BREAKING THE CYCLE OF PREVENTABLE SUFFERING: FULFILLING THE PRINCIPLE OF BALANCE

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I. INTRODUCTION

Therapeutic opioids are essential for anesthesia and palliative care and have proven highly effective in reducing the harms associated with use of illicit drugs.[1]

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Yet, access to therapeutic opioids remains strikingly inadequate in much of the world, resulting in preventable suffering on a vast scale.[2] The World Health Organization (WHO) estimates that 80% of the world's people have no or insufficient access to medically indicated treatment for moderate to severe pain, with substantial under-treatment reported in more than 150 countries.[3] The number of persons suffering severe untreated pain from cancer and HIV/AIDS alone surpasses six million.[4]

Few burdens are as fundamentally crippling and so elegantly reflect global health disparities as untreated pain and addiction.[5] The major industrial countries

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Consortium, which also includes the Pain and Policy Study Group at the University of Wisconsin and the AIDS Project Management Group of Sydney, Australia. The United Kingdom's Department for International Development partially supported work on this article. The opinions expressed in this article are the authors' alone.

1. *See* William Breitbart, *Pain*, *in* A CLINICAL GUIDE TO SUPPORTIVE & PALLIATIVE CARE FOR HIV/AIDS 85, 104, 106 (Joseph F. O'Neill et al. eds., 2003) (finding that morphine and similar opioid medications are the "mainstay" in treatment of moderate-to-severe intensity pain in cancer and HIV patients). Analgesia is also a critical component of post-operative care for surgical patients and those who have suffered serious injury. Likewise, long-term pharmacotherapy using methadone or buprenorphine (referred to here as Medication Assisted Treatment or MAT) has been proven to be an effective treatment for opioid dependence that significantly reduces the risks of HIV/AIDS and other associated harms. *See infra* note 12.

2. World Health Org., *World Health Organization Briefing Note — March 2007*, 1 (2007), *available at* http://www.who.int/medicines/areas/quality_safety/access_to_controlled_medications_brnote_english.pdf. Almost 5 million people suffer from untreated moderate to severe pain caused by cancer, as do 1.4 million people with HIV, and "at least 600 million [people] will experience negative health impacts during their lifetime as a result of not being able to obtain medicines controlled under the international drug control treaties." *Id.* at 1-2.

3. *Id.* at 1.

4. World Health Org., *World Health Organization Briefing Note — February 2009*, 1 (2009), *available at* http://www.who.int/medicines/areas/quality_safety/ACMP_BrNoteGenrl_EN_Feb09.pdf [hereinafter *Briefing Note – February 2009*]; Marie-Josephine Seya et al., *A First Comparison Between the Consumption of and the Need for Opioid Analgesics at Country, Regional, and Global Levels*, 25 J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY 6 (2011). Such pain leads not only to a lower quality of life but also to decreased functional performance and lack of productivity. William Breitbart et al., *The Undertreatment of Pain in Ambulatory AIDS Patients*, 65 PAIN 243, 246, 248 (1996).

5. *See* Laura Thomas, *Access to Pain Treatment and Palliative Care: A Human Rights Analysis*, 24 TEMP. INT'L & COMP. L.J. 365, 370-73 (2010) (recognizing the lack of adequate pain medications in low and middle-income countries as a result, in part, of international drug control). The widespread existence of avoidable pain is a human rights issue of the first order. *See* Frank Brennan et al., *Pain Management: A Fundamental Human Right*, 105 ANESTHESIA & ANALGESIA 205, 205 (2007) (surveying "worldwide medical, ethical, and legal trends and initiatives related to the concept of pain management as a human right"). Disparate access to therapeutic opioids is especially troubling because pain results from diseases whose incidence is strongly associated with low socio-economic status. Incidence of HIV/AIDS is much higher in poorer parts of the globe; the same is true for cancer. Panos Kanavos, *The Burden of Cancer in the Developing World*, 17 ANNALS OF ONCOLOGY 15, 15 (Supp. 2006). Patients with advanced cancer and AIDS suffer from pain which worsens as the disease progresses. M.H.J. van den Beuken-van Everdingen et al., *Prevalence of Pain in Patients with Cancer: A Systematic Review of the Past 40 Years*, 18 ANNALS OF ONCOLOGY 1437, 1441 (2007); *see Briefing Note –*

