 116.

[391] Bewley-Taylor, *The United States and International Drug Control*, p. 116.

[392] Bewley-Taylor, *The United States and International Drug Control*, p. 117

[393] Bewley-Taylor, *The United States and International Drug Control*, p. 118.

and provisions such as inspections and embargoes conducted by PCOB. With support from manufacturing countries, it would be possible increased control the production of opium at the source[394]. The strategy was carried out with a team of like-minded American officials such as Robert May (PCOB) and Elizabeth Wright (PCOB), Helen Moorhead (Foreign Policy Association's Opium Research Committee). Charles Sharman, Canadian,[395] represented his country at OAC and CND. This group also managed to reject the participation of other international agencies from the UN, such as UNESCO, Food and Agriculture Organization, International Labor Organization system to participate in drug fora. Anslinger feared that these agencies would divert attention towards social and economic factors, contributing to addiction treatment and question incarceration, thus avoiding ideas that would come close to human rights principles.[396] It was a lost opportunity to discuss health related issues, and give a more significant role to WHO in the drafting of the Single Convention, despite mentions concerning health in the Preambles of previous treaties (See Appendix 1).

Anslinger used different strategies to reach goals at the Commission on Narcotic Drugs (CND). He was able to influence other delegations taking advantage of the US being a permanent member at CND. The composition of the Commission's members was established by ECOSOC. The original criteria for selecting members were to have adequate representation of countries which were drug producers or manufacturers or victims of illicit traffic. But political factors were also important. The original composition of CND had fifteen members, from which ten were permanent and five were elected at ECOSOC sessions and should stay in office for three years to solve fundamental problems of the international control of narcotic drugs.[397] The first CND permanent members were Canada, France, India, China, Peru, Turkey, the USSR, the UK, the US and Yugoslavia.[398] It was considered an honour to be held part of the first CND and this group of people was called the Gentlemen's Club, in which delegates continued to renew contact attending the Commission for the period of three years.[399]

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[394] Mc Allister, p. 179.

[395] Charles Sharman was the head of the Canadian Narcotics Service from 1927 to 1946 and represented his country at OAC and CND from 1934 to 1954 and was elected to the DSB, from 1948 to 1958. In: Mc Callister, p. 94.

[396] Mc Allister, p. 160.

[397] In 1961, the duration of the mandate reduced to one year. In: Bruun, Pan and Rexed. p. 88.

[398] Bruun, Pan and Rexed. p. 300.

[399] Bruun, Pan and Rexed, p. 88.

As Bruun and others note, an informal gentlemen's club made of persons, was formed and prior to the official opening session of CND, this group used to meet to settle in advance, some of the issues which are expected to emerge in the session.[400]As Anslinger was an US representative for so many years, it was easy for him to make the most use of such informal meetings to reach his objectives.[401]

During the long drafting process of the Single Convention, from 1948 to 1961, Anslinger also used to organize fact-finding missions abroad, after the War, carried out by FBN agents, PCOB DSB and CND officials to collect material to be used at CND, without the acknowledgement of US diplomats. They approached countries in an offensive supply-control campaign to explain reporting procedures, uncover trafficking and search for support. In doing so, they also recommended the activation of national controls. [402]One example of these missions was the visit of FBN agent Wayland Speer to Macau, in 1954, which was identified by the UN as a source of illicit opium. The agent met with authorities making all kinds of indiscreet questions, to find out evidence of opium smuggling and production.[403] As it will be seen in the next chapters, methods such as fact-finding missions are also used by the INCB to collect material, without disclosing any information about the missions.

Among Anslinger's methods of pressure to countries to control and reduce their production was exposing them at CND, with support of PCOB statements.[404] As an example, Iran, which was one of the most recalcitrant countries to accept the terms of the supply control offensive during the Cold War was targeted by Anslinger. It produced a great amount of opium, had good oil reserves and was a candidate to become a Soviet Union supporter.[405] Repeated deficiencies in Iranian statistical reports were material for bullying organized by Anslinger and PCOB[406].

Despite difficulties between Anslinger and the State Department, the prominent position of the US within the UN facilitated Anslingers's work during many years,

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[400] Bruun, Pan and Rexed, p. 122.

[401] Bewley-Taylor, *The United States and International Drug Control*, p. 74.

[402] Mc Allister, p. 162.

[403] Bewley-Taylor, *The United States and International Drug Control*, 81.

[404] Mc Allister, pp. 168-169.

[405] Mc Allister, p. 169.

[406] Mc Allister, pp. 168-169.

giving an impulse on global drug prohibition by proselytizing for a stringent Single Convention using formal and informal methods. He was the US representative at CND (1946-1970) during five presidential administrations (1930-1962). One example that illustrates Anslinger influence was described by the British Foreign Office about the support of Charles Vaille, the French representative to CND and the PCOB for a position at DSB. The appointment of an individual to the DSB, while still a member of PCOB was a violation of ECOSOC regulations, but Anlinger managed to get support for Vailles's appointment from Latin American countries such as Brazil. As Mr. Tom Green from the UK, explained, the Brazilian representative to CND, Mr. Garcia, made as speech believed to have been written for him by Anslinger.[407] It suggests Anslingers's influence made Brazil, other Latin American countries, and opium producers such as Turkey and Afghanistan to align with the US for voting resolutions with the help of Anslinger's army at CND. The threat was possibly to withdraw foreign economic aid.[408] At that time, the American influence reached for instance, Iran. Apart from diplomatic support, the US equipped border patrols, anti-narcotic agents, dogs, military training, and equipment such as the United States Military Mission to the Imperial Gendarmerie (GENMISH).[409]In exchange, Iran outlawed its opium production in 1955.[410]

After a long drafting period the Protocol for Limiting and Regulating the Cultivation of the Poppy Plant, the Production of International and Wholesale Trade and in the Use Opium Protocol was concluded in 1953. Charles Vaille, French pharmacist, representing his government, committed with supply control of narcotics was the chair at CND and conducted negotiations of the agreement very quickly.[411] Points that required attention in the negotiations were "the attempts to define concepts as opium, stocks, territory, imports, and exports. [412]The 1953 Opium Protocol "contained the most stringent drug-control provisions yet embodied in international law".[413] Its basic

[407] Bewley-Taylor, *The United States and International Drug Control*, p. 71.

[408] Bewley-Taylor, *The United States and International Drug Control*, p. 71.

[409] James Tharin Bradford, *Poppies Politics and Power, Afghanistan War and the Global History of Drugs and Diplomacy* (Ithaca: Cornell University Press 2019), Pro Quest Ebook Central, p. 126.

[410] Mc Callister, 196.

[411] Mc Allister, p. 168.

[412] Mc Allister, p. 181.

[413] Mc Allister, p. 181.

provision was that the production of opium would be with a view to equating the amounts harvested to the amounts needed for medical and scientific purposes, but it was very hard to precise the medical and scientific needs of a countries at that time.[414] It suggests that, for Anslinger, the most important question was to eradicate opium production, because, according to his ideals, that was the way to curb drug addiction. Therefore, it was necessary to control sources of drug production. He also believed that, by the time opium production had been eradicated, the development of the pharmaceutical industry would result in the production of new medicines to manage pain that would not cause addiction.

The 1953 Opium Protocol was drafted by Adolf Lande, Austrian, specialist in international law applied to drug treaties. He worked for the American government during the Second World War, for the Division of Narcotic Drugs, Permanent Opium Control Board and was UN consultant for American manufactures [415] He was close to Anslinger and drafted all drug treaties between 1946 and 1971, including the Single Convention, in 1961.[416]The 1953 Protocol's provisions allowed the Board to conduct inspections, embargoes and carry out punitive actions even for states not party of the Protocol. It was the first time that opium use became restricted only to medical and scientific purposes and the quasi-medical use was excluded.[417] Moreover, each country had the obligation to send estimates to DSB on amounts of opium planted, harvested, consumed domestically exported and stockpiled. In return Yugoslavia, Iran, India, Turkey, Greece, Bulgaria and USSR had the monopoly on licit sales [418] This protocol never received enough ratifications to entry into force and was superseded by the Single Convention in 1961.[419]

In the light of this development of drug control treaties it is possible to say that norms are diffused in cascades until a point that it becomes automatic. As Finnemore and Sikkink notes, in the norms cycle this is the moment where norms become internalized, which is powerful because they are not questioned and hard to discern. When norms

[414] Bewley-Taylor, *The United States and International Drug Control*, p. 92.

[415] Mc Callister, p. 225.

[416] Mc Callister 228.

[417] Bruun, Pan and Rexed . p. 17.

[418] Mc Allister, p. 181.

[419] Mc Allister , p. 202.

are taken for granted, they are not controversial, thus seen as perfectly acceptable.[420] The Opium Protocol is an example that shows the policy of one state compromise the sovereignty of other states. States use their power all the time to shape the actions of other states in various ways. Anslinger took advantage of the US as great power to make other states behave the way he desired, in accordance with US domestic beliefs about drugs, making alliances, using leverage in trade and threatening with embargoes. Many of these economic measures can affect seriously the autonomy and control of target states, especially weak ones.[421] According to Finnemore, these are interventions because they involve a compromise of sovereignty by other states that are exceptional in some ways. In the Cold War spheres provided one important context for intervention behaviour in this period. The other critical feature of the system was the nature of sovereignty under the spheres system. Sovereignty was strongly tied to territory and the boundaries of these spheres.[422]

### 3.2.US Foreign Policy and the Single Convention

In this section, it will be discussed that the US used international drug control with a prohibitionist approach to achieve wider objectives in drug policy such as deterring communism and keeping countries under their sphere of influence. However, only when drug control matched State Department's objectives. The following examples show the US strategy in Latin America, Middle East, and Asia.

In Latin America, CND was also used to expand the US dominance towards Mexico, through the issue of drug control. Mexico was accused of being the source of heroin entering in the US and marijuana was asserted to be a stepping stone for a person to become an heroin addict, although there was no evidence for this assertion.[423]The two countries had bilateral diplomacy on drugs since mid-1930s, but in 1948, results of the American pressure were reported by the Mexican representative, who mentioned increased penalties, eradicated poppies on six hundred and sixty-three plantations, arrested 2,284 persons, using the Army, Police and Air Corps; and requested the help of neighbouring countries for this task. Consequently, Mexico developed a similar

[420] Finnemore and Sikkink, p. 904.

[421] Finnemore, p. 11.

[422] Finnemore, p. 119.

[423] Epstein, p. 81.

drug policy, accommodating US desires of strict control. At CND, Mexico gained US support.[424]

Another example of Anslinger tailoring drug policy to US foreign policy objectives such as the fight against communism happened as the tension increased in the relations between US and Cuba, when Batista was overthrown, in 1957. Anslinger blamed Cubans for domestic drug problems and accused Cubans involved in drug trafficking in Florida to be working as Fidel Castro's agents and spreading addiction among Cuban refugees. Anslinger also accused Cuba of distributing opium from communist China throughout Western Hemisphere and starting opium industry with help from Chinese farmers. No evidence was presented to confirm these accusations and today it is known that Fidel Castro was deeply opposed to drug trafficking.[425] Communist China was also blamed during the Korean War for trading opium and heroin in the black market found in the US, that were produced in Chinese laboratories. According to Anslinger, opium and morphine were produced in China and shipped to through Burma to Rangoon, Bangkok, Singapore and then distributed to local population and ending in the US. The whole operation was controlled by the Chinese government to try "to get as many addicts as possible in the US to weaken the country." [426]The information, always anecdotal, not only influenced congressional committees, and was distributed to the press by Anslinger, such as the report mentioning that "subversion through drug addiction is an established aim of Communist China"[427] that originated a vast material linking Red China and dope traffic in the 1950's.[428]

The US interests in controlling states under their sphere of influence in the Cold War, clarify American actions against drug control, despite the background of prohibitionist efforts. The cases involving Iran, Afghanistan and Middle Eastern region illustrate the US changes in stance, to privilege wider foreign policy priorities than international drug control.

The US interest in the Middle East increased after 1946, because of the US-Israeli relations. The area was constantly monitored by the US because it was an opium

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[424] Bewley-Taylor, *The United States and International Drug Control*, p. 66.

[425] Gerber and Jensen, p. 36.

[426] Epstein, p. 34

[427] Epstein, p.33.

[428] Gerber and Jansen, p.33.

production area. In 1957, Egypt proposed the creation of an Anti-Narcotics agency in the region, suggesting that a more effective drug control could be done in the region. The US, going against its drug control objectives to restrict opium production, rejected the Egyptian proposal motivated by a fear that it would be an opportunity for the Arab League to increase its influence in the region. This shows that drug control was a secondary interest that could go against other foreign policy interests and diplomatic efforts in the region.[429]

US concerns with adding states to their sphere of influence in the Cold War, motivated decisions related to international drug control to meet the wider objectives of foreign policy in the case involving Iran and Afghanistan. Opium cultivation in Iran was an important source of revenue and for this reason the country was against controls on the production. This stance changed when Mohammed Mussadiq's government was overthrown with American support, in 1953. Consequently, Iran adopted prohibitionist drug laws, aligned with US and outlawed opium production in 1955.[430]

Iran was one of the countries allowed to produce opium, according to the 1953 Opium Protocol. While Afghanistan petitioned to be included on the list of producing countries, it was smuggling opium to Iran. It was expected that the Americans would support Iran and keep controlling the production at source, in Afghanistan, to prevent the leakage of opium in the illicit market. However, the US wanted to include Afghanistan on the list of licit opium producers and, at the same time, support the Iranian domestic prohibition program, which resulted in great economic losses due to the prohibition of opium smoking initiated by the US. American pharmaceutical industries relied on the high-quality opium coming from Afghanistan to produce morphine, since 1930s and Anslinger criticized companies buying opium from Afghanistan, because it had not signed the Hague Convention.[431] Despite the inconveniences from Afghanistan it was still an opportunity to have an ally in Central Asia and obtain high quality raw material. However, when the US became the strongest advocate for regulation for narcotics control, the fear that the Afghan opium would go to the illicit market increased. As the Afghan exports to the US were an important source of revenue, it not only signed the Hague Convention, but also

[429] Bewley-Taylor, *The United States and International Drug Control*, p.121

[430] Mc Callister, p.196.

[431] Bradford, p. 61

prohibited opium in 1945 to receive foreign aid from the US, but rumours about illicit production persisted. [432] For these reasons, Anslinger feared that opium production in this country would undermine the 1953 Protocol.[433]

With the pressure of increasing controls included in the Opium Protocol, Afghanistan announced a new prohibition of opium production in Badashkan in 1957. The message to the international community was that Afghanistan was ending the production in the most significant region in the country, because it was the source of the greatest amount of raw material and best quality. However, the ban disrupted Afghanistan, creating internal instability, and keeping the country still dependent on foreign aid from the US. Afghanistan had the function of a buffer state towards the Soviet Union. A change in this situation would be a disadvantage for the US. Since the end of the Second World War, Afghanistan asked for political, economic and military support but the Americans preferred to support Pakistan instead, to work against Soviet influence on the region. American aid was denied to Afghanistan and in 1953 this country began to receive economic support from the Soviet Union.[434]

Within this context, the Golden Crescent (Afghanistan, Iran and Pakistan) was a source of tensions in the region. To avoid increasing problems in the region, the US had to improve relations with Afghanistan.[435] As a result, in 1957, Kabul banned opium production and asked for technical aid.[436] Producing countries changed their views on being against restrictive controls, considered an interference on their sovereignty, and realized that stopping opium production was an opportunity to receive development aid. This created a shift in the balance of power within the international drug control regime, because the pressure from producing countries on Western group made them understand that if they wanted to control sources of drug production, they would need to help to pay for the costs.[437]

As this section showed, the role of the US in diffusing prohibitionist norms is undoubtedly relevant due to their hegemony in the Cold War. As Acharya observed,

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[432] Bradford, p. 71.

[433] Bradford, p. 92.

[434] Bewley-Taylor, *The United States and International Drug Control*, p. 126.

[435] Bewley-Taylor, *The United States and International Drug Control*, p. 126.

[436] Mc Callister, 197.

[437] Mc Callister, p. 197.

hegemony is thus viewed less as a matter of coercion than as one of consent, which is generated through ideological consensus. It is the consensus that legitimize the hegemon's preferred ideas keeping the supremacy of the leading state in exchange for some measures of satisfaction of the less powerful.[438] CND decisions are taken through consensus[439] and "this is in the heart of the system."[440]

US ideas were in fact consented by member states in the international drug control regime, sometimes in exchange for economic advantages. As such, it is possible to note that norms on drug control were institutionalized internationally through global and regional institutions through a "process of passive revolution."[441]

In the next section, the negotiations of its very last draft, that led to the adopted text in 1961 will be analysed to show how the element of health is present in the Single Convention and how it generated tensions between sovereignty and states' general obligations.

## 4. The Single Convention 1961: health and drug control

### 4.1. Purposes of the Convention

The Single Convention was an important milestone in the history of the international drug control system. As it was discussed earlier, the identification of "narcotics" for medical and scientific purposes marked the distinction between licit and illicit use of opium. In this section, instead of a simple narrative account about the treaty and its adoption it is discussed here that within the emerging historiography of drug control system's history there are different approaches on the purpose of the system and implications on its function. Forensic analysis of the negotiations of the Single Convention will show how the element of health was approached in this treaty and the

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[438] Acharya, *Constructing Global Order*, p. 37.

[439] United Nations, *Rules of Preocedure of the functional Commissions of the Economic and Social Council*, (E/5975/Rev.1) New York : UN, 1983, Rule 57, https://digitallibrary.un.org/record/50230?ln=en [Accessed 11 June 2022].

[440] Neil Boister, 'Waltzing on the Vienna Consensus on Drug Control? Tensions in the International System for the Control of Drugs', *Leiden Journal of International Law*, 29.2 (2016), 389–409, (p. 389).

https://ir.canterbury.ac.nz/bitstream/handle/10092/101218/Legal%20Tensions%20in%20the%20International%20System%20for%20the%20Control%20of%20Drugs%20v%204.pdf?sequence=2[Accessed 11 June 2022]

[441] Acharya, *Constructing Global Order*, p. 37.

implications of this aspect for the emergence of the tension between sovereignty and states' international commitments.

It is argued by John Collins that the drug treaties represent a system "based on supply control"[442]. And the Single Conventions consolidated previous treaties, the regime followed the American lead and UN treaty framework and agencies moved towards criminalization. [443]

For Bewley-Taylor and Jelsma the Single Convention was a watershed event in the history of the drug control system because it was the moment "when the multilateral work shifted away from regulation and introduced a more prohibitive ethos to the issue of drug control."[444]

They argue that the Single Convention has a prohibition-oriented approach[445], which appears in a combination of a range of elements that go beyond trade. Already in the Preamble, the Conventions states:

> *Recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,*
>
> *Conscious of their duty to prevent and combat this evil,(…)*[446]

In Article 4, General Obligations, paragraph c) it is stated:

> *(c) Subject to the provisions of this Convention, to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs.*[447]

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[442] John Collins, 'The Economics of a New Global Strategy' in: Report *Ending the Drug Wars* (LSE IDEAS, The London School of Economics and Political Science, 2014),

https://www.google.com/search?client=safari&rls=en&q=John+Collins,+%E2%80%98The+Economics+of+a+New+Global+Strategy%E2%80%99+in:+Report+Ending+the+Drug+Wars+(LSE+IDEAS,+The+London+School+of+Economics+and+Political+Science,+2014),+p.+8.&ie=UTF-8&oe=UTF-8 Accessed 11 June 2022].

[443] Collins, p. 9.

[444] David Bewley-Taylor and Martin Jelsma, p. 73.

[445]D. Bewley-Taylor, *International Drug Contr*ol , p.3.

[446] UNTC, *The Single Convention1961 as Amended*, vol .976 No. 14152 p. 106.

[447] UNTC, *The Single Convention1961 as Amended*, vol. 976 No. 14152, p. 106.

Despite that the prohibitionist approach, the Single Convention showed some progress regarding previous treaties that focused in preventing the leakage of excess of production in the illicit market to bringing attention to the individual user and addiction problems, which would become "an increasingly important feature of the international debate."[448]

I argue that despite the concerns with drug trade before 1945 and the prohibitionist approach after 1945, an element of health has always been present in the purpose of previous drug control treaties and in the Single Convention. (See Appendix 1). However, it was neglected, undermined by prohibitionist views on drug use, which had implications for the access to opioids for the treatment of severe pain and drug dependence.

This assertion stems from the analysis of primary sources such as the Official records of the United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs, Volume 1-: Summary Records of Plenary Meetings and Volume 2, Preparatory Documents, Amendments, and Miscellaneous Papers, Proceedings of Committees, Final Act, Single Convention and Schedules, Resolutions are analyzed. Other documents used are Protocol amending the Single Convention on Narcotic Drugs on Narcotic Drugs 1961[449], from 1972 and the Commentary on the Protocol of the Single Convention on Narcotics Drugs 1961.[450]

The first draft of the Single Convention 1961 was released in 1948. The second, came in 1956, kept main features of previous and took and was produced between 1950 and 1955. It led to long discussions at CND due to controversial provisions such as the establishment of an international opium monopoly and a clearing house to regulate

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[448] Carstairs, Catherine, 'The Stages of the International Drug Control System', *Drug and Alcohol Review*, 24.1 (2005), 57–65, p. 61. https://web.p.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=0&sid=3adefce4-0d4b-4050-b400-6bd8df8cd5e0%40redis [Accessed 31 May 2022].

[449] UNTC, *Protocol Amending the Single Convention on Narcotic Drugs*, vol. 976, No. 14151 (Geneva: United Nations 1972)

https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=VI-17&chapter=6&clang=_en [Acessed 31 May 2022].

[450] United Nations, *Commentary on the Protocol amending the Single Convention on Narcotics Drugs 1961*, (E/CN.7/588) (Geneva: United Nations 1972) pp. 1-100.

https://www.unodc.org/documents/treaties/organized_crime/Drug%20Convention/Commentary_on_the_protocol_1961.pdf [Acessed 31 May 2022].

imports and exports. Many countries rejected these provisions because they understood it as threat to national sovereignty. However, the draft kept the prohibition on raw materials of opium, marijuana and coca.[451]The third and last draft used as basis for negotiation came only in 1957**.** This was the main working paper of the Plenipotentiary Conference for the adoption of the Single Convention on Narcotic Drugs held in New York, from 24 January to 25 March 1961[452]. Although it was a significant change to have multiple voices, the conservative approach remained at CND. The negotiation of the Single Convention was built upon the following premises that opium could only be used for medical and scientific purposes**,** as established in previous treaties**.** (See Appendix 2). States formed two main groups that were key players:

The opium producing countries: Turkey, Greece, Yugoslavia and Greece and South American countries producing coca and cannabis. They fought for less stricter controls than the Opium Protocol and argued that manufactured synthetic substances should be controlled as strictly as raw materials. They also wanted to weaken the authority of international control bodies and eliminate on-site inspections which they considered a violation of sovereignty. Latin American states also objected about the restrictions to quasi-medical use of substances consumed traditionally such as coca leaves. However, as Mc Callister observes, those interested in collaborating with enforcement were public health officials, military officials, nationalists, and those not interested in traditional indigenous culture.[453]

The manufacturing group formed by western countries: UK, Switzerland, The Netherlands, Italy, Belgium and Germany. [454] They objected the list of seven states of the Opium Protocol because they didn't want to depend on a small group of raw

[451] Bewley-Taylor, *The United States and International Drug Control*, p. 140.

[452] The first draft was prepared by Steinig. At the same time that he was working on International Opium Monopoly in 1953. The second one was written in 1956, but it was too confusing. In: Mc Allister p.205.

[453] Mc Allister, p. 199.

[454] McAllister, p. 206.

material suppliers. They were also against restrictions to psychotropics drugs highly profitable and promising. [455]

At the end of the negotiations, the Single Convention 1961 retained many features of previous treaties. The Preamble, analyzed later in more detail, kept concerns with "the evil of drugs" but added that the medical use of narcotic drugs "continues to be indispensable for the relief of pain and suffering."[456]The Convention kept the control on distribution of manufactured substances, the system of estimates and the scheduling system had four schedules instead of two. The PCOB and DSB merged to create the INCB. The list of seven countries defined as opium suppliers and the provisions for inspections and embargoes present at the 1953 Protocol were removed. A new feature was Article 38 which brought focus to the treatment and rehabilitation of drug dependence.[457]However, the quasi-medical use of substances embedded in social, cultural, and religious traditions was abolished.[458]

The analysis of the negotiations of the Single Convention shows how States approached the following issues: 1) concerns with health in the discussion of "health and welfare of mankind", mentioned in the Preamble ; 2) the INCB composition and its scope of power, including the power of embargo and the implications of the Amendments of 1972 for health aspects in the drug control regime; 3) the scheduling system and 4) Control and prohibitionism. These three topics have implications for the availability of controlled medicines, such as opioids.

### 4.2. Health Concerns in the Single Convention 1961

The purpose of a treaty is showed in its Preamble. In the Single Convention 1961,the key terms for the analysis of health elements are "protecting health and welfare of mankind." and explicit mentions to the "relief of pain and suffering" and "to ensure the availability of narcotic drugs for such purposes.". They are stated at the Preamble of the Convention as follows:

*The Parties,*

[455] McAllister, p. 206.

[456] UNTC, *The Single Convention 1961 as Amended* ,vol 976 No. 14152, p. 106.

[457] David Bewley-Taylor and Martin Jelsma, p.75.

[458] David Bewley-Taylor and Martin Jelsma, p.80.

> *Concerned with the health and welfare of mankind,*
>
> *Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,*
>
> *Recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,*
>
> *Conscious of their duty to prevent and combat this evil,(…)*[459]

The Preamble reflects three health concerns. First, addiction and the need to fight against it to achieve a state of" health and welfare" for all. Second, the availability of narcotic drugs for pain treatment.

The priorities in the negotiations can be identified for instance by a search the number of terms health, welfare, treatment and well-being mentioned in the official records in the two volumes of the Single Convention's negotiations. They show that word 'control' appears 1351 times, the word 'trade', 359 times, and the word 'health', 335 times. And the representative of WHO took the floor 56 times.

This counting suggests that the concern with control indicates a significant prohibitionist approach and a concern with health, that should not be underestimated if compared to the trade concern. As Robert Weber notes "the most frequent appearing words reflect the great concerns".[460] The participation of WHO appears to be relatively limited and focused on technical issues.

The discussion on the Preamble shows States' ideas, regarding the purpose of the Single Convention, according to the official records show. For instance, While Monsignor Griffths from Holy See stated that the Convention was a "step forward in the moral and social welfare of mankind", [461] the delegate from Denmark added that

[459] UN, *The Single Convention 1961 as Amended Treaty Series*, vol 976 No. 14152, p. 106

[460] Weber, p. 9

[461] (E/CONF/34/24), p. 216.

his country would fight against abuse "not only in its own interests but to contribute to the health and welfare of mankind"[462].

In the context of 1961 negotiations and in previous treaties in 1912 and 1925 (Appendix 1) the insight behind the term "health and welfare of mankind" was to blind people from the exposure to the illicit drug market and drug users, which was perceived as the adequate the strategy to prevent "abuse of substances" and "combat the evil", which, in turn referred to abuse and addiction.[463]This interpretation referred to isolation of people in treatment for drug dependence. As it will be discussed in the next chapters, a human rights approach changed these views.

In 1961, the concern with pain relief and the availability of narcotics for medical use were explicitly expressed for the first time, showing that the concern with pain treatment was also a reason, to create a new treaty. This suggests that those involved in the drafting process of the Single Convention, that lived the at least one of the World Wars were aware of the importance of opioids for pain treatment.

The drafting process of the Single Convention was strongly influenced by US diplomats, who maneuvered drug treaty bodies to replicate US domestic policy's prohibitionist approach to influence the new international treaty. They had support from countries, whose delegates at the Plenipotentiary Conference were seeking to negotiate a treaty that would keep the restriction for drug use for medical purposes, to keep the health and well-being of people by isolating them from the contact with drugs, which were considered "evil".

The official records show that the term 'evil' appeared 29 times in the official records and "scourge" 6 times, both referring to addiction the following contexts. The delegate of Bulgaria, Mr. Grinberg mentioned that[464] a 'crusade against opium' was necessary to eliminate 'the great evil'. [465] He completed saying that "the elimination on the social evil had a great humanitarian importance."[466]This view was shared by Canada, which had invested in "prevent the evil from spreading'[467], bringing to the debate moral fuel

[462] (E/CONF/34/24), pp. 10-11

[463] UN, *The Single Convention 1961 as Amended,* Treaty Series, vol 976 No. 14152, p. 106.

[464] (E/CONF/34/24), p. 12.

[465] (E/CONF/34/24), p. 43.

[466](E/CONF/34/24), p. 12.

[467] (E/CONF/34/24) p. 112.

to increase law enforcement. It was also noted by Mr. Wieczorek, from Poland's delegation and supported by China and Iran. The basic purpose of participating on the negotiation of Article 48 on the procedures for acceptance of the convention was "to rid mankind of the narcotics evil" [468]. The delegate from China, Mr. Cha, hoped that "the Single Convention would help to banish the narcotics evil from the world.[469] The Iranian delegate, Mr. Azarakhsh also observed that "drug addiction was like a contagious disease[470] (…) and when a country like Iran "prohibited the cultivation of poppy to abolish the evil, it was (...) the elimination of a source of danger to the health of the whole world", showing alignment with US and commitment to eliminate opium production.[471] The representative of United Arab Emirates, Mr. Ismail, also supported opium poppy control because his country "had been plagued by the evil of opium"[472], just to mention a few examples.[473]

This selection of speeches confirms the perception that the "mankind" should be isolated from drugs to be safe, satisfied and in good health and that was the motivation of states to be negotiating this treaty. The position of Iran is remarkable. Even being an opium producing country, the Iranian delegate expressed his views against opium because it was a dangerous drug and repeated the hygienist idea that drug dependence was contagious, without any scientific evidence of this assertion. This leads to the discussion on the views on the treatment of addicts and if it should take place in an open or closed institution. [474]. The word 'treatment', for instance, appears 227 times in both volumes. The delegate of the United States, Dr. Ellenbogen declared at one of the meetings[475] that it was necessary to isolate 'addicts' to reduce their opportunities to obtain drugs. His reasoning was the same of isolating people from pathogenic agents since it was a common practice in public health. For him "drug addiction was contagious in the sense that the addict tended to convict others to his morbid act"[476]. It

[468] (E/CONF/34/24), p. 159.

[469] (E/CONF/34/24), p 52.

[470] (E/CONF/34/24), p. 4.

[471] (E/CONF/34/24), p. 4.

[472] (E/CONF/34/24), p. 44.

[473] Other examples for Iran (E/CONF/34/24) p.43; Dahomey, (E/CONF/34/24) p.56, (E/CONF/34/24) p. 103 and (Byelorussia, (E/CONF/34/24) p.104)

[474] (E/CONF/34/24) pp. 105-108.

[475] (E/CONF/34/24) p. 103.

[476] (E/CONF/34/24), p. 103.

suggests an influence of the hygienist movement, associating drug use, prostitution and illegitimacy and considering them obstacles to urban development, based in moral beliefs. Also, as Katherine Pettus noted, the idea of turning international drug trade illicit (for non-medical use) came from a "colonial, overtly racist, socio-historical context that associated 'drug use' with non-white 'uncivilized' peoples".[477]

This kind of stigmatizing language used to categorize drugs entered in the texts of the "multilateral treaties, commentaries and diplomatic discourse that influence narcotics control policies and public policies to this day"[478]. As such, it suggests how the discussions on health and welfare were rather based in conservative moral assumptions than in scientific knowledge.

A more progressive view on drugs was shared by Mr. Koch, delegate from Denmark, legal advisor to the pharmaceutical division of national health, Ministry of Interior. Made it explicit that there was a clear tension between excessive drug control and the availability of controlled medicines. He was against control measures on trade in narcotic, even for legitimate purposes. He affirmed in his general statement that "there was inevitable conflict between the need to protect human being from the evils of narcotic substances and the advantages of their use in the fight against sickness and pain."[479] He continued saying that "empowering the international organs to prohibit certain drugs and establish mandatory embargo would hamper medicine (…) and deprive countries from drugs with essential therapeutic value."[480]

The word 'scourge' was mentioned by Mr. Nikolevic, fromYugoslavia showing that the government "was anxious to assist fighting the scourge of addiction"[481] The word

[477] Pettus, p. 91.

[478] Pettus, p. 91.

[479] (E/CONF/34/24), p.11.

[480] (E/CONF/34/24), p. 11

[481](E/CONF/34/24), p. 10.

was used in the same context by Uruguay[482], India[483], Iran[484], and United Arab Republic[485]

The analysis of the records of the negotiations of the Single Convention[486] also show that from a total of 73 delegations, 21 countries[487] had members related to the ministry of health and only 5 had delegates connected to the ministry of Justice (Pakistan, Philippines, Turkey, US and India). The non-governmental organization were only 3: Interpol, International Conference of Catholic Charities and World Alliance of Young Men's Christian Association[488], suggesting a small but conservative approach from civil society. Civil society organizations were involved in multilateral narcotics control since the Shanghai Commission but, as Pettus notes "very few were involved during the framing of the Single Convention and represented a dominant ideology"[489]

An analysis on the relevance of key individuals on the development of the international drug control system between 1921 and 1971 made by Bruun and others showed that there was a significant number of professionals from the field of health and welfare, medicine (psychiatry), pharmacy, pharmacology, and chemistry. For instance, from the 65 key persons that entered in international drug control scene, 13 were from health and welfare; only four from the police; 19 from universities and research; 9 from revenue and Commerce, 13 from diplomatic service; 2 from international civil service and 5, general civil service. Information available only for two thirds of this group (44 professionals) shows that the background of these key people were: 24 from pharmacy, pharmacology and chemistry; 7 from medicine and psychiatry; 7 from law, 1 from history;1 from accounting; 1 from navy; 3 with non-specialized training. [490] Although these data have limitations because of a lack of information regarding one part of the group, it is possible to observe, that the international drug control system had key

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[482] (E/CONF/34/24), p. 56

[483] (E/CONF/34/24), p. 5.

[484] (E/CONF/34/24), p. 6.

[485] (E/CONF/34/24), p. 6.

[486] (E/CONF/34/24/add.1), p. xviii.

[487] Ghana, Iran, Denmark, Panama, New Zealand, Phillipines, Poland, Spain, Sweden,Switzerland, Thailand, Turkey, United Arab, Republic, United States, Venezuela, Canada, Congo, Indonesia, Japan. In: (E/CONF/34/24/add.1) p. xviii

[488](E/CONF/34/24/add.1), p. xviii.

[489] Pettus, p. 91.

[490] Bruun , Pan, Rexed , p. 121.

people with a background in health, influencing decisions. This data can be used to suggest that that a health concern was present in most of the period of the development of the system. Certainly, Mr Koch from Denmark and Mr. Utin Maung from Burma, and Dr. Halbach, representative of WHO, were representatives of progressive views on health concerns.

Apart from the dominant American approach in the negotiations, Mr. Utin Maung, from Burma, informed the meeting that in his country they were doing what would be regarded today as harm reduction for problematic drug users that did not respond to treatment. "The medical superintendent issued certificates permitting them to purchase their minimum requirements of opium."[491] On the same side, the WHO representative, Dr. Halbach expressed his view, highlighting that 'treatment need not always be provided in a closed institution'.[492] Also, Mr. Koch from Denmark affirmed that in his country it was thought that the medical profession should have the widest possible freedom in the treatment of patients and the prescription of drugs"[493]

### 4.3. INCB's composition and the power of embargo

This section shows the relevance of the power of embargo for the negotiations of the Single Convention and the implications of the 1972 amendments for the elements of health and human rights that will be discussed in the following chapters.

The debate on the INCB's composition shows that it was expected that the class of narcotics produced from plants such as poppy would be substituted by synthetic drugs, therefore there were attempts to limit the influence of producing countries. It became clear when Turkey proposed that the Board should be composed by three representatives of manufacturing countries, three from producing countries and one from a consuming country, apart from specific knowledge on narcotic drugs. The item on having expert members from the producing countries was supported by Greece, Yugoslavia and the UK. Canada, supported by Afghanistan, thought the discussion was not useful because, according to Mr. Curran, the Canadian representative,

[491](E/CONF/34/24), p. 10.

[492](E/CONF/34/24), p. 109.

[493](E/CONF/34/24), p. 11.

"narcotic drugs might well lose their importance"[494] Mr. Acba, from Turkey, responded that "the Board should be adapted to present needs" [495] and suggested a roll call vote on its proposal.[496] The original proposal suggested two members from WHO and seven from a list of persons nominated by members and non-members of the UN. [497]Turkey accepted the language proposed by Mr. Nikole Vic, from Yugoslavia, to include on the Board members with knowledge of the drug situations in the "producing, manufacturing and consuming countries", giving up the right number of representatives from each group and the voting on that issue, showing certain flexibility. But the Turkish proposal for paragraph this paragraph was voted and rejected by 14 votes to 1, with 8 abstentions. [498]Turkey was defeated due to the US influence, supported by Canada.[499]The composition of the Board was defined as three members from WHO and eight from nominations from countries.[500]

The INCB, established by the Single Convention is a quasi-judicial body for the implementation of United Nations drug control conventions.[501] It is technically independent from the governments and from the UN. Today, it is composed of 13 members from different backgrounds such as medical, pharmaceutical or pharmacological but also other backgrounds, for instance in law, economy or administration. WHO nominates three of them, according to Article 9 of the Single Convention[502].

One of the discussions that provoked most tensions in the Single Convention's negotiations were on the scope of power of the INCB, particularly regarding the power of embargo by the Board, which could impact access to controlled medicines. In the Official records for the adoption, the word embargo is mentioned 58 times[503] Some

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[494] (E/CONF/34/24) p. 144.

[495](E/CONF/34/24)), p 144.

[496] (E/CONF/34/24), p. 144.

[497] (E/CONF/34/24/add.1), p. 5.

[498] (E/CONF/34/24/add.1), p. 276.

[499] Robert Curran, legal advisor, Joined the Department of National Health and Welfare in 1945. He was moderate and claim the title of father of the Single Convention. Canadians were concerned with drug abuse which attracted investigatory commissions. In: Mc Callister, p. 193.

[500](E/CONF/34/24/add.1), p. 303.

[501] INCB, Mandate and functions http://www.incb.org/incb/en/about/mandate-functions.html

[502] UN, *Single Convention 1961 As Amended* Treaty Series, vol 976 No. 14152, p.112.

[503] (E/CONF/34/24)), pp.105-292.

states no longer accepted the power of embargo, established at the 1953 Protocol, arguing that it was a violation of sovereignty. States in favor of a provision on embargo in case of non-compliance with the Single Convention were Brazil, Canada, France, China, Greece and the US. Those against the embargo were Ukraine, Afghanistan, Israel, UK, USSR, India, Ghana, Mexico, Turkey, and Denmark.

The term embargo does not appear in the Article 14 on Measures by the Board to ensure the execution of provisions of the Convention' neither in the Single Convention adopted in 1961 nor in the version amended by 1972 Protocol. But it was a term present in the 1953 Opium Protocol, when the prohibitionist approach reached its maximum and was repeated in the third draft of the Single Convention. Article 12 of the 1953 opium Protocol had the title of "Enforcement Measures" referring public declarations, recommendation of embargo and mandatory embargo to be carried by the Board, although states had also the right of appeal. The third draft of the Single Convention included the mandatory embargo and appeal section described in a detailed manner. But as the drafts were written by Adolf Lande, it is possible to see Anslinger's influence in Article 12 – Enforcement Measures, paragraph 2, item 2 of the 1953 Opium Protocol. The recommendation for an embargo shows that it would happen when:

> *(…) excessive quantities of opium are accumulating in any country or territory or that there is a danger of any country or territory becoming a centre of illicit traffic. The Board would recommend to the Parties an embargo on the import of opium, the export of opium, or both, from or to the country or territory concerned, either for a designated period or until shall be satisfied as to the opium situation in such country or territory.* [504]

A mandatory embargo would occur when the conditions above were not fulfilled. In the Single Convention, it appeared in a different language. Instead of Enforcement Measures, the Convention had Article 14 - Measures by the Board to ensure the execution of the Provisions of the Convention. It is important to note that although

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[504] United Nations, '*Protocol for Limiting and Regulating the Cultivation of the Poppy Plant, the Production1953* Opium Protocol, Article 12 of International and Wholesale Trade in and Use of Opium, New York, 23 June 1953', Treaty Series, vol. 456, No. 6555, pp.1-3.

https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-14&chapter=6&clang=_en [Accessed 11 June 2022].

there was no language about mandatory embargo, actions taken in case of embargo remained present also in the 1961 Single Convention as a 'recommendation' for what would qualify as embargo as in Article 14, paragraph 2 as follows:

> *The Board, when calling the attention of the Parties, the Council and the Commission to a matter in accordance with paragraph 1 (c) above, may, if it is satisfied that such a course is necessary, recommend to Parties that they stop the import of drugs, the export of drugs, or both, from or to the country or territory concerned, either for a designated period or until the Board shall be satisfied as to the situation in that country or territory. The State concerned may bring the matter before the Council. 505*

The idea of punishment is present, even if is just a 'recommendation, and not a 'mandatory' embargo. This shows that punishment presupposes prohibition. Also, comparing the texts of the 1953 Protocol (Article 12 paragraph 2) and the Single Convention 1961(Article 14, paragraph 2), the consequences faced by a country endangering the aims of the convention are exactly the same.

Within the framework of the Single Convention, Article 14 has a prohibitionist approach for non-medical use of drugs but it can open an opportunity to improve a health approach. This article, according to paragraph 1 a) provides how the Board should act when it "has objective reasons to believe that the **aims** of the Convention are being seriously[506] endangered by reason of the failure of any party." The Convention is seriously endangered when its aims are not respected. The aims of the Convention are expressed in Article 9- Compositions and Functions of the Board, paragraph 4, as follows. This paragraph was inserted in the Convention with the Protocol Amending the Single Convention on Narcotic Drugs, from 1972[507], opening new possibilities to develop an extended health approach:

> *The Board, in co-operation with Governments, and subject to the terms of this Convention, shall endeavor to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes, to ensure their availability for*

[505] (E/CONF/34/24/add.1) p. 304.

[506] UNTC *Single Convention 1961 as Amended* Treaty Series, vol 976 No. 14152, p.27.

[507] (E/CN.7/588), p. 10.

> *such purposes and to prevent illicit cultivation, production and manufacture of, and illicit trafficking in and use of, drugs."* [508]

The introduction of this paragraph through the amendments in 1972 gives to the Board and governments the responsibility, subject to terms of the convention, to ensure the availability of drugs for medical and scientific purposes, which shows the presence of an element of health element of health present in the international drug control system.

The amendment also introduced paragraph 5 in Article 9 to reinforce the importance of the dialogue between the Board and governments and the possibility of assistance that the Board could give to states.[509]. It reads as follows:

> *5. All measures taken by the Board under this Convention shall be those most consistent with the intent to further the co-operation of Governments with the Board and to provide the mechanism for a continuing dialogue between Governments and the Board which will lend assistance to and facilitate effective national action to attain the aims of this Convention.* [510]

The issue in dialogue is connected to Article 14 para. 1, sub para. a), which includes language about the role of non-governmental organizations, as sources of information that can contribute with the Board's work, as it is clearly expressed in the amended text of the Convention:

> *If, on the basis of its examination of information submitted by Governments to the Board under the provisions of this Convention, or of information communicated by United recommendation, by either other intergovernmental organizations or* ***international non- governmental organization****s which have direct competence in the subject matter and which are in consultative status with the Economic and Social Council under Article 71 of the Charter of the United Nations (…)*[511]

[508] UNTC, *Single Convention 1961 as Amended* Treaty Series, vol 976 No. 1415,Treaty Series, vol 976 No. 14152, p. 112.

[509] (E/CN.7/588), p.10-12.

[510] UNTC, *Single Convention 1961as Amended* Treaty Series, vol 976 No. 14152, p. 112.

[511] (E/CN.7/588), p. 23, emphasis added.

> *(a)The commentary about this article explains that the consultations between the Board and governments should not only take place in case of treaty violations, but also "in the event of serious drug control problems not caused by treaty violations."*[512]

The sub para. C) was also inserted by the 1972 Protocol and it is a provision about the possibility to make a study about a matter referred in sub para-a). According to the Commentary on this paragraph, the matter that deserves to be studied does not necessarily is a non-compliance issue with the convention but can be any drug problem endangering the aims of the convention[513].

As Allyn Taylor notes, Article 14 non-compliance procedure could be a powerful tool for countries to advance the treaties objective of medical availability. This interpretation is made in combination with Article 31 of the Vienna Convention. It sets forth a treaty shall be interpreted in accordance with its ordinary meaning, their context and in light of its object and purpose. This refers to the Convention Preamble [514] When states are endangering the aims of the Convention, paragraph 1a) could be triggered. As it is serious matter, it could be used only in cases when a country consistently neglected to address the issue of pain and furnished no reasonable explanation to the INCB. But this simply threat could be used by the Board to exercise pressure for compliance.[515] The INCB never used Article 14 in a case of medical availability this interpretation could be used as a way improve access to controlled medicines and advance the aims of the Convention.[516]

These amendments opened the possibility for discussions focused on other questions than control and law enforcement, like health and human rights issues such as the lack of availability of pain medicines, although at that time, there was limited understanding of these connections. (Appendix 3 – Amendments). Also, the Board's action regarding "a serious situation that needs cooperative action at the international level with a view to remedying it, described in sub para. d), would not be a sanction, such an embargo,

[512] (E/CN.7/588), pag. 12.

[513] (E/CN.7/588), pag. 12.

[514] Taylor, 567.

[515] Taylor, 567.

[516] Taylor, 567.

but assistance to the government involved in difficulties, through 'Technical and financial assistance', as it is expressed in the new Article 14 bis , also inserted in 1972.[517] This article refers to assistance provided from the United Nations, specialized agencies and governments to support "efforts to carry out its obligations under the Conventions.[518] This interpretation could be used as a way improve access to medicines. In doing so, the Board would not only assist governments for the purpose of implementing the Single Convention but also to advancing its aims.[519]

As these amendments granted the participation of NGOs, an opportunity for a wider discussion on a health approach within the international drug control system was opened, although there were significant obstacles. However, despite these changes in the language of the Convention, there is yet no operational provision regarding the importance of access to medicines to treat pain or any reference to an eventual consequence of countries where the access to medicines is hampered. Moreover, the term "medicine" is not part of the official terminology of the organizations that form part of the international drug control system.[520] And while the term "medical use" is commonly used, neither WHO nor UNODC has a definition for it. The operational paragraphs of the Single Convention place an "emphasis on acts to penalize and prohibit, while neglecting to provide special guidance on how countries should ensure access to controlled medicines",[521] as in article 33 on possession of drugs and 36 penal provisions.

However, in Article 38 which refers to the treatment and rehabilitation of drug dependents, the fear of opioid addiction and its consequences could be mitigated, an opportunity to strengthen the demand side was created. A combination with Article 14 and 14 (bis) could be a possibility to improve the health approach in the international drug control regime. As such, if states are not showing improvements in advancing the aims of the convention, regarding the availability of controlled medicines, for the treatment of pain, it may constitute a treaty violation, because ensuring the availability

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[517] (E/CN.7/588), p. 35.

[518] UNTC, *The Single Convention 1961 as Amended* ,Treaty Series, vol 976 No. 14152, p.116.

[519] (E/CN.7/588), p. 37.