— the United States, Canada, Australia, New Zealand, Europe and Japan — consume nearly 92% of the world's morphine.[6] Meanwhile, poor and middle-income countries, where over 80% of the world's population lives, consume only about 8%.[7] Per-capita consumption of morphine in the United States, for example, is more than 81,000 times that of Mozambique.[8]

The value of therapeutic opioid medications to individual patients and to public health is widely recognized by the international community.[9] The three opioid medications most commonly used in pain care and Medication Assisted Treatment (MAT)[10] are designated Essential Medicines by the WHO, indicating

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February 2009, *supra* note 4, at 1.

6. INT'L NARCOTICS CONTROL BD., NARCOTIC DRUGS: ESTIMATED WORLD REQUIREMENTS FOR 2010, 80, U.N. DOC. E/INCB/2009/2 (2009).

7. *Id.* The United States, with 4.7% of the world's population, consumes 54.6% of the world's morphine. *Id.* Most morphine is converted into other opioids and therefore morphine consumption is a good proxy for overall opioid consumption. *Id.*

8. UNIV. OF WIS. PAIN & POL'Y STUDIES GRP., AVAILABILITY OF MORPHINE AND PETHIDINE IN THE WORLD AND AFRICA 9 (2006), *available at* http://www.painpolicy.wisc.edu/publicat/monograp/africa06.pdf (showing that Mozambique consumes 0.0006 mg per person while the United States consumes 48.8145 mg per person).

9. *See, e.g.,* WORLD HEALTH ORG., ACHIEVING BALANCE IN NATIONAL OPIOIDS CONTROL POLICY 3 (2000), *available at* http://whqlibdoc.who.int/hq/2000/WHO_EDM_QSM_2000.4.pdf [hereinafter ACHIEVING BALANCE] (recognizing the prevalence of cancer pain and the problem of lack of availability of pain medication). *See also* text accompanying notes 10-14.

10. Medication assisted treatment is the provision of long-acting opioids to individuals dependent on short-acting opioids to satisfy cravings and reduce the harms associated with illicit drug use. *See* James R. Roberts, *Miscellaneous Methadone Facts*, EMERGENCY MED. NEWS, Mar. 2009, at 9 (describing the biological response to opioid addiction and how long-acting opioids adjust the biological abnormalities caused by opioid addiction). The most common opioid used in MAT is methadone. Martin C. Donoghoe, *Injecting Drug Use, Harm Reduction and HIV/AIDS*, *in* HIV/AIDS IN EUROPE 43, 49 (Srdan Matic et al. eds., 2006), *available at* http://www.who.int/hiv/pub/idu/hiv_europe.pdf. Methadone is a synthetic opioid listed in Schedule I of the Single Convention. Wien Limburg, *Natural History, Treatment and Prevention of Hepatitis C in Injecting Drug Users: An Overview* 21, 31 (Johannes Jager et al. eds., 2004) (noting that methadone is a synthetic opioid); Single Convention on Narcotic Drugs, 1971, as amended by the Protocol amending the Single Convention on Narcotics Drugs, 1961, Schedules (Aug. 8, 1975), 18 U.S.T. 1407, 976 U.N.T.S. 105 [hereinafter Single Convention] (listing methadone in Schedule I). It is prescribed to relieve cravings and reduce injection of illicit opioids like heroin. *See* Roberts, *supra*, at 10 (explaining the rationale for using methadone maintenance to treat opioid addiction). Methadone has been used for over forty years in the treatment of opioid dependence and has been extensively studied. Michael Gossop et al., *Patterns of Improvement After Methadone Treatment: 1 Year Follow-up Results from the National Treatment Outcome Research Study (NTORS)*, 60 DRUG & ALCOHOL DEPENDENCE 275, 275-76 (2000). Methadone treatment at appropriate doses is associated with improvements in physical health, social health, and retention in substance abuse treatment. *See id.* at 281-85. Patients receiving methadone have consistently been shown to reduce use of illicit drugs, and have reduced opioid overdose deaths, needle sharing, and HIV transmission. *See* David S. Metzger et al., *Drug Abuse Treatment as AIDS Prevention*, 113 PUB. HEALTH REP. 97, 102-04 (Supp. 1 1998); *see generally* Harold Pollack & Robert Heimer, *The Impact and Cost-Effectiveness of Methadone Maintenance Treatment in Preventing HIV and Hepatitis C*, *in* HEPATITIS C AND INJECTING DRUG USE: IMPACT, COSTS AND POLICY OPTIONS 345, 360-62 (Johannes Jager et al.