[520] UNODC, *Terminology and information on drugs*, New York 2003.

https://www.unodc.org/pdf/publications/report_2003-09-01_1.pdf [Accessed 14 June 2022].

[521] *Global Commission on Drug Policy*, p.16.

of controlled medicines is one of the aims of the Convention. When a state is in non-compliance with the Convention a dialogue with the INCB is initiated, according to Article 14. But instead of recommending an embargo, which would even hinder exports and imports of substances to produce medicines, Article 14 (bis) could be applied with views to offer technical and financial assistance to states that need to improve availability of opioids. This, in combination with Article 38 could be extended also for the treatment of drug dependents with opioid substitution therapies. These measures would result in a balanced human rights approach for the regime.

With the insertion of the aims of the Convention in Article 9, a tension between sovereignty and states' international commitment emerged, because, as it was discussed, the prohibitionist approach of the international drug control regime, hampered the availability of controlled medicines. As such, member states to the Single Convention have their sovereignty affected by all the measures of control to prevent diversion of substances. If states privilege excessive controls to respect only one of the two aims of the Convention – preventing diversion - they are in fact neglecting the other aim, which is ensuring the availability of medicines. This means that they are in non-compliance with the Convention.

The heart of the dilemma lies in some states' attempt to comply with their obligations of preventing diversions of illicit substances, and for reasons of excessive control, hamper their international obligation to ensure access to medicines, to which they are committed since they are signatories of the Single Convention as amended by the 1972 Protocol.

### 4.4. Scheduling system

The negotiations of the Single Convention involving WHO were mostly technical discussions such as the criteria for the scheduling system, according to the mandate of the ECDD. As Mr. Halbach, added in the plenary in the Eight Meeting, February 13, 1961: "It is important to show the criteria was valid for the present time", suggesting that possible changes could be necessary in the future due to the development of the pharmaceutical industry or the need to adopt other criteria for scheduling. [522] Changes

[522] (E/CONF/34/24/add.1) p. 110.

in the scheduling system can also occur after the re-evaluation of substances already scheduled, such as the case of cannabis.

Substances scheduled in the Single Convention followed the principle of similarity, which means that if a substance has morphine-like, cocaine-like or cannabis-like characteristics, it can be included on the schedules. Substances in schedule I are highly addictive but have therapeutic use such as morphine. Therefore, in schedule II, substances are less addictive, with therapeutic use, such as codeine. In schedule III, there are preparations containing low amounts of narcotic drugs and in schedule IV, there are substances highly active with no therapeutic value, such as heroin.[523]

The negotiations of the Single Convention included discussions on manufacture trade and distribution of drugs involved countries such as The Netherlands, United States, United Kingdom, Germany, France and Brazil. Topics discussed were details about labels, the use of "proper names and double red bands"[524], manufacture and licenses of pharmaceutical products.[525] These measures would ensure the international uniform practices.[526]As the records show, the word control is mentioned 608 times.

The implications of these discussions consisted in "granting the monopoly of production and distribution of controlled medicines to the pharmaceutical industry"[527]. All substances that did not contain certified labels were considered "diversion and abuse", subject to criminal punishment,[528], which can be seen today, regarding medical cannabis. As such, the way of controlling drug use was to grant the instruments of control to the pharmaceutical industry and to medical knowledge. There is a risk that what happened earlier with opium, could be repeated with cannabis. As a consequence

[523] Christopher Hallam, David Bewley-Taylor and Martin Jelsma, Scheduling in the International Drug Control System, *Series on Legislative Reform on Drug Policy*,No. 25,(TNI, IDPC 2014) pp, 1-24, (p.5) <https://www.tni.org/files/download/dlr25_0.pdf.> [Accessed 10 Jun. 2022]

[524] (E/CONF.34/24) p. 71.

[525] (E/CONF.34/24), p. 124-145.

[526] (E/CONF.34/24) p. 29.

[527] Pettus, p. 91.

[528] Bewley Taylor and Jelsma, p. 72.

of increased controls, the Single Convention has today 232 substances under control, from which 215 are in Schedule I, those with therapeutic use.[529]

### 4.5. Control and prohibitionism

In comparison to the previous treaties, the prohibitionist approach in the Single Convention is the result of a range of different elements. It appears for instance in the Preamble, in Articles 4 and 36 and in the discussion on the quasi-medical use of substances. The Preamble refers to the need to combat drug addiction, qualified as the 'evil'. Article 4 (General Obligations) paragraph (c) has a provision that prohibits the possession and use of drugs, for non-medical and scientific use, although the word used is 'limit'. The Single Convention inherited control measures from the 1931 Limitation Convention such as the scheduling systems (with 4 schedules instead of 2) and has a whole article about penal provisions (Article 36). In this article, the following actions could be punishable even by imprisonment or other penalties of deprivation of liberty. Article 36 article reads:

> *(...) cultivation, production, manufacture, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale, delivery on any terms whatsoever, brokerage, dispatch, dispatch in transit, transport, importation and exportation of drugs.* [530]

In fact, Article 36 is the most evident expression of prohibitionism in the Convention[531].

Such a complete array of prohibited actions related to drug trade helped to demonize the consumption of drugs such as opium and created a pervasive idea that even the medical use of morphine was a dangerous act. Although the word prohibited is not explicitly used, Article 36 is highly intimidating. Also, the term "medical purposes" was discussed at the negotiations of the Single Convention, but quite shortly and resulted in a lack of definitions, since most of the countries found it unnecessary[532]. It

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[529] UNODC, *The International Drug Control Conventions, Schedules of the Single Convention 1961, as amended by the 1972Protocol as of 11 June 2021*. https://daccess-ods.un.org/tmp/3346189.85652924.html [Accessed 10 Jun. 2022]

[530] UNTC, *The Single Convention 1961 as Amended*, Treaty Series, vol 976 No. 14152, p. 127.

[531] UNTC, *The Single Convention 1961 as Amended*, Treaty Series, vol 976 No. 14152, p.127

[532] (E/CONF/34/24/add.1) p. 123-124.

is possible to say that as early as the time of the negotiations it was a point that deserved attention with views to an agreement to be included in the document.

As the analysis of the official records of the negotiations will show discussions on the definition of what would be considered "medical and non-medical use" are reflected on the negotiations regarding quasi-medical use of substances. This shows the difficulty on drawing a line between what is licit and illicit in drug control. As Thoumi notes the lack of definitions could have happened because these terms had obvious meanings, or because they should be defined by a scientific consensus, thus leaving a legal void for interpretations. [533]As Francisco Thoumi notes the terms medical and scientifical were purposely undefined, leaving a legal void for interpretations. [534] Damon Barrett and Rick Lines highlight that John Collins supported by Thoumi affirms that 'medical and scientific' were purposely undefined terms allowing room for policy experimentation.[535] Another point to be considered in this discussion is Article 31 on General rule of interpretation of the Vienna Convention of Treaties:

> *1.A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and of its object and purpose.*
>
> *2.The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and Appendicees: (…)*[536]

Moreover, the Commentary of the Single Convention, which explains the purpose of each article, has no explanation for these terms either. From one hand it is vague, but, as noted in the Commentary on the Single Convention, different interpretations depend

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[533] Francisco E. Thoumi, Re-examining the Medical and Scientific Basis for interpreting the drug treaties. Does the regime have any clothes? *After the Drug Wars, report of the LSE experts on the economics of drug policy*, (London:LSE Ideas, London School of Economics and Political Science. 2016), pp. 1-139. (p. 20) <https://www.lse.ac.uk/ideas/Assets/Documents/reports/LSE-IDEAS-After-Drug-Wars.pdf>[Accessed 11 June 2022]

[534] Thoumi,p. 20

[535] Rick Lines and Damon Barrett, 'Cannabis Reform, "Medical and Scientific Purposes" and the Vienna Convention on the Law of Treaties', *International Community Law Review*, 20.5 (2018), 436–55,

https://heinonline.org/HOL/LandingPage?handle=hein.journals/intlfddb20&div=31&id=&page=[Accessed 19 June 2022], p. 442.

[536] United Nations (UN),*'Vienna Convention on the Law of Treaties*, (Vienna: United Nations, 1969)', *Treaty Series* , vol. 1155, No.18232, pp.-1- 331 (p.15)

https://treaties.un.org/pages/ViewDetailsIII.aspx?src=TREATY&mtdsg_no=XXIII-1&chapter=23&Temp=mtdsg3&clang=_en [Accessed 11 June 2022]

on the evolution of science at a particular moment.[537] The lack of orientation of the term "medical purposes" leads to different interpretations.[538] For instance, regarding the use of substances to alleviate suffering during a withdrawal process, there are states that do not accept this practice. Others accept the use of minimum quantities of a drug to enable drug dependents to have a normal life and there are also countries that do not accept the use of any substance by drug dependents. [539] The Commentary also shows the lack of consensus that could emerge on this issue. The meaning of medical purpose, regarding article 49 of the Single Convention[540] was discussed on the commentary of Article 4 – General Obligations, showing that traditional and modern medicine should be considered when medicines with therapeutic value are used:

> *The term medical purposes does not necessarily have exact the same meaning at all times, at all circumstances. Its interpretation must depend on the stage of medical science at the particular time in questions, and not only modern medicine, sometimes also referred to as "western medicine", but also legitimate systems of indigenous medicines such as those which exist in China, India and Pakistan may be taken into account in this connection.541*

Also, the "quasi-medical use" of substances such as opium, mentioned in the 1953 Protocol, is defined in the Commentary on the Single Convention as "the use of opium without medical aid for the relief of pain, other than that caused by addiction to opium or to other narcotic drugs."[542] Although countries such India, Pakistan and China had quasi-medical use of opium as a common practice, the traditional use of substances was provided only in Article 49 of the Single Convention, on Transitional Reservations. As such, the quasi-medical use of opium, opium smoking, coca chewing,

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[537] United Nations, UN, *Commentary on the Single Convention on Narcotic Drugs, 1961 Prepared by the Secretary General in accordance with paragraph 1 of Economic and Social Council Resolution 914 D XXXIV of* 3 August 1962 (New York: United Nations 1973) pp. v- 489, (p.111)

https://www.unodc.org/documents/treaties/organized_crime/Drug%20Convention/Commentary_on_the_single_convention_1961.pdf [Accessed 11 June 2022].

[538] The term 'medical purposes' include dental and veterinary medicine. UN, *Commentary on the Single Convention on Narcotic Drugs, 1961* , p. 468.

[539] UN, *Commentary on the Single Convention on Narcotic Drugs*, 1961, p.111.

[540] On the *Commentary of the Single Convention* in Article 49, paragraph 1, it is stated that "as regards the "medical use" of drugs by addicts, see comments on Article 4. In: UN, *Commentary on the Single Convention on Narcotic Drugs, 1961*, p. 468.

[541] UN, *Commentary on the Single Convention on Narcotic Drugs*, 1961, p. 111.

[542] UN, *Commentary on the Single Convention on Narcotic Drugs*, 1961,p. 468.

the use of cannabis even for non-medical purposes, and the production, manufacture and trade of these drugs were only temporarily permitted. According to the Transitional Reservations, the quasi-medical use of opium was abolished in 1979 and the traditional of cannabis and coca, in 1989.[543].

The discussions about quasi-medical use in the official records of negotiations show that states expressed their views defending the quasi-medical use of substances, which were for them clear enough and were supported in the negotiations. The discussion on this issue appears in the official records, particularly between Pakistan and the US, represented by Anslinger. Pakistan defends the quasi-medical or indigenous use of opium, to be fully understood that the use of those preparations in indigenous medicine in the sense of Article 39. Mr. Banerji, from India added that "far from wanting to evade measures of control, his government was, on the contrary, concerned to ensure that indigenous doctors could continue to prescribe the preparations permitted by national legislation without contravening the provisions of the Convention" [544]

This led to a discussion whether quasi-medical purpose could also be considered "medical purpose". Mr. Lande said that the conference "could adopt a resolution defining the meaning of it attaching to the expression 'medical purposes' or insert an express provision in the Convention." [545]But Anslinger preferred to keep the 'term quasi-medical use' only in the article of reservations[546]. The president of the Session, Mr. Schurman, from the Netherlands, said that regarding the objections of India and Pakistan "it would be enough if the summary record made it clear that the Conference agreed on the interpretation of the terms of Article 30 as meaning that the use of drugs in indigenous medicine would be treated exactly in the same way as their use in other forms of medicine"[547] In response to that Mr. Aslam observed that the summary records "would not form an integral part of the Convention"[548], even if "they would nevertheless serve to make clear the meaning of its provisions."[549] The term quasi-

[543] UN, *Commentary on the Single Convention on Narcotic Drugs, 1961*, p.470.

[544] (E/CONF/34/24), p. 26.

[545] (E/CONF/34/24), p. 25.

[546] (E/CONF/34/24), p 26.

[547] (E/CONF/34/24)p. 26.

[548] (E/CONF/34/24)), p. 26.

[549] (E/CONF/34/24)), p. 26.

medical use was abolished of the Single Convention and from discussion at CND until today. These terms continued without definition due to a clear US pressure made through Anslinger, which imposed the elimination of the discussion on the boundaries defining illicit from licit use of substances.

## 5. New treaties post Single Convention

In the early 1970's, the Nixon administration in the US Single Convention's[550] initiated discussions for amending the Single Convention. [551] As the pharmaceutical industry in Western countries was developing new medicines such as psychotropics, the US preferred rather a less stringent convention for this kind of medicines, because the pharmaceutical industry was expanding its markets for new medicines. the UN worked to have the 1971 Convention on Psychotropic Substances to extend control to a broad range of fabricated behavior and mood-altering substances, that according to the UN, would lead to dependency. The prohibitionist approach remained focused in narcotic drugs. The US carried out a campaign attacking narcotics drugs, mainly heroin and prepared a plan to increase the powers of the INCB and ban the opium cultivation claiming that with the development of synthetic narcotics, natural substances were unnecessary.[552]

As the Cold War continued, the US, to keep producing countries in their sphere of influence attempted to send a positive sign to producer states, creating in 1971 the United Nations Fund for Drug Abuse Control (UNFDAC) to improve technical assistance for lower income countries. The UN and the Division on Narcotic Drugs (DND) supported the idea of creating the independent fund and it was approved at CND. The US donated 2 million dollars[553] for the fund but not many countries added to it. The main task of UNFDAC was to achieve regulatory goals.[554]

CND continued to be the executive and policy-making body, its original mandate. Changes in the framework of the international drug control bodies, in 1979, moved the DND, UNFDAC and INCB from Geneva to their new headquarters in Vienna. Despite

[550] Bewley Taylor, *International Drug Control*, p. 10.

[551] Bewley Taylor, *International Drug Control*, p. 10.

[552] Mc Allister, p.235-236.

[553] Mc Allister, p. 237.

[554] Mc Allister, p. 237.

the development of a complex drug control system, there were countries that were not yet parties to these treaties. This concern made the UN organize a UN International Conference on Drug Abuse and Illicit Trafficking, in 1987. As a result of the conference, the Comprehensive Multidisciplinary Outline (CMO) of Future Activities in Drug Abuse was created, consisting of 35 targets, or problems to be solved and courses of actions at all levels, but based on the prohibitionist approach adopted by the UN. One year later, in, the 1988 the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances was adopted. As the title shows, this convention was focused on the supply-side of the drugs equation, consequently with illicit trade, and the recommendations included in the CMO.[555] In this work, the 1988 Convention is not examined, due to its focus on illicit use of substances. Here and in the following chapters the concern focused on narcotics, particularly opioids for medical use, thus licit substances.

## 6. Conclusion

This chapter examined how the fundamental character of international control regime was shaped after 1945. By analyzing the expansion of prohibitionism in the regime it was showed that US interests dominated the negotiations of the Opium Protocol from 1953 and the Single Convention 1961. The Opium Protocol never entered into force because of excessive restrictions that were not accepted by states, but it was the basis for the negotiations of the Single Convention. At that point the narrative was that the best way to curb the illicit trafficking was controlling production at sources. In case of non-compliance, inspections could occur, and embargoes could be placed by the drug control body PCOB. The analysis of the discussions on this topic, in the official records, shows that most producing countries considered that an embargo, which is a prohibitionist and punitive approach, would affect states' sovereignty, would hamper medicine, science and deprive countries of drugs they considered to be of essential therapeutic value, announcing a possible lack of availability of medical opioids.

As opium producing countries had their economy affected by the limitation of opium poppy cultivation, such imposed restrictions by the international drug control regime

[555] Bewley-Taylor, *The United States and International Drug Control*, p. 168.

could only be accepted in exchange of financial and development aid from great powers such as US or USSR. It was a way to keep states under the sphere of influence of the great powers. However, the limitation of opium production resulted in a decrease in the global opium production, and stigmatization of opioid's users, even for medical purposes, because this substance was associated with "the evil".

Despite the prohibitionist approach, an original analysis of the official records of the conference for the adoption of the Single Convention showed that there was a concern with health present in the discussions. Discussions on the health aspect of the Conventions raised the importance of use of opioids for medical-use, treatment of drug dependents, and the quasi-medical use of substances, but were restricted to a technical character. Consequently, opioids were subject to increasing excessive controls and were also subject to the pharmaceutical industry's production monopoly, which has implications to the availability of opioids to treat pain today. Moreover, the role of WHO was put aside and restricted to the work of the Expert Committee on Drug Dependence.

The official records also showed that discussions on what would be considered the use of a substance for medical purposes were short and did not result in definitions, although the topic deserved attention to be included in the negotiations. The records also show that discussions of the quasi-medical use of opium for the relief of pain led to the abolition of the quasi-medical use of opium in 1979 and practically disappeared after that.

The analysis of the health aspect on the drafting process of the Single Convention 1961, led to the discussion on the tension between national sovereignty and state's international commitments. All forms of drug control introduced by drug control treaties resulted in a gradual loss of sovereignty of some member states to the international drug control regime. Even though all these control measures were established without intention of affecting access to opioids for medical purposes, it was an unintended consequence of the international drug control regime that some member states face today.

The analysis of the drug treaty Preambles showed that in the Single Convention 1961, the concern with the relief of pain and the availability of narcotics for medical purposes is expressed for the first time, but the concern with addiction continued to be present

and was expressed as “a serious evil”, which refers to addiction. The term“health and welfare and mankind”, in the context of the negotiations of the Single Convention, was related to the perception that to achieve health and welfare, the mankind had to be isolated from the contact with drugs. Consequently, the way to curb addiction was to eradicate illicit drug production. These insights match perfectly with the idea that prohibitionism can lead to the well-being of a healthy society.

Controversies on the issue of the power of the INCB led to treaty’s amendments on the Protocol Amending the Single Convention 1972 and the Commentary on the Protocol. The INCB’s power of embargo was included in the 1953 Opium Protocol and remained as a provision of the Single Convention, in 1961, on the form of “recommendation of embargo” and expressed in Article 14 of the Amended Convention in 1972, without using the term embargo.

In 1972, the Protocol amending the Single Convention on Narcotic Drugs on Narcotic Drugs 1961 brought important changes. First establishing the aims of the conventions which are ensuring the availability of medicines while preventing illicit cultivation, production, manufacturing and illicit trafficking. Second, including in Article 14 in NGOs as sources of information that can contribute with the Board’s and the opportunities for countries to receive international assistance to comply with obligations. Third, changes in Article 36 introduced the idea that rehabilitation could be an alternative to conviction or punishment for drug offence. This provision appears in combination with an amendment in Article 38, which has language on prevention of drug abuse, and treatment, education, after care, rehabilitation and social reintegration of drug abusers.

Having that said, it is important to highlight here that when the aims of the convention were included with the amendment in 1972, the tension between national sovereignty and states’ international obligations emerged. Because in a regime dominated by a prohibitionist approach, as it was showed, if a state is strongly committed with ‘preventing illicit cultivation, production, manufacturing and illicit trafficking’, it will probably contribute to the lack of availability of medicines, thus will not be following compliance with international obligations.

The importance of Article 14 is reinforced through a better interaction between civil society and 14 (bis) through technical assistance for treatment, including the treatment

of pain. This approach could be useful for states and UN bodies to reach balance between the two aims of the convention. Moreover, states applying the combination of Article 14 and 38 on treatment and rehabilitation of drug dependents could mitigate the fear of opioid addiction and its consequences, facilitating access to this substance both for pain treatment and harm reduction practices involving opioid substitution therapy.

The processes involving these changes will be analyzed in the next chapters.

# Chapter 4

# The emerging issue of access to controlled medicines in the international drug control regime (2009-2013)

## 1. Introduction

Health concerns had been present in the treaties and expressed by delegates of some countries when the Single Convention was negotiated. However, the misleading idea that to achieve health and welfare for mankind, it was necessary to isolate people from drugs prevailed for decades. As the HIV-AIDS epidemic emerged among injecting drug users, new approaches to treating drug dependence began to emerge, undermining the conventional approach. This led to renewed attention for this issue and increased importance of access to controlled medicines, including opioids, in the international drug control system.

As outlined in the introduction, this research has three main parts. In chapters 1 and 2, the history of the drug control system was explored to show how opium was demonized and became restricted. This chapter and chapter 5 cover the second part of the research on the institutional tensions in the international drug control system between the World Health Organization and the International Narcotics Control Board (hereinafter INCB) and seeks to address two questions: Firstly, to what extent had the issue of access to medicines increased in importance within the international drug control regime? Secondly, how and why did drug related health issues generate tensions within the international drug control system and within the human rights regime? To answer these questions this chapter examines the roles of the INCB and WHO regarding the issue of access to controlled medicines by analyzing the context that preceded the 2009 Political Declaration. It explores the AIDS epidemic and its implications for access to controlled medicines, the development of harm reduction approaches for among injection drug users to treat dependence and prevent spreading of diseases and discusses examples of tensions between the INCB and WHO such as

harm reduction in Switzerland, the Access to Controlled Medicines Program and the case of ketamine.

This chapter also examines how the international drug control regime interplays with the human rights regime, by analyzing the 2009 Political Declaration at the Commission on Narcotic Drugs and the increasing importance of the right to health until 2013.

This chapter analyzes the context of international drug policy and the AIDS epidemic pre-2009 and the period between 2009 and 2013. In 2009, the Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem was adopted at CND. It was a relevant milestone because it shows an increased concern with health issues and human rights. It reviewed the commitments made by members States at UNGASS in 1998 and evaluated achievements. The objective in 1998 was to eradicate illicit cultivation of coca and opium poppy in ten years, the diversion and trafficking of precursors and money laundering by 2008, which were not accomplished.[556]

The chapter ends in 2013 when states and civil society challenged the international drug control system, pushing for a more progressive approach for the drug problem and showing that a norm shift was emerging. The INCB began to give more attention to the issue of availability of controlled medicines, while showing reluctance with harm reduction approaches. Some states adopted non-punitive drug policies and decriminalized drug use. Also, legalization of cannabis and its market regulation, including for medical use, occurred for the first time in Member States to the international drug control regime. At the same time, the issue of quasi-medical use of drugs, which had been put aside since the negotiations of the Single Convention was brought back to CND by Bolivia. The Andean state was the first state to leave the Single Convention because the quasi-medical use of coca had been abolished,

[556] TNI, *Background of UNGASS 1998*, https://www.tni.org/my/node/12412 paragraph 6 of 15 (2005).[Accessed 11 June 2022]

according to the treaty. Bolivia re-accessed the regime including a reservation allowing the quasi-medical use of coca in the country.

The growing concern with health expressed in the Political Declaration from 2009 is discussed in this chapter from the perspective of access to opioids for pain treatment and harm reduction through medication assisted therapies.

## 2. The context before the 2009 Political Declaration

### 2.1.The HIV-AIDS Epidemic in the 1980s and 1990

As the AIDS epidemic emerged in the 1980s and the increased use of injected drugs led to the spreading of the disease in the United States, Europe and in many parts of the developing world.[557] Mortality was high and effective therapy for HIV came only in mid-1990s.[558] In response to this problem some countries began to adopt harm reduction as an alternative to punishment to treat drug dependence. One of the first countries to adopt harm reduction was Switzerland, first using needle syringe exchange programs and then providing opioid substitution therapy and maintenance therapy.[559]

In this context a Political Declaration was adopted by CND in 1990 when there was a growing awareness about the importance of the health component in the international drug control regime.[560] This practice opened the opportunity to discuss the lack of availability of opioids for pain treatment.

Access to controlled medicines is one of the main objectives of the international drug control system, since 1972, when the aims of the Single Convention were included in Article 9. This led the inclusion of this topic in the Political Declaration adopted in 1990 at the UN General Assembly. Paragraph 23 includes in its plan of action that

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[557] Alcabes, Philip, and Gerald Friedland. "Injection Drug Use and Human Immunodeficiency Virus Infection." *Clinical Infectious Diseases*, vol. 20, no. 6, (1995), pp. 1467–79, (p.1467).

<http://www.jstor.org/stable/4458590> [Accessed 12 Jun. 2022].

[558] Joan Csete, From the Mountaintops What the World can Learn from Drug Policy Change in Switzerland, (New York: Open Society 2013), p.19.

[559] In 1986 Switzerland had 3252 cases of HIV and the second highest was UK with 2600. Incidence and prevalence of HIV in Switzerland was higher than elsewhere in Europe in 1995. In: Csete, p.19

[560] Bridge Et Al., p.4

"rational prescribing and use of narcotic drugs (…) shall be incorporated into the curricula of training institutions for health-care personnel."[561]

In paragraph 24, actors that should be involved to achieve this action are clearly listed as it is stated:

> *"The World Health Organization, in collaboration with United Nations drug control bodies, non-governmental organizations and other organizations involved in the rational use of pharmaceutical preparations containing narcotic drugs and psychotropic substances, shall be encouraged to assist national educational authorities in developing training materials and conducting training courses to ensure that medical practitioners and other health personnel are well trained in rational prescribing and use of narcotic drugs and psychotropics substances."*[562]

The 1990 Political Declaration also called for a balance between supply and demand of raw materials, including for medical and scientific purposes[563] and for international cooperation, solidarity, and assistance for developing countries that were opiate traditional suppliers and needed to manage their excess stock to meet their potential legitimate need of opiates.[564]

These paragraphs in the Political Declaration show that in 1990, the issue of access to opiates was in the agenda of the international drug control system, the concern with education of health care professionals was present to ensure rational use of these substances. It means that patients should receive their medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.[565] It is also

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[561] United Nations General Assembly, *Political Declaration and Global Programme of Action adopted by the General Assembly at its 17th special session, devoted to the question of international co-operation against illicit production, supply, demand, trafficking and distribution of narcotic drugs and psychotropic substances*, (A/RES/S-17/2) (New York: UN 1990) pp. 1-22 (p. 8).

https://www.unodc.org/documents/commissions/CND/Political_Declaration/Political_Declaration_1990/1990_Political_Declaration_and_Programme_of_Action.pdf [Accessed 12 Jun. 2022].

[562] (A/RES/S-17/2), p.9.

[563] Bridge et al., p. 14.

[564] Bridge et al, p 14.

[565] World Health Organization WHO, *Promoting rational use of medicines*. (Geneva: WHO 2022)

https://www.who.int/activities/promoting-rational-use-of-medicines [Accessed 31 May 2022].

important to note that in this document, the United States agreed to call on the WHO, UN drug control bodies and NGOs – to work on these issues together and suggested that WHO and civil society could have a more important role, regarding access to medicines that it have had until this point.

Eight years later, the 1998 UNGASS Political Declaration failed to mention access to controlled medicines or harm reduction. However, in paragraph 17, member states showed their concern with HIV-Aids, reinforcing the link from 1990 that the work on demand reduction should happen in collaboration with public health, social welfare and law enforcement, and significant and measurable result was expected to be achieved in 2008.[566] They called on civil society, media and the private sector to cooperate with governments to "deal with problems related to the transmission of the virus and other infectious diseases, according to the drug control conventions.[567]

In 1998 there was a belief that it was possible to eliminate the drug problem. It was reflected in the slogan "A Drug Free World, we can do it" that was used at the meeting, while Pino Arlacchi was the executive director of UNDCP, (UNODCs predecessor). The message sent by the UN body was so embarrassing that it was denied by Antonio Costa, UNODC's the executive director in 2008.[568]The message suggested that it was possible to eliminate drugs from the world and that the regime was being successful on pursuing this goal, but in fact, at that time drug consumption was increasing accross the world.[569]

As harm reduction approaches were becoming more frequent, a civil society movement was formed after 1998 calling for modern and more pragmatic ideas against the

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[566] United Nations General Assembly (UNGA), *Political Declaration* : [of the Special Session of the General Assembly on International Drug Control] (A/RES/S-20/2) (New York: UN 1998) pp. 1-5 (p. 4)

https://digitallibrary.un.org/record/261561?ln=en [Accessed 12 Jun. 2022].

[567] Economic and Socials Council (ECOSOC) *Joint Ministerial Statement and further measures to implement the action plans emanating from the twentieth Special Session of the General Assembly*.( (E/CN.7/2003/L.23/Rev.1) 2003. pp. 1- 7 (p. 6)

https://documents-dds-<ny.un.org/doc/UNDOC/LTD/V03/832/84/PDF/V0383284.pdf?OpenElement

[Accessed 31 May 2022]

[568] The slogan was all over the place, on the special web page, press briefing kits, and (…) in numerous speeches of the world leaders in the UN building, including then the UN secretary general Koffi Annan. The evidence is abundant also in the official documents. *Tom Blickman, 'Refreshing Costa's Memory'*, (Transnational Institute TNI 2008) https://www.tni.org/my/node/18070 [Accessed 31 May 2022] (para. 2-10)

[569] Buxton, p. 76.

outdated drug control regime and was actively engaged in the UN debates in 2003, 2009, 2014 and 2016.[570]

The tensions within the international drug control system became clear with the Plan of Action of the Political Declaration of 1990. While WHO was encouraged to work with governments in harm reduction policies and assisting countries – together with NGOs and UN bodies – to ensure the rational use of narcotic drugs,[571] the INCB was reluctant to accept harm reduction approaches.[572]

The concern with the availability of medicines was raised by ECOSOC in 1988 in a resolution on demand and supply of opiates for medical and scientific purposes.[573] This resolution was concerned with the excess of stocks of opiates, bearing in mind the importance of the balance of between supply and demand of this substance. As the issue of access to controlled medicines is in the core mandate of the INCB, since 1989 the body raised concerns about it in its annual reports, publishing a special report about medical use of opiates, produced with the collaboration of WHO.[574] The INCB is a quasi-judicial body for the implementation of United Nations drug control conventions. It is technically independent from the governments and from the UN, composed of 13 members from different backgrounds, with medical, pharmaceutical or pharmacological backgrounds. Three of them are nominated by WHO, although it is an administrative entity of the UNODC. INCB's functions are to administer the system of estimates, implement the aims of the Single Convention to ensure adequate supply for licit medical and scientific uses under the drug conventions, while

[570] Bridge Et Al, p 14.

[571] (A/RES/S-17/2), page 8, para 35

[573] ECOSOC, *Demand and Supply of Opiates for medical and scientific purposes* (E/1988/87) (New York: UN 1998) pp. 1-60. https://digitallibrary.un.org/record/85512 [Accessed 31 May 2022]

[574] INCB *Report of the International Narcotics Control Board for1989: demand and supply of opiates for medical and scientific needs* (E/INCB/1989/1 Suppl.) (New York, UN, 1989) pp. 1-21. https://www.incb.org/documents/Publications/AnnualReports/AR1989/1989_ANNUAL_REPORT_eng.pdf [Accessed 31 May 2022]

preventing their diversion, and ensure that the provisions of the international drug control treaties are carried out by governments, through permanent dialogue.[575]

In 1999, the INCB included the issue of freedom from pain and suffering in its annual report. The Board recognized that ensuring adequate supply of controlled medicines for medical purposes was "a principal objective of international drug control treaties."[576] The tensions between the international drug control and human rights regimes is clear here. While pursuing the goal of a "drug free world", the INCB reported the lack of data on opioids consumption for comparative purposes and effective monitoring of the availability of opioids, leaving this responsibility for states.[577] The report mentioned no sign of increased diversion of morphine and other opioids but noted the lack of comparative data among countries and government's poor reporting performance.

The Board's considerations on the causes of the lack of availability of opioids were focused on inadequate prescription of opioids and other controlled medicines. This occurs due to inadequate knowledge, incorrect interpretation of existing legal, regulatory, and medical restrictions, among others.[578] However for States, the causes of this problem included impediments originated in the drug regulatory and drug control system, which stem from the international drug control system, and the power granted to the INCB established by the Single Convention. According to the INCB report from 1999, States also mentioned medical and therapeutic; economic, social and cultural impediments.[579] This shows that States considered that the INCB was part of the problem of lack of availability of controlled medicines, but it was not perceived as such by the UN body. It is clearly expressed in the final comment of the report, regarding impediments to the availability of medicines: "(…) first of all is the

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[575] International Narcotics Control Board (INCB), *Mandate and functions*, paras. 1-9 of 14.

[576] (E/INCB/1999/1.), p.1.

[577] INCB, *Report of the International Narcotics Control Board for 1999*, (E/INCB/1999/1)

(New York: United Nations, 2000), p. 2.

<<https://www.incb.org/documents/Publications/AnnualReports/AR1999/AR_1999_E.pdf >, [accessed 5 June 2022]

[578] (E/INCB/1999/1) , p. 3.

[579](E/INCB/1999/1) , p. 3.

responsibility of the concerned governments and that of medical profession."[580] The narrative of the Board focused on blaming countries for their regulatory problems in complying with their commitments with the INCB, in addition to their economic, social, and cultural impediments. The Board failed to assess the impact of the system of estimates, scheduling and increased law enforcement concerns on the availability of opioids, particularly in lower and middle-income countries. Restrictive international control of opioids had a direct impact in the creation of regulatory law and ordinances of states. It was the case in Brazil, as it will be discussed in chapters 5 and 6.

A few years before the High-Level Segment states parties began to realize that the goals from 1998 were far from being achieved and the drug control system was not working.[581] At that time, Mr. Costa believed that fight against the World Drug Problem was a success and that there was a consensus on how to reach a drug free world, as he stated at the World Drug Report. in 2009:[582] "Past runaway growth has flattened out and the drug crisis of the 1990 seems under control", he affirmed. Mr. Costa added that the markets for opiates, cannabis and coca were in decline. [583] However, the system was giving signals of breaking down. As Julia Buxton explains, the system has not only failed to reduce the consumption of addictive and dangerous drugs, but it has also presided at over a sustained increase in their use.[584] Allyn Taylor notes that 2000 was the year when there we more people using drugs than in any other moment in the history of drug control. In 2008 illicit drug abuse had skyrocketed worldwide, with a total number of drug abusers between the ages of 15 and 64 estimated to be around 200 million.[585] In 2008, Antonio Maria da Costa, executive director of UNODC recognized that the international drug control system had been focused on control and law enforcement and restricted to Vienna, as he stated in the World Drug Report, regarding the drug problem: "Too many people in prison, and too few in health

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[580] (E/INCB/1999/1) , p. 5.

[581] Bewley-Taylor, David, 'The 2009 Commission on Narcotic Drugs and Its High-Level Segment: More Cracks in the Vienna Consensus', *Drugs and Alcohol Today*, 9.2 (2009), 7–12 , ( p. 8)

[582] UNODC, *2009 World Drug Report*, (Vienna: UNODC 2009), p. 1

https://www.un-ilibrary.org/content/books/9789211562903 [Accessed 12 June 2022]

[583] UNODC, *World Drug Report 2009*, p. 1.

[584] Bewley-Taylor, *International Drug Control* , p. 15.

[585] Taylor, p.561.

services."[586] Within this context, a Political Declaration was negotiated and adopted in 2009, at CND.

### 2.2. Tensions between the INCB and WHO

The next sections will show examples of tensions within the international drug control regime, which illustrate cases of intra regime complexity. These tensions increased as human rights gained importance in international fora.

#### *2.2.1. The Access to Controlled Medicines Programme*

The Access to Controlled Medicines Programme (ACMP) is an example that shows how increased importance of access to medicines. It reflected concerns with protection of the right to health and the tensions with the existing norms of drug control that privileged restrictive drug use showing a friction between the international drug control and human rights regime. Also, the program shows tensions with the regime, as it will be discussed in this section. This can be noted when WHO and INCB, two UN bodies which form part of the international drug control regime had different priorities, regarding access to medicines.

After the United Nations General Special Session on Drugs (UNGASS) 1998, despite the prohibitionist approach that considered to be possible to live in a world without drugs, WHO adopted important resolutions that were crucial to the development of the debate on access to controlled medicines, particularly opioids. These included: the adoption of the resolution on Cancer Control and Prevention, in 2005 at the World Health Assembly (WHA) 58.22 [587], and the ECOSOC resolution 2005/25 on treatment of pain using opioid analgesics.[588] These resolutions originated a sequence of contributions of the WHO in the field of access to controlled medicines.

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[586] Tom Blickman, *Commenting Mr. Costa's remarks*, para. 1of 5. <https://www.tni.org/en/article/commenting-mr-costas-opening-remarks>[Accessed 12 June 2022]

[587] World Health Organization, *Cancer Control and Prevention* (WHA 58.22) pp. 82-96, (p. 95) in: World Health Organization, Fifty- Eight World Health Assembly, Resolutions and Decisions, Annex, (WHA58/2005/REC/1) (Geneva: WH0, 2005)

https://apps.who.int/iris/bitstream/handle/10665/20398/A58_2005_REC1- en.pdf?sequence=1&isAllowed=y f [Accessed 12 June 2022]

[588] UNODC, *ECOSOC Resolution 2005/25 Treatment of Pain Using Opioid Analgesics*, pp. 1-2.

https://www.unodc.org/documents/commissions/CND/Drug_Resolutions/2000-2009/2005/ECOSOC_Res-2005-25.pdf [Accessed 12 June 2022]

The resolution 58.22 mentions explicitly the medical availability of opioid analgesics as follows, urging member states to:

> *(...) (15) ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Narcotics Control Board and subject to an efficient monitoring and control system."*[589]

And requesting the Director-General of WHO to:

> (...) *(18) examine jointly with the International Narcotics Control Board the feasibility of a possible assistance mechanism that would facilitate the adequate treatment of pain using opioid analgesics.*[590]

The resolution was supported by the United States[591], Oman[592] and India[593] which asked for the inclusion of the term palliative care in the resolution. As a result, it appears nine times in the approved text.

The official records of the plenary discussion during the WHA in March 2005 show that it was an initiative of the INCB to invite WHO to work in order to facilitate the adequate treatment of pain, according to Mr. Del Vallee, from the French delegation "the Control Board had invited WHO to participate in a feasibility study on the subject during the CND in March of 2005."[594]

The president of the INCB, Hamid Ghodse, Iranian psychiatrist, was present at the meeting and made a statement about the collaboration between the INCB and WHO to ensure adequate provision of drugs for medical purposes, while preventing their diversion, stating that "Essential medicines should be available when needed, in adequate amounts (...) to satisfy the health-care needs of the majority of the

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589 (WHA58/2005/REC/1) p.95.

590 (WHA58/2005/REC/1) p.95.

591 World Health Organization, *Fifty Eighth World Health Assembly Summary of Records, Reports of Committees (*WHA58/2005/REC/3) pp. 1-357 (p.269). http://apps.who.int/gb/ebwha/pdf_files/WHA58-REC3/A58_REC3-en.pdf#page=264 [Accessed 12 June 2022].

592 (WHA58/2005/REC/3) p. 269.

593 (WHA58/2005/REC/3) p. 269.

594 (WHA58/2005/REC/3) p. 269

population."[595] In Geneva, the message of the INCB was to defend access to controlled medicines but in the Annual Report of the same year, only one paragraph was dedicated to the access to pain medicines, in its narcotic drugs' section.[596] But the foreword of the INCB report of the same year has no reference to the issue of access to controlled medicines which demonstrates that ensuring access to medicines was probably not among the priorities of the INCB.[597]

Still in the same year ECOSOC adopted the resolution 2005/25 – Treatment of pain using opioid analgesics, mentioning the importance of improving pain treatment using opioid analgesics[598] and invited the INCB and WHO to examine the feasibility of an assistance mechanism that would facilitate adequate pain treatment using opioid analgesics"[599] according to resolution 58.22. It requests member states to report on the implementation of the resolution to the 49th Session of CND.[600]

In 2007, in response to the resolution WHA 58.22 – Cancer Prevention and Control, the WHO and the INCB prepared an assistance programme to facilitate pain treatment using opioids called the Access to Controlled Medications Programme (ACMP)[601]. Its framework[602] was prepared by WHO and INCB and implemented by WHO. The programme was run by Dr. Willem Scholten, who used to work for the Dutch government and was seconded at WHO to work on the ACMP. According to Scholten, initially, the programme was focused on opioid analgesics because of the objectives of Resolution 58.22 "to enhance relief and other symptoms"[603], but he decided to broaden

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[595] (WHA58/2005/REC/3) p. 272.

[596] INCB, *Report of the International Narcotics Control Board for 200*5, (E/INCB/2005/1) (New York: UN 2006) p. 17. https://www.incb.org/documents/Publications/AnnualReports/AR2005/AR_05_Chapter_II.pdf [Accessed 12 June 2022].

[597] (E/INCB/2005/1), pp.iii-iv.

[598] ECOSOC *Resolution 2005/25. Treatment of Pain Using Opioid Analgesics.* pp. 1-2.

https://www.un.org/en/ecosoc/docs/2005/resolution%202005-25.pdf. [Accessed 12 June 2022].

[599] ECOSOC *Resolution 2005/25*, para 18, p.4.

[600] UNODC, ECOSOC Resolution 2005/25.

[601] WHO, *Collaboration within the United Nations and with other intergovernmental organizations* (A60/39) (Geneva: WHO 2007) pp.1-5,

https://apps.who.int/iris/bitstream/handle/10665/22486/A60_39-en.pdf?sequence=1&isAllowed=y [Accessed 12 June 2022].

[602] Willem Scholten, video call, (27 April 2018).

[603] WHO, WHA 58.22 , annex

it to opioids for all kinds of treatment (including agonist therapies) and all controlled medicines."[604]

The ACMP was divided in 2 phases. The first one, supported by WHO and INCB, was devoted to access to opioid analgesics. The second part included access to opioids for substitution therapy.[605] According to the Biennial Report on the Access to Controlled Medicines Programme (2006-2007), the reason why the programme had to be divided in two parts was that the INCB did not want to support access to opioids for substitution therapy.[606] According to Scholten, in in 2006-2007 the president of the INCB was Philip Emafo, from Nigeria, on the discussions on the framework of the INCB did not accept to include harm reduction practices such as the opioid substitution therapy (OST) in the Programme. He had the support of a Russian member of the INCB, and this was also the official Russian position on OSTs.[607] The resistance to include harm reduction approaches in the programme led to tensions between WHO and the INCB. In the second phase, it was focused on access to opioids for pain treatment.

In the second part of the ACMP the ATOME project was announced (2009-2014). The objective of the project supported by WHO was to investigate why opioids for the treatment of pain and for substitution therapy were not used adequately in 12 Eastern European countries (Estonia, Latvia, Lithuania, Poland, Slovakia, Hungary, Serbia, Slovenia, plus Greece, Cyprus and Turkey).[608]As part of the project, the WHO launched the guide *Ensuring Balance in national policies on controlled substances: guidance and availability of internationally controlled drugs*[609], in 2011, with forewords written by Hamid Ghodse, and by Dr. Carissa Etienne, Assistant Director General (Health Systems and Services) from the WHO. Ghodse stated that opioid analgesics are important for the treatment of severe pain and even recognized that methadone and buprenorphine "are increasingly used for the treatment of

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[604] Scholten.

[605] Scholten.

[606] World Health Organization, *Essential medicines: biennial report 2006-2007*. (Geneva: WHO 2007) pp. 1-8 (p.3). https://apps.who.int/iris/handle/10665/70025 [Accessed 12 June 2022]

[607] Scholten.

[608] Scholten

[609] WHO, *Ensuring Balance in national policies on controlled substances: guidance and availability and accessibility,* (Geneva: WHO, 2011) pp. 1-78. Not available on-line since 2019 due to US political pressure.

dependence."[610] Carissa Etienne referred directly to harm reduction practices (without using this term), stating that "Better access to different controlled medicines could prevent for instance 130 000 new HIV infections among injecting drug users.(...).'[611] That clearly shows the difference in approaches of harm reduction from WHO and the INCB. Although the INCB did work for the availability of controlled medicines for pain treatment in in the framework of the ACMP, it failed in adopting human rights norms, more specifically the right to health, notably regarding harm reduction. In doing so, the INCB still privileged restrictive norms, while WHO was pushing for the right to health. With the release of the final report of the ATOME project, the ACMP also came to an end for lack of funding for the project and for his position at WHO. According to Dr. Willem Scholten after seven years, the Dutch government who was funding his position, decided to cut it and suggested that WHO should take responsibility for this work.[612]

Funding was and will always be crucial for the work carried out by international organizations and bodies. Scholten said he approached possible donors to continue the project some of them rejected it because it was about the treatment of pain, and they wanted to invest in purely palliative care projects. Scholten added that "it is hard to understand how a person involved with palliative care does not realize the connection between access to opioid analgesics and palliative care."[613] In 2012 and under the same presidency of the INCB the document *Guide on Estimating Requirements for Substances under International Control* [614] was released, this time demonstrating an example of coordinated work of the two bodies.

### *2.2.2. Harm Reduction in Switzerland*

The INCB's stance on harm reduction was clear when Switzerland adopted Opioid Substitution Therapy (OST) with heroine assisted therapy in the late 1980s. At the

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[610] WHO, *Ensuring Balance in National Policies on controlled substances* .p. 1.

[611] WHO, *Ensuring Balance in National Policies on controlled substances*. p. 3

[612] Scholten.

[613] Scholten.

[614] WHO, INCB, *Guide on Estimating Requirements for Substances under International Control , developed by the International Narcotics Control and the World Health Organization for use by competent national authorities* (New York : UN 2012) p. 42

https://www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating_requirements/NAR_Guide_on_Estimating_EN_Ebook.pdf [Accessed 12 June 2022]

time, HIV infections, provoked in great part by drug injection use, were considered as being the most serious problem in the country. [615]

The missions of the INCB to Switzerland, initially, were not enough to make the Board accept evidence that the heroin assisted therapy was effective as a harm reduction approach. Visits were made in 1994 and 1995, while Ruth Dreifuss was the Head of the Federal Department of Home Affairs, which includes the Federal Office of Public Health. A national evaluation of heroine assisted therapy in Swiss programs of harm reduction was conducted by government's studies and this practice was legalized by the Swiss Federal Council in 1998. In 1999 WHO carried out an independent evaluation of the Swiss experience. "The INCB berated Switzerland for the controversial experiment"[616] and dismissed Swiss evidence, regarding the use of prescribed heroin.[617] Ruth Dreifuss resisted, arguing that Switzerland wanted to follow the conventions and pointed out that harm reduction had enough evidence to justify its adoption as public policy.[618] The WHO concluded that the treatment with heroine was "safe, clinically responsible and acceptable to the community."[619]

The arguments against harm reduction initiatives used by the INCB were used by right wing parties in Switzerland in campaigns against the federal drug policy which included harm reduction. This is an example that shows how the INCB neglected the importance of human rights, criticizing the health approach adopted by the Swiss government to treat drug dependance.[620] In doing so, it also interfered in the sovereignty of this state, exceeding its mandate, which Bewley-Taylor called "mission creep"[621]. In fact, despite all criticism from the INCB, harm reduction policies are currently part of Swiss public health policies with scientific evidence of its effectiveness.[622] As Amitav Acharya notes, norms can be diffused in a process of

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[615] Csete, p. 19.

[616] Csete, p. 24.

[617] Csete, p. 25.

[618] Csete, p. 25.

[619] Csete, p. 24.

[620] Csete, p. 24.

[621] Bewley-Taylor, *International Drug Control*, p. 246

[622] Federal Office Of Public Health, *Diacetyl Morphine (heroine assisted treatment*), paras. 1-3. https://www.bag.admin.ch/bag/de/home/gesund-leben/sucht-und-gesundheit/suchtberatung-therapie/substitutionsgestuetzte-behandlung/heroingestuetzte-behandlung.html [Accessed 12 June 2022]

subsidiarity, "whereby local actors create rules with a view to preserve their autonomy from dominance neglect violations, or abuse by more powerful central actors."[623] It could be a response to the potential tyranny of higher-level institution and greater powers".[624]

When Switzerland adopted the first initiatives of harm reduction it challenged the existing norms that people should be isolated from drugs to achieve "health and welfare", as the Preamble of the Single Convention states. Furthermore, Switzerland used opioids to treat drug dependence with successful outcomes. It was an initiative that began with local physicians and was embraced by the federal government, as a demonstration of resistance against prohibitionist norms exported by the US through the work of UN bodies. According to Acharya, a form of behavior in relation to a higher authority, subsidiarity by local actors can be "challenging/resisting" or "supportive/subordinating." When local players challenge the existing norms, it implies that they are doing active efforts to deal with their own issues without intervention by a higher authority, thus preserving sovereignty.[625]

### *2.2.3. Ketamine*

The INCB and WHO showed conflicting positions in the attempts of scheduling ketamine. This is an anesthetic[626] medication widely used for essential surgery in many Lower and Middle-Income Countries, prompting the ECDD (WHO) to declare that placing it under international control would precipitate a global health crisis.[627]

In this case both the INCB and WHO were claiming authority to decide about the scheduling of this substance. According to WHO's mandate, the body has the authority to recommend the scheduling of substances. The INCB flagged up the issue of abuse of ketamine in Southeast Asia in its reports between in 2004[628] and 2012 stating that

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[623] Acharya, *Constructing Global Order*, p. 47.

[624] Acharya, *Constructing Global Order*, p. 47.

[625] Acharya, *Constructing Global Order*, p.48

[626] Ketamine is not an opioid. It is used here as example that shows that the INCB, with support of some countries was making the access to medicines more difficult.

[627] Pettus, p. 89.

[628] (E/INCB/2004/1)

placing the substance under control only in national legislations would not be enough.[629]

The Board ran a campaign to schedule ketamine, under the Convention on Psychotropic Substances (1971 Convention), because of it considered the occurrence of "widespread abuse"[630]. The 2005 INCB Report contains a recommendation to WHO to evaluate ketamine with view to schedule the substance.[631] The WHO's Expert Committee on Drug Dependence (ECDD) has the mandate to review substances and make recommendations to CND. These recommendations are determinative. It is an independent group of experts in the field of drugs and medicines that review substances according to evidence of their dependence potential, actual abuse and evidence of likelihood to abuse, and their therapeutic applications. The result of the recommendation of the ECDD are to include in, delete from or move substances to the Convention's schedules (scheduling system, Chapter 2). Placing substances with therapeutic use in schedules with tight control can have an impact on the access to the substance, especially in cases where no alternatives are available, as it is the case of ketamine. According to ECDD's mandate, the WHO body evaluates substances and CND decides, based on these recommendations, to place substances under international control. At CND, when the recommendation of ECDD is presented, member states vote pro or contra ECDD's recommendation. The result is decided by simple majority.[632]

Just to illustrate that the composition of the Board has an influence that goes beyond their work on system estimates, the case of ketamine is a clear case of mission creep, showing that the INCB in different occasions failed to be limited to its role of system's monitor.[633]

In 2006 the INCB, under the presidency of Philip Emafo, Nigerian pharmacist, called governments to implement resolution CND 49/6 "Listing of Ketamine as a controlled

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[629] INCB(E/INCB/2012/1), p. 45

[630] Hallam, Bewley- Taylor and Jelsma, p. 8.

[631] INCB(E/INCB/2005/1).p.99

[632] (E/5975/Rev.1)Rule 58.

[633] IDPC, *NGO dialogue with INCB President Raymond Yans*, para. 3 of 9 <https://idpc.net/incb-watch/updates/2014/03/ngo-dialogue-with-incb-president-raymond-yans> [Accessed 12 June 2022].

substance"[634] without delay.[635] In the same year the recommendation of WHO's ECDD in 2006, was against the scheduling of the substance because its medical benefits are more significant than its harm for recreational use[636]. The WHO repeated the evaluation in 2012, 2014 and 2015, reaching the same conclusions.[637]

In 2007, the INCB in its annual report called member states to implement the CND resolution 50/3 "Responding to the threat posed by abuse and diversion of ketamine"[638]. This resolution calls WHO for an updated review of ketamine and reminds that the subject was addressed already since 2004 in the INCB Reports. In 2007, at CND, Philip Emafo,[639]"urged countries to gather information on abuse of ketamine, to assist the WHO's Expert Committee on Drug Dependence to consider scheduling that medication for tighter control. Since the recommendation of the ECDD is determinative, the Board has no power or mandate to challenge it, but that is what Emafo was trying to do at that point. The secretary of ECDD made a presentation saying that ketamine was the only anesthetic available in many contexts and was "astonished" to see the Board calling governments to schedule the medication. The secretary of the ECDD noted that the Committee had not found evidence of adverse effects to justify scheduling and urged CND to ignore INCB recommendations in their Report from 2007. [640]

The Board literally called member states to do the contrary of what the WHO recommended.[641] Nevertheless, the INCB has no power or mandate to change the recommendation of the ECDD. In 2008[642], the INCB's annual report dedicated nine

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[634] United Nations Commission on Narcotic Drugs CND, Listing of Ketamine as a controlled substance, CND 49/6, *Report on the 49th Session*, (E/CN.7/2006/10) (Vienna: UN, 2005, 2006). p.28

https://www.incb.org/documents/Psychotropics/Resolutions/CND_Res-49-6.pdf [Accessed 12 June 2022]

[635] (E/INCB/2006/1), p. 89

[636] IDPC, *WHO Recommends against control of Ketamine*, para. 1 of 4. (IDPC 2015)

https://idpc.net/alerts/2015/12/who-recommends-against-international-control-of-ketamine [Accessed 12 June 2022]

[637] IDPC, *WHO Recommends against control of Ketamine*, para.3 of 4.

[638] (E/INCB/2007/1), p. 111.

[639] IDPC, *The 2007 Commission on Narcotic Drugs*, (IDPC, 2007), p. 3

http://fileserver.idpc.net/library/IDPC_BP_05_2007UNCND_EN.pdf [Accessed 12 June 2022].

[640] (E/INCB/2007/1), p. 111.

[641] The INCB can only recommend scheduling of precursors under the 1988 Convention.

[642] (E/INCB/2008/1), p.281-289.

paragraphs to inform about abuse of ketamine, mostly in South East Asia, and called member states to assist WHO with as much information as possible to so that substance could be scheduled in the future, in an attempt to influence the Experts from ECDD. [643] The same tone in the comments was repeated in 2009's report paragraphs to this issue asking countries to control ketamine nationally, informing about seizures and abuse.[644]The word ketamine appears 44 times in this report but there is no mention about the importance of its availability, only to its control.[645] Again, in 2014 the report informed that countries in the affected region were seeking for "tighter control"[646]. In the next year, China proposed the scheduling of ketamine at CND, despite repeatedly WHO's recommendations against it. [647]

As mentioned earlier, the WHO's recommendation is determinative (according to its mandate). It is noted in the Commentary of the Single Convention that CND decides whether a substance is to be placed under international control. It can take positive action *only* (emphasis added) in accordance with the recommendation of WHO. [648]Before the voting session China backed off and suggested to include ketamine in Schedule IV (milder control) instead of I in the Convention on Psychotropic Substances of 1971. As Bewley-Taylor observes there was not enough evidence of adverse effect from abuse to justify scheduling[649] and according to Scholten and Hallam the scheduling of ketamine would have an impact in public health of low and middle-income countries from rural areas, about 2 billion people with no access to essential surgery.[650] Member states, and not the Board, can appeal on the decision of CND about scheduling but only in social or administrative grounds, not on scientific grounds presented by the ECDD, according to the Commentary on the Single

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[643] (E/INCB/2008/1), p.281-289.

[644] INCB, *Report of the International Narcotics Control Board for 2009*, (E/INCB/2009/1) (New York: UN 2010) p.46. https://www.incb.org/incb/en/publications/annual-reports/annual-report-2009.html [Accessed 12 June 2022].

[645] See for instance (E/INCB/2009/1), pp .44-46.

[646] INCB, *Report of the International Narcotics Control Board for 2014*, (E/INCB/2012/1) (New York: UN 2015), p. 70. https://www.incb.org/incb/en/publications/annual-reports/annual-report-2014.html [Accessed 12 June 2022].

[647] Other attempts to schedule ketamine occurred in 2009 ((E/INCB/2009/1), p. 44), 2014 (E/INCB/2014/1), pp. 16 and 65.

[648] UNODC, *Commentary on the Single Convention on Narcotic Drugs, 1961*, p. 90.

[649] Bewley-Taylor, *International Drug Control*, p. 249.

[650] Willem Scholten and Christopher Hallam, *Fact Sheet on the Proposal to discuss the international Scheduling of Ketamine at the 58Th CND*.http://idhdp.com/media/400336/ketamine-fact-sheet.pdf

Convention 1961[651] within 90 days. Philip Emafo was one of the conservative presidents of INCB (2002-2004) and (206-2007) and his attempts to influence the scheduling of ketamine could have affected the access to this medicine.

In 2006 CND passed a resolution which called upon States to "consider controlling the use of ketamine by placing it on the list of substances controlled under their national legislation."[652]. In the ECDD report from 2006 a critical review of ketamine was carried out and it was concluded that if controls were enforced, problems with the availability would occur due to increased administrative efforts. Consequently, ketamine would be restricted to a limited number of certain professionals not available in remote areas.[653] References made by countries to administrative barriers are precisely those created by the international drug control system and monitored by the INCB.

As the INCB repeatedly mentioned the issue of ketamine abuse in its annual reports, in the next ECDD meeting, in June 2012, a critical review[654] of ketamine was conducted and the Committee recommended not to schedule it because it did not "appear to cause public health risk"[655] and "its control would pose a risk to it" [656]. The critical review also concluded that the scheduling of ketamine would result in a public health crisis, since it would have the same administrative barriers in procurement as opioids.[657] China continued to push for the scheduling of ketamine in the following years. This an example showing difficulties on collaboration between WHO and the INCB failed to collaborate.

This section discussed the three examples that shows tensions within the international drug control regime. As discussed above, different positions of WHO and the INCB regarding harm reduction in Switzerland, in the Access to Controlled Medicines

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[651] UNODC, *Commentary on the Single Convention on Narcotic Drugs, 1961*,p. 99.

[652] (E/CN.7/2006/10), p. 28.

[653] The ECDD makes pre-reviews and critical reviews. The critical reviews are fully documented with information about drug abuse which causes significant public health and drug abuse in: WHO, *WHO Committee on Drug Dependence, Thirty Fifth Report*, (Geneva: WHO 2012) p. 8.

https://apps.who.int/iris/bitstream/handle/10665/77747/WHO_trs_973_eng.pdf [Accessed 12 June 2022].

[654] WHO, *WHO Committee on Drug Dependence*, Thirty Fifth Report ,p. 8.

https://apps.who.int/iris/bitstream/handle/10665/77747/WHO_trs_973_eng.pdf [Accessed 12 June 2022].

[655] WHO, *WHO Committee on Drug Dependence*, p. 8.

[656] WHO, *WHO Committee on Drug Dependence*, p. 8.

[657] WHO, *WHO Committee on Drug Dependence*, p. 8.

Programme and the case of ketamine clearly show the intra-**regime complexity**. They are two UN bodies, belonging to the international drug control regime and should have the same goals. But this example showed that the INCB and WHO had different priorities. The collaboration between the two bodies showed obstacles regarding harm reduction, while the WHO considered that heroine and methadone used in OSTs a medical use of these substances, the INCB rejected this idea, undermining the overall result of the programme. While the INCB made efforts to maintain the status quo regarding its stance against harm reduction, both UN bodies such as WHO, civil society and several states, were challenging the existing norms and pushing for changes.

These three examples also show that it became clear that a health–oriented approach was necessary to treat drug dependence and prevent the spread of infectious blood-borne diseases and opening space to expand the discussion on access to pain medication and other controlled medicines. This is an important shift in the drug control debate, increasing the importance of health discussions in Vienna.

## 3. Human rights meet drug control: The 2009 Political Declaration

The *Political Declaration and Plan of Action on International Cooperation Towards and Integrated and Balanced Strategy to counter the World Drug Problem* was adopted at the High-Level Segment at CND, in 2009. The objective of the meeting was to review the progress made on the World Drug Problem according to the objectives from UNGASS in 1998. This was an important milestone in the history of the international drug control because it is the point when human rights met drug control in international fora, as it will be discussed in this section by comparing language of this document and previous political declarations. Although the connection between the international drug control regime and the international human rights regime opened the opportunity for increased discussions on the right to health and access to medicines for pain treatment and harm reduction, tensions between the two regimes became clear. This showed a lack of consensus in the international drug control regime about its global drug policy, as it will be discussed later.

The 2009 Political Declaration introduced references to human rights and harm

reduction without explicitly expressing them, by incorporating the ideas from CND resolution 51/12, "Strengthening the cooperation between the United Nations Office on Drugs and Crime and other United Nations entities for the promotion of the implementation of the international drug control treaties".[658] In so doing, it linked the importance of conducting drug policy according to the UN Charter, international law and the Universal Declaration of Human Rights raising the importance of states' sovereignty and 'the inherent dignity of all individuals'[659]. Respect for the dignity of all individuals is the goal to be achieved through the access to pain medicines, palliative care, and treatment of drug dependence. The structure of the 2009 document is divided in demand reduction, supply reduction, and money laundering and related measures. The availability of medicines was considered an issue of demand reduction. It presents a list of problems and a plan of action for each of them. The issue of availability of medicines such as opioids for the relief of pain appears twice. First, the Preamble, in paragraph 19, calls for continued cooperation between Member States, the INCB and WHO to:

> *(…) ensure the adequate availability of narcotic and psychotropic drugs under international control, including opiates, for medical and scientific purposes, while concurrently preventing their diversion (…).*[660]

The second reference is stated in the Plan of Action, item 5, on the availability of and accessibility to drug demand reduction services. This paragraph presented the barriers to access them as "the problem" regarding availability of services.[661] Among the actions that should be taken by Member States were problem stated in paragraph10 item 5 (c)

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[658] UNODC, CND Resolution 51/12 Strengthening cooperation between the United Nations Office on Drugs and Crime and other United Nations entities for the promotion of human rights in the implementation of the international drug control treaties, *Report of the fifty-first session*, (E/CN.7/2008/15) (New York: UN, 2007-2008)

https://documents-dds-ny.un.org/doc/UNDOC/GEN/V08/529/94/PDF/V0852994.pdf?OpenElement [Accessed 12 June 2022], p. 32

[659] Bridge Et Al., p. 7.

[660] UNODC, *Political Declaration and Plan of Action on International Cooperation Towards and Integrated and Balanced Strategy to counter the World Drug Problem*, (New York, UN, 2009)

https://www.unodc.org/documents/commissions/CND/CND_Sessions/CND_52/Political-Declaration2009_V0984963_E.pdf (New York, UN, 2009) >[Accessed 12 June 2022]

[661]UNODC, *Political Declaration and Plan of Action*, p.19.

would be that Member States should:

> *(…) Continue to comply with the procedures established under the drug control conventions (…) to enable the Board, in cooperation with governments, to maintain a balance between the demand for and the supply of those drugs in order to ensure the relief of pain and suffering and the availability of medication-assisted therapy as part of a comprehensive package of services for the treatment of drug dependence, bearing in mind, in accordance with national legislation, the WHO Model List of Essential Medicines*.[662]

By comparing this and previous political documents it is possible to see changes in the language referring to human rights, particularly the right to health. In 2009, the word health occurs 51 times mostly linked to demand reduction. It included references to the availability of medicines for pain, and medication-assisted therapy, directly linked to the access to medicines.[663] It also mentioned the importance of measures based in scientific evidence[664] and the importance of a balanced approach between supply and demand reduction strategies.[665] "Drug dependence turned to be regarded as a multifactorial health and social problem"[666]. The declaration encouraged the cooperation between the INCB and human rights bodies[667] in the dialogue on demand reduction, opening space for the discussion and adoption of harm reduction policies by member states.

For instance, in 1990 the Political Declaration has limited references to human rights treaties. It mentioned the UN Charter, but only referring to the respect for sovereignty and territorial integrity of state[668] and the word health appears 4 times. In 1998, the term health appears 3 times, regarding for instance the set-up of programmes of

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[662] UNODC, *Political Declaration and Plan of Action*, p. 21.

[663] UNODC, *Political Declaration and Plan of Action*, p.21.

[664] UNODC, *Political Declaration and Plan of Action*, p. 20.

[665]UNODC, *Political Declaration and Plan of Action*, p. 18.

[666]UNODC, *Political Declaration and Plan of Action*, p. 17.

[667] UNODC, *Political Declaration and Plan of Action*, p. 18.

[668] Bridge Et. Al. p. 6.

demand reduction in collaboration with public health, social welfare and law enforcement authorities as goal for 2008.[669]

In the 2009 Political Declaration it is possible to note the drug debate going towards human rights. This term appears 13 times linked to fundamental freedom and dignity as in previous treaties but for the first time, referring to access to the highest attainable standard of health, thus to the right to health.[670] Here, it is important to note that even provisions in such high-level agreement around the term human rights do not result in any kind of sanctions for member states if not implemented on the ground. But member states that are signatories of a political declaration commit themselves to follow the norms of international law, respecting them. As Mark Kauppi amd Paul Viotti note, when norms take the form of principled beliefs human rights, they can lead in certain circumstances to states redefining their interests and even sense of self (identity) as well as influence international outcomes.[671] This was showed by states pushing for the protection of the right to health, through the debate on access to medicines and harm reduction.

Although this work is not focused on harm reduction, the debate regarding this approach is relevant to understand the emergence of access to medicines as an issue in the agenda of drug control and human rights and in the discussion about the lack of consensus within the international drug control system.

The term harm reduction appears once in the statement of Antonio Costa, UNODC's executive director in the opening of the High-Level Segment of CND in 2009 referring to measures against the spreading of AIDS and the importance of prevention and treatment of dependence as an illness in the period ahead the declaration, reflecting the debates around the approach and terminology.[672] Mr. Costa called the INCB, WHO and UNAIDS, team up with UNODC, to reduce the risk of HIV. Also, in the preamble of the Political Declaration the term "related supported services", used to refer to harm

[669] (A/RES/S-20/2), p. 4.

[670] UNODC, *Political Declaration and Plan of Action*, p. 20.

[671] Kauppi, and Viotti, p. 153.

[672] UNODC, *Political Declaration and Plan of Action*, p. 2.

reduction was repeated 6 times.

Discussions on human rights at CND started in 2008 with resolution 51/12, from 2008, on the cooperation among UN bodies to implement control treaties.[673] This resolution was led by Uruguay and supported by 16 countries[674] plus Slovenia (on behalf of the European Union) and gathered all the elements, regarding human rights from previous Political Declarations made at CND.[675] This view was not shared by all member states. The Chinese rejected the idea that CND was the place to work 'in accordance with human rights law' and Thailand announced that it could break the consensus anticipating the fragile connection among member states at that point.[676] This shows clearly that the engagement of with the human rights regime created a tension that would challenge the international drug control regime, as it will be discussed later in this chapter.

In fact, in 2009 it was expected that harm reduction would be a term included in the Political Declaration but after the negotiations of the final text, the term was excluded, indicating that a prohibitionist consensus would remain at CND. However, in the States' statements during the meeting, harm reduction was present in the speeches of Brazil, Argentina, Holanda, Germany, among others.[677] According to Bewley-Taylor, the Interpretative Statement on harm reduction presented at High Level Segment in 2009 was representative of the increasingly fractured consensus on international drug control.[678]Other examples defective behaviors came up within this period such as the regulation of cannabis market, decriminalization of drug use, the discussion on quasi-

[673] (E/CN.7/2008/15), p.32.

[674] Argentina, Belgium, Bolívia, Finland, France, Ireland, Finland, France, Germany, Italy, the Netherlands, Norway, Peru, Romania, Spain, Switzerland and UK. In : Bridge et al., p. 7.

[675] Bridge Et Al., p. 7.

[676] Bridge et. Al., p.7.

[677] Luciana Boiteux, "Política Internacional de Drogas e Redução de Danos. O fim do consenso de Viena? *Revista Versus*, (Rio de Janeiro: UFRJ 2011), pp. 102-108, (p.107)

https://www.dropbox.com/s/kh3fh42zelb3ljg/Versus6b.pdf?dl=%3E%EF%81%9BAccessed%2012%20June%202022%EF%81%9D [Accessed 12 June 2022].

[678] Bewley-Taylor, *International Drug Control*, p.281.

medical use of coca showed that there was a push for modernization and reform of the international drug control regime.[679]

To illustrate the engagement of UN bodies with the health-oriented approach in 2010, the INCB released a report on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes which included a list of factors affecting the availability of opioids for medical needs, such as concerns with addiction, reluctance to prescribe or stock, insufficient training of professionals, law restricting activities, administrative burden, cost, difficulties in distribution, insufficient supply and absence of policy, in decrescent order.[680] At CND two resolutions on this issue were adopted. In 2010, Resolution 53/4 Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse. [681] And in 2011, resolution 54/6 Promoting adequate availability of internationally controlled narcotic drugs and psychotropic substances for medical and scientific purposes while preventing their diversion and abuse. [682]

In the 2000s harm reduction became a common practice. Beneficial effects of the use of methadone in OSTs for problematic heroine were observed in North America, and Western Europe, by 2009, mostly in the UK, France, Italy, Spain, and Germany.[683] Since 2000, the Chinese government has established more than 500 methadone clinics and by 2009 thirteen states in Asia were prescribing methadone, including Cambodja and Bangladesh. Also, Australia, New Zealand, Puerto Rico, Mexico, Iran, Israel and

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[679] Bewley-Taylor, *International Drug Control*, p. 333

[680]INCB, *Report of the International Narcotics Control Board, Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes*, (E/INCB/2010/1/Suppl.) (New York: UN, 2011), p. 44.

https://www.incb.org/documents/Publications/AnnualReports/AR2010/Supplement-AR10_availability_English.pdf [Accessed 12 June 2022]

[681] UNODC, 'Resolution 53/4, Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abus*e', Report of the fifty-third Session*, (E/2010/28), pp. 12-15. (New York: UN 2010-2011)

https://documents-dds-ny.un.org/doc/UNDOC/GEN/V10/520/82/PDF/V1052082.pdf?OpenElement [Accessed 12 June 2022]

[682] UNODC, 'Resolution 54/6, Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse'. *CND Report of the Fifty-fourth Session* (E/2011/28), pp. 12-15. (New York: UN 2010-2012),

https://documents-dds-ny.un.org/doc/UNDOC/GEN/V11/819/03/PDF/V1181903.pdf?OpenElement [Accessed 12 June 2022]

[683] With some resistance of France, Germany and Sweden, in: Bewley-Taylor, *International Drug Control*, p. 66

Lebanon had programmes of OSTs.[684]

The common use of harm reduction, despite the resistance of more conservative countries, provoked what might be called a "healthification" of the drug control system, which was defended by human rights bodies such as the Human Rights Council. The increasing importance of the issue of access to medicines such as opioids, used both in opioid substitution therapies and pain treatment added complexity to the drug debate and draws attention to the fragile relationship between the INCB and WHO and between the international drug control regime and the international drug control regime. As it will be discussed in the next section, the Human Rights Council began to get involved in drug control issues through the work of Special Rapporteurs on the Right to Health, Paul Hunt[685] and on Torture and other cruel, inhuman, or degrading treatment or punishment, Manfred Novak.[686]

### 3.1. Preparing for changes in the regime

As it was mentioned in the introduction, the right to health is established in Article 12.2 of the International Covenant on Economic Social and Cultural Rights. It spells out the right to "the enjoyment of the highest attainable standard of physical and mental health" and the obligation of States "for the provision of essential drugs".[687]

Before CND resolution 58/12 and the 2009 Political Declaration the international human rights and drug control regimes existed in isolated silos, according to Paul Hunt, Special Rapporteur on the highest attainable standard of health. In 2008 he stated that it was imperative that the international drug control system, referring explicitly to CND, UNODC and the INCB, and the international human rights regime that evolved since 1948, cease to behave as they existed in "parallel universes".[688] Hunt also pointed

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[684] Bewley-Taylor, *International Drug Control*, p. 281.

[685] Paul Hunt, *Human Rights, Health and Harm Reduction, States' Amnesia and parallel universes*. 2008 International Human Rights Association, 2009).

https://www.hr-dp.org/files/2014/05/06/HumanRightsHealthAndHarmReduction_ParallelUniverses.pdf[Accessed 12 June 2022], p. 8

[686] Rick Lines, Deliver us from evil? p. 7.

[687] United Nations, OHCHR *CESCR General Comment no. 14: The Right to the Highest Attainable Standard of Health (art. 12)*, adopted at the Twentieth-second session of the Economical Social and Cultural Rights, (E/C. 12/2000/4) (OHCHR: 2000, paragraph 17), <https://www.refworld.org/pdfid/4538838d0.pdf> [Accessed 31 May 2022].

[688] Hunt, p. 9.

out that member state's representatives agreed on resolutions on the right to health in the Human Rights Council, which are forgotten when they take part in other international fora such as CND in Vienna or WHO.[689]

Created in 2006, the Human Rights Council is the UN body "responsible for strengthening the promotion and protection of human rights around the globe and for addressing situations of human rights violations"[690] It makes recommendations on thematic issues such as the world drug problem.[691] It has 47 members and replaced the United Nations Human Rights Commission established in 1946.

The increased engagement of human rights bodies in the international drug control system contributed to enhance the importance the availability of opioids for pain treatment. From the perspective of the human rights law, the failure of states to provide access to medicines for pain and suffering was pointed out by Manfred Novak on the Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment,[692] from 2009, dedicating three paragraphs for the barriers to palliative care and pain relief.[693] In the same report, a recommendation was included, asking States Parties, to reassess their policies to ensure access to pain relief and overcome "regulatory, educational and attitudinal obstacles to ensure full access to palliative care". [694] The report was presented at the Human Rights Council, in Geneva, in December 2009 and points out questions for a human rights-based approach for drug policies.

Also, the Report of the Special Rapporteur on the Right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines, states that "Under the right-to-health framework, States have an immediate obligation to take legal and administrative measures to ensure that access

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[689] Hunt., p. 9.

[690] Human Rights Council, https://www.ohchr.org/en/hrbodies/hrc/pages/aboutcouncil.aspx, [Accessed 12 June 2022], para. 1 of 24.

[691] Human Rights Council, https://www.ohchr.org/en/hrbodies/hrc/pages/aboutcouncil.aspx.

[692] Rick Lines, Deliver us from evil? p. 7.

[693] Manfred Novak, Report of the Special Rapporteur on torture and other cruel, inhuman to degrading treatment or punishment (Geneva: UN Human Rights Council: 2009), (A/HRC/10/44),

https://documents-dds-ny.un.org/doc/UNDOC/GEN/G09/103/12/PDF/G0910312.pdf?OpenElement

[Accessed 12 June 2022], para. 68-70.

[694] Novak, para74 (e).

to essential medicines for their populations is secured by all available means." [695]In the same report he urged States to adopt a national plan of medicines backed by a strong political will and commitment that prioritizes access to medicines within the public health budget and allocates resources accordingly.[696]

According to Rick Lines, "the State obligation to ensure access to medicines is one that is reflected in, and reinforced between, the two legal regimes."[697]But as the reports presented on the Human Rights Council, mentioned above show, despite this reinforcing norms, the issue of access to medicines remain a global human rights challenge.[698] Here, it is argued that there are States where the access of controlled medicines is low and this lack is justified or excused "because of abusive policies or practices supported by international drug control laws or are implemented as part of an obligation."[699] For instance, in the Single Convention Article 39 on the application of **stricter** national control measures than those required by this Convention allows States to create a national regulations and controls that can result in barriers to access to controlled medicines, on top of those already established by the Single Convention, if it is "necessary or desirable for the protection of the public health and welfare."[700] This can clearly generate a tension between drug control and human rights obligations. The case study will discuss this issue in more detail in Chapters 6 and 7.

The examples of engagement between drug control and human rights regimes show the establishment of a regime complex, overlapping through the right to health. When Paul Hunt affirmed that it seems that States' representatives hear from the right to health in the Human Rights Council and forget about them in other international fora, such as at CND, he is in fact highlighting a situation of regime complexity.[701] As Alter and Raustiala note, regime complexity "makes it harder for individuals to understand

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[695] Anand Grover, *Report of the Special Rapporteur on the Right of everyone to the enjoyment of the highest attainable standard of physical and mental health, on access to medicines*, (A/HRC/23/42) (Geneva, UN Human Rights Council, 2013)

https://www.ohchr.org/sites/default/files/Documents/HRBodies/HRCouncil/RegularSession/Session23/A-HRC-23-42_en.pdf[Accessed 12 June 2022], p. 5.

[696]Grover, p. 5.

[697] Rick Lines, *Drug Control and Human Rights in International Law*, (Cambridge: Cambridge University Press, 2017), p. 85.

[698] Lines, *International Drug Control and Human Rights* p. 85.

[699] Lines, *International Drug Control and Human Rights* p. 85.

[700] UNTC, *Single Convention 1961 as Amended*, Vol 976, N. 1452, p, 119.

[701] Hunt, p. 9.

which actors, institutions, and rules apply; it is more difficult to hold national and global institutions accountable for outcomes."[702]

While the importance of human rights in drug debates was growing, significant changes were occurring in Bolivia, regarding the traditional use of coca leaf and in Uruguay, Canada and the US, regarding the domestic legislation on cannabis. These issues challenged the international drug control system showing the lack of consensus and the weakening of the regime, as it is shaped since 1961.

Under the government of Evo Morales, (2006-2019) a domestic reform in drug policy occurred when the new constitution of Bolivia was adopted in 2007. It included an article stating that the State protected coca as a cultural patrimony, a natural resource of Bolivia's biodiversity and a factor of social cohesion.[703] In order to find coherence with domestic policy, in 2009, Evo Morales proposed an amendment in the Single Convention to withdraw coca leaf from schedule 1. It was the first proposed amendment in drug control norms, in 50 years. The proposal was rejected by the US, Canada, France, Germany, Italy, Japan, UK, US, Russia and Mexico – the only Latin American State to share this position. In response to that Bolivia withdrew from the treaty and requested re-accession with a reservation that would allow the traditional use of coca leaf only in Bolivia.[704]In 2011 the INCB criticized Bolivia for the proposed amendment, because it would undermine the integrity of the international drug control system. Criticism came also from the US, which in the same period had several states legalizing marijuana. Despite the attempts to reject the re-access, Bolivia re-joined the treaty in 2013.

The international drug control system was also challenged because of the legalization of cannabis in Uruguay. In 2013 under the government of José Mujica, the Congress and Senate passed a law to regulate production, distribution, sale and consumption of medical and adult use of cannabis, promoting education, information and prevention while protecting the rights of users. The idea of having more humane and safer drug policies was supported and recommended by the Latin American Commission on

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[702] Alter and Raustiala, p. 12.

[703] Zoe Pearson, 'Bolivia, Coca and Culture and Colonialism', edited by David R. Bewley-Taylor, and Khalid Tinasti, *Research Handbook on International Drug Policy*, ed. by David R. Bewley-Taylor and Khalid Tinasti (Cheltenham: Edward Elgar Publishing Limited, 2020) pp. 283-301, (p. 287).Ebsco ebook.

[704] Pearson, p. 289.

Drugs and Democracy between (2009 and 2011) created by former Latin American Presidents Ernesto Zedillo (Mexico), Fernando Henrique Cardoso (Brazil) and Cesar Gaviria (Colombia). They called for full regulation of all drugs to eliminate illicit market.[705] Later, this group expanded and became the Global Commission on Drug Policy. This commission has leaders from political, economic and cultural areas that advocate for drug policies based in human rights, public health and security.[706] There was sense of need of reforms shared among several countries, particularly in Latin America, where increased levels of violence were occurring due to excessive punitive drug policies. Presidents of the region met to discuss drug policy at the Summit of the Americas and called the Organization of American States (OAS) to analyze results and explore alternatives. The governments of Colombia, Guatemala and Mexico included the issue of drug policy reform in the UN General Assembly Meeting, which resulted in a resolution[707] adopted in 2012 to hold the third UN General Assembly Special Session on the world drug problem, the UNGASS, in 2016, in New York.

In 2012 the US state of Colorado legalized adult and medical use of cannabis. The analysis of the legalization and regulation processes of cannabis in various countries is out of the scope of this work. But here it is important to note that States concerned with human rights issues regarding drug control adopted non-punitive policies, depenalization and decriminalization and regulation of medical marijuana, which Bewley-Taylor called "soft defection".[708]

States adopting these measures continued to be Parties to the Conventions and to regime. This shows a desire of States to comply with their drug control and human rights obligations. However, keeping consensus and complying with both regimes requires from States the ability to navigate to regime complexity. These two regimes form an international regime complex. According to Alter and Raustiala these

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[705] Zara Snapp and Jorge Herrera Valderrábano, regulating Cannabis in Uruguay, the United States and Canada., edited by David R. Bewley-Taylor, and Khalid Tinasti, *Research Handbook on International Drug Policy*, ed. by David R. Bewley-Taylor and Khalid Tinasti (Cheltenham: Edward Elgar Publishing Limited, 2020) pp. 301-323, p. 310. Ebsco ebook.

[706] Global Commission on Drug Policy (GCDP), *Mission and History*,(paras. 1-7)

https://www.globalcommissionondrugs.org/about-usmission-and-history [Accessed 12 June 2022].

[707] UN General Assembly, *International Cooperation against the World Drug Problem*, (A/RES/67/193) ( New York: UN, 2012)pp. 1-12.https://www.unodc.org/documents/commissions/CND/Drug_Resolutions/2010-2019/2012/GA_Res-67-193.pdf [Accessed 12 June 2022].

[708] Bewley-Taylor, *International Drug Control*, p. 191.

elemental institutions with an authority claim for a particular issue area, with an absence of hierarchy.[709] In this case, drug control and human rights. The engagement between them generates regime complexity. The case of Bolivia showed how to craft a policy solution, that was coordinated with regime actors and implemented in a regime complex, thus, accommodating State's obligations in both regimes.[710]

## 4. Conclusion

The issue of access to controlled medicines has increased importance since HIV- AIDS epidemic. As harm reduction initiatives began to be adopted to curb the spread of the disease and OSTs were used in the treatment of drug dependence, concerns on the right to health gained importance both in drug control and human rights fora. This opened the opportunity to discuss the importance of opioids for pain treatment.

After examining the tensions between WHO and the INCB in the cases of the harm reduction policy adopted in Switzerland, the case of ketamine and in the Access to Controlled Medicines Programme, it is possible to conclude the INCB had a more conservative approach regarding harm reduction and sidelined WHO's role.

The INCB rejected the Swiss initiative, which later became a federal policy, dismissing the results of evaluations of the harm reduction projects made by Swiss scientists and by WHO, which concluded that this was a successful experience. In the Access to Controlled Medicines Programme, the INCB showed interest in collaborating with WHO, only if carrying out work for pain treatment. The work on harm reduction including OSTs was rejected by the UN body, which undermined the programme. In the case of ketamine, the INCB seemed to ignore the WHO reviews of the substance and the recommendation not to schedule it, because it could provoke a public health crisis in some low-income countries. There was also Chinese pressure to schedule ketamine, but the INCB, as an 'independent and quasi-judicial body', technically independent, preferred to defend stricter controls of this medicine, instead of ensuring its access in countries without other alternatives.

These three examples showed that in rejecting harms reduction initiatives, particularly OSTs (Opioid Substitution Therapies) affects access to medicines because opioids are

[709] Alter and Raustiala, p. 2.

[710] Alter and Raustiala, p. 10.

used for medical purposes. The INCB behavior in these cases neglects human rights, especially the right to health.

By analyzing the Political Declarations from 1990, 1998 and 2009, it can be concluded that the differences in language on harm reduction, human rights and access to medicines. There was a growing importance of a health approach in in the international drug control system since 2009, motivated by the success of harm reduction initiatives in many countries. This was an important turning point. For this reason, the Human Rights Council also engaged in drug policy discussions on access to medicines, as it was possible to see in the reports of Special Rapporteurs, adding complexity to the discussions on drug policy and reminding States of their obligations in both regimes.

In the period between 2009 and 2013, the tensions between the international drug control and human rights increased because of a range of factors. First, the issue of access to controlled medicines attracted attention from the INCB, which published a special report on the availability of controlled medicines in 2010, while at the same time it rejected harm reduction approaches using the same medicines. Second, countries pushed for non-punitive policies, depenalization, and decriminalization of drug use policies throughout 2000s, which was a longer process that was still occurring between 2009 and 2013. Third, cannabis was legalized in the US state of Colorado in 2012 and regulated in Uruguay in 2013, including for medical use. Fourth, Bolivia withdrew and re-accessed to the Single Convention, with a reservation allowing the traditional use of coca leaf only in this country. In the next chapter it will be explored how these changes impacted both regimes until the Political Declaration of 2019, focusing on access to controlled medicines for pain treatment.

# Chapter 5

# Changes in international drug control regime and tensions with the human rights regime (2014-2019)

## 1. Introduction

This chapter continues the analysis initiated in Chapter 4 about two distinct kinds of tensions. First, the tensions discussed within the international drug control regime, involving the INCB and WHO. Second, the tensions between regimes show the friction between the international drug control and human rights regimes, typical from a regime complex.

This chapter focuses on the period between 2014 and 2019, which includes three relevant moments for the international drug control system: CND High Level Meeting and Joint Ministerial Statement,[711] the 2016 UNGASS and the Outcome Document,[712] and the 2019 Ministerial Declaration *on Strengthening our actions at the National Regional and International Levels to Accelerate the implementation of our Joint Commitments to Address and Counter the World Drug Problem*.[713]

In 2015, the UN General Assembly adopted Agenda 2030, establishing the Sustainable Development Goals (SDGs), which entry into force in 2016. The document has 17 Goals, with 169 targets, reaffirming the importance of the Universal Declaration of Human Rights. [714] The SDGs, UN wider strategy of the SDGs reinforced the importance of addressing access to controlled medicines at UNGASS 2016 because

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[711] UNODC, *Joint Ministerial Statement of the 2014 High-Level Review by the Commission on Narcotic Drugs(CND) of the Implementation by Member States of the Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem*, (New York: United Nations 2014) https://www.unodc.org/documents/hlr/JointStatement/V1403583_E_ebook.pdf [Accessed 6 June 2022]

[712] UNODC, *Outcome document of the 2016 United Nations General Assembly Special Session (UNGASS) on the World Drug Problem: Our Joint Commitment to effectively addressing and countering the World Drug Problem*, pp. 1-26. (New York: United Nations 2016)

https://www.unodc.org/documents/postungass2016/outcome/V1603301-E.pdf [Accessed 6 June 2022].

[713] UNODC, *Ministerial Declaration Strengthening our actions.*

[714] United Nations General Assembly, *Transforming our World: the 2030 agenda for sustainable development*, (A/RES/70/1), *(*New York: UN, 2015).

<http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E, p. 14/35> [Accessed 6 June 2022].

Goal 3 is “Ensure healthy lives and promote well-being for all at all ages”, and target 3.8 “Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”.[715] As a result the drug World Report mentioned the goal and target in 2016 adding that the drug control conventions recognize the use of narcotics for pain as indispensable.[716]

These milestones lead to the analysis of five main points. First, the increased importance of the issue of access to controlled medicines especially since 2014, characterizing a normative shift in the international drug control system. Changes rely on meaning of the “health and welfare of mankind”, stated in the Preamble of the Single Convention. When the Single Convention was negotiated, there was a belief that to achieve health and welfare it was necessary to isolate people from drugs. However, with the increased importance of human rights, the adoption of harm reduction policies it became clear that isolating people from narcotic drugs goes against the protection of the right to health. This shows the tension between the international drug control and human rights regimes. Second, a paradigm shift in the International Narcotics Control Board (INCB). Prior to 2014 the INCB was “a bastion of supply side supervision” but in this period began to give considerable visibility to the issue of access to controlled medicines.[717] Third, tensions in the system due to attempts to schedule ketamine and the role of civil society in avoiding it. Fourth, the increased involvement of civil society at UNGASS will be discussed, showing how the increased importance of human rights led to a wider lack of consensus in the international drug control system. Fifth, it will be showed how the international drug control regime approaches the issue of access to controlled medicines in 2019, the target date set in 2009 Political Declaration for States to eliminate or reduce significantly the illicit cultivation of opium poppy, coca bush and cannabis plant.[718]

This chapter will show that in 2019 Member States failed to meet the goals set in 2009. While the objective of eliminating cultivation of opium poppy, cannabis plant and coca

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[715] UNGA, (A/RES/70/1). p.16.

[716] United Nations Office on Drugs and Crime, *World Drug Report 2016*, p.28 (New York: United Nations 2016) https://www.unodc.org/doc/wdr2016/WORLD_DRUG_REPORT_2016_web.pdf [Accessed 6 June 2022]..

[717] Katherine Pettus, p. 97.

[718] UNODC, *Political Declaration and Plan of Action 2009* , p.14.

bush was not met, the importance of the use of natural opioids such as morphine was recognized, and governments reiterated their commitment to ensuring access to these substances. The following sections discuss the main political documents in this period and their implications for the issue of access to controlled medicines.

## 2. 2014 Joint Ministerial Statement and access to medicines

The objective of the CND High Level Meeting, in 2014 was to review the progress made against the goals in the Political Declaration since 2009 and challenges encountered since then. It has set the scene for the UNGASS meeting in 2016.[719] A norm shift could be noted at the negotiation of the Joint Ministerial Statement in 2014. It took nine months to be negotiated due to the difficulties in reaching consensus and failed to present an objective assessment of what had been achieved until 2014.[720]

As a result of previous resolutions and States' commitments to a health-centered approach since 2009, the Joint Ministerial Statement included a paragraph on the availability of internationally controlled medicines for medical and scientific purposes, particularly for the relief of pain and palliative care, in the section "Challenges and Priorities". It also highlighted the need for Member States, the INCB, CND, UNODC and WHO to ensure their availability and accessibility in accordance with national legislation.[721]

The issue was eclipsed for a long time in the international drug debate due to efforts in preventing illicit trafficking, which contributed to a chronic shortage of pain medicines, particularly in lower- and middle-income countries. In 2014 several side events and statements made by NGOs and UN agencies on this issue took place in the High-Level Segment and 57th CND. As an example, the representative of India noted that the original spirit of the drug control conventions were the protection of health and welfare of mankind, referring to the Preamble of the Single Convention. He continued stating that advancements in public health are not only achieved by

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[719] TNI, *UN High-Level segment on Drugs, March 2014*, preparations for General Assembly Special Session on Drugs (UNGASS), 28 February 2014, https://www.tni.org/en/article/un-high-level-segment-on-drugs-march-2014 [Accessed 6 June 2022], para 3of 9.

[720] IDPC, *Taking Stock: a decade of drug policy, a civil society shadow report*, (IDPC, 2018),p.19

<http://fileserver.idpc.net/library/Shadow_Report_FINAL_ENGLISH.pdf> [Accessed 6 June 2022].

[721] UNODC, *Joint Ministerial Statement 2014*, p.8.

preventing illicit drug use, but also by making them available for alleviating pain and suffering.[722] The importance of a health approach was also expressed by Yuri Fedotov, executive director of UNODC during an informal dialogue with NGOs, as part of the 57th CND. He stated that UNODC was prepared to expand its work on developing international standards access to medicines, demand reduction and prevention, and to work closely with WHO.[723]

Also, in 2014, a meeting of the INCB with NGOs, during CND, showed that concerns with access to medicines were increasing. Raymond Yans, Norwegian, INCB president between 2012 to 2014 received eight questions on this topic. While answering questions, he seized on the opportunity to highlight the need for existing control framework such as the estimates system. According to Yans, the reason for controlling the amounts of imports and exports of drugs was to protect people from "dangers" provoked by drug addiction. He also rejected the idea that harm reduction protected human rights of drug users. [724] Yans's assertions showed that the INCB was not aligned with Fedotov's ideas to work closely with WHO, at least regarding demand reduction. The health agency recognized harm reduction as a health measure to protect the right to health.

Also, in the same year, in Geneva, WHO adopted a resolution on palliative care (WHA67/19). It requested the Director General, through WHO's Access to Controlled Medicines Programme to ensure access to controlled medicines, while preventing its misuse, diversion and trafficking.[725] Pain treatment is a key component of palliative care, according to its definition by the International Association for Hospice and Palliative Care:

"It includes prevention, early identification, comprehensive assessment and management of physical issues, including pain and other distressing symptoms,

[722] IDPC, *The 2014 Commission on Narcotic Drugs and its High-Level Segment, Report of the Proceedings,* (2014) p.32 <http://fileserver.idpc.net/library/CND-Proceedings-Document-2014_ENGLISH.pdf >[Accessed 6 June 2022].

[723] IDPC, *The 2014 Commission on Narcotic Drugs and its High-Level Segment*, p. 30.

[724] IDPC, *The 2014 Commission on Narcotic Drugs and its High-Level Segment*, p. 31.

[725] (WHA 67/19), para. 4 of 50.

psychological distress, spiritual distress and social needs. Whenever possible, these interventions must be evidence based. (…)"[726]

This resolution opened space for an increased discussion on access to medicines for pain treatment because it is one of the most important symptoms to be managed on palliative care and indicates the level of quality of palliative care services.

## 3. UNGASS, INCB and changes in the regime

From the perspective of constructivism ideas spread because they have a moral purpose. Changes in principles in the international drug control system were occurring because some states and civil society acknowledged the importance of human rights. They began to be recognized, even if slowly and selectively by the INCB. According to Amitav Acharya, actors accept ideas, build institutions around them, and behave accordingly because these ideas and the behavior they shape are understood to be good, desirable, and appropriate.[727] Developments in 2014 started to show this adaptation.

The INCB is known for its conservative approach and narrow views regarding human rights and the participation of civil society in the drug debate at CND (as it was discussed in chapter 4). The body also began to show that it was trying to adapt to new principles. Prior to 2014 the Board preferred to stay away from the discussions involving human rights, Raymond Yans, president of the INCB in 2014 encouraged States to abolish the death penalty[728] and recognized, the use of methadone for Opioid Substitution Therapy (OST) to manage drug dependence, and the importance of pain relief for conditions other than cancer, such as "surgery and delivery" in his statement at CND in the same year.[729] He also added that people that do not receive these drugs

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[726] International Association for Hospice and Palliative Care (IAHPC), *Palliative Care definition*, paras 1-3https://hospicecare.com/what-we-do/projects/consensus-based-definition-of-palliative-care/definition/ [Accessed 6 June 2022].