that they "should be available at all times in adequate amounts and in the appropriate dosage forms."[11] The WHO Expert Committee on Cancer Pain Relief has declared that "freedom from pain should be seen as a right . . . and access to pain therapy as a measure of respect for this right."[12] The United Nations Office of Drugs and Crime (UNODC), the WHO, and the Joint United Nations Program on HIV/AIDS advise that "[s]ubstitution maintenance therapy is a critical component of community-based approaches in the management of opioid dependence and the prevention of HIV infection among injecting drug users. . . ."[13] Major donors actively support access to therapeutic opioids and a network of NGOs has emerged to advocate for medically indicated access to opioid treatment for pain and dependency.[14]

Law is centrally important to the global problem of inadequate access to therapeutic opioids. Many of the impediments to access are found in overly restrictive law, policy and regulation at the national level. Although countries are required by international conventions to place certain controls on opioids, many national regulatory regimes far exceed the requirements of international law.[15]

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eds., 2004) (finding methadone maintenance treatment to be a cost-effective means of HIV prevention and harm reduction). In addition, patients receiving methadone report less criminal activity, improved family ties, a reduction in number of sexual partners, fewer attempts at suicide and increased adherence to HIV medication. *See* Gregory S. Zaric, *Modeling the Costs and Effects of Maintenance Treatment for Opiate Addiction*, *in* OPERATIONS RESEARCH AND HEALTH CARE: A HANDBOOK OF METHODS AND APPLICATIONS 333 (Margaret L. Brandeau et al. eds., 2005). In July 2005, the World Health Organization added methadone, the most widely used MAT drug to its Model List of Essential Medicines, where it joins morphine, the mainstay opioid analgesic and codeine, which is widely used to treat pain, coughing and diarrhea. *See* WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 25 (2007), *available at* http://www.who.int/medicines/publications/08_ENGLISH_indexFINAL_EML15.pdf.

11. WORLD HEALTH ORG., THE USE OF ESSENTIAL DRUGS 2 (1998), *available at* http://whqlibdoc.who.int/trs/WHO_TRS_882.pdf; WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 1-2, 23, 28 (2009), *available at* http://www.who.int/selection_medicines/committees/expert/17/sixteenth_adult_list_en.pdf (listing codeine, morphine, and methadone as essential medicines).

12. WORLD HEALTH ORG., CANCER PAIN RELIEF AND PALLIATIVE CARE 10-11 (1990), *available at* http://whqlibdoc.who.int/trs/WHO_TRS_804.pdf.

13. WORLD HEALTH ORG., SUBSTITUTION MAINTENANCE THERAPY IN THE MANAGEMENT OF OPIOID DEPENDENCE AND HIV/AIDS PREVENTION 2 (2004), *available at* http://whqlibdoc.who.int/unaids/2004/9241591153_eng.pdf.

14. *See* Scott Burris & Corey S. Davis, *A Blueprint for Reforming Access to Therapeutic Opioid Medications*, TEMP. UNIV. CTR. FOR HEALTH L. POL'Y & PRACTICE (2008), *available at* http://www.painpolicy.wisc.edu/internat/DCAM/Burris_Blueprint_for_Reform.pdf. [hereinafter *Blueprint*] (describing the efforts of NGOs advocating for balanced access to therapeutic opioids).