[727] Acharya, *Constructing Global Order*, p 39.

[728] United Nations Information Service (UNIS), *INCB encourages States to consider the abolition of the death penalty for drug-related offence*, (UNIS/NAR/1199)

https://www.incb.org/documents/Publications/PressRelease/PR2014/press_release_050314.pdf [Accessed 6 June 2022]

[729] INCB, *Statement by Mr. Raymond Yans, President, International Narcotics Control Board, at the fifty-seventh session of the Commission on Narcotic Drugs*, (Vienna: INCB 2014), p. 2

http://www.incb.org/documents/Speeches/Speeches2014/INCB_President_statement_CND_2014_Item_10d_with_INCB_logo_DRAFT_170314_am.pdf [Accessed 6 June 2022].

when necessary "will not be able to derive the health benefits to which they are entitled under the Universal Declaration of Human Rights,"[730] showing concern with the right to health. In Geneva, WHO adopted a resolution on palliative care (WHA67/19), which was a positive sign that a topic on the right to health was on the agenda of others multilateral fora. [731]

After the High-Level Segment in 2014, the preparation for the UN General Assembly Special Session (UNGASS) on the World Drug Problem, to be held in 2016, began at CND with the negotiations of a resolution about the outcome, place of preparations, the engagement of other UN agencies and civil society.[732] UNGASS was proposed by Colombia, Mexico, and Guatemala in 2012, at the General Assembly. These states had been suffering the consequences of the war on drugs and believed that the global drug approach should be revised prior to 2019, the target date established in the Political Declaration of 2019.[733]

The INCB has been mostly focused on the supply reduction side of drug policy. Since 2014 the Board has been gradually changing stance on issues involving the right to health. The changes were particularly important for the access to controlled medicines for pain treatment. Other shifts of the Board's position on decriminalization of drugs in Portugal and on the adoption of drug injection rooms are briefly discussed here to show that these changes correspond to a change in norms in the international drug control regime, instead of isolated facts.

The change in the INCB's tone since 2014 was one of the most remarkable changes in the international drug control system, in the period of this research. Although it was positive, the Board remained conservative in its positions regarding human rights.

In 2014, Lochan Naidoo, South African, took office as the new president of the INCB, showing a different approach from his predecessors, particularly emphasizing that the focus of his presidency would be drug abuse prevention and access to medicines.[734] In

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[730] INCB, *Statement by Raymond Yans, 57th CND*, p.2.

[731] (WHA 67/19), (pp. 1-5).

[732] IDPC, *The 2014 Commission on Narcotic Drugs and its High-Level Segment*, p. 2.

[733] IDPC, *Taking Stock of a half a decade of Drug Policy, a civil society shadow report* (London, IDPC), p. ii http://fileserver.idpc.net/library/Shadow_Report_FINAL_ENGLISH.pdf [Accessed 12 June 2022].

[734] United Nations Information Service (UNIS), Press release, *INCB reviews availability of medicines and drug abuse worldwide* (2 June 2014), (UNIS/NAR/1212) para. 1of 12.

his statement at the 110th INCB Board Meeting , in June 2014, he reminded that the INCB Report on availability from 2010, previous resolutions on the availability of access to medicines at CND in 2011, and the resolution on palliative care at WHO, in 2014, were showing that concluding that it was time for governments to "take the next step now, moving from words to action". He affirmed his intention of working closely with the WHO to reverse "the abysmal reality of limited access, where today's use of medicines containing narcotic drugs for pain relief is concentrated primarily in North America, Western Europe and some countries of Oceania".[735] Having the INCB working closely with WHO was a sign of openness to increase work on drug issues involving the right to health.

The same approach was kept in 2015 in Lochan Naidoo's statement at 58th CND. He admitted that the world had changed, and the world drug problem had also evolved, although he believed that the objectives of drug treaties remained valid. He not only opened space for an increasing debate on access to medicines, but also defended the importance of human rights and the Board's opposition to death penalty.[736]Despite these concessions, he was reluctant with harm reduction, cannabis regulation in Uruguay and decriminalization of drugs.[737] This showed the INCB was open to discuss some selected topics regarding drug control and human rights, and harm reduction was not among them.

In the NGOs Dialogue with the INCB, in 2015, Mr. Naidoo used a conciliatory tone, regarding access to medicines. He disregarded the multifactorial cause of the lack of access to opioids according to him it was a problem of interpretation of the Convention at the domestic level and encouraged states and NGOs to remove barriers to access to opioids.[738] This showed three problems. First, the INCB did not recognize that most states create legislations based on the Conventions and the body leaves the

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https://www.incb.org/documents/Publications/PressRelease/PR2014/press_release_020614.pdf [Accessed 6 June 2022].

[735] (UNIS/NAR/1212).

[736] IDPC, *The 2015 Commission on Narcotic Drugs and its Special segment on preparations for the United Nations General Assembly Special Session on the World Drug Problem, Report of Proceedings*, p.5 (IDPC, 2015),

< http://fileserver.idpc.net/library/CND-proceedings-report-2015.pdf> [Accessed 6 June 2022].

[737] *IDPC, The 2015 Commission on Narcotic Drugs and its Special segment on preparations for the United Nations General Assembly Special Session on the World Drug Problem,* p. 5.

[738] IDPC, *The 2015 Commission on Narcotic Drugs and its Special segment on preparations for the United Nations General Assembly Special Session on the World Drug Problem*, p.29.

responsibility to eliminate barriers, without recognizing that it was in fact the INCB that created them. Moreover, it is the INCB's mandate to ensure the availability of medicines, according to Article 9, paragraph 4 of the Single Convention, on the aims of the Convention. Second, the lack of consensus in the international drug control system made the work of the INCB, more difficult, according to Naidoo, leading to tensions in the system, as it was discussed in the attempts to schedule ketamine, tramadol and harm reduction using OST (Opioid Substitution Therapy). The difficulty relied on the fact that Member States are sovereign and the INCB is "only a compliance body."[739] This statement showed that the INCB was leaving the responsibility of advancing on access to medicines to Member States. The INCB is a compliance body with power granted to build a dialogue with States and through dialogue it should contribute to resolve tensions.[740]

The INCB also changed stance regarding other issues with implications for human rights such as decriminalization of drug use in Portugal and the establishment of drug injection rooms. During UNGASS preparations the INCB's positions seemed to soften regarding other topics such as decriminalization of drug possession in Portugal, adopted since 2000, when the issue of personal possession moved from the realm of law enforcement to public health.[741] As a result of successful policy through the work of dissuasion commissions,[742] drug use did not increase, the number of HIV infections and drug related deaths dropped significantly. Drug dependent individuals began to receive treatments and were reintegrated into society. As the police became free to focus on large scale trafficking, increasing safety.[743]

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[739] IDPC, *The 2015 Commission on Narcotic Drugs and its Special segment on preparations for the United Nations General Assembly Special Session on the World Drug Problem*, p.29.

[740] IDPC, The 2015 Commission on Narcotic Drugs and its Special segment on preparations for the United Nations General Assembly Special Session on the World Drug Problem, p. 29.

[741] Artur Domostavski, *Drug Policy in Portugal, The Benefits of Decriminalising* Drug Use, (Open Society Foundations, 2011), p.8.

[742] Dissuasion Commissions are formed by three people nominated by the Ministry of Health and Justice. When drug users are stopped by the police, they are not detained , but after having their documents verified, are sent to the Dissuasion Commission to talk about the reasons to use drugs, history of addiction, family background and work status. The objective is to send people with problematic drug use to treatment, without stigmatizing them. If there is no dependence issue, drug possession is treated as an administrative offence. Domostavski, p. 29.

[743] Domostavski, p.8.

After missions to Portugal, in 2004[744] and 2012[745], the Board was reticent on the policy of decriminalization adopted in the country, in its annual reports. Since 2000, Portugal adopted a successful drug policy through the work of dissuasion commissions, formed by health care and justice professionals. Drug dependent individuals began to receive treatments and were reintegrated into society, while the police became free to focus on large scale trafficking, increasing safety. The number of HIV infections and drug related deaths dropped significantly.[746] Only in 2015, Werner Sipp, German, president of the INCB, worked also in the German ministry of health, made a statement at CND event on public health approach as a base for drugs policy about the Portuguese case. He had a legal background and

worked also in the German ministry of health. Werner Sipp approved the dissuasion commissions implemented in Portugal and even said that they would be "useful for other countries where alternative sanctions for possession of drugs for personal consumption are implemented or under consideration"[747]This example shows that the INCB showed a changed its stance on decriminalization policies.

The Bard softened its position about drug injections rooms in 2016. In 2008, it urged governments to "refrain from establishing drug consumption rooms. [748]In Western Europe, drug consumption rooms had been operating for three decades and were established in Denmark, Netherlands, Switzerland, Germany, Luxembourg, Norway, Spain and France. In 2016, the Board recognized that "that the ultimate objective of such measures is to reduce the adverse consequences of drug abuse," showing room for dialogue.[749]

The INCB's change in stances discussed here shows how norms were changing in the international drug control system. As human rights, particularly the right to health achieved increased importance in this period, the INCB had to adapt to new norms, otherwise it could risk losing its relevance in the system. The recent developments

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[744] (E/INCB/2004/1), p. 80.

[745] (E/INCB/2012/1), p. 80.

[746] Domostavski, p.8.

[747] Domostavski, p.8.

[748] (E/INCB/2008/1), p. 103.

[749] INCB *Report of the International Narcotics Control Board for 2016*, (E/INCB/2016/1) (New York: UN 2017), https://www.incb.org/documents/Publications/AnnualReports/AR2016/English/AR2016_E_ebook.pdf [Accessed 6 June 2022], p.26.

involving the regulation of cannabis in Uruguay and its legalization in the US, the increased importance of access to controlled medicines included in several UN documents since 2014, successful harm reduction policies in several countries, and the withdrawal of Bolivia from the Conventions showed that changes were occurring in the national level in many countries. In fact, governments were resisting existing norms imposed by the system and pushing for change. Acharya's 'norm subsidiarity' is understood as a "process whereby local actors create rules with a view to preserve their autonomy from dominance, neglect, violation, or abuse by more powerful central actors."[750] Resistance is a form of behavior of local actors in relation to a higher authority. It implies active efforts on the part of local players to deal with their own issues without intervention by a higher authority.[751]

In addition, changes in the INCB also reflect the importance of SDGs and the influence of individuals in this process. For instance, previous presidents, such as Hamid Ghodse, Iranian, shared conservative views on drug policy while in office for eleven years. In contrast, Naidoo, was a catalyst for the process of norm change that could happen at the State level. He played a significant role to influence the debate on several topics. He contributed particularly to drawing international attention to the issue availability of pain medicines. His background and knowledge contributed to his engagement with the topic. Moreover, pressure from the civil society, demanding more assertive actions from the INCB on access to medicines and the proximity of UNGASS, in 2016, led to norms change in this period. Naidoo acted as a norm antipreneur when he raised the issue of access to controlled medicines and human rights. As noted by Alan Bloomfield and Shirley Scott, norm antipreneurs can most readily be identified where the new norm challenges a specific deeply held and institutionally entrenched by those most powerful actors in the issue area.[752]

In 2014 it was possible to see an important norm shift regarding the meaning of "health and welfare of mankind" as stated in the Preamble of the Single Convention. Earlier,

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[750] Acharya, *Constructing Global Order*: p. 47.

[751] Acharya, *Constructing Global Order*, p. 48.

[752] Alan Bloomfield and Shirley Scott, 'Norm antipreneurs in World Politics', pp. 1-20. in *Norm Antipreneurs and the Politics of Resistance to Global Normative Change*, edited by Alan Bloomfield and Shirley Scott, (New York, Routledge, 2017), p. 8,

https://books.google.ch/books?id=szQlDwAAQBAJ&pg=PA1&hl=de&source=gbs_toc_r&cad=3#v=onepage&q&f=false [Accessed 6 June 2022].

protecting health and welfare was interpreted as the need to isolate people from drugs, to prevent addiction. In 2014, protecting health included the need to make drugs available to alleviate pain and suffering.

## 4. Ketamine, tramadol and civil society

As the preparations of UNGASS and discussions on human rights topics advanced, civil society space increased in international drug control fora. The cases of tramadol and another episode involving attempts to schedule of ketamine shows how the mobilization of civil society played a significant role in influencing states' decisions against the scheduling. The international control of these substances would have impacted access in low- and middle-income countries, without other alternatives to substitute it.

A campaign to schedule tramadol started in 2014 when the Chair of CND in 2014 was the Egyptian Ambassador Khaled Shamaa, also elected to be the Chair of UNGASS Board in 2016. Tramadol is an opioid widely used to treat moderated pain and has a low risk to provoke abuse. As it is not internationally controlled, it is used in cases when morphine is not available. The scheduling of tramadol would result in serious difficulties for public health systems in Lower- and Middle-Income countries.

At CND, during the plenary debate, the Egyptian representative, from the Ministry of Health, specialist in regulation of medicines, Fadila Amer, spoke about the decision of scheduling of Tramadol in Egypt, according to the INCB's calls for stricter regulations and called WHO to schedule tramadol, saying that it facilitated access to these medicines. However, WHO argued exactly the contrary not recommend the scheduling of the substance.[753] A campaign to schedule tramadol continued in the following years, as another example to countries marginalizing WHO and failing to protect the right to health.

The UNGASS preparation's period was to rebalance the control system away from punishment and towards public health, another attempt to schedule ketamine occurred.[754] Prior to 2015, China proposed to include ketamine in schedule I, of the

[753] IDPC, *The 2014 Commission on Narcotic Drugs and its High-Level Segment, Report of the Proceedings*, (IDPC, 2014) http://fileserver.idpc.net/library/CND-Proceedings-Document-2014_ENGLISH.pdf [Accessed 6 June 2022], p.18.

[754] IDPC, *The Commission on Narcotic Drugs and its High-Level Segment 2014*, p. 26.

Convention on Psychotropics Substances, in 1971, as it was discussed in chapter 4. In 2014, a resolution (57/10) on preventing the abuse of ketamine was submitted by Thailand and co-sponsored by Egypt, China, Indonesia, Sweden and USA. In 2015, the Chinese proposal was to include ketamine in schedule IV, the least restrictive and supported by several states including Pakistan, which made a statement saying that ketamine caused child abnormalities. The proposal was rejected by Tanzania, which considered important the medical use of this substance.[755] States supporting China called the WHO's Expert Committee on Drug Dependence to consider economic, social, legal, administrative and other factors on ketamine. But in fact, the ECDD's review is medical and scientific, and it is the Commission on Narcotic Drugs that must examine economic, social, legal and other factors. At this point, some countries suggested that a vote should be carried out to decide the scheduling ketamine, in the absence of a recommendation by the WHO. The history became even more complicated when UNODC asked the UN Office of Legal Affairs (OLA), in New York, for a legal opinion[756] on the question "Can the Commission on Narcotic Drugs schedule a substance under the Convention on Psychotropic Substances of 1971 if there is a recommendation from the World Health Organization that the substance should not be placed under international control?"[757]

The opinion was confused and questionable but concluded that "the Commission can schedule a substance under the Convention on Psychotropic Substances even if there is a recommendation from WHO that the substance should not be placed under international control."[758] In doing so, OLA's opinion bypassed WHO's mandate on reviewing substances for scheduling. According to WHO's mandate, the health body's recommendation is determinative. Also, according to the Commentary of the Convention on Psychotropics, if WHO 'recommends in its communication to the

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[755] IDPC, *The 2015 Commission on Narcotic Drugs and its Special Segment on preparations for the United Nations Special Session on the World Drug Problem, Report of Proceedings*, (IDPC, 2015) p. 19.

http://fileserver.idpc.net/library/CND-proceedings-report-2015.pdf [Accessed 6 June 2022].

[756] Economic and Cultural Council (ECOSOC), *Legal Opinion from the Office of Legal Affairs of the Secretariat*. (E/CN.7/2015/14) (New York: UN 2015) pp. 1-8.

https://documents-dds-ny.un.org/doc/UNDOC/GEN/V15/012/04/PDF/V1501204.pdf?OpenElement [Accessed 6 June 2022]

[757] Martin Jelsma, *The ketamine controversy continued*, (Amsterdam: TNI, 2015) para. 3 of11.

http://www.undrugcontrol.info/en/weblog/item/6126-the-ketamine-controversy-continued. [Accessed 6 June 2022].

[758] Martin Jelsma, The ketamine controversy continued, para. 7 of 11.

Commission that the substance should not be controlled, the Commission would not be authorized to place it under control.'[759] The legal opinion given OLA ignored both the mandate of WHO and the Commentary of the Convention on Psychotropics, which explains in detail the purpose of each article of the Convention.

These examples showed that previous WHO's recommendations against the scheduling of ketamine were being ignored, marginalizing its role, thus the right to health.

While China was making pressure at CND to put the scheduling of ketamine to vote, civil society played an important role to convince other Member States to vote against the scheduling. A group of clinicians, anesthetists and civil society organizations specialized in drug control teamed up to launch a campaign against the scheduling of ketamine. The delegation of Switzerland at CND warned the International Committee of the Red Cross, in Geneva, that ketamine was about to be scheduled.[760] The organization contacted ministries of health in various countries and other NGOs. In an advocacy effort, diplomats and NGO representatives sent an alert to their counterparts in Vienna to vote against the scheduling of ketamine.[761] China decided to withdraw the proposal in 2015 and the substance was not scheduled.

The cases of ketamine and tramadol showcase two main developments in the evolution of the drug regime. First, the role of civil society in influencing decisions. Margaret Keck and Kathryn Sikkink developed the concept of transnational network in the seminal book Activists beyond Borders. The mobilization of NGOs in 2015, around the issue of ketamine showed how they can influence discursive positions of states and international organizations, policy change and "target actors", which can be states, international organizations, private actors or influence state behavior.[762]

As it occurred at CND, transnational advocacy is most likely to emerge in "conferences and other forms of international contact create arenas for forming and strengthening

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[759] IDPC , *The 2015 Commission on Narcotic Drugs and its Special Segment on preparations for the United Nations Special Session on the World Drug Problem*, p. 22.

[760] Martin Matter, personal communication with the Swiss Delegation in Vienna, March 2015.

[761] IDPC, *The 2015 Commission on Narcotic Drugs and its Special Segment on preparations for the United Nations Special Session on the World Drug Problem*, p. 20.

**[762]** Margaret Keck and Katrhyn Sikkink, Margaret E.; *Activists beyond Borders* . (Ithaca: Cornell University Press 1998.) Kindle Edition, Location 559.

networks."[763] The campaign ran by civil society is 2015 showed the tactics used by transnational networks in their efforts at persuasion and pressure, which includes the ability to quickly and credibly generate politically usable information and move it to where it will have the most impact.[764] Since transnational networks are not powerful in the traditional sense, they use the power of ideas to alter the context where states make decisions.[765] For instance, as a strategy, activists' networks seek influence also calling upon powerful actors to affect a situation where weaker members of a network are unlikely to have influence.[766]Second, the fact that another attempt to schedule ketamine was made in 2015 after several reviews of the substance show that WHO continued to be marginalized by states such as China which belongs to the group of states not interested in protecting human rights. WHO's authority to review the substances is clearly expressed in the Commentary of the Convention of Psychotropics but it was not respected by States at CND.[767]

## 5. UNGASS, civil society and tensions between regimes

As UNGASS was approaching, preparations for the Special Session began to be organized. Contributions came from civil society through the Civil Society Task Force (CSTF), UNODC, WHO and other international organizations[768], the Human Rights Council[769], among others. As human rights acquired an increased importance in the drug control debate, the lack of consensus within the international drug control regime

[763] Keck and Sikkink, Location 318.

[764] Keck and Sikkink, Location 390.

[765] Keck and Sikkink, Location 385.

[766] Keck and Sikkink, Location 396.

[767] UN *Commentary on the Convention on Psychotropics Substances*, 21 February 1971 (E/CN.7/589) (New York: UN 1976), p.30

https://www.unodc.org/documents/commissions/CND/Int_Drug_Control_Conventions/Commentaries-OfficialRecords/1971Convention/1971_COMMENTARY_en.pdf [Accessed 6 June 2022], p.30.

[768] UNODC, *Special Session of the United Nations General. Assembly on the World Drug Problem 2016. Contributions* < https://www.unodc.org/ungass2016/en/contributions.html> [Accessed 6 June 2022]

[769] General Assembly, *Outcome of the panel discussion on the impact of the world drug problem on the enjoyment of human rights, Report of the United Nations High Commissioner for Human Rights*, (A/HRC/3145) New York, UN 2015) ]

https://www.unodc.org/documents/ungass2016//Contributions/UN/Human_Rights_Council/Panel_Drugs_HRC_31_45_Eng.pdf[Accessed 13 June 2022].

became clear, especially regarding harm reduction and death penalty. However, the issue of access to medicines did not raise strong differences among Member States.

In this section, contributions involving access to controlled medicines are discussed to show how this issue was addressed in the UNGASS Outcome Document, for the first time, in an operational paragraph. It means that this was no longer only an idea representing the purpose of the document, as it was stated in the Single Convention. Access to controlled medicines required concrete actions clearly defined, to which states had to commit.

### 5.1. Drafting Process

The drafting process started in September 2015, the UNGASS Board presented the 'Elements Paper', to define the structure of the document. Later, other actors involved in the process sent contributions for the Zero Draft of the UNGASS Document. The negotiations of the Outcome Document showed tensions between the human rights regime and drug control regimes. The lack of consensus within the international drug control regime was noticed, which will also be discussed in this section.

In September 2015, the Human Rights Council presented the study "Impact of the World Drug Problem on the enjoyment of Human Rights", which addresses the right to health, in accordance with article 12 of the International Covenant on the Economic Social and Cultural Rights and is the maximum expression of the right to health. [770] The study was the Human Rights' Council Contribution to the UNGASS 2016 on the World Drug Problem. It devotes one section to the topic of access to essential medicines, explaining that restricting access to opioids affects a) management of moderate and severe pain, including as part of palliative care for people with life/limiting illnesses, b) certain emergency obstetric situations (...) and included one section on harm reduction.[771]

The involvement of transnational networks was particularly relevant in this process. In the field of access to medicines, important contributions came from the Global Commission on Drug Policy (GCDP) and the Civil Society Task Force on Drugs

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[770] United Nations *Treaty Collection, International Covenant on the Economic Social and Cultural Rights. In: International Covenant on the Economic Social and Cultural Rights (ICESCR)*,New York, 16 December 1996, vol. 993, 14531, (New York: UN 1967), p. 6

https://treaties.un.org/doc/Treaties/1976/01/19760103%2009-57%20PM/Ch_IV_03.pdf [Accessed 6 June 2022].

[771] (A/HRC/3145), p.2.

(CSTF), however the negotiations of the UNGASS Outcome Document showed increased lack of consensus within the international drug control regime, and tensions between the international drug control and human rights regimes. Among the priorities identified by the CSTF for the UNGASS document directly linked with the right to health were drugs and health, which included availability of harm reduction and access to controlled pain medicines.[772]

In October 2015, the Global Commission on Drug Policy (GCDP – introduced in Chapter 4) published the report, '*The Negative Impact of Drug Control on Public Health: The Global Crisis of Avoidable Pain*.' In this report the Global Commission group of former heads of state and leaders from the political, economic and cultural arenas made ten recommendations, from which 3 mention the role of the INCB, to increase the availability of controlled medicines, including those for pain treatment.[773]

They called for high priority for "access to controlled medicines, including opiates for pain relief, palliative care, anesthesia, dependency and all other forms of suffering" [774]

The GCDP recommended: 1) WHO, UNODC and the INCB to provide governments with the necessary technical and financial support to States to ensure that they produce and import enough medicines from the WHO Model List of Essential Medicines; 2) Governments to fund an international program overseen by WHO, in partnership with UNODC and the INCB to ensure affordable access to controlled medicines, where they are unavailable; 3) More assertive steps for the INCB in working with countries that consistently fail to ensure adequate access to controlled medicines"[775] and work with governments to improve the quality of estimates.[776]

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[772] VNGOC, *Civil Society Task Force Recommendations for the Zero Draft of the Outcome Document for UNGASS 2016*.p. 4.

http://vngoc.org/wp-content/uploads/2016/08/CSTF-Recommendations_0-draft-UNGASS.pdf [Accessed 6 June 2022].

[773] Global Commission on Drug Policy (GCDP) *The Negative Impact of Drug Control on Public Health: The Global Crisis of Avoidable Pain*, (2015), p.6,

http://www.globalcommissionondrugs.org/wp-content/uploads/2012/03/GCODP-THE-NEGATIVE-IMPACT-OF-DRUG-CONTROL-ON-PUBLIC-HEALTH-EN.pdf [Accessed 6 June 2022].

[774] GCDP, Global Commission on Drug Policy (GCDP), *The Negative Impact of Drug Control on Public Health: The Global Crisis of Avoidable Pain* p.6.

[775] GCDP, *The Negative Impact of Drug Control on Public Health* , p.7.

[776] GCDP, *The Negative Impact of Drug Control on Public Health*, p.6.

A Civil Society Task Force was created in 2015 to secure comprehensive participation of civil society actors in the preparation process of UNGASS. Similar groups were formed in 2008 for the High-Level Segment of 2019. The CSTF on Drugs[777] is part of the Vienna Non-Governmental Organization Committee (VNGOC), created in 1983, and both are the civil society link with UNODC and CND. [778]

The IDPC (International Drug Policy Consortium) published a list of five "asks", after a series of consultations among its members, in April 2015. Among them, the NGOs highlighted that it was necessary to re-set the objectives of drug policies, changing "process measures" - more focused on law enforcement - to new indicators that would have an impact in health security and development such as public health, harm reduction and well-being, the availability of controlled medicines, human security, development aligned with the Sustainable Development Goals 2015 (SDGs) and human rights.[779] The Egyptian Ambassador Khaled Schamaa, Chair of the UNGASS Board asked for contributions for the UNGASS. His task was to facilitate the participation of civil society and other actors from the scientific community.[780] The Civil Society Task Force (CSTF) conducted a civil society survey and prepared a document with recommendations for the UNGASS Outcome Document.[781]

In the process of the negotiations of the Outcome Document the engagement of the international human rights and drug control regimes became clear, characterizing a regime complex. As Alter and Raustiala note, the regime complex is an array of partially overlapping and non-hierarchical institutions governing an issue area. The point of intersection between the international drug control and human rights regimes is the right to health. According to Alter and Raustiala, in a regime complex, it is not pre-defined that institutions, memberships and mandates and rules overlap are

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[777] Vienna NGO Committee on Drugs, *Vienna NGO Committee on Drugs*, https://vngoc.org/ministerial-segment-2019/ [Accessed 6 June 2022], para 5 of 9.

[778] Vienna NGO Committee on Drugs, *Vienna NGO Committee on Drugs, https://vngoc.org* [Accessed 6 June 2022], para.1.

[779] IDPC, *The Road to UNGASS 2016: Process and Policy Asks from the IDPC*, (IDPC, 2015), p.3,

http://fileserver.idpc.net/library/UNGASS-asks_External_04-2015_ENGLISH.pdf> [Accessed 6 June 2022].

[780] IDPC, *The United Nations General Assembly Special Session (UNGASS) on the World Drug Problem, Report of proceedings*, (2016) p. 3

http://fileserver.idpc.net/library/UNGASS-proceedings-document_ENGLISH.pdf [Accessed 6 June 2022]

[781]Vienna NGO Committee on Drugs (VNGOC), *Civil Society Task Force Recommendations for „Zero Draft" of the Outcome Document for UNGASS 2016.*

conflicting, but interpretive conflicts can emerge.[782] The range of contributions coming from different actors in the UNGASS drafting process showed the entanglement of the regime and are an example that regime complexes generate regime complexity.[783]

Both the INCB and WHO included access to controlled medicines for pain treatment as priorities. The INCB launched a special report on availability of controlled medicines in February 2016[784] and the WHO presented the report on the Public Health Dimension of the World Drug Problem, in the context of UNGASS at the World Health Assembly, in January 2016. Included as priority "Freedom from pain and suffering". The INCB's recommendations were presented at CND Reconvened session in December 2015.[785]

At the beginning of 2016, the UNGASS Board presented a first draft outcome of the document and that is how the negotiations of the document started through intersessional and informal meetings in Vienna. Civil society is normally excluded from the informal meetings creating barriers for civil society participation on the process. Many decisions were taken in such meetings and the discussions were not opened in other opportunities, in formal sessions.[786]

Although the issue of access to medicines gained traction as never before in international fora and was a rare point of consensus in the negotiations, the negotiations showed the lack of consensus within the system and tensions between the drug control and human rights regime. As an example, this could be perceived on the performance of the Chair of UNGASS Board, Egyptian Ambassador Shamaa. Being in this position since 2013 and as Chairman of CND in 2014, he managed to control the design and delivery of the processes at UNGASS.[787] Access to medicines was not his concern, since Egypt has been leading strong campaign for the scheduling of

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[782] Kal and Raustiala, p. 3.

[783] Kal and Raustiala, p. 4.

[784] (E/INCB/2015/1/Supp.1), pp. 1-99.

[785] Werner Sipp, *Views and Priorities, of the INCB, in the lead up to UNGASS 2016*, Briefing to Permanent Missions to the UN in Vienna, (11 November 2015), INCB,

https://www.unodc.org/documents/ungass2016//Contributions/UN/INCB/Statement_Briefing_to_permanent_missions.pdf [Accessed 6 June 2022].

[786] IDPC, *The United Nations General Assembly Special Session (UNGASS*), p.3.

[787] IDPC, *The United Nations General Assembly Special Session (UNGASS)*, p.3.

Tramadol,[788] and was pro scheduling of ketamine, as mentioned earlier. An example, that shows his approach to the importance of pain treatment occurred when he mentioned, during a reception at the Swiss Embassy in Vienna, in the presence of Ruth Dreifuss[789] from the Global Commission on Drug Policy, negotiations of the UNGASS document that "pain elevates the soul,"[790] to try to reduce the importance of the issue in the UNGASS document. The "opaque and questionable" performance of Ambassador Shamaa frustrated member states interested in reforms because of the lack of transparency and his reluctance to engage in difficult discussions[791] such as the regulation of cannabis market and harm reduction.

Right to health-related issues such as access to medicines and harm reduction, and other issues with human rights implications such as cannabis regulation, including its medical use, demonstrate that as the increased importance of human rights and responses from the human rights regime to the world drug problem made clear the existence of an international regime complex. According to Karen Alter and Kal Raustiala a regime complex is a compound institution composed of elemental institutions. The element of intersection of the human rights and international drug control regimes is the right to health. The attitude of Ambassador Shammaa to deny access to controlled medicines both in the in the UNGASS negotiations and as a CND Chair, shows the tensions between regimes. Both have an "authority claim for a particular area", such as access to controlled medicines.[792]

In regime complexes, because of mandates and rules overlap interpretive conflicts can emerge. Even if state membership is identical, it is likely that different decisions and different interpretations of the same rules occur, according to the different institutions from different regimes, that intersect. [793] The human rights regime claims authority for protecting people from violation of their rights through the denial of drug supply for

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[788] Tramadol is not in a scheduled substance in the drug control conventions and after a review, the ECDD(WHO) did not recommend its scheduling in December 2018.

[789] Former president and Ministry of Interior of Switzerland adopted harm reduction policies in her country and is one of the Commissioners of the Global Commission on Drug Policy.

[790] Martin Matter, Personal communication, 20 March, 2016.

[791] IDPC, *The United Nations General Assembly Special Session (UNGASS) on the World Drug Problem, Report of proceedings, September* (IDPC, 2016),

http://fileserver.idpc.net/library/UNGASS-proceedings-document_ENGLISH.pdf [Accessed 6 June 2022], p.3.

[792] Alter and Raustiala, p.4.

[793] Alter and Raustiala, p.4.

pain treatment, harm reduction. At the same time, the drug control regime claims authority to prevent diversion of drugs and recognizes the importance of the availability of drugs for pain treatment. As it occurs in regime complexes both the international drug control and human rights regime are governing the issue area of access to controlled medicines. And as regime complexes introduces significant rule complexity, states work across different fora to promote their objectives, navigating through complexity.[794]

### 5.2.The Outcome document and controlled medicines

The fact that human rights gained traction during the UNGASS document negotiations created tensions in both regimes and made Ambassador Shamaa and the Executive Director of UNODC made use of tactics to try to neutralize the influence of human rights regime in the realm of drug control. Despite that, the issue of access to medicines for pain treatment was a point of consensus in the UNGASS negotiations.

Regarding other topics involving a human rights approach, tensions increase even more the lack of consensus in the drug control regime, such as in harm reduction, the abolition of death penalty for drug related offences, as it is discussed here.

As a result of negotiations, the UNGASS Outcome document of the 2016 United Nations General Assembly Special Session on the World Drug Problem The document presented a different structure from previous political declarations.[795] It has a preamble and seven commitments, or operational paragraphs. They cover demand reduction, access to controlled substances for medical and scientific purposes, supply reduction and related measures, human rights and cross cutting issues, emerging challenges, international cooperation and alternative development.

It was an important milestone on access to controlled medicines for pain treatment because it recognizes this key objective of the conventions. For the first time, a

[794] Alter and Raustiala, p.3

[795] The structure of the UNGASS document was different from the previous Political Declaration from 2009 and the Joint Ministerial Statement from 2014. As said above, the 2009 and 2014 documents were divided in Demand reduction, supply reduction and money laundering and international cooperation.

document addressing the world drug problem included an operational paragraph entirely dedicated to the issue, as follows:

> *We reiterate our strong commitment to improving access to controlled substances for medical and scientific purposes by appropriately addressing existing barriers in this regard, including those related to legislation, regulatory systems, health-care systems, affordability, the training of health-care professionals, education, awareness-raising, estimates, assessment and reporting, benchmarks for consumption of substances under control, and international cooperation and coordination, while concurrently preventing their diversion, abuse and trafficking, and we recommend the following measures:(...)* [796]

The paragraph is followed by actions that need to be taken by governments to improve access to controlled medicines. The text encourages member states not only to ensure access, but to improve it, by removing barriers from national legislation, education and administration, using INCB's and WHO's published guides, resolving issues of affordability, expediting import and export process for authorizations, providing capacity building, particularly for the case of pain medicines, developing effective supply chain, and updating Essential Medicine's lists[797].

The Outcome document highlights the role of WHO and UNODC in to provide capacity building and training to health care professionals, including pharmacists, on adequate use of controlled substances for the relief of pain. [798]. Therefore, it refers to WHO's publication *Ensuring Balance in National Policies on Controlled Substances: Guidance for Availability and Accessibility of Controlled Medicines*.[799] This WHO document was launched in 2011. [800] In 2019, this guide was withdrawn from WHO's

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[796]UNODC, UNGASS *Outcome document of the 2016 United Nations General Assembly Special Session on the World Drug Problem: Our Joint Commitment to effectively addressing and countering the World Drug Problem*, (New York: United Nations 2016) https://www.unodc.org/documents/postungass2016/outcome/V1603301-E.pdf [Accessed 6 June 2022] p.8.

[797] UNGASS, *Outcome Document 2016* , pp. 8-9.

[798] UNGASS, *Outcome Document 2016* , pp. 8-9.

[799] UNGASS, *Outcome Document 2016* , pp. 8-9.

[800] UNGASS, *Outcome Document 2016* , pp. 8-9.

web site. The opioid crisis in the US led to political pressure on WHO to review this publication.

According to Martin Matter, Swiss delegate that participated in the negotiations of the UNGASS document, the points of contention started in the first sentence. The fight included change from the original 'ensure access to controlled substances' to "improving access." [801]The idea was to suggest countries to improve their situation and not only ensure what was already occurring. The resistance to include the language on improvements relies on the fear that States' must bear the costs related to access to medicine. However, morphine is an off patent and inexpensive medicine, in comparison to other synthetic opioids. This means that even lower income countries should afford to improve access to morphine.

### 5.3.The Outcome document and human rights

The Outcome Document devoted one chapter to human rights, which shows the overlapping of the two regimes. It mentions in the preamble that the drug control must be in full conformity with the Charter of the United Nations International law and the Universal Declarations of Human Rights, although several member states continued to their own interpretations of human rights and insist that the CND is not a place to discuss this subject.[802] Still on the positive side, the text shows strong language on rights related to gender and health.

The negative points of the Outcome documents are highlighted by the Global Commission on Drug Policy that qualified it as outdated, because it failed to approach the end of incarceration for drug users, the abolishment of death penalty for drug

[801] Martin Matter, personal communication, 10 September 2018.

[802] Juan Ochoa, Marie Nougier, *How to capitalise on progress made in the UNGASS Outcome Document, IDPC, briefing paper* (IDPC, 2017).

http://fileserver.idpc.net/library/IDPC-briefing-paper_How-to-capitalise-on-UNGASS-O-D.pdf [Accessed 6 June 2022], ), p. 10.

related offences, did not defend harm reduction, did not propose to regulate drugs and did not recognize the support for change made by governments and civil society [803]

The attempts to include these topics failed due to lack of trying. The use of informal meetings for negotiations of difficult topics resulted in the exclusion of the approach on abolishment of the death penalty in the Outcome Document. According to Martin Matter,[804] Swiss delegate, at a certain point the Chair of Board presented a version of the document, recompiling proposals of language from different countries. "But some proposals were excluded and there was a list of paragraphs called "the graveyard" that were entirely unacceptable by some delegations. Harm reduction and death penalty paragraphs were among them. Mr. Matter proposed the paragraph on death penalty and for this reason was in charge to facilitate the negotiations this paragraph with those against it in one of the informal meetings among delegations. Ambassador Shamaa said that if he managed to convince others to accept, it would be included in the document. The meeting was carried out with the presence of China, Indonesia and Brazil, Switzerland and Norway. Despite all the arguments presented to include the topic the Chinese, without discussing any substance said they did not like the subjects and that Vienna was not the place to discuss it, which means a total lack of consensus. As a result, the closest achievement to discuss death penalty in the document was in the chapter on Proportionate and effective policies and responses:

> *(k) Consider sharing, through the Commission on Narcotic Drugs, information, lessons learned, experiences and best practices on the design, implementation and results of national criminal justice policies, including, as appropriate, domestic practices on proportional sentencing, related to the implementation of the three international drug control conventions, including article 3 of the 1988 Convention*[805].

Paradoxically, this paragraph shows, although not in the strongest way, that the CND is in fact a place to discuss the proportionality of sentences, and consequently the death penalty.

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[803] GCDP, *Public Statement by the GCDP on UNGASS 2016*, (GCDP, 2016) http://www.michelkazatchkine.com/?p=248 [Accessed 6 June 2022]para. 3 of 6.

[804] Martin Matter

[805] UNODC, *Outcome Document*, p. 16.

The strongest resistance, however, came from China, Japan, Vietnam, Malaysia, Iran, and many Arab countries, according to Matter. But also, there was resistance even against the right to health from China, because they affirmed drug dependents have no right to health. Again, this demonstrates an overlapping between the two regimes. This shows that Switzerland navigated through regime complexity, contesting the rule that CND was not a place to discuss human rights. As Karen Alter and Kal Rautiala note, there are legal scholars that worry that regime complexity contributes to a fragmentation the undermines the authority of international law. But it in fact it can also enhance accountability by contestation about legal rules, as it was the case at the UNGASS document, regarding the language about death penalty.[806]

The last negotiations took place at CND in March 2016, and the input for the Outcome document came from the Director General of UNODC, Yuri Fedotov, in March 10th, four days before the endgame of the negotiations in Vienna, although the official document dates from February 2016[807], in Vienna. The document was approved by consensus, although a fragile one, in the first day of the UNGASS in New York, 19 April 2016.[808] The fragility of this consensus refers to a document adopted by a group of member states that on the legalization of cannabis, while others are executing people for trafficking it. As Mr. Fedotov explained to a journalist in 2016, "It is a broad consensus".[809] The UNGASS took place in New York, from 19 to 21 April, in 2106. The document negotiated in Vienna was adopted in the first day. Analyzing the statements of UNODC, WHO and INCB in the General Assembly Special Session it is possible to understand the tensions in the international drug control system in this period. Yuri Fedotov, executive director of UNODC highlighted that "global drug policy must put people first."[810] Vladimir Galuska, Chair of CND in 2016 mentioned

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[806] Alter and Raustiala, p. 14.

[807] UNODC, *Contribution of the Executive Director of UNODC to UNGASS on the World Drug Problem to be held in 2016,* (Vienna, UNOC 2016)

https://www.unodc.org/documents/frontpage/2016/UNGASS/ED_paper_21March2016final.pdf[Accessed 6 June 2022].

[808] Bewley Taylor and Jelsma, *UNGASS 2016, A Broken or a Broad consensus?* (TNI, GDPO, 2016)

https://www.tni.org/en/publication/ungass-2016-a-broken-or-b-r-o-a-d-consensus-d-consensus [Accessed 6 June 2022] p. 2.

[809] Bewley Taylor and Jelsma, *UNGASS 2016,* p. 2.

[810] IDPC, *The United Nations General Assembly Special Session (UNGASS)non the World Drug Problem, Report of Proceedings*, (IDPC, 2016), p. 2

http://fileserver.idpc.net/library/UNGASS-proceedings-document_ENGLISH.pdf, p. 2 [Accessed 6 June 2022].

the spirit of consensus, 'despite our differences'. Werner Sipp, president of the INCB made one of the more progressive statements in recent memory, emphasizing that the conventions never called for a war on drugs, and there was no treaty obligation to incarcerate people for small quantities for personal use. However, he considered that regulation of cannabis for non-medical use was not compatible with the conventions.[811] The statement of WHO' Director General, Margaret Chan referred to the importance opioids for pain treatment and harm reduction, with Opioid Substitution Therapy and the significantly reduction of crime in Hong Kong, after methadone maintenance programs.[812]

Examining the history of the international drug control system, especially after 1945, the hegemonic power of the US forced a consensus on the prohibitionist approach of global drug policy. According to Acharya, a good indicator of normative consensus in hegemonic or great power-led institutions would be the willing participation of the "ruled" or the less powerful actors. When a great power fails to obtain such participation, despite its expressed wishes, the outcome is a legitimacy deficit capable of crippling its alliance framework. Hence, the legitimacy of institutions created and maintained by powerful actors can be affected by subsidiary norms developed at the local level.[813] The clear lack of consensus among member states at UNGASS showed that the international drug control system was changing its ordering principle, which is prohibition. While the INCB recognized the importance of human rights fearing to lose its relevance in the system, CND gradually increased the space given to civil society in the following years.

The UNGASS outcome document is an example that show that mechanisms of change occur through international institutions and law. According to Martha Finnemore, Agents seeking to change social purpose often target law and institutions as means of converting their alternative vision into widely influential social reality. Individuals, social movements, and activist states have all found that codifying a new social

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[811] IDPC, *The United Nations General Assembly Special Session (UNGASS) on the World Drug Problem, Report of Proceedings*, p. 2.

[812] IDPC, *The United Nations General Assembly Special Session (UNGASS) on the World Drug Problem, Report of Proceedings 2016* (IDPC, 2016),

http://fileserver.idpc.net/library/UNGASS-proceedings-document_ENGLISH.pdfp. [Accessed 6 June 2022] p. 2.

[813] Acharya, *Constructing Global Order*, p. 51.

purpose into a treaty, into a new organization, or into new resolutions by existing organizations are powerful ways to reshape social structures and social purpose.[814]

## 6. The post UNGASS period

After UNGASS, the follow up on the implementation of the Outcome document began in multilateral fora in the international drug control system. This section discusses the developments between 2016 and 2019, regarding the increased role of health in the international drug control regime.

As a result of UNGASS, a change occurred in the role of WHO. Prior to the Outcome document, it was restricted to the work of the Expert Committee on Drug Dependence and the reviews of substances for international control. The Outcome Document increased role for WHO to support states, together with UNODC, in providing capacity building and training of health care professionals and national authorities on adequate access to medicines for the relief of pain.[815]

The Outcome Document opened space for a resolution on the Public Health Dimension of the World Drug Problem. In May 2016, it began to be drafted and took a year to be negotiated.[816]

A new draft resolution (A69/12) about the role of WHO, the Public Health Dimension of the World Drug Problem and negotiated during the 69th WHA and member states could only reach an agreement about that in May 2017. The historic antecedents of WHO's marginalization within the international drug control system were the reason why it took so long for states to agree on this resolution, which was the most controversial one in the WHA in May 2016.[817] In 2017, a shorter version, highlighting the role of WHO in improving access to medicines through strengthening its activities to develop and disseminate normative guidance and provide technical support, in coordination with the INCB and UNODC.[818]

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[814] Finnemore, p. 150.

[815] UNGASS *Outcome Document* 2016, p. 9.

[816] WHO, *The Public Health Dimension of the World Drug Problem*, 2016 (WHA/69.12) 2016 https://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_12-en.pdf , [Accessed 6 June 2022].

[817] (WHA 69.12)

[818] (WHA 69.12)

The controversy on this resolution originated a decision to postpone negotiations of this resolution. The increased importance of WHO in drug control upset some countries. Katherine Pettus, senior advocacy and partnership director of the International Association for Hospice and Palliative Care was present in most of the meetings involving access to controlled medicines at WHO and at CND. She reported that about six months before the World Health Assembly, which normally happens in May, a group of like-minded countries met in Geneva to try to increase the role of WHO in drug policy. These countries were Colombia, Australia, United States, Mexico, Norway, Zambia and Panama, countries that upheld the importance of a public health and human rights-based approach They prepared a decision/resolution to WHO to consider a strategy and impact drug policy. The decision was blocked by Russia, South Africa, Nicaragua; China and Cuba, which were not included in the previous meetings and considered that drug policy should be discussed only in Vienna.[819] This showed another attempt within the international drug control regime to marginalize the role of WHO and revealed the tension that stems from intra-regime complexity.

The difficulty to reach agreement in May 2016 at WHA illustrates that intra-regime complexity. Russia considers the drug problem should be taken care by at CND, by UNODC and INCB. These organizations tend to have a repressive behavior regarding the drug problem, because their concerns with law enforcement are stronger than with the right to health and the protection of human rights in general. As such, blocking a resolution on the public health dimension of the drug problem can be perceived as an attempt to weaken WHO's action. This shows that there is tension or attempt to measure forces to see if the balance is pending to the public health-oriented approach, enhancing access to medicines and harm reduction initiatives, or it is pending for the prohibitionism and law enforcement approach. The fact that Russia and like-minded

[819] Katherine Pettus, personal interview, 25 January 2017.

states blocked a resolution at WHO show how states can act in different forums, to affect discussions on the same issue.

To strengthen the collaboration between UN bodies within the international drug control system the Memorandum of Understanding[820] was signed between WHO and UNODC, in which they are committed to fully implement within their mandates, the recommendations of the UNGASS 2016 Outcome Document. However, sources from UNODC and WHO commented, at the time of the signature of the MoU, in February 2017, that it was not going to improve the relationship between the two bodies[821]. They often complain about difficulties in coordinating activities and overlapping of functions between UNODC and WHO.

The complexity of the drug problem and lack coordination within the international drug control system create tensions that are reflected at the national level, depending on how coordinated ministries are in each country. For instance, all the Ministries of Health relate to WHO, while the UNODC addresses mostly issues of the Ministries of Justice, even if the ministries of health are also present at CND in certain cases. As the drug conventions are the models for drug laws at the national level, and these norms fail to protect the right to health, barriers to access to medicines will keep existing. However, if WHO, UNODC and INCB can function in good coordination, it is likely that Ministries of Health and Justice in each state can address drug issues such as access to medicines in a more effective manner, with better outcomes. One of the challenges to address barriers to access to controlled medicines is the integration of the health and justice systems, with a common vision within them and among them to produce effective multidisciplinary approach towards the common goal. This will also be discussed in the case study, in the last chapter. The Memorandum of Understanding

[820]WHO, *Memorandum of Understanding between The World Health Organization and the United Nations Office on Drugs and Crime*, (6 June 2018) https://www.who.int/publications/m/item/mou-who-unodc-controlled-substances [Accessed 6 June 2022].

[821] In February 2017 I was an intern at the Prevention, Treatment and Rehabilitation Section at UNODC and was in contact with both UNODC and WHO employees. They prefer not to be identified.

is an attempt to formalize the need of coordination and a balanced approach that is expected to become normal practice by the agencies involved.

## 7. UN bodies adapting to changes in the regime

During the period between UNGASS and the 62nd CND and High-Level Segment in 2019, the issue of access to controlled medicines continued to be in the agenda of the international drug control system. As the health approach gained importance in the international drug control regime because of the adoption of SDGs, UNGASS Outcome Document and the increased interplay between drug control and human rights regimes, UN bodies tried to adapt to new changes. This section discusses how the INCB and UNODC seized on this opportunity to keep their relevance within the regime.

It was an opportunity for UN bodies to work on this issue and attract funding. In the period post UNGASS, the INCB continued to support the issue of access to medicines, through the e-learning program created in 2016 to provide training in countries to address barriers to access to medicines, funded by Belgium, the US, Thailand, Australia, France and Russia. Viroj Sumyai president of the INCB showed concern with this issue on several occasions during his presidency.[822] In 2019, the INCB launched a report with a special supplement on availability[823] and ran the E-learning program, created in 2016 to provide training in countries to address barriers to access to medicines. UNODC continued to run the GLOK 67, the Joint Global Program on Access to Controlled Medicines, while preventing its diversion, created in 2012 with very limited funding shared with WHO and the INCB.

In 2018, the crisis of excess of opioid consumption in the US was an opportunity for UNODC to create the Opioid Strategy in 2018, mostly funded by the US and Canada. The strategy is based in five pillars focused on trend analysis, prevention, law

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[822] INCB, *Statement by Dr. Viroj Sumyai, the INCB President, Opening of the Ministerial Segment of the 62nd Session of CND*, Vienna, 14 March 2019, https://www.incb.org/incb/en/news/news_2019/incb-presents-at-the-opening-of-the-62nd-session-of-the-cnd.html [Accessed 6 June 2022] para.4 of 12.

[823] INCB, *Progress in ensuring adequate access to internationally controlled substances for medical and scientific purposes* (E/INCB/2018/1/Supp.1) (New York: UN 2019)

<https://www.incb.org/documents/Publications/AnnualReports/AR2018/Supplement/Supplement_E_ebook.pdf> [Accessed 6 June 2022].

enforcement and counter narcotic capacity and rational prescribing of opioids to promote "inter agency- cooperation."[824]

It is important to note that the opioid excess crisis affects mostly the US, and this is not the reality of lower- and middle-income countries facing the lack of access to opioids for pain treatment. Although the opioid crisis gained relevance in drug control fora and attracted international attention, this crisis in the US is not the focus of this dissertation. The opioid strategy has one of its pillars on rational prescribing of opioid but until 2019 there was no funding for work in this field, only for the other pillars, which are analysis of trends, prevention and treatment, international law enforcement operations and strengthening counternarcotic capacity.[825]Although donations are welcome, they generate competition for funds among UN bodies, undermining genuine "inter-agency" cooperation.

After analyzing the momentum of access to controlled medicines after UNGASS, UN bodies were mobilized to work on this issue because it attracted some funding, however intra-regime complexity makes it harder for Member States to understand the differences in specific mandates of each body and decide to which of them funding should be allocated. As inter agency cooperation was recommended by UNGASS and reiterated in the MoU, a question arises about how funding should be shared among them. While this is part of UN bodies' routine, the interaction between bodies can

[824] UNODC, *Opioid Strategy*, *para 8 of 1*,

https://www.unodc.org/unodc/en/opioid-crisis/the-strategy.html [Accessed 6 June 2022].

[825] UNODC Officer, Personal communication with UNODC officer working on the Opioid Strategy (prefer not to be identified), 18 September 2019.

generate conflicts within the regime on how to proceed to manage even small projects, with modest funding.[826]

## 8. The 2019 Political Declaration

The 2009 Political Declaration set out the date for States to eliminate or reduce significantly and measurably illicit drug supply and demand, mentioning explicitly opium poppy, the diversion and trafficking of precursors and money laundering.[827]

High-Level Segment of 62nd CND in 2019 was planned with the objective of reviewing progress made about the world drug problem in the previous ten years. The Political Declaration from 2009 stated that Member States should enable the INCB, in cooperation with governments to maintain a balance between demand and supply of drugs to ensure the relief of pain and the availability of medication assisted therapy for the treatment of drug dependence.[828]

In 2019, 5 billion people were living with little or no access to controlled medicines for pain treatment, anesthesia and drug dependence, according to the INCB Report in 2014, affecting mostly low- and middle-income countries. Considering only opioids for pain control, 84, 25% of the world's population lack access for this kind of essential medicines.[829] As such, the goals from 2009 were not met in 2019, despite the political commitments of Member States in 2014 and 2016 at CND, WHO and in the Human Rights Council and the joint inter agency efforts.

Apart from the small progress achieved on access to medicines, drug markets were expanding and diversifying like never before, according to the 2018 World Drug Report. Furthermore, the harms caused by repressive policies to eradicate illicit drug market skyrocketed between 2009 and 2019.[830]

The lack of consensus was evident during the debate among States. The discussion was about which document would prevail after 2019: the 2009 Political Declaration or

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[826] Based on participant observation while I was an intern at UNODC between September 2016 and March 2017.

[827] UNODC, *Political Declaration and Plan of Action, 2009*, p.14

[828] UNODC, *Political Declaration and Plan of Action 2009*, p. 22.

[829] Connor, p. 34.

[830] IDPC, *The 2019 Commission on Narcotic Drugs and its Ministerial Segment, taking stock of the implementation of the commitments made to jointly address and counter the world drug problem, in particular in light of the 2019*

the 2016 UNGASS Outcome Document. States defending the status quo emphasized the importance of the 2009 document, while more progressive states preferred the 2016 Outcome Document. This behavior was also reflected among NGOs, which were more than 500 at CND in 2019. The representative for the International Hospice and Palliative care was an exception. In her statement, she emphasized the importance of both documents.[831] States that opposed the UNGASS process tend towards the position of maintaining the status quo, restricting the space of civil society, associating drug use to deviance. By identifying problematic drug use with progressive tendencies in drug policy, downplaying the importance of human rights and restricting civil society space these countries widen their epistemic gap. Therefore, they fail to understand the importance of opioids for the treatment of pain.[832]

Despite the rhetoric of consensus, the Ministerial Declaration on Strengthening our actions, at the national, regional and international levels to accelerate the implementation of our joint commitments to address and counter the world problem[833] was published before Members States' debate, at the Ministerial Segment. It means that the text was negotiated at CND intersessional and informal meetings at closed doors. The debates reflected disagreements mostly about cannabis and its policies of control at the regular CND session and at the Committee of the Whole where resolutions are negotiated.[834]

The 2019 Ministerial Declaration reads that States "reiterate their resolve (…) to ensure access to and the availability of controlled medicines for the relieve of pain and suffering"[835]. In 2019, a UN common position on drug policy was published, which is the first inter-agency articulation of a shared commitments to strengthening human rights and placing people in the center of drug policy and practice. The document was developed with collaboration of Member States, civil society, WHO, UNODC,

*target date* (London: IDPC, 2019). http://fileserver.idpc.net/library/CND-Proceedings-Report_2019.pdf [Accessed 6 June 2022].

[831] IDPC, *The 2019 Commission on Narcotic Drugs and its Ministerial Segment*. p. 24.

[832] Pettus, p. 94.

[833] UNODC, *Ministerial Declarations on Strengthening our actions*, pp. 1-6.

[834] IDPC, *The 2019 Commission on Narcotic Drugs and its Ministerial Segment*. p. 3.

[835] UNODC, *Ministerial Declaration on Strengthening our actions*, para. 12 of 37.

UNAIDS, and United Nations Human Rights Office of the High Commissioner (OHCHR).[836]

As the importance of human rights increased in the international drug control regime, notably with advancements in the UNGASS Document, the lack of consensus also grew in this forum. While the issue of access to medicines seemed to be one of the few points of consensus at UNGASS, the opioid crisis in the US attracted great attention and fueled more conservative views on the use of opioids and other drugs. It is undoubtedly a public health issue that needs to be addressed, but it can be misguiding for states taking part in drug control fora, because opioids continued to be demonized.

At the same time, despite the engagement of some states with genuine interest in improving the availability of opioids for pain treatment, notably Belgium, and the efforts of UN officers directly involved in this issue to makes changes in the field, the implementation of measures agreed at international fora, lack implementation

As Katherine Pettus notes, INCB reports and supplements show that countries that improved levels of consumption and access to controlled medicines tend to be Middle to Upper Income countries, with established and developing human rights system and reasonably well functioning judicial systems. But it is important to realize that access is improved not because it is perceived as a human right obligation. Drivers of improved access are strong health systems, strong civil society participation, in countries where civil society organizations are valued as sources of information and expertise. [837]

## 9. Conclusion

After analyzing the issue of access to controlled medicines for pain treatment in this period it is possible to conclude that between 2014 and 2019, the issue of access to controlled medicines reached great importance in the international drug control regime. This topic was included in political documents, reports and resolutions at CND, WHO and the Human Rights Council and culminated with the inclusion of an operational paragraph on this issue in the UNGASS Outcome Document. According to this document the role of WHO was no longer restricted only to the recommendation

[836] Hannah and Lines, p. 241

[837] Pettus, p. 93.

of substances for scheduling. Now it had the role to assist governments on the rational use of opioids for pain treatment, together with UNODC.

A change in principles occurred regarding the meaning of "health and welfare of mankind", stated at the Single Convention. While earlier these terms had the meaning that it was necessary to isolate people from drug, in the period analyzed in this chapter, the norm became to protect the health and welfare of mankind, thus the right to health. Therefore, it is necessary to ensure access to controlled medicines, drugs for pain treatment and drug dependence, among other measures focused on human rights.

To adapt to the new paradigm, the INCB also changed its stances in health and human rights related topics to maintain its relevance in the regime. The importance given by the INCB to access to controlled medicines for pain treatment contributed to draw international attention to the issue of availability of pain medicines, through its reports and projects to assist states on sending good quality data for the estimates system. This helps countries to assess what is their real need on opioids, so that pain is not undertreated for the lack of access to this substance. However, the INCB still failed to recognize that some of the bureaucratic barriers that hinder access to opioids were created by this UN body and serve as a model for national authorities on drugs regulations.

The pressure for changes in the system stemmed for civil society, as the case of ketamine showed. The mobilization of transitional networks resulted in the non-scheduling of the substance, protecting the right to health of people in lower- and middle-income countries. Civil society also had an increased participation on the UNGASS process and on the follow up of its implementation. This shows what Acharya called norms subsidiarity. Changes occur because actors at the national level resist or challenge existing norms.

As human rights gained importance in the realm of drug control, pressure at the "international prohibitionist drug control regime" to adopt a human rights-based approach increased, creating a lack of consensus within the international drug control regime and showing the existence of a regime complex involving the international

human rights regime. The element of overlapping between them is the right to health, where the issue of access to controlled medicines belongs.

In 2019, as it was discussed, the lack of consensus between states that pushed for a human rights and health approach and those who preferred to defend the status quo, led to tensions that resulted in a weak political document at CND. Member states failed to meet the goals set in 2009 to eliminate or reduce significantly the illicit cultivation of opium poppy, coca bush, and cannabis plant. Instead, the importance of the use of natural opioids such as morphine was recognized, and governments reiterated their commitment to ensuring access to these substances. The cannabis market was regulated or legalized in several countries and its medicinal use was recognized at CND in 2020. The right to traditional use of coca was recovered by Bolivia in 2013 thanks to a reservation this government inserted in the Sigle Convention.

# Chapter 6

# Case Study: The international drug control regime, Brazilian drug policy and access to opioids in Brazil

## 1. Introduction

The objective of this case study is to show the reasons behind the lack of adequate access to opioids for the treatment of pain in Brazil, and the impact of the international drug control system on the low consumption of these medicines today. The case study is divided in two chapters. This chapter discusses the historical antecedents that led to the low consumption of opioids in Brazil. The next chapter – Chapter 7 - analyzes the current situation of access to opioids in Brazil.

This chapter discussed the development of the Brazilian drug control framework. In doing so, it examines to what extent the international drug control regime had an influence in the prohibitionist approach of Brazilian legislation and control organs that led to the current low consumption of opioids substances for pain treatment. The analysis will show that despite the international regime's influence, other aspects played a role on the low consumption of opioids in Brazil such as endogenous prohibitionism shared among Brazilian elites and US-Brazil bilateral relations. It will be argued that according to the perspective of Amitav Acharya on norm localization, there was a construction of foreign ideas by local actors, developing significant congruence with local belief and practices.[838]

As mentioned in the introduction, Brazil was chosen as a case study because the INCB considers the country has having "adequate"[839] consumption of opioids. The analysis, however, will show how there is still a long way to go to prevent untreated pain in Brazil today, as discussed in the next chapter. The problem of qualifying as "adequate" the consumption of opioids is that for a Brazilian diplomat, new in Vienna in 2015, it is reassuring to see the country among those with "adequate consumption". But the INCB figures are useful only for comparisons among countries but do not say much about the situation on the ground or how were these barriers created. This makes the

[838] Amitav Acharya, *Constructing Global Order*, p. 42

[839] (E/INCB/2015/1/Supp.1), p. 17

problem unnoticed and voices of patients unheard. Also, according to the Global Drug Policy Index, from November 2021, Brazil occupies the last position in the ranking of 30 researched states from all the regions of the world, based on data from 2020.[840]

The development of the Brazilian legal and institutional framework for drug control, and related health approaches will be analyzed in four periods. First, the Brazilian drug law from 1921, which was a response to the Hague Convention. Second, the period under the government of Getúlio Vargas from 1930 to 1945. It includes a period of dictatorship between 1937 and 1945, when Brazilian politics was shaped by authoritarianism, anti-communism and nationalism. The basic structure of drug control was developed, following the model of the international conventions from 1931 and 1936. Third, the civil-military dictatorship, the alignment with the US, the sophistication of the domestic drug control apparatus, and the most restrictive drug laws. Fourth, the democratic period, when a new constitution was enacted recognizing the right to health. Harm reduction policies were adopted and the discussion on access to medicines gained traction to meet the needs of HIV/AIDS patients. The increased importance on the right to health led, also in Brazil, to the tension at the national level, between adequate access to medicines and the control of illicit drug markets.

## 2. Endogenous Prohibitionism

Brazilian drug laws were developed in accordance with its commitments as part of the international drug control regime. This section analyzes the development of Brazilian drug laws, showing to how the international drug control system influenced them and how endogenous ideas about prohibition - shared among elites - contributed to Brazilian conservative approach on drugs. In doing so, it discusses the development of the Brazilian health system and how the Brazilian legislation on drugs impacted access to controlled medicines such as opioids in the country.

At the end of the 19th century, in Brazil, there was a lack of physicians, the population counted on popular knowledge published in a few books such as the *Dictionary of Popular Medicine*, where substances such as opium and cocaine featured for self-medication. Opium, for instance, was indicated for the treatment of pain but also

[840] *Global Drug Policy Index*, 2021 , p.61.

wounds, cough, prevention of asthma attacks, nausea and vomiting in pregnant women, and morphine was also recommended as a medicines for different symptoms morphine, although the *Dictionary* mentioned that its use could be habit forming and it should be gradually discontinued.[841] Few people within the economic elite made use of morphine and cocaine, whereas opium was considered a non-elegant addiction that affected Chinese immigrants in Rio de Janeiro.[842] At this time, sanitary and criminal measures regulated packaging and marketing of substances seen as poisonous and showed that these substances were a concern for the health of society. This was a period heavily influenced by the hygienist discourse coming from Europe such as the criminal anthropology of Cesare Lombroso, an Italian criminologist and physician. He believed that motivation for crime was originated in physical and mental characteristics of an individual, reinforcing, thus, certain stigmas.[843] As Beatriz Labate and Thiago Rodrigues note, medical and legal knowledge in Brazil reconciled the discourse with the strongly rooted scientific pretension and racism that are found in social practices in Brazil.[844]

In the first three decades of the 20th century, Brazil was a rural country, illiteracy reached 70% of the population, and the first social questions emerged with the first working class demonstrations. Politics were dominated by an oligarchy and the electoral process had no credibility. The first health policies in Brazil came in the late 1910's, focused on contagious diseases, beginning in Rio de Janeiro and São Paulo. Other states were considered abandoned territories.[845]

Within this context, in 1912, Brazil signed the International Opium Convention (Hague Convention) and in 1920 signed the Protocol relative to the entry into force of the convention.[846] The (Brazilian) National Medicine Academy recommended the ratification of the Hague Convention and the parliament was favorable for two reasons. First, without ratifying the convention Brazil could have the importing of drugs such

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[841] Denis Petuco, *O pomo da discórdia, drogas, saúde e poder*. (Curitiba: Ed. CRV, Curitiba, 2019).p. 48.

[842] Petuco, p.49.

[843] Thiago Rodrigues and Beatriz Labate, Brazilian Drug Policy in: Beatriz Labate et al. (eds.). *Drug Policies and the Politic of Drugs in the Americas,* (Switzerland: Springer, 2016). pp. 197-208, (p.189.)

[844] Rodrigues and Labate, p. 189.

[845] Nísia Trindade Lima, Cristina Fonseca and Gilberto Hochman, A saúde na construção do Estado Nacional no Brasil: Reforma Sanitària em perspectiva histórica in: – *Saúde e Democracia: história e perspectiva dos SUS*, organized by Nísia Trindade Lima and others (Rio de Janeiro, editora Fiocruz, 2005), pp. 27-58 (p. 31).

[846] UNTC, *The Hague Convention 1912*, Treaty Series, vol. 8, No. 222.

as opium cocaine and its derivates stopped. Second, there was a belief that risks such as poisoning and addiction related to these drugs could be prevented with trade regulation.[847] In fact, as it will be discussed in this chapter strict regulations contributed to the lack of access to medicines such as opioids. The First World War also affected the morphine production and distribution by Germany, putting many countries in risk of lacking this drug. This was a reason for some countries to expand their pharmaceutical industries.[848]

As the Brazilian health system was initially being formed, with the creation of National Department of Public Health, in 1920, the government's idea was to have a federal health ministry with autonomy against the power of oligarchies. [849] The basis for the creation of a national health system was created between 1910 and 1930, characterized by centralized and verticalized actions from the federal government.[850] This centralized model changed later with the creation of the Unique Health System (SUS-Sistema Único de Saúde), in 1988 which has operated since then in a decentralized manner. Such changes are important to understand part of the difficulties on access to opioids in Brazil, as it will be discussed later in this case study.

The basic structure of the Brazilian health system was formed as addiction was becoming an increasing concern domestically and abroad, particularly in the US. The development of drug control frameworks in Brazil accompanied the establishment of the international drug control system. The Hague Convention entered into force in 1920 after the end of the First Drug War and it was incorporated in Brazil through its first drug law, federal law 4294, in 1921.[851] It criminalized traffickers but not users. The latter should be under the custody of the state in a closed institution, considered victims of their own addiction.[852]

In Article I the law refers to drugs as **poisonous** substances with narcotic effects. The process of passing this law was strongly connected with social medicine, since jurists expanding the Brazilian legal framework, based their work in medical knowledge. It

[847] Petuco, p. 49.

[848] Lopes da Silva, p.82.

[849] Lima, Fonseca and Hochman, p. 36.

[850] Lima, Fonseca and Hochman, p. 37.

[851] Rodrigues and Labate, p.190.

[852] Rodrigues and Labate, p. 190.

also reflected a widespread social disbelief, still present today, that users had fallen morally and needed medical care and moral forgiveness, and dealers fed this moral decay[853].

Addictions were considered "degenerative morbidities" by medical practitioners. This idea gave support to the police discourse that justified harsh and ostensive measures against drug use. This gave fuel to elites' anxieties at that time.[854] The elites, pretended to use medical reasons[855] to qualify as inappropriate excessive drug use, with an authoritarian bias.[856] It means that law enforcement was serving elites' interests, based in moral assumptions. The Brazilian law from 1921 was a shift in the views on drugs in Brazil and survived until 1976. While earlier there were no specific laws regarding drugs, this first drug law began to shape the narcophobic perspective that Brazil pursued both domestically and internationally in the following decades.

As it was mentioned in chapter 2, at that time, the prohibition movement was gaining force against drug use in the US[857] and this influence reached Brazil, having physicians, druggists and drug manufacturers as targets of the US government. As an example of the American ideas among health professionals in Brazil, the pharmacist Julio da Silva Araújo noted in the session of the National Academy of Medicine in 1920, that the US government had requested importers to strengthen control of morphine, cocaine and other hypnotics. Brazil was, then, one of the six countries that had not responded to this US "demarche" and he asked the academy's support to convince the government to follow the US government's recommendations.[858]

After the end of the First World War the international discussions on drugs was again on the agenda in the newly established League of Nations. The idea of the Brazilian government for the Drug Conferences for the negotiation of the Geneva Convention in 1924 and 1925 was to send two prestigious physicians to represent the country. The

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[853] Rodrigues and Labate, p. 190.

[854] Silva, p. 189.

[855] Carlos Eduardo Martins Torcato, A política de Drogas no início do século XX, uma leitura a partir da pediatria, in: *Drogas, Perspectivas em Ciências Humanas*, organized by Beatriz Cayuby Labate and Frederico Policarpo, (Rio de Janeiro, Terceiro Nome, 2018) pp. 79-98 (p. 90).

[856] Labate and Policarpo (orgs.), p.90

[857] The Hague Convention was internalized in the US through the Harrison's Narcotics Act, approved in 1914 and entry into force in 1920.

[858] Petuco, p. 49.

US sent congressmen to Geneva, the United Kingdom sent officers from the Ministry of Interior, Canada sent war veterans, and France sent officer from the Ministry of Colonies. It is important to note that it was the first time that Latin American and Caribbean countries showed interest in drugs issues. Not only Brazil sent a delegation to this conference but also other seven countries from the region. However, these countries did not sign the Convention and Brazil left the League of Nations in 1926.[859]

According to Luiza Lopes da Silva, in the initial period of the drug control history Latin American and Caribbean countries had a "marginal role"[860] and a "non-assertive attitude "[861], in comparison to the US role in the negotiations. However, Carlos Eduardo Torcato presents a different view, explaining that Brazil was represented by ambassador Gurgel do Amaral[862], posted in the Netherlands, and the report of the Brazilian Foreign Affairs Ministry shows that the Brazilian position was to defend the limitation of the production of substances for medical and scientific purposes, in accordance with the US position. In the views of the Brazilian diplomacy, it was necessary to improve means of drug control, which was going in favor of US interests .[863] The participation of Brazil was far from unassertive, as Torcato observes.[864]

The reasons that led Brazil to leave the League of Nations in 1926 had to do with the frustrated attempt to occupy a permanent seat in the League's Council. Brazil accompanied the meetings in 1924-25, when the US left the negotiations because their interests were not met. Since the Paris Conference (1919-1920), Brazil had occupied a non-permanent seat at the League's Council, with the support of the US. But the permanent seat at League's Council was one of the objectives of the foreign policy of the government of President Artur Bernardes (1922-1926). As it was discussed earlier in this dissertation, the moral arguments to control drug trade were opposed to European countries' interests. In this context, Brazil defended the American system, against the Europeans. Since the US was not part of the League, Brazil would be the best candidate to represent the Americas and the US interests in the League. The great

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[859] Luiza Lopes da Silva, *A questão das drogas nas relações internacionais: uma perspectiva brasileira*, (Brasília, Fundação Alexandre de Gusmão 2013), p.85, E-book

[860] Lopes da Silva, p. 90.

[861] Lopes da Silva, p. 90.

[862] Carlos Eduardo Martins Torcato, *A história das drogas e sua proibição no Brasil*, p. 148.

[863] Torcato, *A história das drogas e sua proibição no Brasil*, p. 148.

[864] Torcato, *A história das drogas e sua proibição no Brasil*, p. 148.

powers knew that the US would continue to be aloof, if Brazil took the permanent seat.[865] Despite Brazilian efforts, European countries managed to give the permanent seat to Germany.[866]

Moreover, the prohibitionism defended by Brazil and the US was noticed in Peru and Bolivia. The Bolivian position, backed by the lobby of the domestic coca producers' elite, within the League of Nations, was to prevent coca from being labeled as a narcotic. In the Hague, Bolivia also defended its licit use. Also, Peru had a population that consumed coca, had a legal cocaine industry and rejected the participation in the League. This attitude inspired poppy producer countries in the Balkans. Peru only signed the Hague Convention through the Treaty of Versailles, in 1921.[867]

The Andean countries did not agree with the Brazilian position in the negotiation of the Geneva Convention and worked firmly against it. And that also explains why Brazil did not get a permanent seat in the League's council. It shows that these countries did not act in an assertive manner in Geneva and in the Hague. On the contrary, trade control of substances was one of the ambitions on the League of Nations and the Brazilian withdraw was a blow towards the organization. Brazil was proud of being able to affect the stability of the League but was not powerful enough to have its demands met. However, after leaving the League, Brazil continued to pay annual contributions and kept a friendly and collaborative relation with the purposes of the international organization.[868]

Although the first Brazilian drug law was passed in 1921, until 1930, opiates such as heroin, morphine, codeine and derivates from opium were also largely used to treat pain and respiratory diseases in the country. Opiates were widely available, and physicians used to prescribe formulas with these substances also for children, or they were acquired in ready-made preparations, by patients of all social classes. There was no 'opiophobia' and the habit of using opiates in patients with chronic diseases was

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[865] Torcato, *A história das drogas e sua proibição no Brasil*, p.151.

[866] Norma Breda dos Santos, 'Diplomacia e fiasco, repensando a diplomacia brasileira na Liga das Nações'. *Revista Brasileira de Política Internacional* 46.1, 2003, pp. 87-103, (p.101)

<<https://www.scielo.br/j/rbpi/a/JZKHQvrbfbV6gsQWGdXbwky/?format=pdf&lang=pt> [Accessed 7 June 2022]

[867] Torcato, *A história das drogas e sua proibição no Brasil*, p.152.

[868] Torcato, *A história das drogas e sua proibição no Brasil*, p.149.

well accepted and even considered as an option, part of the treatment.[869] Apart from that, physicians did not hold the only power to make prescriptions. Patients themselves used to decide how much and how to use opioids such as morphine and heroine.[870] Today it is the medical authority that decides how much and in which specific circumstances opioids should be used.

As the international drug control regime was being established, Brazil fully committed to its international obligations expressed in the Hague Convention and Geneva Convention, not only to benefit from being a member of the regime, but also because being a relevant player at the League of Nations was an ambition of Brazilian foreign policy in this period. The Brazilian position on drug policy aligned with restrictive approaches on this issue and it was used as an instrument to achieve a more prominent role. Even though Brazil's attempt to achieve its goal was unsuccessful, in international fora, the government was proud to show restrictive drug laws. This shows that the idea of prohibitionism was already present in Brazil, and it was mutually endorsed by physicians and lawyers, the elites that influenced the creation of subsequent laws.

While Brazil was supporting prohibitionist ideas in international drug control fora, a permissive environment regarding opioid use prevailed at the national level. It turns out that the Brazilian position at the international level was strongly influenced by its desire to increase its international standing.

## 3. Brazilian drug control and international drug treaties

Important shifts occurred in Brazil in the 1930's. This section shows that the political situation in Brazil facilitated the internalization of the international drug control conventions in the Brazilian drug law and the creation of the Brazilian drug control organs. It also shows how the law enforcement character of the drug control apparatus contributed to develop the fear of health care professionals in prescribing opioids. As Beatriz Labate and Thiago Rodrigues note Brazilian criminal law consolidated the prohibitionist policy that combined health safety with public security, heavily based

[869] Torcato, *A história das drogas e sua proibição no Brasil*, p.194.

[870] Torcato, *A história das drogas e sua proibição no Brasil*, p. 202.

on moralistic social demands. The Brazilian legislation closely followed the international drug control regime at the end of 1920's and beginning of 1930's.[871]

In Brazil, the economic crisis of 1929 strongly affected the hegemony of the coffee oligarchs that had dominated state politics. Starting in 1930, under the government of Getúlio Vargas (1930-1945) there was an increased need for the development of an internal market and industrial activity. Legitimate political practices supported by scientific knowledge were used and justified by the need to build a new social order, urban, familiar, and medical capable to change habits in the federal capital, Rio de Janeiro. [872]This work was characterized by the use of a hygienist and social medicine, the so called "epidemic's medicine" or "medical police" to investigate morbidities, the context in which they occurred, and the best ways to fight them. [873]

Two examples of connection between national and international governance, show how international drug conventions from 1931 and 1936 influenced the development of Brazilian drug control system and found a fertile soil in the country to grow prohibitionism. First, the drug law reform in 1932, which criminalized drugs dealers and included penal sanctions for health professionals, for unduly prescription of opioids. Second, the creation of the Standing Committee on Narcotics Control (CNFE), [874] (Comissão Nacional de Fiscalização de Entorpecentes - CNFE), inspired by the League of Nations created to boost the internal trade control, imports and exports of narcotics and the internal consumption of this substances. It was similar to the US Federal Bureau of Narcotics (FBN) created in 1930, a government agency solely concerned with narcotic drugs.[875]

In the negotiations for the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, adopted in 1931 by the League of Nations, Brazil was proud to present its drug law from 1921, perfectioned with a prohibitionist approach one decade, and to belong to the vanguard of public control of inebriation.[876] Shortly after the adoption of the 1931 Convention, Brazil enacted executive order

[871] Rodrigues and Labate, p. 191.

[872] Lima, Fonseca and Hochman. p. 39

[873] Silva, p. 186.

[874] Rodrigues and Labate, p. 191.

[875] Bewley-Taylor, *The United States and International Drug Control*, p. 37.

[876] Torcato, *A história das drogas e sua proibição no Brasil*, p. 164.

20.930, in 1932 according to "the request of the Permanent Central Opium Committee of the League of Nations."[877]This legal reform in the drug law extended the criminalization of the drug dealers to the drug user. It included penal sanctions for a pharmacist including fine and imprisonment from two to five years and license's suspension. For physicians, dentists and veterinarians responsible for unduly prescribing narcotics, consequences included a fine, imprisonment from four to ten years and licenses' suspension for a couple of years.[878]

Brazil was aligned with the US in the late 1930's due to commercial and military agreements. When President Getúlio Vargas initiated the dictatorship period known as "Estado Novo" (1937-1945), a nationalist and anticommunist emphasis was given to its institutions. Brazil incorporated proposals debated in international fora, in alignment with the US and they included American views on drugs.[879] As such, the Brazilian Ministry of Foreign Affairs, José Carlos Macedo Soares suggested the creation of a system to fight against the "propagation of toxicomania and illicit traffic of narcotics" and to put in practice the recommendations provided by the 1931 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs.[880] Consequently, the Standing Committee on Narcotics Control - (Comissão Nacional de Fiscalização de Entorpecentes - CNFE)[881] was created to control the imports and exports of drugs and sending statistics to the Permanent Central Opium Committee.[882] The Standing Committee was tied to the Ministry of Health, which held branch responsible for customs inspection; police repression; control of legal commerce in pharmacies and with the medical profession; pedagogical actions through normative instructions, such as questionnaires, lectures, and, finally, in pathologizing users, through of scientific publications reinforcing the link between recreational use

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[877] Diário Oficial da União (DOU), *Decreto 20390*, Seção 1 - 16/1/1932, Página 978, (Rio de Janeiro 1932) https://www2.camara.leg.br/legin/fed/decret/1930-1939/decreto-20930-11-janeiro-1932-498374-publicacaooriginal-81616-pe.html [Accessed 7 June 2022]

[878] DOU, *Decreto 20.930*, Article 26.

[879] Jônatas Carvalho, 'The creation of the National Commission of Fiscalization of Narcotics. Institutionalization and Internalization of the Prohibition in Brazil'. *Revista Inter Legere - Drogas Políticas e Culturas. Revista de Pós-graduação em Ciências Sociais*, (Universidade Federal do Rio Grande do Norte 2014) (pp- 15-38), p. 20. https://periodicos.ufrn.br/interlegere/article/download/6379/5001/ [Accessed 7 June 2022].

[880] Carvalho, p. 18.

[881] In this dissertation I refer to this institution as Standing Committee on Narcotics Control/CNFE (the acronym in Portuguese).

[882] Carvalho, p. 18.

and drug addiction.[883] This drug control framework corresponds to what Agência Nacional de Vigilância Sanitária (ANVISA – Brazilian Health Regulatory Agency) is today. The Standing Committee (CNFE) was the point of connection between domestic and international drug control.[884] Brazil was one of the first countries to put such a structure in practice in Latin America.[885] Similar initiatives came only after the Single Convention in 1961.[886]

## 4. Estado Novo's dictatorship and the adoption of Executive Order 891/1938 on drug policy

After the adoption of the Convention for the Suppression for the Illicit Trafficking in 1936, a new drug law[887] was passed in Brazil in 1938. It met the obligations provided in the international Convention as in Article 11: differentiating penalties for "drug addicts" and "traffickers".

According to Article 11 of the 1936 Convention:

> *1. Each of the High Contracting Parties shall set up, within the framework of its domestic law, a central office for the supervision and co-ordination of all operations necessary to prevent the offences specified in Article 2, and for ensuring that steps are taken to prosecute persons guilty of such offences.*[888]

And 11b):

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[883] Carvalho, p. 18.

[884] Carvalho, p. 19.

[885] Carvalho, p. 18.

[886] Comissão contra o uso Indevido de Drogas (CCUID), Venezuela 1971, Comissão Nacional de Toxicomanias e Narcóticos (CONATON, Argentina and National Commission against the non-authorized use of Drugs (CONADRO), Costa Rica, 1972. Colombia created National Council of Narcotics, 1973, National Commission to Fight against Toxicomanias, 1974 and, Mexican Center of Studies in Chemical Dependence, 1975. In :Rosa del Omo, *A Face Oculta da Droga*, (Rio de janeiro: ed. Revan, 1990), p. 45.

[887] Diário Oficial da União (DOU), *Decreto-lei 891/1938 de 25 de novembro de 1938*, Seção 1 - 28/11/1938, Página 23843 (Rio de Janeiro: Imprensa Oficial, 1938)

http://www.planalto.gov.br/ccivil_03/Decreto-Lei/1937-1946/Del0891.htm [Accessed 7 June 2022]

[888] United Nations Treaty Collection, (UNTC) *Convention of 1936 for the Suppression for the Illicit Traffic in Dangerous Drugs*, Vol. 198, No. 4648, (Geneva: United Nations 1936), p.3

https://treaties.un.org/doc/Treaties/1936/06/19360626%2006-49%20AM/Ch_VI_12_ap.pdf [Accessed 7 June 2022].

*Shall centralize all information of a nature to facilitate the investigation and prevention of the offences specified in Article 2.*[889]

The executive order 891/1938 was accompanied by a document with 69 instructions for its execution, which became the most important instrument for carrying out the Brazilian government's drug policy. [890] It regulated private behavior or conduct in institutions such as hospitals, pharmacies, laboratories and other health services. As such, physicians, pharmaceutics, veterinarians and dentists, among others, absorbed these new codes of conduct.[891]

In fact, Brazil included penal sanctions in domestic drug laws and regulations ahead of the international treaty of 1936. The Executive Order 891 from 1938, kept provisions from 1932, particularly those on the fines and imprisonment of health professionals. Dealers would receive a prison sentence, and the same would happen to health professionals that did not observe the medical prescription system. Also, the possession of drugs without medical prescription or authorization could lead to 4 years of imprisonment and a fine.[892] Punishments for prescribers were harsher than for those who made indiscriminate use of the substances.[893] Drug dependents would receive compulsory or voluntary hospitalization according with the judge's decision based on medical statement and would be sent to an "official hospital for psychopaths". [894] Provisions from 1932 and 1938 were consolidated in the penal code reformed in 1940, in which also punishment for drug users were foreseen through hospitalization. [895]

The executive order also established that the Standing Committee would supervise the Control of Professional (medical) Practice Section[896] created in 1921; the only organ

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[889] UNTC, *Convention of 1936 for the Suppression for the Illicit Traffic in Dangerous Drugs* Vol. 198 No 4648, p. 3

[890] Carvalho, p. 27.

[891] Carvalho, p. 27.

[892] Julio Delmanto, *Camaradas Caretas, Drogas e Esquerda no Brasil após 1961*, Faculdade de Filosofia, Letras e Ciências Humanas (FFLCH), unpublished master thesis Universidade de São Paulo (USP 2013), p. 58https://www.teses.usp.br/teses/disponiveis/8/8138/tde-29052013-102255/pt-br.php [accessed 14 June 2022].

[893] Carvalho, p 29.

[894] Delmanto, p. 58.

[895] Rodrigues and Labate, p. 191.

[896] Seção Nacional de Fiscalização da Medicina (SNFM)

authorized to give certificates and permit imports, exports and reexports of narcotic substances, responsible to control prescriptions of narcotics and licenses for new medical specialties.[897] Another agency for the control of trade and use of narcotics[898] was created to meet the demands in the commerce of narcotics from pharmaceutical industry, domestically, and control medical practitioners in the country. The creation of new sections within the existing structures refined the drug control system and strengthened the centralized national administration system. These new administrative units were not created exclusively due to the need of assuring trade and use of narcotics, it was an attempt to organize a range of health services working interdependently.[899]Pharmacies were the most affected by the new instructions.

According to executive order 891/1938, prescriptions could only be approved by the sanitary authority if prescribed by a registered professional at the Control of Professional Practice Section. Patient and physician's details, reasons for prescribing. narcotics[900], such as morphine had to be registered in books, in a special format provided by the Standing Committee, with the prescription number, doctor's name and date of prescription had to appear in the medicine bottle's label.[901] As Carvalho notes, all these rules constituted a pact between health professionals and the state, giving physicians the monopoly of licit prescription and at the same time putting them under strict state control.[902]

Internationally, Brazil became an example of drug control legislation and it started to send other States parties of the 1936 Convention, a copy of executive order 891/1938. The Committee also exported its repressive logistic model to Argentina and Uruguay, conducting visits and inspections to pharmaceutical industries, laboratories and pharmacies and distributed a complete dossier to sanitary authorities of each country,

[897] Between 1930 and 1935 10,441 narcotics prescriptions and 551 new licenses were registered, and only in 1939 the number of prescriptions was 9,576. In: Carvalho, p. 2.

[898] Seção de Fiscalização do Comércio e Uso de Entorpecentes (SFCUE)

[899] Carvalho, p. 26.

[900] Group I, including opium, morphine, heroin, cocaine and cannabis, among others) and II, including codeine, among others.

[901] DOU, Seção 1 - 28/11/1938, Página 23843, Chapter 2, Article 16, § 3

[902] Carvalho, p. 26.

including copies of the legislation, instructions, prescription models for narcotics and maps.[903]

These examples show that Brazil was ahead of the international drug convention regarding drug prohibition, showing that such approach was already present in the political, medical and judiciary elites. The executive order 891/1938 and the creation of the Standing Committee show that the Ministry of Foreign Affairs and the Ministry of Health and Education were working closely towards the centralization of health system, which led to the sophistication of the drug control apparatus in Brazil in this period.

However, this process resulted in harsh drug laws, which included punishment for health professionals, prescribers of narcotic drugs such as morphine, for pain treatment. Brazil accepted international norms and principles that drugs were evil and, for this reason people should be isolated from them. The influence of international drug conventions in Brazil was clear as drug legislation was being developed. The bilateral relations with the US served to reinforce prohibitionist ideas already present in the international treaties. While the prohibition law was taking place in the US (1920-1933), Protestantism sustained by the American missions penetrated in every part of Brazil.[904] At the same time, in Brazil, there was no resistance to these ideas. In fact, the Brazilian elite believed on the same principles against drugs propagated by the US that were reflected in the Brazilian legislation on drugs. This shows the process of norm localization, developed by Amitav Acharya. When principles and norms are diffused, a process of localization can occur. It is the active construction (through discourse, framing, grafting, and cultural selection) of foreign ideas by local actors, which result in the former developing significant congruence with local beliefs and practices.[905] When the international drug control conventions were adopted, Brazil had already passed restrictive drug laws. Both international and domestic law were congruent. According to Acharya, "the main driving force of localization is the localizer's desire of legitimation and empowerment."[906] Since the Brazilian federal

[903] Carvalho, p. 33.

[904] Moniz Bandeira, *A presença dos Estados Unidos no Brasil*, (Rio de Janeiro, Editora Civilização Brasileira, 2007), p. 211.

[905] Acharya, *Constructing Global Order*, p. 43.

[906] Acharya, *Constructing Global Order*, p. 43.

government was a dictatorship fighting against the interests of oligarchs, the idea of adopting restrictive drug laws matched perfectly with the desire to establish a strong and centralized government, involving the work of the Ministries of Foreign Affairs, Health and Education and Justice. The examples examined in this section showed how Brazil used "foreign ideas as a frame to express local beliefs and practices."[907]

### 4.1.Scarcity of opioids in Brazil during the Second World War

The restrictions on the trade and use of narcotics brought a wide range of difficulties. In the period between the First and Second World Wars there was a concern about how to meet the needs of morphine, which became an important commodity in this period. There were three suggestions to overcome the difficulties of obtaining narcotic during the war. First, it was forbidden to import opium, morphine and cocaine, procured from the German pharmaceutics Merck and Bayer and the Swiss Roche using air freight or mail, according to Article 9, paragraph b of executive order 891/1938. [908]

The second idea came in 1936 from the Brazilian consul in Turkey, Affonso Lopes de Almeida, who suggested to the Brazilian government to import Turkish opium, instead of buying it from Europe. Turkey used to export opium to Germany, Switzerland and Russia and the advantage of buying directly would be to produce morphine in Brazil. [909] Although this was allowed by executive order 891/1938, [910] there were no laboratories and plants to extract active principles of opium.

Therefore, studies were carried out in Brazil by the Alcaloida Fabrica Quimica S.A., based in Budapest, which resulted in the Kabay *dossier*. It was a proposal to explore the process of producing opium alkaloids known as Patent Kabay[911]. Also, the Ministry of Agriculture had been trying to cultivate poppy, in the highlands of Brazil, and with the local climate crops would be produced twice a year. The Hungarian company's proposal required 37000-45000 square miles for cultivation, which would be enough

[907] Acharya, *Constructing Global Order*, p.44

[908] Carvalho, p. 30.

[909] Carvalho, p. 30

[910] DOU, Seção 1 - 28/11/1938, Página 23843, (Chapter 2, Artice 3).

[911] This process was created by Janos Kabay, a Hungarian chemist that discovered, in 1920, the method of producing morphine from poppy flowers and their straws without necessarily producing opium. In: Carvalho, p. 31.

to supply the domestic market and export for neighbor countries. The Brazilian government would not have to pay for set up the producing plants and the company would be a public corporation, with stocks belonging to the State. The advantages of this project were the production of morphine, codeine and heroin, and no more opium imports would be necessary. Control would be easy, illicit trade could be eliminated and the Kabay process was recommended by the League of Nations.[912]

Despite all the advantages, the project of cultivating poppy and producing morphine in Brazil was rejected, by the Ministry of Foreign Affairs, Oswaldo Aranha.[913] The difficulties on importing morphine from Europe due to the war, were exposed to the US Department of State. Diplomatic negotiations between US and Brazil resulted in the American committed to supply all the necessary substances, as long as the Brazilian government did not allow the cultivation of poppy and production of medicines in the country.[914] This is a clear case of pressure to keep Brazil dependent on the US. It was also a good opportunity to expand the market of American pharmaceutical industry in a country with continental dimensions.

During the government of President Vargas (1930-1945) the economic model was to replace imports for national products and create a Brazilian industrial capacity. Therefore, the idea of setting up a plant to produce opioids was part of this plan. However, the US was developing its own pharmaceutical industry and became the world leader in chemical technology producing synthetic medicines[915] which were seen as superior to medicines produced from plants such as opiates like morphine. With the disruption in the supply chain of medicines in the war, the US seized the opportunity to increase their market for newly developed medicines. They were presented as an alternative to narcotics to treat severe pain such as barbiturates. Later came benzodiazepines and antidepressants sold freely and considered safer. However,

[912] Carvalho, p. 32.

[913] It was revealed in a ministerial report in 1944, signed by the Ministry of Foreign Affairs, Oswaldo Aranha, explaining that due to the difficulties of importing opium and its derivates for medicines production from Europe, particularly, from UK, as it used to be done before the war, the Standing Committee/CNFE decided with Itamaraty (Ministry of Foreign Affairs) to negotiate the supply of these substances. In: Carvalho, p. 33.

[914] Carvalho, p. 33.

[915] At this point the US became the world leader in chemical technology, producing medicines to treat diseases such a tuberculosis and hanseniasis, they produced the first chemotherapeutics, and anti-histaminic.

barbiturates such as phenobarbital are not the golden standard to treat severe pain and are more toxic, less safe and have a high propensity to create dependance.[916]

During the war, both international and Brazilian drug politics in the authoritarian regime increased control and facilitated law enforcement actions. Morphine and derivates did not represent a problem of abuse because of the rigorous repression.[917] Medicines produced in the US presented as alternative to narcotics with no restrictions to access created optimistic feelings.[918] In 1945, Brazil imported only narcotics for medical purposes in lower quantities of other countries in Latin America. Heroin importation had been banned in 1939[919], and morphine replaced by codeine and dionine, both weak analgesics[920] due to education campaigns carried out to physicians and pharmaceutics in the country, run by Roberval Cordeiro de Farias, director of the Standing Committee/CNFE.[921]

The history of dossier Kabay showed that Brazil missed an opportunity to establish a national production of opioids that could have put the country in a good position to produce a highly valued commodity in the whole world at that time. Besides that, Brazil could have grown its own pharmaceutical production, without relying on private or foreign pharmaceutical industries, subject to their profit strategies. This is one of the aspects that contributed to the current ack of access to opioids, as it will be discussed in the next chapter.

Instead of developing a pharmaceutical industry able to meet Brazilian demands on medicines, the drug control apparatus increased its law enforcement character. In 1941, a new executive order 3114/1941 brought a few changes to the composition of the Standing Committee/CNFE, including representatives of the army, navy and ministry of industry and trade, ministry of justice, to strengthen the Committee, increasing its members from 7 to 11. These new representations in addition those from the field of health gave to the Standing Committee/CNFE a new strictly national status after the war. Its members began to have police power, initiating a strong campaign against

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[916] Torcato, *A história das drogas e sua proibição*, p. 305.

[917] Torcato, *A história das drogas e sua proibição*, p.309.

[918] Torcato, *A história das drogas e sua proibição*, p. 305.

[919] Torcato, *A história das drogas e sua proibição*, p. 202.

[920] Currently on Schedule III of the Single Convention, which lists substances unlikely to be abused.

[921] Torcato, *A história das drogas e sua proibição*, p. 306.

adult use of cannabis and using strong propaganda that referred US orientation. The Standing Committee/CNFE continued to internalize the international drug control policy, with US leadership, for the next four decades, consolidating a prohibitionist approach in the Brazilian drug control policy. Government after government, laws regulations and norms crystalized social practices used by the State.[922]

In this period of the dictatorship, the influence of the international drug control regime was clear, since the Brazilian drug legislation internalized the conventions, passed restrictive laws with penal sanctions for health professionals not observing narcotics' prescription rules, and created the machinery to administer a repressive drug control system. With the establishment of the Standing Committee (CNFE), there was a clear interaction between the Ministry of Foreign Affairs, and the Ministry of Health and Education and the Ministry of Justice, in which they reinforced each other's work on drug control.

The Brazilian government internalized principles and norms coming from the international regime. But in fact, they matched with existing principles of prohibition in Brazil. This congruence validated Brazilian elite views on drugs, demonstrating the relevance of local practices. According to Acharya, this shows an act of localization in which the foreign idea may remain intact, but its contents are infused with local beliefs and practices. Norm-takers may resort to infusion to validate existing beliefs, demonstrating the broader relevance and appeal of local beliefs and practices, and selling "homegrown" ideas to a larger market. [923]

## 5. The Cold War and the legislation reforms in the civil-military dictatorship (1964-1985)

After a democratic period between 1945 and 1964, Brazil's bilateral relations with the US intensified throughout the Cold War. This section discusses the drug legislation in Brazil after the adoption of the Single Convention 1961. It shows that it was the most

[922] Carvalho, p. 36.

[923] Acharya, *Constructing Global Order*, p. 44.

prohibitionist period in Brazil regarding drug laws, which continued to foresee penal sanctions of imprisonment for health care professionals.

When president Juscelino Kubitschek (hereinafter JK) (1956-1961), a physician, was elected, he affirmed that "health is a complete condition of physical, mental and social well-being"[924], but to reach that goal, American cooperation was necessary. Also, president JK was convinced that there was a growing anti-US feeling in Brazil and was dissatisfied with US cooperation with the country. For the US, the idea of stability was deeply connected with countries development. As such, the only way to deter communism would be to protect populations from poverty and promote economic development. This idea was strongly accepted, adopted and defended by Brazilian diplomats, originating the Pan-American Operation, in 1958, which requested more significant bilateral relations between Brazil and US and the valorization of multilateralism as an instrument of international action.[925] In 1961 Brazil joined the Alliance for Progress, created by the US to foster development in Latin America and, at the same time curb the expansion of socialism in Latin America. The US seized on the opportunity to influence Brazil through different areas, including education and health. Also, the United States Information Agency (USIA) had the major responsibility for educating the Latin American public about the menace of drugs and about US efforts to fight the War on Drugs.[926] USIA played an important role in the propaganda of the American way in Brazil, through publications, exchange programmes, and the contact with pro-American journalists, the establishment of bi-cultural centers, among other activities. [927]

This context and the bilateral relations US-Brazil explain the Brazilian position in the Single Convention's negotiation, supporting the US prohibitionist approach, as it was previously discussed.

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[924] Lima, Fonseca and Hochman, p.53.

[925] Antonio Carlos Lessa, 'Há cinquenta anos a Operação Pan-Americana', *Revista Brasileira de Política Internacional*, 51.2, (Brasília, Universidade de Brasília, 2008), pp. 5-7 (p.5)

https://www.scielo.br/j/rbpi/a/hV6jFrcV9wBLbYjN4HRTQkJ/?lang=pt [Accessed 13 June 2022].

[926] Gerber and Jensen, p. 170.

[927] Rafael Ioris and Josiane Mozer, 'Parceiros em quê? A Aliança para o progresso e a política editorial de modernização da América Latina no contexto da Guerra Fria', *Esboços, histórias em contextos globais*, 23.46 (Florianópolis: Esboços, 2019), pp. 529-548 (p.536)

https://periodicos.ufsc.br/index.php/esbocos/article/view/2175-7976.2019.e61478/41006 [Accessed 13 June 2022].

Diplomatic agreements between the US and Brazil opened the market for American medicines in Brazil, which relied heavily on imports and created difficulties in maintaining the supply chain with European products. In 1961, under the government of President Jânio Quadros (1961-1961) the price of pharmaceutical raw materials was exorbitant.[928]For this reason, President João Goulart (1961-1964) passed an executive order, to control prices of pharmaceutical products in the whole country, forcing pharmaceutical industries to reveal costs, which generated strong debates between Brazil and the US at WHO in 1964. As soon as the civil-military dictatorship took power in 1964, this order was revoked in 1976, showing that the interests of the (American) pharmaceutical industry in selling a new set of recently developed medicines related to the regime change in Brazil.[929]

In the first year of the dictatorship under the government of Humberto Castelo Branco (1964-1967)[930], Article 281 of the Brazilian penal code was reformed through the law 4451, in 1964[931], establishing fines and imprisonment for health care professionals as it states:

> *(…) imprisonment from 1 to 5 years for those who "cultivate, import, offer, even for free, transport, possess, stockpile, administer, delivery in any terms, whatsoever without authorization or legal determination*[932]

and in Paragraph 1:

> *If the agent is pharmaceutic, physician or dentist: imprisonment from 2 to 8 years (…)" and a fine.*[933]

And in paragraph 2:

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[928] Torcato, *A História das Drogas e sua proibição*, p. 312.

[929] Torcato, *A História das Drogas e sua proibição*, p. 313.

[930] In the context of the Cold War, there were new approaches in the US policies to Latin America such as Program Point IV, in 1949, from President Truman and Alliance for Progress in 1961, from President Kennedy, both bilateral programmes with aims to foster economic development and stop Soviet Union's influence in Latin America. In: Lima, Fonseca and Hochman, p. 47.

[931] Revoked by drug law 1976.

[932] Diário Oficial da União (DOU), *Lei 4451de 4 de novembro de 1964*, Seção 1 - 6/11/1964, p. 10017 (Rio de Janeiro: Imprensa Oficial, 1964) https://www2.camara.leg.br/legin/fed/lei/1960-1969/lei-4451-4-novembro-1964-376671-publicacaooriginal-1-pl.html [Accessed 13 June 2022] Article 1.

[933] Diário Oficial da União (DOU), *Lei 4451de 4 de novembro de 1964*, Seção 1 - 6/11/1964, p. 10017, Article 1, para. 2.

> *Imprisonment from six months to two years and a fine (…) for physicians and dentists prescribing substances for cases other than those recommended for therapies or in higher doses than necessary*, (…).[934]

Here, it is important to note that that are no definitions about what a high dose is, or what would be an adequate dose. Therefore, the parameters to qualify a health professional as a dealer or as a professional treating someone's pain were never clearly defined, but penal sanctions were severe, deterring the prescriptions of substances such as opioids.

Brazil ratified the Single Convention in 1964, shortly after the military coup in 1964 and updated the legislation in 1968. Between 1968 and 1976, both users and dealers were treated the same way and were subject to incarceration. This was the most repressive period in the dictatorship and in terms of drug related penal sanctions.[935]

The most comprehensive reform in the Brazilian drug law came in 1976. It followed the model of the Single Convention 1961 and explicitly criminalized physicians, dentists, pharmacists and nurses prescribing or administering substance causing chemical dependance, in higher dose than necessary, which subject to detention from 6 months to two years and a fine. This drug law was valid until 2006.This Brazilian law differentiated users and traffickers, providing harsher penalties for crimes committed under the influence of illicit drugs. The use of drugs was not penalized but the possession of any quantity for personal consumption was, which means that, in practice, the use was criminalized. The principles of the law to promote prevention and regulate repression, as mentioned above, were in tune with the prohibition in Brazil and the principles of "moral regeneration" of the authoritarian regime at that time, when the left-wing resistance was a threat to the regime.[936]

The law established three categories of punishment due to the increased use of drugs in the 60's and 70's by white people and middle class: "sick person", subject to

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[934] Diário Oficial da União (DOU), *Lei 4451de 4 de novembro de 1964*, Seção 1 - 6/11/1964, p. 10017, Article 1, para. 2.

[935] Delmanto, p. 60.

[936] Rodrigues and Labate, p. 191.

compulsory hospitalization, “criminal”, with traditional criminal punishment and “occasional user”, subject to education to “moralize” behavior. [937]

Brazilian health care professionals educated in civil-military dictatorship in Brazil, arguably have acquired fear to prescribe opioids, due to the risk of being qualified “criminal” being incarcerated and paying fines. This fear was passed from generation to generation of physicians, as it will be discussed in the next chapter. In fact, the Single Convention does not foresee penal sanctions for health professionals in its article 36, however, in Article 39[938] it permits the application of stricter control measures than those required by the Convention. The 1976 Brazilian Drug Law, chapter III, Article 15 on sanctions for health care professionals are a clear example of stricter interpretation of the Convention.

## 6. The democratic period and shifts in drug policy

In the 1980’s important shifts occurred in Brazil. The civil military dictatorship officially ended in Brazil in 1985. While in previous decades health and justice approaches were aligned, regarding a prohibitionist drug policy, at this point, a tension between adequate access to health services, including access to medicines, and control of the illicit drug market emerged. This section analyzes changes in drug laws, control machinery and health system, to understand how they impacted access to controlled medicines, the treatment of severe pain and drug dependence. Therefore, this section explores the changes in the drug policy approach through the adoption of harm reduction initiatives to prevent the spread of HIV, and the creation of a universal public health system. It also analyzes new drug laws and the tension between adequate access of medicines and the control of illicit markets that emerged with the new Constitution in 1988.

A new Constitution came into force in 1988, which explicitly recognized the right to health as a duty of the Brazilian State. This led to the creation of a new public health system, Unique Health System (SUS – Sistema Unico de Saúde, acronym in Portuguese) health care based on collective medicine, universal, decentralized, free

[937]Rodrigues and Labate, p. 192

[938]UNTC, *Single Convention 1961 as Amended*, vol. 976, No. 14152, p. 129.

and with strong primary health care.[939] In 1993 a regulatory agency, the National Health Surveillance Agency (ANVISA), was established. It is linked to the Ministry of Health and oversees internationally controlled medicines, such as opioids for pain treatment, and is responsible for sending data for the INCB's estimates system, among other responsibilities.

As the AIDS epidemic was a great concern in Brazil, harm reduction practices began to be adopted to curb the spread of the epidemic in the country, showing that problematic drug use was a public health problem and required a human rights approach. However, from the perspective of the Ministry of Justice, there was resistance to accept more progressive and pragmatic approaches on drug policy. In the 1980's there was an increase in drug consumption and in prejudices related to drug consumption, since drug trafficking groups were disputing territory in *favelas.*[940] A demand for harsher penalties and tougher public security policies emerged in Brazil.[941] As a result the Heinous Crimes Act from 1990, included drug trafficking as one of the most serious crimes in the Brazilian criminal justice system, alongside with terrorism, genocide, rape, murder and torture.[942]

Example of such views was the constitution from 1988, which also includes the same provisions on drug trafficking as a heinous crime, alongside with terrorism, genocide, rape, murder and torture. As such, the tensions between the adequate access to health services such as access to medicines, and the control of illicit markets, is expressed in the Brazilian Constitution from 1988. In Article 196 it is stated that:

Article 196

> *Health is everyone's right and state's duty (...) guaranteeing through social and economic policies to reduce the risk of diseases and other harms e and the universal access to actions and services for its promotion, protection and rehabilitation"*[943]

[939] Lima, Fonseca and Hochman, p. 80.

[940] Slums

[941]Rodrigues and Labate, p. 192.

[942] Rodrigues and Labate, p. 192.

[943] Brasil, *Constituição da República Federativa do Brasil*, (Brasília: Presidência da República, 1988), Article 196, http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm [Accessed 13 June 2022].

But in Article 5,

> *(XLIII) The law shall consider torture, illicit trafficking of narcotics and other drugs and terrorism as heinous crimes and not subject to bail or amnesty (…).*[944]

The language of the constitution shows that despite the advancement in the recognition of the right to health, drug legislation continued to have a prohibitionist approach, as if human rights and drug policy were parallel universes.

The Constitution from 1988 also established Unique Health System (SUS), the Brazilian universal health coverage system through Organic Law on Health 8080, from 1990. This law establishes the health system's goal to provide access to medicines in Article 6:

> *SUS includes I actions such as: d) Integral therapeutic assistance, including pharmaceutic". In addition, Article 19-M states that "only medicines included in the lists elaborated by the health system's organs should be provided.*[945]

Article 6 referred to the Essential Medicine's list based on WHO's model. It included medicines for the treatment of HIV/AIDS patients and opioids such as morphine for pain treatment. Here it is important to note that also in Brazil, the HIV-AIDS epidemic was an impulse to demand for access to medicines as a state's duty and, with that, ensuring access to other essential medicines for patients in severe pain, such as morphine, codeine and methadone became also an obligation of the state. The epidemic opened the opportunity to understand that the drug problem was not only a law enforcement, but also a public health issue. Since opioids were internationally controlled, the tension with the framework of drug control emerged. Until then, the prohibitionist approaches of drug laws and related regulations prevailed over concerns with treatment of drug dependence.

Changes in the drug control framework began to occur when the Standing Committee/CNFE, mentioned earlier, was replaced by CONFEN (National Council on

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[944] Brasil, *Constituição*, Article 5.

[945] Brasil, *Lei 8080 de 19 de setembro de 1990*, (Brasília, Presidência da República 1990) Chapter1, Article 6. http://www.planalto.gov.br/ccivil_03/leis/l8080.htm [Accessed 13 June 2022].

Narcotics Control/ Conselho Nacional de Fiscalização de Entorpecentes) in 1980. Initially its mandate was to coordinate and supervise narcotics' policy.[946] Nevertheless, CONFEN expanded its activities including prevention practices, treatment and research and members of scientific organs could engage in a dialog with representatives from the government's repressive apparatus.[947] It was the moment of "healthification" of drug policy in Brazil, CONFEN was formed by ministries of Justice, Health, Education and Culture, Federal Police, National Regulatory Authority, and Armed Forces, one psychiatrist and one jurist. Initially it addressed only illicit drug issues, but still in the before the end of the decade, it addressed also licit drug's issues.[948] Thus, it played a role on regulations of internationally controlled medicines, such as opioids.

The favorable position of CONFEN towards harm reduction on the syringe exchange program prevailed, despite the resistance of Federal Police, Public Prosecutor's office and Catholic Church and legal obstacles provided by the 1976 Drug Law, then still in force.[949]

The objective of this work is not to analyze the treatment of patients suffering with drug dependence but show that but through the attempts of treating HIV/AIDS patients and controlling the epidemic among injectable drug users, a demand for adequate pain treatment emerged, through a new health system, with universal coverage for primary health care.

### 6.1 Harm reduction in Brazil

The first AIDS case was reported in Brazil in the State of São Paulo and since then, the injection drug users (IDU) have played a key role in the spread of HIV/AIDS in the country, disseminating the virus among IDUs and among the general population. In the 1990's the first harm reduction approaches took place in the city of Santos, state

[946] Ana Regina Machado and Paulo Sérgio Miranda. 'Fragmentos da história da atenção à saúde para usuários de álcool e outras drogas no Brasil: da Justiça à Saúde Pública'. *História, ciência e saúde-Manguinhos* (Rio de Janeiro: Fundação Oswaldo Cruz, 2007), 14.3, pp. 801-821 (p. 806).

https://www.scielo.br/j/hcsm/a/fmMpJSxrL6wNT8B3KkcB3Bj/abstract/?lang=pt [Accessed 13 June 2022].

[947] Machado and Miranda, p. 807.

[948] Machado and Miranda, p. 806.

[949] Machado and Miranda, p, 809.

of São Paulo. In the same year that a law was enacted including drug traffic on the list of heinous crimes, showing a strong prohibitionist approach in the Brazilian drug policy.

By the end of 2000, the Federal STD/AIDS Control Program estimated that approximately 25% of the AIDS cases were directly or indirectly related to injectable drug users (IDUs).[950] The first attempt to control the epidemic was a needle exchange program, coordinated by the physician Fabio Mesquita in 1989, in Santos, state of São Paulo, a city known as the Brazilian AIDS capital. As a consequence, public attorneys decided to sue the health authorities for the initiative, based on their interpretation of the Brazilian Toxics Law from 1976, trying to prosecute health authorities as drug dealers.[951]The political support from the city of Santos, and the federal government to the needle exchange program helped the health authorities in the trial. It was the starting point of a fight for human and civil rights for IDUs.[952] the city of Santos' health department was the first in Brazil to provide zidovudine (AZT), antiretroviral medicine for Aids treatment and IDUs received this medicine as others Aids patients, on the basis of the **universal right to health** stated in the Brazilian Constitution of 1988 and guaranteed by the Brazilian public health system since 1990.The program was replicated later in other cities of Brazil[953]

The impact of this health initiative was felt in legal framework regarding the treatment of drug users. The work carried out in the research centers of universities producing evidence-based results were important to influence the position of agencies such as CONFEN[954]. Despite the antagonism from the police and Public Prosecutor's office regarding harm reduction practices such as the syringe exchange programs, CONFEN issued a favorable decision for the development of such programs.[955] The strong

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[950] Fábio Mesquita, Denise Doneda, Denise Gandolfi, Maria Inês Battistella Nemes, Tarcísio Andrade, Regina Bueno, Daniela Piconez e Trigueiros, Brazilian Response to the Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome Epidemic among Injection Drug Users, *Clinical Infectious Diseases*, 37.5, (2003) Pages S382–S385, https://doi.org/10.1086/377547, p.S382. [Accessed 13 June 2022].

[951] Mesquita et al., p. 383.

[952] Mesquita et. Al., p. 583.

[953] In 1991, The impulse of the first needle syringe initiative was seen when the program was replicated in the city of Salvador, state of Bahia and later in other cities of the Northeast of Brazil, with participation of civil society. In: Mesquita et.al., p. 583.

[954] Such as Proad, Programa de Orientação de Atendimento a Dependentes and Cebrid (Centro Brasileiro sobre Drogas Psicotrópicas), with extensive research on cannabis. Both at Unifesp – Universidade Federal de São Paulo).

[955] Machado and Miranda, p. 808.

position of CONFEN convinced president Itamar Franco (1992-1994) to support for harm reduction this became the Brazilian position also in international for a, despite the traditional prohibitionist approach on drugs.[956]

This led to the amendment of the Drug Law of 1976, allowing harm reduction practices.[957] The technical regulation on substances and medicines subjected to international control was a responsibility of ANVISA, the national regulatory authority. It is the key organ in the federal government regarding access to controlled medicines because it regulates, registers, authorizes and monitors the use of controlled medicines. It also establishes the list of substances of special control, such as morphine. In 1998, this agency issued this new institutional development, Ordinance 344[958]on activities and regulations related to medicines, such as opioids. It expresses the international drug control conventions' provisions on the use of drugs for medical purposes, with an extra layer of national bureaucracy. As such it includes provisions to control opioids according to the Single Convention's schedules. The ordinance has detailed regulations, monitored by the police and the National Health Surveillance Agency (ANVISA). Although not all the details are referred in the Single Convention, the national regulations shows that they were considered necessary by legislations to keep Brazil in compliance with the international drug control conventions.

The Ordinance, which is still in force today, is signed by Gonzalo Vecina Neto, physician, who was ANVISA's president at that time. Vecina Neto notes that, this Ordinance was extensively discussed, and its spirit is to control the use of narcotic substances. There is a strong difficulty in prescribing such drugs and the ordinance was written in a way to create difficulties for physicians to prescribe it. It was on purpose."[959], he says. "Brazil had the most draconian legislation in the world regarding opioid use. This is the reason why we had one of the lowest consumption of opioids in the world. Patients in Brazil experience a great amount of pain."[960] He added that at that time there was a strong influence of INCB on ANVISA to increase controls. It

[956] Machado and Miranda, p. 809.

[957] Machado and Miranda, p. 810.

[958] Brasil, Ministério da Saúde, *Portaria No. 344 de 12 de maio de 1998*, (Brasília, Ministério da Saúde 1998) https://bvsms.saude.gov.br/bvs/saudelegis/svs/1998/prt0344_12_05_1998_rep.html. [Accessed 13 June 2022].

[959] Gonzalo Vecina Neto, video call , 25 October 2021.

[960] Vecina Neto

was extremely difficult to increase import quotas of controlled substances. Once we received the visit of an officer from an international agency and he acted like a police officer."

As a president of ANVISA, Dr. Vecina Neto, physician was a member of CONAD, the National Council of Antidrug policies. This federal body was created when CONFEN was replaced by the National Antidrug System (SISNAD), to conduct repressive activities against drug misuse, illicit trafficking and drug production. CONAD was an organ of the drug control framework, responsible for the orientation on drug policy in all government levels. SISNAD was created by President Fernando Henrique Cardoso (1994-2002)[961] and is formed by representatives of several ministries, including, Health, Defense, Woman, Family and Human Rights, Justice, Foreign Affairs and Citizenship, among others.

The activities of prevention, treatment, rehabilitation and social reinsertion of dependents were executed by SENAD[962], National Antidrug Department, responsible for sanitary activities for drug dependents. It was a result of one of the commitments agreed by states at UNGASS 1998 and these organs were located in the Military Cabinet of the President. [963]

The creation of new framework for drug control with SISNAD and ANVISA's measures on controlled medicines showed that there was a resistance to abandon the strong importance given to law enforcement views on the issue. Dr. Vecina Neto noted that when drafting Ordinance 344, he managed to put ayahuasca out of the list of controlled substances, because it is used in religious rituals. But there was pressure from other members from CONAD for increased controls because they had a law enforcement approach on drug issues. He added that usually, the most enthusiasts on these views were pharmacists and psychiatrists.[964] This shows that the elite of medical practitioners and other health care professionals are embedded from the most conservative views, which continues to give fuel and justify a repressive approach from law enforcement on drugs.

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[961] Today presidente Fernando Henrique Cardoso is one of the Commissioners of the Global Commission on Drug Policy.

[962] SENAD replaced CONAD – Conselho Nacional Antidroga

[963] The creation of SENAD benefited therapeutic communities, which did not happen within the health system (SUS). However, SENAD was ambivalent regarding harm reduction practices. In: Machado e Miranda, p. 813.

[964] Vecina Neto

It could be argued that, with the concerns with the HIV/AIDS epidemic and the adoption of harm reduction policies would lead to more progressive drug laws. But the new drug laws from 2006 and 2019 showed limited progress. Drug trafficking continued to be considered a heinous crime in the Brazilian Constitution until today. The implications of drug laws for access to controlled medicines rely on the provisions on what is considered drug trafficking. Because the amounts of opioids that a physician possesses or prescribes can qualify a health professionals or patients as dealers.

When President Lula da Silva was elected in 2003 the Ministry of Health followed a logic like harm reduction paradigm until the approval of the next Law on Drugs 11.343, in 2006. The text of the law incorporated a progressive tone and was considered a "breakthrough" by government's representatives in comparison with the previous law on drugs, from 1976. The law opened possibilities for drug dependence treatment, focused on harm reduction policies, thus seeking to respect human rights views and balance between the goals of prevention and treatment and suppressing illicit trafficking.[965] However, major decisions were the decriminalization of "misuse", which is a vague term. The possession of illicit drugs was decriminalized, while the possession of drugs for shared use, previously considered trafficking, had the sentence cut.[966] It also made a distinction between drug dealer and occasional trafficker, and included alternative penalties such as warnings, provision of community services and compulsory attendance at courses or educational programs for the drug users. [967]

In comparison to the previous law, it can be seen as a progress not to criminalize explicitly physicians, dentists and pharmacists, which would contribute with opiophobia developed since 1930's. But in practice kept repressive practices that contributed with excessive incarceration in Brazil.

By making the distinction between drug dealer and occasional trafficker this law officializes the historical penal selectivity.[968]That had been occurring in Brazil for many years, since certain individuals and social groups specially, young, black and dwellers of the favelas are those traditionally sought in arrest, due to drug related crimes. The main problem of this law relies on the lack of objective definition of

[965] Rodrigues and Labate, p. 193.

[966] Rodrigues and Labate, p. 193.

[967] Rodrigues and Labate, p. 194.

[968] Ulianelli, Guanabara, Fraga and Blickman, p.19.

quantity to qualify someone as a trafficker or consumer. This decision is taken by the judge, who received the process as recorded by the police authority.[969] As Luciana Boiteaux notes there is a significant number of cases in which the judge assumes that the defendant is involved in criminal activities based in mere suspicions.[970]

The criteria to differentiate quantities of drug for trafficking and for consumption are subjective and the result is that only poor people go to jail.[971]Also, the subjectivity of the matter is enough to intimidate patients and their families that tend to believe carrying and using medicines in higher doses would qualify as trafficking. This fear also affects health professionals that are afraid to transport medicines to their patients, because they could be considered traffickers.

The last changes in the Brazilian drug law occurred in 2019. The law 13.840 increased penal sanctions for drug trafficking from 5 to 8 years and eliminated the harm reduction policies from SISNAD the System of National Antidrug Public Policies. Instead, the law provides the possibility of compulsory treatment in therapeutic communities.

## 7. Conclusion

After examining the historical account of the legal and institutional framework of drug control in Brazil, it is possible to conclude that the international drug control system influenced the development of the prohibitionist Brazilian drug policy. All international treaties were incorporated into Brazilian legislation. However, an endogenous prohibitionism was revealed when Brazilian restrictive legislation showed an excessive concern with law enforcement approach even ahead of restrictions established by international conventions. Drawing from the theory of norm localization developed by Amitav Acharya, Brazil accepted to take international principles and norms, incorporating them even on a more draconian way than it was provided in the international conventions. In fact, there was a congruence of ideas between the international and Brazilian drug policy.

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[969] Rodrigues and Labate, p. 194.

[970] Luciana Boiteux, Tráfico de Drogas e Constituição, um estudo jurídico-social do tipo do artigo 33 da lei de drogas diante dos princípios constitucionais penais, *Revista Jurídica*, Brasília, pp. 1-29 (.17) (Brasília: Presidência da República, 2009) https://www.tni.org/es/publicacion/trafico-de-drogas-e-constituicao[Accessed 13 June 2022]

[971] Ulianelli, Guanabara, Fraga and Blickman, p. 19.

The impact of prohibitionism on access to internationally controlled medicines occurred because of three factors discussed in this chapter: the influence of the international drug control regime and its restrictive drug control conventions, the influence of US-Brazil bilateral relations, and endogenous prohibition at the domestic level.

Since the first Brazilian drug law, enacted in 1921, not only the legislation developed towards increased restrictions, but drug control organs have become more sophisticated. Prohibition culminated in the periods of Estado Novo (1937-1945), with the creation of the Standing Committee of Narcotics Control CNFE, and in the civil military dictatorship (1964-1985), with the enactment of the Toxics Law in 1976, in response to the Single Convention 1961. The whole set of legislations had intimidating provisions, regarding the prescription of opioids. They created fear in both patients, to take a medicine perceived as "dangerous" and health care professionals subject to penal sanctions, in case of inadequate prescriptions. It is important to highlight that the Brazilian legislation never defined objectively the amount of substance that differentiate an adequate from inadequate prescription, or how much substance qualifies trafficking or personal use. Since it is the police that decides who qualifies as a dealer or not, both prescribers and patients in possession of an amount of substance considered high are subject to sanctions.

In the democratic period, concerns with HIV epidemics led to a shift in drug policy and revealed the tension, at the domestic level, between adequate access to medicines and the control of illicit markets. The creation of the Unique Health System and the Constitution from 1988, which recognizes the right to health, were advancements towards a human rights-based approach on drug policy in Brazil. Harm reduction practices had been carried out successfully in many parts of the country and HIV/ patients gained access to free medicines for the treatment of this disease, opening the opportunity to discuss the issue of low consumption and lack of access to opioids in Brazil. However, the Constitution still considers drug trafficking as a heinous crime, which created fear in a generation of physicians, dentists and pharmacists of prescribing opioids. It was expected that the new drug law from 2006 would be more progressive. Even though harm reduction was adopted as federal strategy for drug treatment, the drug law decriminalized the only use of drugs, but not their possession.

This means that in practice repressive practices continued because a drug user also possesses the substance.

Harm reduction approaches were eliminated from the federal drug policy strategy in 2019 and the treatment of drug dependence is now focused on abstinence and the work of therapeutic communities. Despite the progressive human rights approach in the Brazilian drug policy, motivated by the AIDS epidemic, the prohibitionist approach and focus of law enforcement are still strong in the legislation and pervades the health system, drug control organs and education and practice of health care professionals. As this historical account showed, the development of the prohibitionist Brazilian drug control framework contributed to the current situation of the low consumption of opioids in Brazil, discussed in the next chapter.

# Chapter 7

# Brazil: consequences of a prohibitionist approach on access to opioids

## 1. Introduction

This chapter is the second part of the case study about Brazil and analyzes the current situation of access to opioids in the country. It also analyzes the period between 2009 and 2019, showing the consequences of the prohibitionist approach of the international drug control regime and how it interplays with Brazilian drug policy and regulations of opioids in the health system. In doing so, the tension between access to medicines and the control of illicit markets at the national level reveal that the lack of adequate access of opioids lead patients to rely on the illicit market to obtain medication that the public health system fails to deliver. Also, the chapter discusses aspects of the Brazilian culture that have implications for the low consumption of opioids.

The analysis is focused on the ambulatorial consumption of opioids prescribed to patients using the Brazilian public health system, Unique Health System (SUS). Today, Brazil has a population of approximately 214 million people[972], of which 75% rely only on SUS[973]. Ambulatorial consumption of opioids means that severe pain can be treated at home, and that medicines could be provided at the level of primary health care (PHC), leaving hospital beds free for patients in need of other treatments. According to WHO, primary health care is defined as: a whole-of-society approach to health that aims at ensuring the highest possible level of health and well-being and their equitable distribution by focusing on people's needs and as early as possible along the continuum from health promotion and disease prevention to treatment, rehabilitation and palliative care, and as close as feasible to people's everyday environment. [974] As PHC plays an important role on palliative care, it is crucial that opioids for pain treatment are available through this level of assistance.

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[972] Instituto Brasileiro de Geografia e Estatística (IBGE), (Rio de Janeiro: IBGE, 2022) https://www.ibge.gov.br [Accessed 13 June 2022].

[973] IBGE, *Tabela 7573 – Pessoas que tinham algum plano de saúde médico*, (Rio de Janeiro: IBGE, 2022 https://sidra.ibge.gov.br/tabela/7573#resultado [Accessed 13 June 2022].

[974] World Health Organization, *Primary Health Care* https://www.who.int/news-room/fact-sheets/detail/primary-health-care [Accessed 13 June 2022], para 6 of 18.

The chapter is organized in five main sections. First, the situation of access opioids in Brazil is discussed according to data from the INCB and the Walther Center in Global Palliative Care and Supportive Oncology, Indiana University. Also, data provided by the Brazilian Ministry of Health on ambulatorial consumption of opioids is analyzed. The second section discusses regulations and ordinances and protocols created in within the public health system, in accordance with international and Brazilian drug laws. In doing so, barriers are analyzed, such as onerous regulatory frameworks, gaps in the education of health care professionals, corruption and poor management and cultural attitudes. The third section discusses access to medicines and the relation of patients with drug traffickers and armed militias to show how they obtain prescribed controlled medicines, when they are not available in the public health system. The fourth section shows how patients circumvent barriers to access to opioids when they are far from reference centers of treatment, which offer high complexity health assistance. These centers offer treatments of high technology and high costs. In doing this, the approach of the Ministry of Health on access to opioids in PHC is analyzed. In the fifth and last section, cultural attitudes regarding opioid use are analyzed, particularly in the northern region of Brazil, which hosts most of the indigenous population and lowest consumption of opioids in the country. Thus, this section discusses also particular difficulties to provide palliative care and home care in the region revealed by original data collected in several interviews with key informants from all Brazilian regions.

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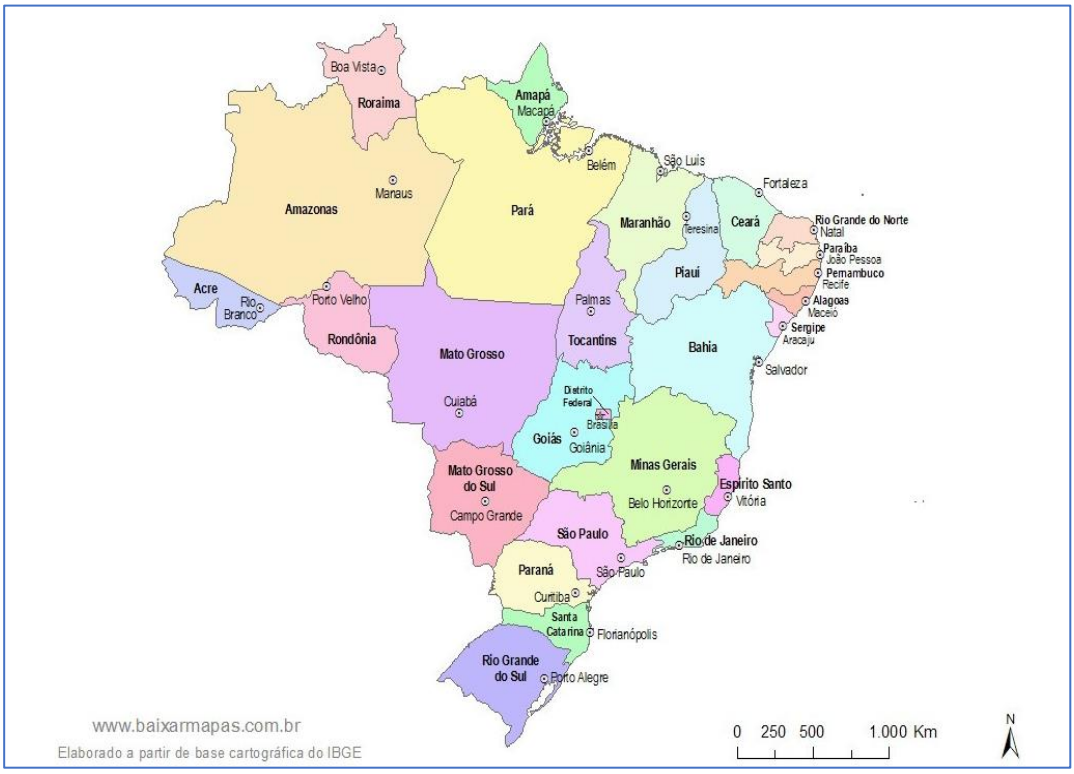
**Figure 1: BRAZIL - States and capitals** [975]




[975] Baixar Mapas, *Brasil, Estados e Capitais* https://www.baixarmapas.com.br/mapa-do-brasil-estados-e-capitais [Accessed 13 June 2022].

## 2. Data on access to opioids in Brazil

Data on opioid consumption in Brazil is scarce. In this section the sources of available data and barriers identified by the INCB to access to opioids are discussed to show that although the INCB considers the consumption of this substance "adequate", the access of these substances for pain treatment is low.

Data provided by the INCB show one aspect of the issue of availability, which is the amounts that the competent national authority report as consumed. It verifies reported consumption by using data from export and import notifications. The INCB recognizes that the quality of reports varies, and information is not always reliable, but the S-DDD, defined daily doses for statistical purposes, is a technical unit of measurement and it is not a recommended prescription dose. S-DDDs are useful to ascertain the degree of over prescription and under prescription of opioids in each country.[976] According to the INCB Brazil has a consumption of approximately 365 S-DDDs per million inhabitants per day (Figure 2).[977] Germany has also adequate consumption, which is about 24,000 S-DDDs per million inhabitants per day.[978] According to Lukas Radbruch, president of the European Association for Palliative Care and Board Member of the International Association for Hospice and Palliative Care, Germany is a country with adequate consumption of opioids because it is result of good clinical guidance, widespread education, and balanced regulations ensuring adequate access to opioids, for those who need them. At the same time, Germany has a low rate (3.2) of opioid related deaths per million inhabitants, in 2015. According to the German Federal Statistical Office, Germany had 3.2 opioid related death per million inhabitants and the US, 144.6 in the same year.[979] As such, despite high opioid consumption, Germany is not facing the same opioid crisis occurring in North America.

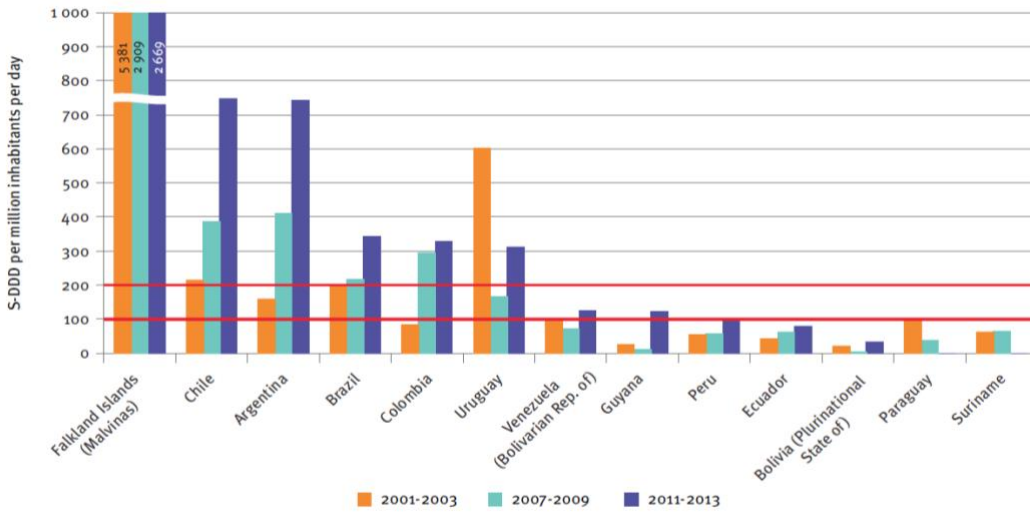
[976] (E/INCB/2015/1/Supp.1), p. 6.

[977](E/INCB/2015/1/Supp.1), p. 17.

[978] (E/INCB/2015/1/Supp.1), p. 7.

[979] Lukas Radbruch. 'Rising opioid prescriptions may not be a crisis.' *British Medical Journal BMJ* (Clinical research ed.) vol. 367 l6452. (2019), <https://www.bmj.com/content/367/bmj.l6452> [Accessed 13 June 2022].

**Figure 2: Average consumption of opioid analgesics in South America, 2001-2003, 2007-2009 and 2011-2013** [980]



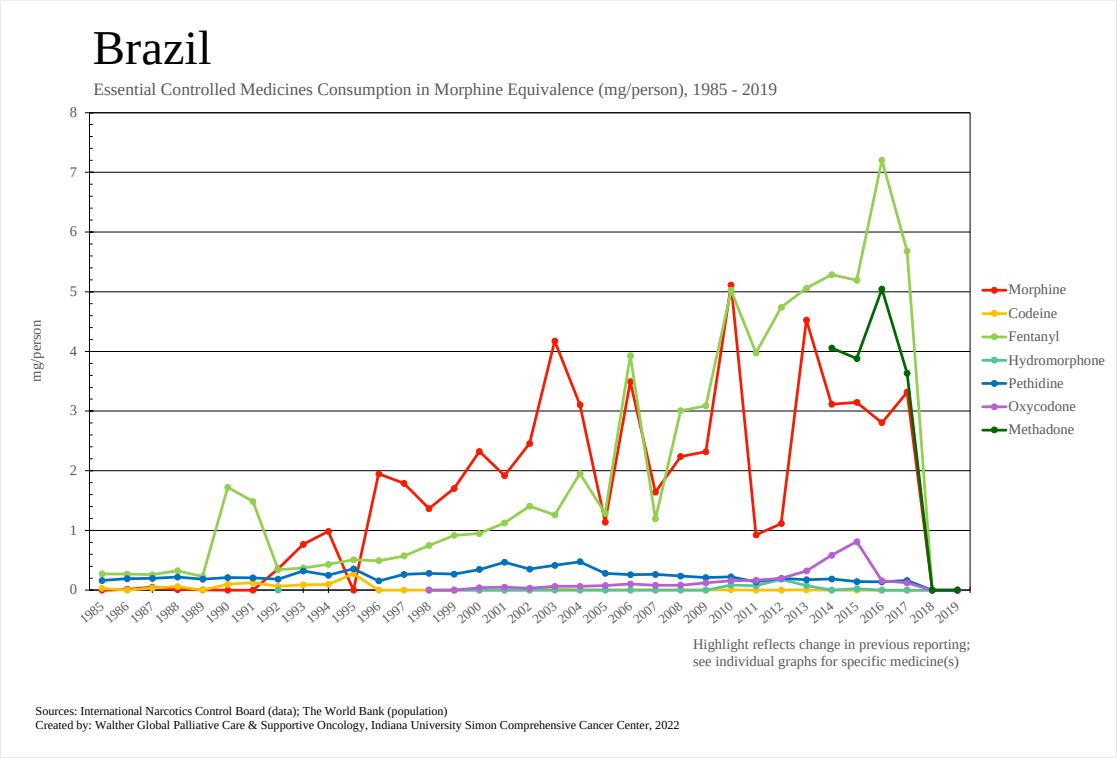

*Source*: International Narcotics Control Board.
*Note*: Red lines: levels less than 200 S-DDD are considered inadequate; levels less than 100 S-DDD are considered very inadequate.

The Walther Center in Global Palliative Care and Supportive Oncology at Indiana University uses data collected by the INCB to present the consumption of opioids in morphine equivalents. This is the dosage of a substance that equals the analgesic potency of 1 mg oral morphine and is expressed in per capita units to allow the comparison among countries. [981] Here, the graphics are used to show a comparison between Brazil and Germany. Both are considered by the INCB to have adequate consumption of opioids. Figure 3 shows that the consumption of opioids in Brazil is low and does not reach 8 mg/ per capita of morphine equivalents.

[980] (E/INCB/2015/1/Supp.1), p. 17.

[981] Seya, Marie-Josephine et al. 'A first comparison between the consumption of and the need for opioid analgesics at country, regional, and global levels.' *Journal of pain & palliative care pharmacotherapy*, 25.1, (2011), pp. 6-18 (p.7) https://www.researchgate.net/publication/50807295_A_First_Comparison_Between_the_Consumption_of_and_the_Need_for_Opioid_Analgesics_at_Country_Regional_and_Global_Levels/link/0c9605395d3c015d74000000/download [Accessed 13 June 2022].

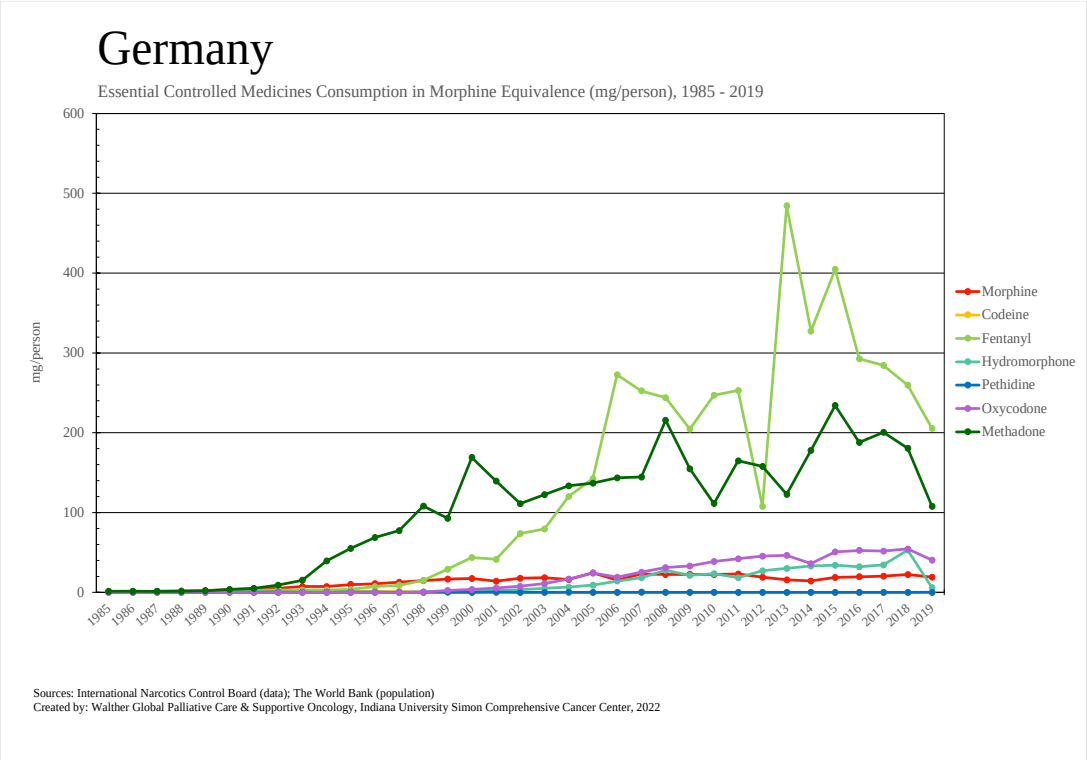
**Figure 3: Opioid consumption in Brazil in Morphine Equivalence** [982]




[982] Walther Center in Global Palliative Care and Supportive Oncology, *Brazil*, Indiana University. (2022) https://walthercenter.iu.edu/essential-medicines/country/brazil.html [Accessed 6 June 2022].

In Figure 4 Germany shows an opioid consumption of approximately 500 mg/per capita of morphine equivalents.

**Figure 4. Opioid consumption in Brazil in Morphine Equivalence** [983]




[983] Walther Center in Global Palliative Care and Supportive Oncology, *Germany*, Indiana University, (2022) https://walthercenter.iu.edu/essential-medicines/country/germany.html [Accessed 6 June 2022].

Other methods were used to calculate opioid consumption. For instance, in 2010 Beatrice Duthey and Willem Scholten calculated that the consumption of opioids in Brazil was 13.13 mg per capita of Morphine Equivalent. But in fact, adequate consumption in the country would be 192.91 mg per capita of morphine equivalent.[984]

The analysis of data shows that while the S-DDDs are useful to compare opioid consumption among countries they may lead to inaccurate interpretations of what "adequate" consumption means in each country. A common conversation among diplomats sitting at Vienna International Center (VIC), where the Commission on Narcotic Drugs takes place is about the annual report of the INCB. They usually check if figures on the lack of availability of opioids is affecting their countries and if their country is mentioned in a negative way in the report. If there is no criticism, no action is required. In fact, if the report says the consumption of opioids is "adequate", it is possible that the issue requires no further action in Vienna and is kept out of the radar of country's mission, regarding access to medicines.

As the history of the international drug control system showed, concerns with control and law enforcement have tended to receive more attention, while the health aspect was marginalized.

The same happens at the national level in Brazil. Misleading assessments about the availability of opioids can turn the issue invisible to the eyes of delegates that come from the capital to CND in Vienna. As Luís Guilherme de Paiva noted, when he was Director of Special Projects and International Affairs at SENAD (National Antidrug Department) and part of the Brazilian delegation at CND in 2015, the issue of access to and availability of opioids was never articulated between at the Ministry of Justice and the Ministry of Health.[985] In the field of drug policy, in Brazil, the availability of opioids was considered a "non-problem", and in the Ministry of Health it is considered an issue for medical specialists without connection with drug control policies.[986] According to Paiva, the issue of access to medicines for pain treatment could be part

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[984] Béatrice Duthey, Willem Scholten, Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, Its Relationship With Development Level, and Changes Compared With 2006, *Journal of Pain and Symptom Management*, Volume 47, Issue 2, 2014, pp. 283-297 (p.286).

https://www.jpsmjournal.com/article/S0885-3924(13)00272-8/pdf [Accessed 6 June 2022]

[985] Luís Guilherme de Paiva, personal interview, 13 March 2015.

[986] Paiva

of the Brazilian drug policy agenda if it happens at the international level.[987] In fact, in 2016 the issue gained attention with the adoption of the UNGASS document, which included one operational chapter on the improvement of access to medicines for pain treatment. However, as it will be discussed in this chapter, medical use of opioids has never been among dimensions of drug policy in Brazil.

Data available at DATASUS, the Brazilian databank from the Ministry of Health, shows that there are barriers to access to opioids, especially for ambulatorial use, when patients with severe pain are treated at home. In the period between 2009 and 2019, there was an increase in the quantity of dispensed opioids (morphine, methadone and codeine).

In 2009 opioids were prescribed and dispensed by physicians working at SUS 6,044,917 times, for ambulatorial use. In 2019 it occurred 14,019,326 times. Although these figures show that the consumption increased more than twofold, the distribution of opioids is still concentrated in the state of São Paulo and dispensed mostly by patients treated in high complexity institutions.[988] In 2009 the state dispensed 50% of the opioids consumed in the whole country, and in 2019, patients treated in São Paulo consumed 60% of in Brazil.[989] In 2019 the most prescribed opioid in Brazil is codeine in tablets of 30 mg, for moderate pain. Morphine ranks second with dispensation of tablets of 10 mg. The least used opioid is injectable methadone, available only in the state of São Paulo, prescribed only 235 times.[990] Research also showed that Brazil had the lowest availability of opioids among Upper Middle-Income countries.[991]

In this section it was showed that Brazil has a low consumption of opioids if compared to other countries, even if adequate access to controlled medicines is considered "adequate by the INCB". This can be a misleading information for national authorities and diplomats following this issue in Vienna. Measures that calculated adequate need

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[987] Paiva

[988] Brasil, Ministério da Saúde, *Sistema de Informações Ambulatoriais do SUS, SIA-SUS.*

https://datasus.saude.gov.br/informacoes-de-saude-tabnet [Accessed 6 June 2022].

[989] Brasil, Ministério da Saúde, *Sistema de Informações Ambulatoriais do SUS, SIA-SUS.*

[990] Brasil, Ministério da Saúde, *Sistema de Informações Ambulatoriais do SUS, SIA-SUS.*

[991] Liliana de Lima, Tania Pastrana, Lukas Radbruch, Wenk R. Cross-sectional pilot study to monitor the availability, dispensed prices, and affordability of opioids around the globe. *Journal of Pain Symptom Management*. 2014 Oct;48(4):649-59.p. 652 https://www.jpsmjournal.com/article/S0885-3924(14)00146-8/fulltext ,Epub [Accessed 15 June 2022].

of opioids in Brazil showed that pain is undertreated, despite legislation that recognizes the right to health and a structured public health system with universal health coverage. Data show the inequality of opioids' distribution in Brazil, concentrated in richer regions and where the reference centers for cancer treatments are located, such as São Paulo and Rio de Janeiro. The Amazon region, in the northern part of Brazil has the lowest consumption of opioids.

The following sections will show reasons why the distribution is unequal among Brazilian regions and the barriers that led to low consumption of the substance in the country.

## 3. Opioids provided by the Brazilian Unique Health System (SUS)

In 2010 the INCB published a report listing the barriers that produce impediments to the availability of controlled medicines such as opioids, according to a survey carried out by the body. Barriers identified were lack of training, fear of addiction, problems in sourcing, fear of diversion, limited financial resources, international trade control measures, onerous regulatory framework, cultural attitudes, and fear of prosecution/sanction, and actions by the Board. [992]

In this section, the most important laws, regulations and ordinances are discussed to show how opioids are provided by the Brazilian Unique Health System (SUS) and the tension between access to internationally controlled medicines and the control of illicit markets. In doing so, the barriers facing patients and health care professionals, and the alternative strategies to bypass them to treat severe pain will be analyzed.

Today, the key Brazilian legislation and regulation with implications on access to controlled medicines such as opioids are: 1) drug law 13840 from 05 June 2019, which refers to the illicit use of drugs and has focus rather on drug treatment in therapeutic communities than in harm reduction policies. 2) ordinance 344/98, which expresses the obligations of the Single Convention in Brazil and 3) List of National Medicines from Specialized Component of Pharmaceutical Assistance (CEAF)[993], introduced in 2009, and 4) Protocol for Chronic Pain and Therapeutic Guidelines. These are the

[992] (E/INCB/2010/1/Suppl.), p. 29.

[993] Brasil, Ministério da Saúde, *Relação Nacional de Medicamentos do Componente Especializado da Assistência Farmacêutica* – CEAF, https://www.saude.gov.br/images/pdf/2020/June/22/Elenco-de-medicamentos-do-CEAF-junho2020.pdf,[Accessed 15 June 2022].

regulations that create bureaucratic barriers for the prescription and use of opioids, the first obstacle for access to opioids discussed in this section.

### 3.1. Onerous Regulatory Framework

The drug law from 2019 and ordinance 344 were discussed in chapter 6. The List of National Medicines from Specialized Component of Pharmaceutical Assistance (CEAF) includes the only opioids provided by SUS for ambulatorial use: Morphine, methadone and codeine. Within CEAF, they belong to Group 2, which are medicines acquired, financed and dispensed by the Health Department of each state of Brazil.[994] CEAF establishes that these medicines are used to treat chronic, degenerative and complex diseases, including untreatable chronic pain and other chronic pain. [995] These conditions are listed at the WHO's International Code of Diseases CID.[996]

In Brazil, a physician treating a patient eligible to receive opioids listed in CEAF needs to follow the Protocol of Chronic Pain and Therapeutic Guidelines established in 2012 by the Ministry of Health.[997] It means that the physician must fill one form on pain scale and the patient must sign a liability agreement and present other documents listed in the Protocol. [998] According to the protocol, patients with chronic pain shall be primarily evaluated in chronic pain or palliative care specialized services, from more complex levels of care.[999] Having that, the patient can go to the state's pharmacy and obtain medicines for free, as long as they are available. When this stage of pain treatment is reached it means that this patient had been sent to another a secondary or tertiary level care unit, which are known in Brazil as UNACON[1000] – a high complexity

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[994] Brasil, Ministério da Saúde, *Grupos de Medicamentos*, para 2 of 8.

https://www.gov.br/saude/pt-br/composicao/sctie/daf/componentes-da-assistencia-farmaceutica-no-sus/ceaf/grupos-de-medicamentos [Accessed 6 June 2022].

[995] Brasil, Ministério da Saúde, *Grupos de Medicamento*, para. 8 of 8.

[996] WHO, *International Classification of Diseases*, *11th Revision* ( ICD -11),

https://icd.who.int/en 1https://icd.who.int/browse10/2019/e [Accessed 6 June 2022].

[997]Brasil, Ministério da Saúde, *Protocolo Clínico e Diretrizes Terapêuticas para Dor Crônica*, (2012) anexo 5 and 10, from10http://conitec.gov.br/images/Protocolos/DorCronica.pdf, [Accessed 6 June 2022],

[998] Brasil, Ministério da Saúde, *Protocolo Clínico e Diretrizes Terapêuticas para Dor Crônica*, Anexo 9, from10.

[999] Brasil, Ministério da Saúde, *Protocolo Clínico e Diretrizes Terapêuticas para Dor Crônica*: Anexo 9.

[1000] Unidade de Assistência de Alta Complexidade em Oncologia.

assistance in Oncology or CACON[1001] – a reference center on the treatment of chronic pain.[1002]

At CACONSs and UNACONS, opioids are dispensed against the presentation of a white prescription used for controlled medicines in two copies. One of them is collected at the moment of dispensation and the patient keeps the other copy, depending on the state. Sometimes there is an agreement between the state's health secretariat and health units mentioned above for the use of white prescription. Otherwise, a yellow prescription A1 is requested, which is more difficult to obtain. To have the yellow special prescription pad with twenty pages, a physician needs to be accredited in the health department of the state, according to the regulations about prescriptions established in Ordinance 344.[1003] This prescription can be also used to buy opioids in commercial pharmacies and the quantity of medicines allowed to be dispensed is for no more than thirty days.

Bureaucratic demands for physician prescribing opioids with a yellow prescription according to ordinance 344 are harsher in comparison to psychotropics that require the blue prescription. [1004] For yellow prescriptions, a physician must request a pad, which has only 20 pages and they need to be printed at the sanitary authority printshop. The blue pad, for used for instance for benzodiazepines has more pages and can be printed anywhere with the number sequence informed by the sanitary authority. The obligations provided by Ordinance 344 are monitored by the police and the sanitary authorities and can be a burden for physicians as Claudia Naylor physician at the National Institute of Cancer (INCA) states:

> *A small number of doctors have the prescription pad for opioids in their names and professional register because they are afraid to have it robbed and have to respond to administrative investigations, or because of the burden of bureaucracy. The prescription pad is an issue, says Claudia Naylor. It is an immense bureaucracy that physicians must face to get a*

[1001] Centro de Referência em Tratamento de Dor Crônica.

[1002] Lilian Krause, Letícia Freitas e Priscila Daflon, Cuidados Paliativos e medicina de família e comunidade: conceitos e interseções. *Revista do Hospital Universitário Pedro Ernesto*, (Universidade Federal do Rio de Janeiro, 2016), pp. 286 -293 (p. 288). https://www.e-publicacoes.uerj.br/index.php/revistahupe/article/view/30644/23252 [Accessed 13 June 2022].

[1003] Brasil, *Ministério da Saúde*, *Portaria 344, de 12 de maio de 1998*, (1998)

https://bvsms.saude.gov.br/bvs/saudelegis/svs/1998/prt0344_12_05_1998_rep.html [Accessed 6 June 2022]. Artigo 40 of 110.

[1004] Brasil, Ministério da Saúde, *Portaria 344, de 12 de maio de 1998*, Artigo 36.

*prescription pad for opioids. It is not impossible, but it is hard for doctors that rush from one place to another, to have it at all times.*[1005]

Medicines requiring prescription A1 and A2 correspond to the schedule 1 of the Single Convention and therefore are more strictly controlled. Elisaldo Carlini, physician, former director of ANVISA and former Board member of the INCB conducted a survey on the prescription of methylphenidate (Ritalin), which can be prescribed only with yellow prescription A1. He concluded that this kind of prescription provoked fear in patients and their families because they considered that if such medicine was so strongly controlled, it could only be dangerous and even cause harm (72.5% of answers). Other 70% mentioned that families presenting the yellow prescription at the pharmacy felt embarrassed, because looks at the counter were "different", as if they were buying medicines for an addicted person.[1006]

While patients and their families fear taking such controlled medicines, physicians fear the consequences of problems with prescriptions. Before 2002, physicians, dentists and pharmacists were subject to penal sanctions, in case of inadequate prescriptions. Today, ordinance 344, article 98 provides that in case of non-compliance with these regulations, it is a sanitary infraction. Penal and civil sanctions are excluded.[1007]Although it was a positive change, it is relatively recent and the fear of criminalization was present in generation of health professionals, that were formed while previous drug laws (1932, and 1976 and 2006) were in force or were educated by professionals formed in this period. Gonzalo Vecina Neto, former director of ANVISA adds that a physician can still be punished with imprisonment, if it is proved that the professional is part of a criminal scheme of selling prescriptions, for instance.[1008]

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[1005] Claudia Naylor, video call, 02 August 2020.

[1006] Elisaldo Carlini, Solange Nappo, Vagner Nogueira and Fernando Naylor, 'Metilfenidato: influência da notificação de receita (A), cor amarela sobre a prática da prescrição por médicos brasileiros', *Revista de Psiquiatria Clínica*, 30.1 (2003) pp. 11-20 (p.16).

https://www.scielo.br/j/rpc/a/6q8gBQmTh7fhFGwQ47ywGnR/?format=pdf&lang=pt [Accessed 6 June 2022].

[1007] Brasil, Ministério da Saúde, *Portaria 344, de 12 de maio de 1998*, Artigo 98.

[1008] Vecina Neto

To illustrate that legislative and bureaucratic burden, such defensive behavior regarding opioids is still common as it is noted by Cristina Moro, dentist, director of Hospital Amaral Carvalho, reference in cancer treatment in Jaú, state of São Paulo, Brazil:

> *Normally hospitals have a prescription on behalf of the health care unit with the register number of one of the directors. In case of prescriptions misuse, the responsible person is the one whose name is on the prescription pad, in case of an administrative process. "There are physicians that prefer not to have this kind of prescription pad on their names because they are afraid to be involved in any administrative process. A doctor that needs such a prescription must think carefully on this responsibility and it restricts the use of drug. However, the disease is even worse.*[1009]

This shows that physicians constantly confront the tension between giving access to medicines to their patients and fear the implications of the control of illicit markets, acting often as gate keepers of pain treatment.

Excessive bureaucracy on access to controlled medicines is undoubtedly a result of a prohibitionist approach of national drug laws that followed the restrictive tone of the Single Convention. Even if Brazil recognizes the right to health on the constitution, has committed to international human rights treatment and has a structured health system, the tension between access to medicines and control of illicit markets often affects patients relying on SUS. An example that illustrates how bureaucracy can lead to difficulties in accessing opioids in Rio de Janeiro is the death of Lívia Pereira's patient. The geriatrician and palliative care doctor, assists patients in home care in Rio de Janeiro and coordinates a home care program to elderly people with incapacitating diseases and in need of palliative care (PADI).[1010] She works for the city of Rio de Janeiro in several slums, some of these areas are dominated by the drug traffickers, thus she works under permanent security risk, as she reported: [1011]

> *In 2015 I had a 45-year patient with lung cancer, living in a community (slum). My team was working in the area, and we*

[1009] Cristina Moro, video call, 04 September 2020.

[1010] Programa de Atenção Domiciliar ao Idoso (PADI), is coordinated by managed by the city of Rio de Janeiro. This program does not belong to Melhor em Casa Program.

[1011] PADI is coordinated by managed by the city of Rio de Janeiro. This program does not belong to Melhor em Casa Program.

> *were always observed by the Movement*[1012]*. She was in strong pain, and our program did not have the yellow prescriptions. We asked the local hospital to give us the prescription, but it was denied. The hospital could not understand the need of morphine in a program that is not connected to a tertiary level hospital, such as the National Institute of Cancer. Apart from that, the hospital considered that a patient with such pain could only be in the hospital, not at home. We had to send her to the hospital and then she died in the emergency room, because here we do not have a hospice. Since then, I worked to have this kind of a yellow prescription type A1, and it took me three years to have it, because the local health authority (Prefeitura) said our service was not allowed to have it.*[1013]

Lívia Pereira has been working in this home care service for 10 years, treating patients with cancer, neurologic diseases and rehabilitation after accidents. She affirms that the access to opioids in the city of Rio de Janeiro is difficult both in poor areas – the slums, "favelas" or communities – and in privileged neighborhoods such as Ipanema and Copacabana."

Opioids like morphine and codeine (internationally controlled) and Tramadol (not controlled) are listed in REMUME – the list of essential medicines of the city of Rio de Janeiro [1014] since 2018 but it is difficult for patients at home to receive them from primary health care. These medicines are available mostly in hospitals such as INCA (National Cancer Institute) a high-complexity care institution from the tertiary level, where patients are assisted by specialists. In the secondary level of assistance which involves specialized care, it is also not available, explains the Livia Pereira[1015].

The influence of the international drug control regime in burdensome regulations in Brazil relies mostly on Ordinance 344/98, which incorporates the provisions of the Single Convention, regarding access to controlled medicines and was elaborated under

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[1012] The Movement, 'o Movimento' is the local term to refer to drug traffickers.

[1013] Lívia Pereira, vídeo call, 31 July 2020.

[1014] Brasil, *Ministério da Saúde, Resolução 41 de 31 de outubro de 2018* dispõe sobre as diretrizes para a organização dos cuidados paliativos à luz dos cuidados integrados no âmbito do Sistema Único de Saúde- SUS(Brasília 2018)

https://www.in.gov.br/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/51520746/do1-2018-11-23-resolucao-n-41-de-31-de-outubro-de-2018-51520710 [Accessed 6 June 2022].

[1015] Pereira

strong influence of the INCB. This ordinance adopted within the context of restrictive drug laws adopted in Brazil. It had certainly a clear influence in the creation of CEAF and the Protocol for Chronic Pain and Therapeutic Guideline. They make access to opioids for pain treatment difficult for patients and for prescribers, due to excessive bureaucracy. The tension between access to controlled medicines and control of illicit markets is clear. On the one hand Brazil recognizes the right to health in its constitution and has opioids included in the national list of essential medicines, based on the WHO's Essential Medicines' list. Although the public health system has an obligation to make these medicines available, it creates burdensome regulations that may affect access to them, particularly for Primary Health Care.

This is an example that shows that prescribers of opioids need to navigate through rule complexity to facilitate access to medicines for their patients. At the domestic realm, they show an example of a regime complex generated by the intersections between the Justice and the Health systems. They are both inserted in a regime complex involving the international drug control, and international human rights regimes. As Karen Alter and Sophie Meunier note "a regime complex introduces significant rule complexity and rule complexity exist in the domestic realm."[1016] At the national level, in Brazil, the complexity of the regime relies in creating health regulations with the intention of protecting the right to health of patients, but the result is an additional barrier to the access of controlled medicines for pain treatment. At the same time this barrier shows compliance with the international drug control regime, in accordance with its restrictive approach.

### 3.2. Gaps in the education of health care professionals

Another relevant barrier that affects access to opioids in Brazil is the insufficient education of health care professionals, according to the INCB Report in 2015[1017]. Generations of physicians, pharmacists, nurses, dentists, veterinarians and law practitioners were trained under Brazilian dictatorships that adopted restrictive legislation on drugs. During these periods bilateral relations between Brazil and the US were close and the American model of training the health care work force, played

[1016] Alter and Raustiala, p.3.

[1017](E/INCB/2015/1), p. 29

a role on the way pain management has been taught in Brazil. This section discusses how gaps in the education of health care professionals lead to fear of prescribing, inadequate prescriptions with weak opioids, and the fear of addiction both in patients and prescribers.

Physician Claudia Naylor from the National Cancer Institute in Rio de Janeiro notes that in regions far from Rio de Janeiro and São Paulo, where reference hospitals are located, inadequate prescriptions are common. She stated that:

> *About 60% of the patients that arrive at INCA, with severe pain have never been treated with opioids. She collects stories from colleagues that worked in other regions. I have a resident working with me that told me in a hospital she worked in the northeast (see Figure 1), they were giving 2 mg of morphine diluted in 500 ml of saline solution to treat severe pain. This is nothing. It is necessary to train them continuously.*[1018]

Luís Fernando Rodrigues, a trained palliative care doctor, works at *Hospital do Amor* in the city of Barretos[1019], state of São Paulo, a reference hospital in cancer treatment. He treats patients not only from Barretos, but also from several parts of Brazil. One of his colleagues described what physicians do, when they lack knowledge on how to prescribe opioids:

> *In the state of Mato Grosso do Sul (see Figure 1), in a city with 42 thousand inhabitants there is no home care service. There is no more than one person doing this kind of care. In the case of this patient, morphine was prescribed in the hospital in Barretos. But in Mato Grosso do Sul it is difficult to find morphine and doctors does not like to prescribe it, so they create strange formulas with cyclobenzaprine, tramadol and amitriptyline*[1020]*. Doctors there like to invent these mixes of medicines, but they do not alleviate severe pain.*[1021]

[1018] Naylor

[1019] Barretos has approximately 125 thousand inhabitants.

[1020] Amitriptyline is an internationally controlled antidepressant that does not require the same kind of prescription required for morphine.

[1021] Luís Fernando Rodrigues, vídeo call, 23 June 2020.

This shows clearly that such physicians were trained to use weak opioids or medicines under less stricter controls, to avoid the risk of prescribing an opioid. Also, when physicians know how to manage opioid prescriptions, their work is often undermined by colleagues fearing the use of these substances. Maria Goretti Maciel, physician in São Paulo, palliative care specialist, founder of Brazilian National Academy of Palliative Care[1022], a professional association of palliative care professionals in Brazil reported this behavior of her colleagues:

> *When a physician knows how to prescribe opioids, there are colleagues that does not accept the use of such medicines for their patients. It happens frequently in private hospitals. Sometimes the palliative care team is required, and it is common to treat pain with opioids, but in such hospitals, there is always a doctor assisting that patient, who is the patient's "owner" and disagrees with the prescription. So even if we prescribe, medicines are changed by the specialist', who is responsible for that patient*[1023]

It is a common practice not only by specialist physicians but also by nurses, which shows the lack of knowledge on the use of opioids in different levels of health care, as it was noted by Ana Claudia Quintana Arantes, physician in São Paulo, renowned specialist in palliative care.

> *Sometimes I prescribe opioids and come the next day to see the patient and he or she says that the night was awful because of the pain. When I ask why the medication was not taken, the patient explains: The nurse said I was going to become addicted.*[1024]

The negative impact of training physicians specialized in certain field there is a gap when they need to treat severe symptoms that are present in all knowledge areas of

[1022] Academia Nacional de Cuidados Paliativos

[1023] Maria Goretti Maciel, personal interview, 15 September 2016. This practice was also referred by Ana Claudia Quintana Arantes, personal interview, 30 March 2017 and Luís Felipe Nogueira Padi, video call 31 August 2020.

[1024] Arantes

medicine, such as pain. This problem is pointed out by Maria Goretti Maciel, palliative care doctor.

> *The management of pain is part of the basic medical knowledge. It does not belong to any medical specialization and that is why medical students do not learn it properly. In Brazil, medical education is based in specialties and our doctors are good in their fields of study, but they are not trained to work with populations like children, elderly people and women.*[1025]

Regarding palliative care, in Brazil there are few public hospitals training professionals to manage pain properly, as it is observed by Maria Goretti Maciel:

> *There are few university hospitals that have a service of palliative care, so the professors do not teach it and the students do not see the palliative care team working and that is why they do not learn pain management properly. Or even worse, if they do it incorrectly, the patient has a bad experience with the medicine and rejects it in the future.* [1026]

The issue of lack of proper training for health care professionals stems arguably not only from the prohibitionist approach of drug legislation in Brazil, but also due to changes in regulations at all levels of education, including universities, occurred in 1968 with the universities' law reform .[1027] During the Cold War Brazil and US had a close bilateral relationship, fearing USSR influence in the Western hemisphere At that time, the public health system was centralized and available only for citizens registered in the formal job market. Medical services were provided by private companies that privileged curative medicine and specialties, there was no collective health or regulatory authority. Rural workers, indigenous people, and informal workers had to count on a poor-quality service[1028] In 1970's a growing number of private courses of

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[1025] Maciel

[1026] Maciel

[1027] Sarah Escorel, Dilene Raimundo do Nascimento and Flavio Coelho Edler, 'As Origens da Reforma Sanitária e do SUS', in: *Saúde e Democracia, História e Perspectivas do SUS*, organized by Nísia Trindade Lima, Silvia Gerschman and Julio Manuel Suárez, pp. 59-82, (p. 63), (Rio de Janeiro: Fiocruz, OPAS, OMS, 2005).

[1028] Escorel, Nascimento and Edler, p. 62.

medicine were created in the country, following an American model of universities, which was hospital-oriented focused on research, individualism, with emphasis in specializations.[1029] These courses were not focused on the Brazilian reality, but on a medicine based in technological sophistication and new pharmaceutical products and medical equipment.[1030] Physicians educated in Brazil as off 1968 were trained to work in foreign companies and its subsidiaries located in the country to assist patients formally employed. Until 1974, the health policy adopted by the military governments emphasized an individualist approach based on a medicine of specialties a not in a health system of collective interest with a holistic view of the patient.[1031]

Today, consequently, basic knowledge such as treating severe pain is mostly restricted to postgraduation programs, as the palliative care specialist Ana Claudia Arantes highlights:

> *A small number of schools of medicines have a formal class on pain management, with the analgesic ladder. "The collegiate bodies understand that pain management is learned at some point when students learn orthopedics, or anesthesiology, but tin fact, it does not happen.*[1032]

Health professionals lacking this basic knowledge are afraid of prescribing and prefer not to learn, since opioids are seen as dangerous drugs as it is highlighted by Lívia Pereira, palliative care doctor working in Rio de Janeiro. "There are doctors working in palliative care that say*: "I do not touch this kind of 'thing', referring to prescribing opioids"*[1033].She acquired experience in prescribing opioids firstly, studying by herself and then in the specialization in palliative care. [1034]The fear of prescribing remains in

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[1029] Clarisse Daminelli Borges Machado, Andrea Wuo and Marcia Heinzle, `Brazilian Medical Education, a Historical Analysis of Academic and Pedagogical Education`, *Revista Brasileira de Educação Médica*, 42.4 (2018), 66-73, (p.68),

https://www.scielo.br/j/rbem/a/kj4F6KSJnvPfjJjLGhkPKqL/?format=pdf&lang=pt [Accessed 6 June 2022].

[1030] Escorel, Nascimento and Edler, p. 61.

[1031] Escorel, Nascimento and Edler, p. 62.

[1032] Arantes

[1033] Pereira

[1034] Pereira

those professionals that lack proper knowledge on opioids, something basic for the management of symptoms, as Lívia Pereira explains:

> *Many colleagues in the team I supervise do not even have the prescription pad required for opioid prescription. They limit their prescriptions until the level of tramadol (weak opioid) and think the patient will become dependent. They think morphine is only necessary for the very end of life. "For instance, in February 2020, the program I coordinate had 950 patients from which only 5 were taking opioids. I realized there were more patients that needed opioids, but the doctors did not prescribe them, because of prejudice against this kind of medicine.* [1035]

The lack of knowledge on opioids is also present in the daily routine of pharmacists, and law practitioners. It begins with how they are presented to the topic, still at the university as it is referred by Cejana Passos, lawyer and pharmacist working at ANVISA, the national regulatory agency on drugs:

> *Law practitioners also have a problem of knowledge. The general idea about morphine is that that the first dose, the first, tablet will lead to dependance. There is a horror about the first dose. No one wants to be part of it. In the pharmacies there is fear to be part of a trafficking chain. It is common to find oncologists and orthopedists that prefer to ignore pain and its management.* [1036]

Cejana Passos told her own experience, when she first learned about opioids, when she studied Pharmacy at the university, in Brazil.

> *I was educated in the 80's and my education was based on the psychology of terror. Look what is going to happen with you, I use to hear. Drugs kill you! I am a clinical pharmacist and I remember how opioids were presented to me at the university. We do not see this subject in much detail. It is part of the topic "analgesics", but what we learn in the undergraduate level is very basic. And we learn to look at them as 'controlled' medicines, so it means we must be particularly cautious. Opioids are not named medicines for pain. If we compare to medicines for cancer, they can also produce harm, but they are*

[1035] Pereira

[1036] Cejana Passos, personal interview, 15 March 2017.

*not seen as something to be 'controlled', they are just called cancer medicines.*[1037]

Although Brazil has showed an endogenous prohibitionist approach in drug legislation, there was undoubtedly an influence from the international drug control system on Brazilian drug policy. The close US-Brazil bilateral relations especially in the civil-military dictatorship between 1964 and 1985 played a role not only in the development of Brazilian drug laws, but also in the education of health care professionals.

Today the US influence still affects international drug policy because of the increased opioid morbidity and mortality particularly in the US and Canada.[1038] It may be argued that the same crisis affecting North America could happen in Brazil. Although this dissertation is not focused on the excess of opioid consumption, it is important to note that North America and Brazil have different realities regarding access to opioids. As Keith Humphreys argues, "the North American crisis emerged when insufficient regulation of the pharmaceutical and health-care industries enabled a profit-driven quadrupling of opioid prescribing."[1039] These established procedures have been occurring since 1990's and involved particularly expanded prescribing of extremely potent opioids for a broad range of chronic, non-cancer pain conditions, which led to hundreds of thousands of opioid related deaths due to overdose.[1040] Research conducted in Brazil about opioids prescription show that although the rates of prescription opioid use in the country have increased, they remain well below those observed in North America.[1041] Hence Brazil's issue regarding opioids consists of a different challenge. As the North American crisis gained traction in international fora, this added an

[1037] Passos

[1038] Keith Humphreys et al. 'Responding to the opioid crisis in North America and beyond: recommendations of the Stanford–Lancet Commission', *The Lancet*, (London, 2022) 399.10324, 555 – 604, (p.555),

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02252-2/fulltext [Accessed 13 June 2022].

[1039] Humphreys et al. p.555.

[1040] Humphreys et al. p.555.

[1041] Noa Krawczyk, M Clare Greene, Rafaela Zorzanelli, Francisco Bastos, 'Rising Trends of Prescription Opioid Sales in Contemporary Brazil, 2009-2015'. *American Journal of Public Health*, 108.5, (2018) pp. 666-668. (p.3) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5888056/ [Accessed 13 June 2022].

additional obstacle that may increase the fear of prescribing and fear of addiction regarding opioid in Brazil.

### 3.3. Corruption and poor management

As it was discussed in chapter 6, Brazil seriously considered producing morphine in the country, when medicines coming from Europe became scarce due to World Wars. Today, as Claudia Naylor, physician at the National Institute of Cancer (INCA), states that "in Brazil the production of opioids is in hands of the pharmaceutical industry. It is not in public domain."[1042] According to the Stanford Lancet Commission responding to the opioid crisis in North America and beyond, one of the recommendations to ensure adequate access to opioids and at the same time prevent opioid crisis beyond the US and Canada, is to distribute free generic morphine for analgesia in hospitals in lower-income countries, so patients can take it home. It is an alternative to relying on morphine bought from private laboratories. This practice eliminates profit of pharmaceutical industries and prevents fraudulent and corrupting practices. [1043]

In Brazil, the procurement of opioids is made through public electronic bidding. Opioids are financed, procured and dispensed by the Health Secretariat of each of the 27 federal units, as reported by[1044] Heber Bernarde, head of the Technical Advisory Group on Pharmaceutical Assistance[1045], from the National Council of Health Secretariats (CONASS).[1046] However, establishing the adequate quantity of opioids to buy is troublesome, according to Domício Arruda, former secretary of the Health Secretariat of Rio Grande Do Norte, northeast of Brazil, in 2011-2012. He notes that:

> *The quantity bought is defined by managers that not always understand the use of the medicine, and do not make procurements based in scientific evidence. They usually buy opioids according to the figures from previous years. But*

[1042] Naylor

[1043] Humphreys, p.565.

[1044] Heber Bernarde, video call, 07 August 2020.

[1045] Câmara Técnica de Assistência Farmacêutica from Conselho Nacional de Secretarias da Saúde

[1046] CONASS – Conselho Nacional de Secretarias da Saúde

> *usually the needs are bigger than what is available for consumption.*[1047]

Arruda adds that a frequent problem affecting access to medicines is corruption, as he points out that:

> *Distribution only takes place if payment is made correctly. There is a lot of corruption in the health system at the end of the year there is always money missing. There is great political interference in the procurement of medicines and the needs are bigger than what is available for consumption.*[1048]

## 4. Drug trafficking, militias and access to medicines in Brazil

The tension between access to medicines and the control of illicit markets is particularly evident when patients need to use alternative ways to have access to opioids. Often, they find support in an illicit support network to obtain controlled medicines, such as opioids. This section will discuss how patients and prescribers circumvent difficulties to obtain medicines when they are not available, by analyzing situations that occurred in the states of Rio de Janeiro, Rio Grande do Sul and São Paulo.

The city of Rio de Janeiro deserves special attention. Data from National Institute of Cancer (INCA) estimate that in 2014, 55.632 patients in the state of Rio de Janeiro needed palliative care, 12.576 only in the capital. The city shows a clear demand for the use of opioids, which should receive greater attention from health care professionals, education professionals and managers.[1049]

In Rio, as drug trafficking became more organized in the slums since the 1980's, drug traffickers were equipped with high-powered firearms, some of which are used exclusively by the armed forces.[1050] The competition between traffickers for ruling areas of influence has provoked conflicts because certain groups divide the city's territory and monopolize sales in certain neighborhoods. Conflicts between rival groups are common and result in the death of many people. In addition, traffickers

[1047] Domício Arruda, video call, 17 June 2020

[1048] Arruda

[1049] Krause, p. 288.

[1050] Iulianelli Et al., p. 23.

make their own rules, impose curfews and mourning periods forcing commercial establishments to close the doors, and block the entrance of the 'favelas'.[1051] Their inhabitants need education, health, employment, social promotion and security, but the only state authority that enters this area is the police, normally treating residents with negligence.[1052]

More recently a new element was included in the day-to-day life in the slums. Currently, the slums are dominated by two groups: the traffickers and the militias. The militias are organizations formed by retired policemen or military, retired and active prison guards, which guarantee security in exchange of monthly payments. They impose this service onto slums' dwellers, and sell other products such as illicit cable connection, charge a percentage from earnings of alternative transport circulating in the region they dominate, or from the real estate business in the area.[1053] Militias strongly reject drug use, and their interests are political power, financial gains and territory domination.[1054]

Within this context Lívia Pereira, palliative care doctor works in areas dominated by drug traffickers and militias in Rio de Janeiro. She reported the experience with patients when they need opioids and other controlled medicines:

> *If I ask where patients get medicines, they lie, they tell me a friend gave them. It is always a mystery. I think medicines are diverted from hospitals or robbed from pharmacies. It is common because traffickers get hurt and they need medicines. To work in the slums, we learn not to ask where things come from. I was trained to work in these areas by the Red Cross. I learned that this is the same situation of a civil war, and this is the safest way to behave.*[1055]

It is not possible to know the origins of all the medicines that reach patients. There is a common procedure in commercial pharmacies that allows an unofficial extra stock of medicines that can be negotiated by commercial pharmacies. That is how the

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[1051] Iulianelli Et al, p. 26.

[1052] Iulianelli Et. al, p. 28.

[1053] Zaluar, Alba and Isabel Conceição, Favelas sob o controle das milícias no Rio de Janeiro, *São Paulo em Perspectiva*, 21. 2 (2007), p. 89-101. p. 89. http://produtos.seade.gov.br/produtos/spp/v21n02/v21n02_08.pdf [Accessed 13 June 2022].

[1054] Zaluar and Conceição, p. 95.

[1055] Pereira

scheme works to circumvent the lack of prescriptions according to the regulations according to Rodrigo Luz, psychologist, director of education at Elisabeth Kübler-Ross Foundation Global, a palliative care NGO working in Rio de Janeiro:

> *If someone comes with a prescription of three boxes of morphine, which is not unusual for a patient with chronic pain, the salesperson at the pharmacy would say, that not all the three boxes are available, but only one or two. If the patient agrees to take only one or two, the prescription stays in the pharmacy and the patient cannot come later to get the total number of tablets.*[1056]

Rodrigo Luz explains that the patient is put in a difficult situation:

> *Either the patient buys what is available or must wait until the pharmacy has the three boxes, that would come a few days later. If the patient decides to wait, must bear pain until the medicines come. If it decides to take what is available, the pharmacy has a "spare" prescribed quantity of medicines to negotiate, that were not sold to the patient and may be negotiated at any price. So, it is hard to know what happens with these medicines.* [1057]

The assistance offered by traffickers is real. Although physicians would prefer not to rely on this network, it is effective, and usually the last resource. Lívia Pereira explains her approach when she needs to ask permission from the traffickers to see a patient:

> *I live in Quinta da Boa Vista, in Floresta da Tijuca, up here in this mountain, there is a very small community, dominated by local traffickers. When I go there, I have to say that I am going to Mr. Antonio's house. And they ask me at the entrance of the community: – What is going on there? and I explain he is not feeling well, he has cancer. They know him and his condition and then, he lets me in, saying: - If you need anything, let me know. They get not only medicines, but everything else that is necessary.*[1058]

[1056] Rodrigo Luz, video call, 05 June 2020.

[1057] Luz

[1058] Pereira

She affirms that sometimes help from traffickers is necessary. Drug traffickers, as well as drug users prefer not to use the health system, because they are afraid of the police. Therefore, they create a parallel structure of care, as she points out:

> *Once I needed gauze and saline solution and in the next day, I found a great quantity of the material, even more than I needed. It is not something I usually do, but it was my last resource. Also, it is always the patient who order medicines, not the doctors. Traffickers are usually young, and they die young, because of the violence. The problem is that when they die, patients become even more vulnerable, because part of this support network is gone. Also, antibiotics have a great value in the slums. I was told to provide antibiotics in order to enter in the community. As a toll payment, I had to give a pack of Clavulim (antibiotic).*[1059]

This quote also illustrates how traffickers often close gaps in the health system and patients overcome difficulties to have access to opioids for pain treatment:

> *I went to see a patient that was in strong pain, she had cancer. I took a physician with me, and she prescribed morphine to this patient. When she was beginning to write the prescription, the patient said: You don't need to do it, just give me the name of the medicine. A few hours later good quality medicines were delivered to her.* [1060]

This shows clearly the tension between the access to medicines and the control of illicit markets. It is precisely the drug trafficking the international drug control regime tries to eliminate, that provides opioids to patients not well assisted by the public health system. It shows that international drug control regime failed to control illicit traffickers and local regulations on controlled substances are inefficient because they create obstacles for the health system to ensure the availability of opioids.

When strong opioids are not available at SUS in the primary health care or home care, patients must buy them in commercial pharmacies and the price is high, approximately GBP 7.00 a pack with 50 pills (that lasts about a week, if prescribed every four or 6

[1059] Pereira

[1060] Luz

hours), depending on the case. Livia shows that opioids are expensive and sometimes only less potent medicines than morphine are available, such as tramadol:[1061] (see also p.274 for morphine prices):

> *It is expensive for a patient that lives with less than GBP 196.00 per month, if Tramal/Tramadol is prescribed 3 times a day, it will cost GBP19.00. This corresponds to 10% of the minimum wage. Consequently, the most vulnerable patients will find a way to buy it or will get it from informal markets, or from drug traffickers.*[1062]

Since the militias increased their presence in Rio de Janeiro, the informal pharmaceutical assistance provided by drug traffickers became even more difficult, as Lívia Pereira reported:

> *The militias have a different view on drugs. They have their own moral. They see opioids are drugs and they do not help patients with getting medicines. But it is not necessary to ask for permission to go and see the patient at home. Doctor's access to the patient is facilitated in areas dominated by militias. The growth of the militias and the presence of new organized drug trafficking groups are making the situation more difficult for these patients. Militias' members are, mostly Evangelic, and there is a religious issue regarding the use of morphine. They don't accept it. Some Catholics also have this prejudice. They associate the use of morphine to euthanasia; they think the medicine is given to kill the patient.*[1063]

Although militias are against drug use, they realize that coexisting with the traffickers has more advantages than trying to eliminate them from the communities. Militias charge traffickers for a financial contribution called "arrego" (protection money).The payment of "arrego" was crucial to consolidate the drug market in Rio in the 1990's. It is a kind of informal regulation of the drug market, to keep "Moviment" (the organization of traffickers) tolerated by the police and the militias.[1064]

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[1061] See also p.274 for morphine prices

[1062] Pereira

[1063] Pereira

[1064] Bruno Paes Manso. *A república das Milícias, dos Esquadrões da Morte à Era Bolsonaro*, (São Paulo:ed. Todavia, 2020), location 468.

## 5. Difficulties to find medicines in commercial pharmacies

Considering big cities in Brazil such as Rio de Janeiro and São Paulo and difficulties in public transport and long distances even within the city, it is often not feasible for patients to see the doctor and obtain the "rare" yellow prescription for opioids, so they must improvise a combination of telemedicine and trafficker's support, always for legitimate use:

> *Patients with a severe disease usually have a good relationship with the doctor. They receive indications on adjusting the doses. Sometimes it takes three hours by car between the residence and the health service. In public transport, it takes even longer, and if the patient is in strong pain, so it is very practical to count on informal sources such as those provided by the dealers.*[1065]

Interviews showed that opioids are scarce, and the lack of availability becomes an impediment for prescriptions:

> *Colleagues are not prescribing morphine because it is hard to buy it in a local pharmacy and expensive. But there are places where it possible to buy any kind of medicine without prescription in pharmacies, not only opioids, but also benzodiazepines, and antibiotics.*[1066]

In Rio de Janeiro a common way to find medicines for vulnerable people in the slums is to ask for them in the "bank of medicines" in various catholic churches in the city. *Dona* Edileuza is a community leader at Rocinha, one of the biggest slums in Rio.

> *I belong to Whats app groups that connects all these churches, and when a medicine is needed, I ask the group to find where it is available.*[1067]

However, for opioids, churches are only allowed to store them if there is a pharmacist responsible to keep the medicines locked in a box, and have all the licenses from

[1065] Pereira

[1066] Pereira

[1067] Edileuza da Silva, vídeo call, 01 July 2020.

ANVISA, the national authority, according to ordinance 344/98. “It is less likely that churches have these permissions to store them.”[1068]

As Claudia Burlá, geriatrician and palliative care specialist notes, “If a patient needs opioids, in southern areas of Rio de Janeiro[1069], it will be hard to find”.[1070] She sees her patients at home, mostly suffering from dementia. She lives in the southern part of Rio, where Copacabana is located. “There are 5 pharmacies close to my place. No one has morphine, and when I find, it is very difficult to find injectable morphine.”[1071]

> *In Copacabana, patients with a prescription of morphine have better financial resources to buy medicines, since they find it in the commercial pharmacies. However, they are not taken care by the traffickers, and in this sense they are alone. If they are alone, they are lost*[1072].

In the state of Rio Grande do Sul, as Dr. Julieta Fripp - a palliative care doctor, who coordinated home care programs and professor at Federal University of Pelotas, in Rio Grande do Sul - observes that:

> *It happens sometimes that the patients do not find opioids in the state’s pharmacies and tell doctors they get it from AAPECAN.*[1073]

The Association of Support to Cancer Patients (AAPECAN)[1074] is an NGO that helps patients with cancer in various cities in this state.[1075] However, it is not possible that organizations like AAPECAN have a stock of opioids with them. As the social assistant, Fernanda Ayres, from AAPECAN, in the city Pelotas, state of Rio Grande do Sul clarified, “the organization is not allowed to keep and distribute opioids, because they do not belong to the health system.”[1076]

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[1068] Pereira

[1069] The Southern area of the city of Rio de Janeiro is one of the upmarket areas.

[1070] Claudia Burlá, video call, 23 May 2019.

[1071] Burlá

[1072] Luz

[1073] AAPECAN, *Associação de Apoio à Pessoas com Câncer* http://aapecan.com.br/pelotas/ [Accessed 13 June 2022].

[1074] AAPECAN- Associação de Apoio à Pessoas com Câncer.

[1075] Julieta Fripp, vídeo call, 26 June 2020.

[1076] Fernanda Ayres, phone call, 06 July 2020.

The main concern for doctors is that their patients have access to medicines they need, but usually they ignore their provenance, as Julietta Fripp notes:

> *When medicines are not found in the state's pharmacies, sometimes they lie about how they obtained what was prescribed. Patients that search for medicines out of pharmacies act so informally and quick that it is hard to be controlled. I have no idea where they get their medicines from.*[1077]

The examples discussed in this section showed that even in the most developed areas of Brazil like Rio de Janeiro, (southeast) and Rio Grande do Sul (south), patients have difficulties in finding opioids, both in state and commercial pharmacies. Alternative support networks are created to fill gaps in the Brazilian public health system and the poorest patients might end up relying on drug traffickers for legitimate use of opioids. In most privileged areas, where these alternatives are not available, it is even more difficult to obtain opioids because pharmacies' chains prefer not to store and not sell such a controlled substance in their facilities. It requires additional licenses and bureaucracy, a locked box or cupboard and careful management of special prescriptions detailed in Ordinance 344/98. Most of the pharmacies are not interested in going through all these procedures and contribute to the low consumption of opioids in Brazil.

## 6. Gaps and barriers in a complex health system

After the analysis of alternative methods patients use to have access to opioids involving illicit networks, in this section, the analysis will show how barriers appearing in the work routine of physicians, health system managers and patients. The analysis will also cover why it is important to improve primary health care and integrate the dispensation of opioids in their services.

São Paulo is the state with highest consumption of opioids and several reference hospitals for cancer treatment and all other diseases. It counts on research centers and university hospitals. From the 547 high complexity hospitals in Brazil, 169 are located in the Southeast region (states of São Paulo, Rio de Janeiro, Minas Gerais e Espírito

[1077] Fripp.

Santo.[1078] In São Paulo, access to opioids is relatively organized, particularly in reference centers for the treatment of cancer and high complexity hospitals and for this reason these hospitals attract patients from many other states, that begin their treatment in São Paulo and then go back home, but often depend on prescription and medicines that are not available where they live.[1079]

The Hospital do Câncer in Barretos, state of São Paulo, is a reference in cancer treatment in Brazil. Luís Fernando Rodrigues is palliative care specialist in this hospital and says that patients treated there leave the hospital taking the medicines with them.[1080] According to ordinance 344/1998 the prescription of opioids is valid for 30 days[1081] and patients cannot rely on the health system to obtain their medicines, as the case of Rodrigues illustrates:

> *I have a patient from the south of Minas Gerais (See Figure 1), he lives about 700 km far from the hospital and I ask if they can find the medicines where they live and answer with disappointment: Iiiih, doctor, no! So, I tell him to call when the opioids are about to finish, the personnel at the ambulatory separates his medical records e they leave a note to give them a new prescription. In this case I can use a simple white prescription with a copy. The original stays at the hospital, when the medicines are dispensed in our unit and someone sends it to him, or he comes to pick up his medicines.* [1082]

When the patient is in the same region "the local authorities from SUS send an ambulance to the city of Barretos and the driver gets the medicines and brings them to patients."[1083]But if the patients live in states like Maranhão or Pará (see Figure 1), that requires 4-5 hours by plane (2,500 km) to reach the hospital, the procedure is so organized:

> *When they come for the first time, they find a way to make friends here. One of the patient's friends comes to the hospital*

[1078] DATASUS

[1079] Rodrigues

[1080] Brasil, *Ministério da Saúde, Portaria No. 344 de 12 de maio de 1998.*

[1081]Brasil, *Ministério da Saúde, Portaria No. 344 de 12 de maio de 1998.*

[1082] Rodrigues

[1083] Rodrigues

*with the prescription, get the medicines and send them per post to the patients.*[1084]

These examples show that patients cannot rely on the public health system to have access to medicines to treat their pain. They need to be creative, make special arrangements and count on the goodwill of people they meet at the hospital to continue their treatment as prescribed, or travel long distances. This would not be necessary if opioids were adequately prescribed and dispensed by services of primary health care.

Patients and health care professionals navigate through the complexity of the system. As an example of entangled rules that often emerge from international regimes, they also occur at the national level and shows the implications of regime complexity reflected at the national level. As Karen Alter and Kal Raustiala note, the concept of regime complexity can be applied to the domestic setting, with the difference that there is the presence of hierarchy, which does not appear at the international level.[1085] However, regarding access to opioids, the hierarchy that could be responsible for aligning rules is not aware of the issue and its implications.

## 7. Primary Health Care (PHC) and access to opioids

States including Brazil agreed in 2016 at UNGASS, that Primary Health Care is essential "to improving access to controlled substances," as it is stated at the Outcome Document.[1086] According to the recommendation of the Lancet Commission report on alleviating the access abyss in palliative care and pain relief , "all doctors, including those worked in primary care settings, should be legally and institutionally empowered and appropriately trained to prescribe an adequate supply of morphine for inpatients and outpatients"[1087] In Brazil and in other parts of the world, Primary Health Care is wrongly understood as the kind of care for simple diseases but it is not always the case. On the contrary. As Lilian Krause et al. note, Primary Health Care is the best level of

[1084] Rodrigues

[1085] Alter and Raustiala, p. 4

[1086] UNODC, *Outcome Document* 2016, p. 6.

[1087] Knaul, Felicia Marie, Paul E Farmer, Eric L Krakauer, Liliana De Lima, Afsan Bhadelia, Xiaoxiao Jiang Kwete, and others, 'Alleviating the Access Abyss in Palliative Care and Pain Relief—an Imperative of Universal Health Coverage: The Lancet Commission Report', *The Lancet* (British Edition), 391.10128 (2018), 1391–1454, (p. 1417). https://www.proquest.com/docview/2022104287?accountid=14680&pq-origsite=primo [Accessed 15 June 2022]

assistance for the application and coordination of palliative care, which can also reach complex needs.[1088]

According to the International Association for Hospice and Palliative Care (IAHPC), Palliative care is the holistic care of individuals across all ages with serious health-related suffering due to severe illness, and especially near the end of life. It aims to improve the quality of life of patients, their families and their caregivers. It includes the management of pain[1089]. A good quality death includes characteristics such as death without pain. [1090]

Having said that, the Strategy of Family Health was set up in Brazil in 1994 to reorganize the model of health assistance built upon primary health care in accordance with the principle of a decentralized health system like SUS. [1091] But as the history of the Brazilian health shows, Brazil has a universal health care system built upon a structure of specialized care. Patrícia Chueiri, family doctor, that worked in Ministry of Health in 2015, notes, that Brazil is in the transition from a hospital-centered system to a decentralized system. This is an ambitious project that aims equal assistance in all country regions but there are adjustments to be done, regarding the availability of opioids, particularly at the state level management. [1092]

Within this context, both Luís Fernando Rodrigues and Patrícia Chueiri, family doctors, have similar experiences with patients from other states that cannot rely on primary health care to obtain their medicines:

> *They come to Barretos because in primary health care they have no access to the medicines they need, or physicians do not know how to prescribe correctly. Also, they have no time and patience to complete forms and requirements to prescribe opioids.* [1093]

Rodrigues points out issues affecting the quality of primary health care in Brazil:

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[1088] Paiva

[1089] IAHPC, Palliative Care Definition.

[1090] Krause, Freitas e Daflon, p. 288.

[1091] Krause Freitas e Daflon, p. 289.

[1092] Patrícia Chueiri, vídeo call 24.08.2020.

[1093] Rodrigues

> *The problem of primary health care is that doctors change frequently from time to time, they do not have much experience and the salaries are low. Therefore, these positions not very attractive for physicians. Many of them are just there to work while they are studying to pass the exam for residency. There is also politics involved. In small cities, when the mayor is elected, he hires doctors from his connections and when he leaves, the next mayor hires someone else. The structure is weak.*[1094]

Patrícia Chueiri perceived that there is a lack of trust in primary health care professionals. This could be a reason why improving access to opioids at this level of care is not a priority at the MoH:

> *In my opinion the bottleneck for access to opioids is in the Department of Pharmaceutical Assistance,*[1095] *in the Ministry of Health. The Department of Pharmaceutical Assistance does not allow the use of opioids in primary health care. They do not trust us. The discussions about access to medicines did not advance because of them.*[1096]

The distrust on PHC is arguably a consequence of the lack of education of health care professionals in Brazil. This affects the quality of services and generate excessive bureaucracy as Patrícia Chueiri notes:

> *They (MoH) do not trust that a physician working in primary health care can prescribe opioids correctly. From one side it is a prejudice, because there are professionals trained to do it and it is necessary. From another perspective, there is a frequent lack of training in medical education, in the undergraduate level, to treat pain, using opioids.*[1097]

While discussions on improving access to opioids for pain medication in primary health care (do not advance, the excessive bureaucracy for prescribing opioids requires the attention of a specialist, as Patrícia Chueiri points out:

> *In Brazil, patients having access to opioids have gone through specialist doctors. In the primary health care, the bureaucracy*

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[1094] Rodrigues

[1095] I requested an interview with the Department of Pharmaceutical Assistance of the Brazilian Ministry of Health *but* had no reply from them.

[1096] Chueiri

[1097] Chueiri

> *to prescribe is a hindrance. Physicians need to meet specific requirements to get a prescription on behalf of the service they work in primary care.*[1098]

Opioids belong to the list of "Items from Specialized Pharmaceutical Assistance," one of the groups of medicines from RENAME, the national Essential Medicine's List[1099]. These medicines are procured by the health authorities of each state and according to Patrícia Chueiri but health management is not always efficient as she reports:

> *Of course, there are states that are more organized than others but the quantity of medicines that needed to be bought should be calculated, based on evidence available in the literature, in the epidemiology of diseases. There are methods to do that. But this is not the way it is done. Sometimes, data is not available, but we need to improve the quality of data to be able to improve the adequate flow of medicines to patients.*[1100]

Currently in Brazil, the management of pharmaceutical assistance in each state plays an important role, regarding access to opioids, because:

> *There is no public policy that regulates the supply chain of medicines: Years ago, a group of experts that asked the ministry of health years ago to create a basic list of opioids for the use of primary health care, but it did not work. Patients keep running a 'via sacra'.*[1101]

This is the case of opioids and others and other medicines as well. Julieta Fripp, palliative care doctor from Rio Grande do Sul, often prescribes morphine and methadone, since she coordinates home care programs. "Primary health care should guide care as a bottom-up process, not the contrary. Only the states of Rio Grande do Sul and Goiás have a public palliative care policy in the whole country, which should result in a wider use of opioids."[1102]

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[1098] Chueiri

[1099] Brasil, Ministério da Saúde, *Relação Nacional de Medicamentos Essenciais*, (Brasília: Ministério da Saúde, 2022) https://bvsms.saude.gov.br/bvs/publicacoes/relacao_medicamentos_rename_2020.pdf [Accessed 13 June 2022]

[1100] Chueiri

[1101] Fripp

[1102] Fripp

Olívia Ugarte, works at the general coordination of management and primary health care access to opioids at the Brazilian MoH and admits that:

> *Within the MoH, it is a subdued discussion, and her team has not been focusing particularly on this issue. Both the coordination on PHC and home care are not aware about the situation on access to opioids across Brazil, and particular challenges on this issue in different states or regions. This is because each state and each city*[1103] *decide on how to organize access on medications such as opioids.*[1104]

Management of symptoms such as severe pain in primary health is adequate because it is easier for patients to be assisted and contributes to leave vacant beds in hospitals for more complex needs. This means also that financial resources can be saved. The figures of DATASUS[1105] show that the average cost of hospital admissions in a public hospital in Brazil is approximately BRL1530.00 (224.87 GBP), in March 2019. The average of permanence of each patient is 6,5 days, or BRL235.00 (34.54 GBP) per day. A box of morphine with 50 tablets of 10 mg costs BRL 42.00 (6.17 GBP) and 30 mg costs BRL90.00 (13.23 GBP). Normally tablets are taken every 4 hours, so it lasts for a week. The cost of morphine per month stays between BRL 168.00 (24.69 GBP) and BRL 360.00 (52.91 GBP) which means that a patient with controlled pain does not need to be at the hospital, saving costs of hospital costs for the health system.

As interviews confirmed, Rio de Janeiro has low ambulatorial dispensation of opioids in the public health system, possibly because the dispensation is centralized at INCA, a reference center for cancer treatment that does not provide primary health care.

The state of Paraná has a program to dispense opioids called Paraná without pain (Paraná sem Dor)[1106] which provides opioids such as morphine, codeine, methadone

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[1103] Large urban centers such as São Paulo and Rio de Janeiro have autonomy for procurement of medicines.

[1104] Olivia Ugarte, communication via e-mail, Ministry of Health, 08 September 2020.

[1105] Brasil, Ministério da Saúde. Banco de dados do Sistema Único de Saúde – DATASUS, Informações de Saúde, Sistema de Informações sobre Internações. Disponível em http://tabnet.datasus.gov.br/cgi/menu_tabnet_php.htm [Accessed 13 June 2022 ].

[1106] Paraná, Secretaria da Saúde, *Elenco Complementar de Assistência Farmacêutica*, https://www.saude.pr.gov.br/Pagina/Elenco-Complementar-da-Assistencia-Farmaceutica [Acessado em 13 June 2022] paras. 1-2 of 3.

and gabapentin in several cities of this state. “This is an example of successful dispensation program.”, as Roberto Bettega, oncologist working at Paraná, notes.[1107]

In 2018 the Brazilian MoH passed resolution 41[1108] on the guidelines for the organization of palliative care in the public health system. This resolution has in Article 3 its objectives, such as integrate palliative care in the health care, offer medicines to control symptoms, including opioids to treat severe pain and promote education of health care professionals in palliative care since undergraduate level, as well as specializations, offer education in palliative care for health professional, information on palliative care for society and develop humanized, equal health assistance, based in evidences, in all levels of attention, with emphasis in primary health care, home care and integrated in specialized services. In addition, Article 4, II mentions the promotion of pain relief as one of the principles of palliative care to be observed. This resolution also mentions the recommendation made in the WHA 67, in 2014 that each country should develop and implement palliative care policies. This was considered a victory by palliative care practitioners in Brazil. However, a resolution does not have the same importance of an ordinance, or in other words, does not generate resources in the field to improve access to opioids for pain treatment.[1109]

For the MoH it is difficult to assess if opioid consumption in Brazil is adequate because the system is decentralized, and the country has continental dimensions. In the Ministry of Health there is currently a limited number of staff that understand the importance of opioid use. Working groups organized to work on strengthening primary health care, palliative care, and family health strategy, which would contribute significantly to put the issue of access to opioids in the agenda of the Ministry of Health, were interrupted and teams were changed due to constant changes in the Brazilian federal government since 2016, with the impeachment of President Dilma Roussef.[1110]

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[1107] Roberto Bettega, vídeo call, 24 June 2020.

[1108] Brasil, *Ministério da Saúde, Resolução 41 de 31 de Outubro de 2018* dispõe sobre as diretrizes para a organização dos cuidados paliativos à luz dos cuidados integrados no âmbito do Sistema Único de Saúde-SUS(Brasília 2018) https://www.in.gov.br/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/51520746/do1-2018-11-23-resolucao-n-41-de-31-de-outubro-de-2018-51520710 [Accessed 13 June 2022]

[1109] Fripp

[1110] Chueiri

The regulatory agency (ANVISA) has data about imports and exports of opioids, but it does not trace the distribution of medicines across the country. At the level of states' health management, collecting and analyzing data on epidemiology to understand the needs and trends of opioid consumption with views to guide adequate procurement of substances is not among priorities.

This section showed that opioids prescription and dispensation is concentrated in the state of São Paulo and in Rio de Janeiro, mostly at the National Institute of Cancer (INCA). Opioids are dispensed at high complexity institutions, according to the regulations of the MoH. Patients must find alternative ways to obtain their medicines, especially when they come from other Brazilian states with no reference centers, relying on the collaboration of other patients and their families. This shows that there is a lack of access to opioids particularly in primary health care services, which goes against the recommendation of the Lancet Commission to improve inequalities in palliative care and pain relief. Moreover, the Brazilian MoH shows insufficient attention on integrating prescription and dispensation of opioids in primary health care services. This is the level of attention could improve access to opioids for pain treatment by integrating palliative care and family health strategies.

## 8. Local Cultural Attitudes

This section discusses how the influence of cultural attitudes create difficulties for the treatment with opioids. It focuses on the resistance against opioid use in urban areas and remote areas in the northern region of Brazil, where traditional knowledge on pain treatment is a common practice by indigenous people and challenges of health care professionals working on home care services. In the Amazon region, a particular mindset shows resistance for the use of opioids. But also, patients in big urban centers show that having pain is associated with guilt for wrong doings in the past.

Every time a patient is treated with the wrong dose of opioids and has adverse effects that are not well managed due to lack of knowledge, it reinforces the idea that the medicine is dangerous, and it becomes part of the cultural attitudes against these drugs. As a result, health care professionals and patients prefer to keep distance from opioids and it is repeated through generations of physicians, influencing the mainstream of health care education.

Even in urban and developed areas like São Paulo, in Hospital Albert Einstein, that provides health care for the wealthiest part of Brazilian population, it is noted by Ana Claudia Quintana Arantes, palliative care doctor that, "pain is commonly understood as something that purifies the character of someone."[1111]. This shows how strong and widespread is the resistance against pain treatment.

The undertreatment of pain in Brazil among indigenous people is an example of cultural attitude against opioids. In 2010, the population of indigenous people in the country was 817,963[1112] inhabitants. Most of them live in extreme poverty and rely on SUS and on their traditional knowledge, to treat health conditions, including pain treatment.

The North of Brazil (see map Fig 1) , a region that corresponds to the states of Amazonas, Pará, Acre, Rondônia, Roraima, Amapá and Tocantins has the lowest consumption of opioids in the country.[1113]Although it is the second least populated region (18.672.591 inhabitants)[1114], it concentrates most Brazilian indigenous peoples. Research about pain conducted in Amazonas and Acre showed that there are cultural inferences in the pain experience and treatment in this ethnic group.[1115] As Elaine Barbosa Moraes note, pain thresholds in indigenous people and in the population with close indigenous heritage is higher than in other ethnic groups due to cultural aspects.[1116]

Elaine Barbosa de Moraes, nurse, carried out two expeditions to remote areas such as Javari Valley in the state of Amazonas, the biggest reserve of isolated indigenous group in the world, and Juruá valley, in the state of Acre, close to the border with Peru. She interviewed indigenous from the groups Matis, Kamanary and Marubo about their pain and reported that:

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[1111] Arantes

[1112] IBGE, *Indígenas* (Rio de Janeiro, 2022) <https://indigenas.ibge.gov.br/graficos-e-tabelas-2.html.> [Acessado em 13 June 2022].

[1113] Brasil, Ministério da Saúde, Sistema de Informações Ambulatoriais do SUS, SIA-SUS,

https://datasus.saude.gov.br/informacoes-de-saude-tabnet/ [Accessed13 June 2022]

[1114] IBGE, *Indígenas.*

[1115] Elaine Barbosa Moraes, 'Perfil e manejo da experiência álgica na perspectiva dos indígenas das etnias Mattis, Kanamary, Marubo e dos Profissionais de Saúde do Vale do Javari', (unpublished master thesis, Faculdade Israelita de Ciências da Saúde, Albert Einstein – FICSAE, São Paulo, 2018)

[1116] Elaine Barbosa Moraes, video call 27 August 2020.

> *After talking to them and observing their rituals we realized that suffocating pain for them means to be strong, a good warrior. It gives a sense of advancement in comparison to their peers.* [1117]

As Elaine Barbosa notes, pain is also strongly related to indigenous rituals:

> *Rituals of growth and improvement of social status involve the capacity to bear pain. Also, punishment for wrong doings is often applied by an entity, that comes to beat someone to correct mistakes or laziness. Indians cannot afford to have pain, they live in extreme poverty and need to produce vegetables to eat, go fishing and hunting and it interferes with the reporting of their pain and its treatment.*[1118]

The most common traditional medicine used in the Amazon region are Ayahuasca,[1119] and 'rapé' "to alleviate pain."[1120] "Rapé is used in a ritual after work to relaxation and pain relief in the body and head. It eliminates physical, mental and spiritual discomfort."[1121]

Ayahuasca is also used in ritual of 'pajelança'(shamanism) in the Amazon region, according to Elaine Barbosa:

> *Other nurses saw one of the rituals to treat an indigenous woman, which had a diagnose of cervical cancer. She was in severe pain and after the ritual with smoke and herbs, nurses from the Brazilian Army, present at the ritual noticed that her pain was relieved.*[1122]

In Brazil, the lack of knowledge of traditional medicines and poor education of health professionals to deal with these patients and the cultural interferences lead to undertreated pain or dangerous interactions between traditional drugs and other drugs provided by the health system or acquired in commercial pharmacies.

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[1117] Moraes

[1118] Moraes

[1119] Ayahuasca – mixture of plants macerated or boiled. It has medicinal properties and produce a psychedelic effect. Used in the Amazon region in spiritual rituals by shamans.

[1120]Moraes

[1121] Barbosa, 'Perfil e manejo da experiência álgica na perspectiva dos indígenas', p. 122.

[1122] Barbosa

## 9. Logistics of opioids in the Amazon region

As the Amazon regions is an immense area with limited transport connections, logistics involving the supply chain of opioids are an additional challenge in the region. This section shows why it is difficult to for patients to reach their medicines.

The state of Amazonas has only one reference center for cancer treatment, the Fundação Centro de Oncologia do Estado do Amazonas (FCECON) in Manaus, state of Amazonas. According to Mirlane Cardoso, anesthesiologist and manager of the palliative care system in the hospital, opioids are available at FCECON, for oncologic pain but her experience shows that having opioids for her patients is rather an exceptional situation, than a standard procedure. She notes that:

> *Outside FCECON pain treatment is restricted. In the end of the 1990's I came to work in this hospital and since then there is an gentlemen's agreement that we would dispense opioids.*[1123]

Access to opioids is difficult also in commercial pharmacies in the Amazon region as Mirlane Cardoso observes:

> *"Patients assisted in private health system have no other alternatives since opioids are not available in commercial pharmacies, because such medicines are not widely used, and pharmacies have no interest in having them."* [1124]

In the Amazon region, the difficulties to prescribe opioids and the bureaucracy involved are added to a lack of interest of having medicines available Mirlane Cardoso explains:

> *The problem with imported medicines is that "they arrive (in Manaus) with the expiration date for consumption for less than 12 months, which is something required at pharmacies. That is why they prefer not to have it. Patients had to contact friends or relatives in Rio de Janeiro, São Paulo or Brasília to send them the medicines.* [1125]

[1123] Mirlane Cardoso, vídeo call, 14 August 2020.

[1124] Cardoso

[1125] Cardoso

Other challenges in Brazil are great distances and internal rules in hospitals. The distance between the city of Atalaia do Norte in Vale do Javari and Manaus, capital of the state of Amazonas, is 1.604 km and the most common mean of transport used is the boat. In addition, even when the medicine was available, access was denied, while Elaine Barbosa worked in home care in Manaus at FCECON and in Rio de Janeiro, assisting palliative care patients in the state of Amazonas.

> *It was hard to have opioids to take with us for home care. The doctor in our service made a special request for the Health Department of the state in Amazonas. Medicines arrived at the hospital, but it was always locked, and there were special authorizations required to open the cupboard, prescriptions and other obstacles to have the medicine in our hands. And if it was weekend, even more difficult. Sometimes the director of the hospital keeps the prescription pads in his possession, and if it was a weekend, we could not get it.*[1126]

Treating patients at home require a good management of their symptoms, and patients in pain need to have access to opioids, if they are assisted by home care services. The Brazilian Health Ministry has a home care program called "Melhor em Casa" (Better at Home) which treats patients of different complexities at home, including palliative care patients. Mariana Borges, General Coordinator of Home Care at the MoH highlights that:

> *According to the Ministry of Health, there are 1500 home care teams working across the country, but the coordination of the program has not a clear figure of the situation so far about the medicines used by the teams, which often assist palliative care patients, because each local health service organizes it on their own way.*[1127]

Patients assisted through "Melhor em Casa/Better at Home", in home care have the following possibilities:

> *There are services that belong to a hospital, so the team take the medicines at the hospital's pharmacy to the visit, others have the yellow prescription pad, for opioids; some use the*

[1126] Moraes

[1127] Mariana Borges, communication via e-mail, 26 August 2020.

> *medication available in emergency rooms. Some cannot prescribe because the access to opioids is not previously agreed about where to get it from, although we insist on this agreement before the team starts to work.*[1128]

Ensuring access to opioids in the Amazon region is a specially challenging. While it is difficult to have them distributed in the region, health care professionals require specific knowledge about traditional drugs and their effects to administer other medicines, when they are available.

As the Brazilian health system is decentralized and drug control policy is restrictive, it is difficult for the MoH to articulate an efficient policy to ensure basic needs such as opioids to treat common symptoms such as pain, in the whole country.

## 10. Conclusion

After analyzing available data on opioid consumption in Brazil it is possible to conclude that although it is considered adequate by the INCB, in comparison to other countries with adequate consumption, there is plenty of room for improvement. Brazilian diplomats are reassured by available data in international reports, and the issue becomes invisible to national authorities in the field of public health and justice, responsible for drug policy.

Data from the Brazilian Ministry of Health show that opioid distribution is unequal, and consumption is concentrated in richer regions where the reference centers for cancer treatment are located, in the southeast. The lowest consumption occurs in the Amazon region. In this region, cultural attitudes on the perception of pain create an additional barrier to the treatment of pain in indigenous peoples. While traditional use of medicines by these populations is not recognized as licit by the international drug control regime, they have very limited access to opioids, which would be the licit alternative.

Low access to opioids in Brazil today is certainly caused by a prohibitionist approach of the international drug control system, endogenous prohibitionism, and additional barriers such as corruption, lack of education of health care professionals are causes

[1128] Borges

of the lack of adequate access to opioids in Brazil. Also, burdensome regulations and bureaucracy pervade the routine of health care professionals at all levels of assistance and were created under strong influence of the INCB to comply with drug control conventions. This shows that the INCB, is responsible for creating some of the barriers faced by countries, but usually fails to recognize that, leaving the responsibility for failures solely for countries. Despite that the INCB has taken significant actions to improve access to controlled medicines, including opioids for pain treatment, since 2010 through e-learning courses and reports devoted especially to this issue.

Interviews showed that these barriers create a tension between access to controlled medicines and the control of illicit markets. While the Brazilian constitution recognizes the right to health, the Brazilian health system has regulations that limit access to opioids, that are justified by international obligations on drug control. A clear expression of this tension occurs in the communities of Rio de Janeiro. Traffickers are the last resort of patients living in poor areas, when formal ways of obtaining controlled medicines that should be ensured by the state fail. Medicines are dispensed precisely from the structure that the international drug control system is trying to eliminate.

As opioids are dispensed mostly by high complexity institutions such as reference centers for cancer treatment, unequal distribution of medicines creates the need for informal networks that navigate through rule complexity to assist patients living in remote areas to obtain prescribed controlled medicines. This is an example on how the complexity of the regimes – international drug control regime and human rights regime – are reflected at the national level.

Improving access to opioids for pain treatment could happen in Brazil by integrating palliative care and family health strategies in primary health care. In a decentralized health system, allowing services at this level to prescribe and dispense opioids for pain treatment would ensure a more equal distribution of these medicines across the country instead of keeping it concentrated in high complexity services in richer areas of the country.

# Conclusion of the dissertation

This dissertation has showed that the international drug control regime contributes to the lack of adequate access to opioids for the treatment of pain, especially in lower and middle-income areas, including Brazil. This was influenced by the US prohibitionist approach in the international drug control regime, particularly since the Cold War. Consequences of the US approach in the international drug control regime, were observed in the case study about Brazil. Based on field research, and conduct of extensive interviews with practitioners in Brazil, it is possible to conclude that part of the Brazilian population suffers unnecessarily due to undertreated pain. This is a risk for 75% of Brazilians relying solely on the public health system - SUS. Despite that, the International Narcotics Control Board considers the country's consumption of opioids "adequate." The research has also highlighted that cultural attitudes regarding pain and endogenous prohibitionism play a role when it comes to the interpretation of the international drug conventions. They worked alongside external factors in the case of Brazil.

Although the main contribution of this dissertation is based on empirical work, an informed based theoretical approach was used, as it was discussed in Chapter 1. The overarching theory used was constructivism to analyze the three levels of tension examined in this work. First, the analysis of tension between national sovereignty and states' international commitments draws on the theory of norm dynamics from Martha Finnemore to show the role of power in norm diffusion. Second, the tension between the international human rights and the international drug control regimes, and tensions within the international drug control regime, between WHO and the INCB.

The theory of regime complexes and regime complexity developed by Karen Alter and Kal Raustiala was used to show the friction between the international drug control regime and human rights regime. The intra-regime complexity was used to discuss the tensions between WHO and the INCB, within the international drug control regime. Regime complexity was also useful to analyze the tension between adequate access of internationally controlled medicines and control of illicit drug markets.

From this perspective, the theory of norm dynamics was used to discuss the changes occurred in the international drug control regime that led to the increased importance

of the issues of access to controlled medicines in drug control fora. The theory of regime complexes and regime complexity were also used to show the friction between the international drug control regime and human rights regime. The idea of intra-regime complexity was useful to discuss tensions between WHO and the INCB, within the international drug control regime.

Chapter 2 showed the analysis of historical antecedents that led to the lack of adequate access to opioids and the demonization of opium in the international drug control regime. This chapter discussed that prohibitionist ideas were brought from the Far East and spread by moral entrepreneurs to the US at the beginning of the 20th century. While the prohibition regime was being developed and becoming more sophisticated, it gradually limited production and use of drugs even with penal sanctions, except for medical use. However, it is important to highlight that, boundaries between medical and non-medical use have never been defined. In fact, it is in these areas of ambiguity that different interpretations of norms spread. Consequently, prescribing and using opium and its derivates such as morphine has always implied risks, and the possibility of punishment, which has been intimidating even for patients using it for medical purposes.

Chapter 3 showed the expansion of prohibitionism since 1945, after the foundation of the UN, the adoption of the Single Convention and the Protocol of its amendment, in 1972. In this chapter, my contribution comes from an original analysis of the official records of the Conference for the adoption of the Single Convention and proposal to use Allyn Taylor's interpretation of Article 14 of the Single Convention, that can contribute to improve access to internationally controlled medicines for pain treatment.

This chapter showed that as states accepted increased controls, the first level of tension emerged between their sovereignty and international commitments under the regime. The US, using the advantage of its prominence as great power, pushed for stricter drug control regulations, justified by the idea that the best way to curb illicit trafficking was to control opium production at the source. The limitation of opium production affected the economy of producing countries and decreased the global production of opium. Its quasi-medical use was abolished as established by the Single Convention 1961. As such, producing countries became interested in US financial aid, as a consequence of becoming part of the American sphere of influence in the Cold War. In doing so, they accepted countries to stop their opium production or limit their production according

to the regime. This shows clearly that US interests, regarding drug control, were not connected with consequences of drug dependence, but with geopolitical interests. International drug control was used as means to reach other goals of American foreign policy. Moreover, at that time the American pharmaceutical industry was developing new medicines that promised to control pain as well as morphine does, without causing dependence. In fact, barbiturates, antidepressants and other psychotropics have gained a relevant market across the world, cause dependence, and never substituted opioids to treat severe pain.

The analysis of the official records of the conference for the adoption of the Single Convention 1961showed that the tension between sovereignty and states' obligations in the international drug control regime appears in discussions on the scope of power of the International Narcotics Control Board (INCB). It was among the most controversial topics during the negotiations, which led to amendments in the Single Convention in 1972 and deserved clarifications on the Commentary on the Protocol. The discussions on the power of embargo show that most producing countries suffered from a prohibitionist and punitive approach. Consequently, it affected states' sovereignty, hampered access to medicines, science and deprived countries of drugs they considered to be of essential therapeutic value. These discussions announced the lack of adequate access to opioids for pain treatment that occurs today in most Member States to the Convention.

With the amendments made in the Single Convention, in 1972, the INCB was granted only the recommendation of embargo, instead of a mandatory embargo to states. It included international NGOs as sources of information to contribute to the INCB's work. The participation of NGOs provided for innovative approaches to the treatment of drug dependance of opioids for pain treatment. In this sense, Article 14 (bis), inserted in 1972, created possibilities for States to receive international assistance to meet obligations under the Conventions, such as ensuring access to medicines. According to Allyn Taylor, when states privilege excessive drug control through law enforcement and neglect adequate access to medicines, they are endangering one of the aims of the Single Convention, which is to ensure the availability of drugs for medical purposes. I validate Taylor's interpretation of Article 14, that the INCB should use the threat to trigger Article 14 to make pressure on States for compliance with

ensuring access to medicines and advance the aims of the Convention in a balanced manner.

Chapter 4 showed the first period of changes in the regime while human rights were gaining an increased importance in drug control fora. The issue of access to controlled medicines emerged in this context, with the HIV-AIDS epidemic in the 1990s. When harm reduction initiatives began to be adopted to curb the spread of the disease among injectable drug users, opioids started to be used on the treatment of drug dependence and this topic became part of the agenda of drug control and human rights fora. This opened space for discussion on the importance of the availability of opioids for pain treatment. This issue achieved increased importance as the Human Rights Council engaged in drug control discussions through its special rapporteurs on the right to health, increasing the tension between the human rights and international drug control regimes. The international drug control and human rights regimes overlap through the right to health forming a regime complex, according to the concept developed by Karen Alter and Kal Raustiala. A detailed examination of UN documents and of the relevant involvement of civil society showed that there was a shift on the international drug control regime, when States adopted non-punitive policies in the period between 2009 and 2013, such as the legalization of cannabis in the US, regulation of cannabis market in Uruguay, in 2013, and the withdrawal and re-access of Bolivia from the Single Convention. Changes gained impulse with strong participation of civil society and are an example of the concept subsidiarity of norms developed by Amitav Acharya. Subsidiary norms developed at the local level affect the legitimacy of institutions created and maintained by powerful actors. Developments in this period led to a different interpretation in one of the principles of international drug control. That to keep 'the health and welfare of mankind' it was necessary to isolate people from drugs, as it is stated in the Single Convention. A new principle that drugs are necessary for pain treatment, treatment of drug dependence and are part of tradition became part of the debate on drug fora. These different interpretations on how to approach drug policies showed a clear lack of consensus within the regime and the tension between the human rights and the international drug control regimes.

Chapter 5 showed that between 2014 and 2019 the issue the availability of opioids for pain treatment gained increased importance between 2014 and 2019 and culminated with the adoption of the Outcome Document at the UNGASS 2016. This document

included an operational paragraph on the improvement of the availability of access to controlled medicines for pain treatment. Prior to that, the issue appeared only in the Preamble of the Single Convention.

Nevertheless, availability of opioids both for harm reduction and for pain treatment became a source of tensions within the international drug control regime, between the INCB and WHO. The issue of access to medicines attracted attention from the INCB, which published special editions of its annual reports devoted to this topic in 2010, 2015 and 2018. While the INCB has been reluctant on the use of opioids in harm reduction practices, WHO recognized it as a scientific based approach to treat drug dependence and pain treatment. Based on UN documents and participant observation of several Commission on Narcotic Drugs (CND) and WHO meetings in this period, it was possible to see that the tensions between these two bodies increased due a range of changes in drug policy. The regime complex formed by the international drug control and the human rights regime, intersected by the right to health, generated a friction between regimes and a situation characterized by Alter and Raustiala of regime complexity. As such, the observation of meetings in the plenary and as a civil society representative showed that, that despite the changes in principles of drug control policies, in 2019, states preferred to navigate through the complexity of the system and produced a weak political document, but the issue of access to medicines continued to be in the agenda of CND, WHO and INCB. While it reflected the tensions between WHO and the INCB, states continued to be parties to the regime, despite increasing differences on drug policy views and approaches.

The first part of the case study about Brazil was covered in Chapters 6. It showed that the international drug control regime had an influence on the development of the drug control framework in Brazil. By examining the development of the Brazilian drug legislation, it is possible to affirm that the Brazilian government complied promptly with obligations established by the international drug control treaties, reflecting them at Brazilian legislation on drugs. This impacted the adequate access of opioids in Brazil today.

Endogenous prohibitionism was expressed in the excessive concern with law enforcement and punitive approach of Brazilian drug legislations ahead of the international conventions. According to the concept of norm localization developed by Amitav Acharya, there was congruence between Brazilian norms on drugs and

international treaties. Based on this congruence, Brazil incorporated international drug conventions in even in more restrictive terms, particularly in dictatorship periods.

As the HIV-AIDS epidemic became a great concern in Brazil in the democratic period, human rights gained increased importance and harm reduction policies were adopted as a federal policy, which opened space for the discussion of access to medicines. As this research has detailed, the tensions between drug control policies and the right to health became evident in four aspects. First, discussions on harm reduction and access to medicines gained traction in Brazil since late 1990's when rights of injectable drug users to receive dependence treatment and access to medicines were discussed. Paradoxically, at that time, a law was passed qualifying drug traffic as a heinous crime. This showed the friction between the justice and the systems, regarding drug policy. Second, the constitution enacted in 1998 recognized the right to health and created a public health system with universal coverage, but regulations on controlled medicines were restrictive. Third, my field work interviews with key informants involved on the process of elaborating regulations on controlled medicines showed that they were drafted under strong pressure of the INCB for restrictive regulations on internationally controlled medicines. They included burdensome procedures for controlled medicines' prescriptions, particularly opioids. This provoked fear of prescribing among medical professionals and fear of drug dependence in patients. Fourth, the education of health care professionals in Brazil, since 1970's followed the American model of schools of medicine, more focused on technical advancements than on symptom's management. This was due to strong bilateral US-Brazil relations in the Cold War when the US was running the war on drugs and strongly influenced international drug policy. All these aspects show the influence of the international drug control regime and US influence on the views about drugs in Brazil that contributed to the low consumption of opioids for pain treatment in the country today.

In Chapter 7, available data showed that opioids consumption in Brazil today is low, although it is still considered "adequate" by the INCB. This chapter includes field work interviews with key informants in the Ministry of Health, the national regulatory agency, oncologists, geriatricians, palliative care specialists, family doctors working in primary health care, psychologists, nurses, and community leaders covered all regions of Brazil. Some of them work in remote areas and territories dominated by drug traffickers and militias in Rio de Janeiro or in indigenous territories affected by

action of drug traffic in the Amazon region. Interviews also showed that patients particularly affected are those living far from reference centers of cancer treatment and other high complexity institutions.

Data collected on interviews resulted in original research showing that strictly prohibitionist approach on drug legislations and regulations on access to medicines is fostering drug traffic in areas not reached by the State. According to physicians and health care professionals working in these areas, providing palliative care, patients rely on help from drug traffickers to obtain medicines in a timely manner to treat their pain, since access through the health system is slow and complicated. Patients in need of controlled medicines have drug traffickers as their last resource to treat pain. Moreover, drug traffic is filling a gap of the health system giving access to medicines to patients making perfectly legitimate use of medicines, prescribed by well-educated physicians working in these areas. These are examples that show that the right to health is denied by the state and the solution comes precisely from illicit market that the drug control regime is trying to eliminate.

This research showed a new aspect regarding cultural attitude as a barrier for access to opioids in Brazil. The cultural attitude of indigenous populations regarding pain is an aspect not connected to international influence but plays a role in the low consumption of opioids in the northern region of Brazil. This work identified that there are different perceptions of pain thresholds in indigenous populations and the traditional use of substances, other than opioids to treat pain. It occurs in this region not only in indigenous peoples living in remote areas, but also in people living in urban areas influenced by indigenous beliefs and culture such as Manaus, capital of the state of Amazonas.

After examining antecedents and the current situation of opioids in Brazil it can be concluded that an improvement in access to controlled medicines could occur with improvements in the education of health care professionals on pain management and palliative care, working at all levels health system. Future research would be necessary on how implement the opioid use for pain treatment in primary health care and

integrating palliative care, and family health strategies in this level of service assisting patients adequately in all regions of Brazil.

Management of pain in primary care services would permit to treat such a basic symptom at this level, which usually occurs in the area where the patient lives, leading to a more equal distribution of medicines. The real demand for treatment could be communicated to health management of each state. As such, procurement of opioids would be based on the epidemiology of diseases and the treatment of symptoms at home would lead to a rational occupation of beds in hospitals.

# Appendices

## Appendix 1:

## Preambles - Normative claim about the nature of the international regime

| International Drug Conventions | Title | Purpose of treaties |
|---|---|---|
| 1909 | Shanghai Opium Commission | - |
| 1912 | Suppression of Abuse of Opium and Other Drugs, 1912 (The Hague Convention) | **being desirous** to take one step further in the way marked out by the International Commission at Shanghai in 1909; **resolved to pursue** progressive suppression of the **abuse** of opium, morphine, cocaine as well as drugs prepared or derived from these substances giving rise or which may give rise to analogous abuses; **taking into consideration** the necessity and the mutual profit of an international understanding on this point; **being convinced** that they will meet in this humanitarian effort the unanimous adhesion of all the nations interested, **have resolved** to conclude a Convention for this purpose and have appoint- ed as their Plenipotentiaries, to wit; |
| 1925 | International Opium Convention<br><br>Geneva Convention | Taking note of the fact that the application of the provisions of the Hague Convention on January 33rd, 19x2, by the Contracting Parties has produced results of great value, but that the **contraband trade** in and abuse of the substances to which the Convention applies still continue on a great scale ;<br><br>Convinced that the contraband trade in and **abuse** of these substances cannot be effectual]y suppressed except by |

| | | |
|---|---|---|
| | | bringing about a more effective limitation of the production or manufacture of the substances, and by exercising a closer control and supervision of the international trade, than are provided for in the said Convention ;<br><br>Desirous therefore of taking further measures to carry out the objects aimed at by the said Convention and to complete and strengthen its provisions ;<br><br>Realising that such limitation and control require the dose co-operation oi all the Contracting Parties;<br><br>Confident that this humanitarian effort will meet with the unanimous adhesion of the nations concerned :<br><br>follows :<br><br>Have decided to conclude a Convention for this purpose,<br>The High Contracting Parties have accordingly appointed as their Plenipotentiaries |
| 1931 | Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs | - |
| 1936 | Convention of 1936 for the Suppression of Illicit Traffic in Dangerous Drugs | Having resolved, on the one hand, to strengthen the measures intended to **penalise** offences contrary to the provisions of the International Opium Convention signed at The Hague on January 23rd, 1912, the Geneva Convention of February 19th, 1925, and the Convention for limiting the Manufacture and regulating the Distribution of Narcotic Drugs signed at Geneva on July 13th, 1931, and, on the other hand, to combat by the methods most effective in the present circumstances the illicit traffic in the drugs and substances covered by the above Conventions, |

| | | |
|---|---|---|
| 1961 | Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961 | *Preamble*<br><br>*The Parties,*<br><br>*Concerned* with the health and welfare of mankind,<br><br>*Recognizing* that the medical use of narcotic drugs continues to be indispensable for the **relief of pain** and suffering and that adequate provision must be made to ensure the **availability** of narcotic drugs for such purposes,<br><br>*Recognizing* that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,<br><br>Conscious of their duty to prevent and combat this evil, Considering that effective measures against abuse of narcotic drugs require<br><br>co-ordinated and universal action,<br><br>*Understanding* that such universal action calls for international co-operation guided by the same principles and aimed at common objectives,<br><br>*Acknowledging* the competence of the United Nations in the field of nar- cotics control and desirous that the international organs concerned should be within the framework of that Organization,<br><br>*Desiring* to conclude a generally acceptable international convention replacing existing treaties on narcotic drugs, limiting such drugs to medical and scientific use, and providing for continuous international co-operation and control for the achievement of such aims and objectives, |

## Appendix 2:

## How states' sovereignty changed throughout the development of the international drug treaties

| International Drug Conventions | Title | Sovereignty of states affected by: |
|---|---|---|
| 1909 | **Shanghai**<br>**Opium Commission** | opium trade only for medical purposes |
| 1912 | **Suppression of Abuse of Opium and Other Drugs, 1912**<br>**(The Hague Convention)** | system of licencing,<br>record keeping<br>and international reporting on the production<br>lack of administrative structure to apply these measures with provisions on how these principles should be put into practice.[1129]<br>restrictions on opium, coca, and Indian hemp |
| 1925 | **International**<br>**Opium Convention or**<br>**Geneva Convention** | fixed estimates of drugs for medical purposes both for parties and non-parties of the Convention<br>regulated distribution through the creation of PCOB international control body, which had the power to determine, the quantity of drugs manufactured each year, based on information of imports and exports provided by countries. |

[1129] Bewley-Taylor, The United States and International Drug Control, p. 24

| | | |
|---|---|---|
| | | Obligations that earlier were domestic became international since 1925. |
| 1931 | **Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs** | system of schedules<br>kept system of estimates<br>limitation of manufacture<br>power of embargo for PCOB |
| 1936 | **Convention of 1936 for the Suppression of Illicit Traffic in Dangerous Drugs** | penal sanctions,<br>criminalized cultivation, production, manufacture and distribution – related use of opium, coca and its derivatives for non-medical and scientific purposes.[1130] |
| 1953 | **The Opium Protocol 1953 (never entered into force)** | power of embargo to PCOB<br>inspections<br>opium **use** became restricted only to medical and scientific purposes<br>obligation to send estimates |
| 1961 | **Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961** | recommendation of embargo<br>punitive actions even for states not party of the Protocol<br>systems of schedules<br>system of estimates of amounts of opium planted, harvested, consumed domestically exported and stockpiled.<br>penal provisions criminalizing cultivation, production, manufacture, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale, delivery, brokerage, |

[1130] David Bewley Taylor and Martin Jelsma (2012) 'Regime Change':Re-visiting the 1961 Single Convention on Narcotic Drugs, *International Journal of Drug Policy 23*, p.74.

| | | |
|---|---|---|
| | | dispatch, dispatch in transit, transport, importation, exportation.<br><br>Opium production restricted only to seven countries.<br><br>232 substances scheduled, from which 215 are in Schedule I[1131] |

[1131] UNODC, The International Drug Control Conventions, Schedules of the Single Convention on Narcotic Drugs of 1961 as Amended by the 1972 Protocol as of 27 May 2022.

https://documents-dds-ny.un.org/doc/UNDOC/GEN/V22/026/86/PDF/V2202686.pdf?OpenElement [Accessed 21 June 2022], pp. 3-7. Schedule I – includes for instance morphine and methadone (semi-synthetic).

**Appendix 3:**

**Amendments of the Single Convention 1961, made in 1972, with implications for the availability of medical opioids**

These amendments opened the possibility to shape further discussions on a health and human rights-based approach, as it will be analyzed in the next chapters. The most significant amendment, regarding the role of the INCB that have implications for the availability of medical opioids were:

1) In Article 9, Compositions and Functions by the Board, paragraph 4, on the aims of the Convention were included, which are ensuring the availability of medicines while preventing illicit cultivation, production, manufacturing and illicit trafficking; and paragraph 5, on the importance of the dialogue between the Board and governments. This amendment has implications to Article 14, 1a) on the inclusion of international NGOs in consultative status with ECOSOC as sources of information that can contribute with the Board's work, as well as ECOSOC, IOs, UN organs and specialized agencies.

2) In Article 14: The recommendation for an embargo is provided in Article 14, paragraph 2. As such, opium producing countries are subject to have their import or export of drugs cut, in case of non-compliance with the Convention, causing a particular threat to the economy of producing countries, when the Single Convention was negotiated.

3) Article 14 (bis) was inserted by the Amending Protocol, which creates the opportunities for countries to receive international assistance in order to comply with obligations, including those on article 38, on the prevention, treatment, rehabilitation and social reintegration of drug abusers. The recommendation for an embargo is provided in Article 14, paragraph 2. As such, opium producing countries are subject to have their import or export of drugs cut, in case of non-compliance with the Convention, causing a particular threat to the economy of producing countries, when the Single Convention was negotiated.

4) It changed Article 36 one Penal provisions, paragraph 1 b), expressing, that rehabilitation was seen as an alternative to conviction or punishment for drug offence, according to measures of Article 38, [1132] which were:

5) The provision of prevention of drug abuse, and treatment, education, after care, rehabilitation, and social reintegration of drug abusers. [1133], It became the "passage" form, also measures taken by states, regarding human rights and health.

[1132] *Protocol Amending the Single Convention*, Article 14, Amendments to Article 36.

[1133] *Protocol Amending the Single Convention*, Article 15, Amendments to Article 38.

**Appendix 4:**

**List of events – Participant observation**

All meetings in Vienna took place at the United Nations, Vienna International Center (VIC)

**Commission on Narcotic Drugs**

1. CND Commission on Narcotic Drugs 2014, Vienna, 13-21 March
2. CND Commission on Narcotic Drugs 2015, Vienna, 9-17 March
3. CND Commission on Narcotic Drugs 2016, Vienna, 14-22 March
4. CND Commission on Narcotic Drugs 2017, Vienna, 13-17 March
5. CND Commission on Narcotic Drugs 2018, Vienna, 12-16 March
6. CND Commission on Narcotic Drugs 2018, Vienna, Intersessional, 26 September
7. CND Commission on Narcotic Drugs 2018, Reconvened Session, 5-8 December
8. CND Commission on Narcotic Drugs 2019, Vienna, 14-22 March
9. CND Commission on Narcotic Drugs 2019, Vienna, Intersessional, 16-18 October -presentation on the Thematic Session: "Synthetic Opioids and the non-medical use of prescription drugs pose increasing risks to public health and safety as well as scientific legal and regulatory challenges, including with regards to the scheduling substances"
10. CND Commission on Narcotic Drugs 2020, Vienna, 9-17 March
11. CND Commission on Narcotic Drugs 2021, on-line, Vienna, 12-16 April
12. Intern at UNODC, Vienna, at the Prevention, Treatment and Rehabilitation Section, doing research on access to opioids for the Global program on access to controlled medicines for medical purposes, while preventing diversion and abuse (GLOK 67) between, September 2016 – March 2017
13. Member of the Civil Society Task Force of the Vienna NGO Committee (VNGOC) 2018-2019 on the preparation for the 2019 High Level Meeting
14. Vienna NGO Committee (VNGOC), elected Deputy Treasurer in 2021

**Other Meetings:**

1. UNGASS- United Nation General Assembly Special Session on the World Drug Problem, New York, 2016
2. Expert Group Meeting on Access to Controlled Medicines. Establishing technical Guidance on increasing access to and Availability of Controlled Drugs for Medical Purposes: Key areas of focus, Vienna, 19-21 September 2017
3. Geneva-Vienna Dialogue on the World Drug Problem, Geneva, Palais de Nations, 11 May 2018
4. Preparation Meeting on views concerning the 37th Human Rights Council- Permanent Mission of Brazil in Geneva, 16 February 2018
5. Expert Group Meeting on the International Challenge posed by the non-medical use of synthetic opioids, Vienna, 3-4 December 2018
6. Meeting WHO-ECDD Informal Meeting with WHO colleagues, Vienna, 22 March 2019
7. Human Rights Council 37th Session, 2018, Geneva, 14 March, Geneva, Palais des Nations
8. World Health Assembly, Executive Board, 26 January 2019
9. VII ABRAMD Conference, Associação Brasileira Multidisciplinar de Estudos sobre Drogas, Curitiba, Brazil, 5-June 2019

# Glossary

**Harm reduction** - Harm reduction refers to policies, programmes and practices that aim primarily to reduce the adverse, health, social and economic consequences of the use of illegal psychoactive drugs without necessarily reducing drug consumption.

**Opiates** – Natural opioids produced from *Papaver somniferum*, commonly known as opium poppy.

**Opioids** – Class of medicines that includes synthetic and natural opioids.

**Primary Health Care** -According to WHO, Primary Health Care is defines as a: whole-of-society approach to health that aims at ensuring the highest possible level of health and well-being and their equitable distribution by focusing on people's needs and as early as possible along the continuum from health promotion and disease prevention to treatment, rehabilitation and palliative care, and as close as feasible to people's everyday environment

**Schedule system-** The system of schedules classifies substances in the drug control conventions, according to the principle of similarity with morphine, cocaine and cannabis. In the Single Convention substances are listed in four groups, according to their propensity of causing addiction and therapeutic use.

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