15. We would be remiss not to note that there is a socio-cultural component to how the international drug control system developed that is, to say the least, rich. While the explicit language of pertinent treaty law is oriented on paper towards promotion of public health, the history of the development of the international drug control system is characterized by a pointed ideological valence concerning controlled substances. The same forces that animated the creation of the system have continued to influence the way that system is understood and implemented. Because of this, work to change the international forces that influence national drug law is a natural complement to the country-by-country reform strategy. *See generally* David R. Bewley-

Where unbalanced laws are in place, the system can perpetuate a negative feedback loop: poor access limits exposure to opioids for prescribers and patients thereby sustaining inaccurate perceptions about the feasibility and safety of opioid treatment; this in turn keeps demand, and therefore estimates of need, at an artificially low level. That low level then becomes the ceiling for importing and producing opioids, further limiting access and so on in a self-sustaining cycle of suffering.[16]

Despite broad recognition of the problem and sustained action by dedicated reformers, large-scale improvements in access have proven elusive.[17] Where progress has been achieved, it has come almost exclusively through targeted, intensive, country-specific interventions. Reform efforts often focus on removing one or more key impediments to access such as national laws banning specific formulations of medically-indicated opioid medicines (e.g., hydrocodone in Romania)[18] or limiting prescription powers to a small number of professionals (e.g., physicians in Uganda).[19] Elsewhere in this issue, Chiu and colleagues

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Taylor, *The American Crusade: The Internationalization of Drug Prohibition*, 11 ADDICTION RESEARCH AND THEORY 71, 73 (2003), *available at* http://informahealthcare.com/doi/abs/10.1080/1606635021000021377 (noting that the progenitor to the Single Convention in the United States, the Harrison Act, was once described by Norman Clark as "a strange triumph of pseudoscience, racism, and mild hysteria on the part of a few people and indifference on the part of most others"); H. Richard Friman, Narcodiplomacy: Exporting the War on Drugs (Cornell Univ. Press 1996) (describing how the U.S. has shaped drug control laws in Germany and Japan from 1900 through the 1990s); University of Wisconsin Pain & Policy Studies Group, *Do International Model Drug Control Laws Provide for Drug Availability?*, 23 J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY 145, 148 (2009), *available at* http://www.painpolicy.wisc.edu/internat/model_law_eval.pdf.

16. For information about the role of international law in the continued lack of access to therapeutic opioids, *see generally* Allyn L. Taylor, *Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs*, 35 J.L. MED. & ETHICS 556 (2007); Willem Scholten et al., *The World Health Organization Paves the Way for Action to Free People from the Shackles of Pain*, 105 ANASTHESIA & ANALGESIA 1 (2007); Cecilia Sepúlveda et al., *Palliative Care: The World Health Organization's Global Perspective*, 24 J. PAIN AND SYMPTOM MGMT. 91 (2002); David E. Joranson et al., *Improving Access to Opioid Analgesics for Palliative Care in India*, 24 J. PAIN AND SYMPTOM MGMT. 152 (2002). Many other impediments such as lack of training, lack of funding, fear, and stigma also frustrate access, but as we detail below these constraints are very often a result of excessively restrictive laws and regulations. *See generally* Thomas Lynch et al., *Barriers to the Development of Palliative Care in the Countries of Central and Eastern Europe and the Commonwealth of Independent States*, 37 J. PAIN AND SYMPTOM MGMT. 305, 305-06, 309-10 (2009) (describing barriers to opioid availability).

17. *See id.* at 2 ("In spite of all the reasons that access to therapeutic opioid medications should be routine everywhere, there remains a huge unmet need and a striking global inequality in access.").

18. *See* Jessica Chiu, Evan Anderson & Sarah Happy, *Romania: A Case Study of Policy Reform to Improve Access to Opioid Medicines*, 24 TEMP. INT'L & COMP. L.J. 489 (2010) (discussing reform in Romania).

19. Evan D. Anderson et al., *Closing the Gap: Case Studies of Opioid Access Reform in China, India, Romania & Vietnam* , TEMP. UNIV. LEGAL STUD. RES. PAPER NO. 2009-25 (2009), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1356769 (describing case

propose a systematic model for increasing the breadth and scale of these interventions.[20] This paper supports that model by illustrating the considerable latitude that countries have to adopt national laws that fulfill the requirements of international drug law.

We pursue this goal through two avenues. First, we provide a thorough explanation of the requirements set out by international conventions – regarding both access promotion and diversion prevention – with which countries must comply in regulating opioids. Our description of these requirements – the first of its kind in the literature – is organized along the control points in the opioid supply chain. Our second aim is convey the breadth of flexibility that countries have in formulating locally appropriate regulation through the use of examples that compare how different countries comply with requirements at each control point. This suggests, for example, that controls that work well in a country with a well-developed pharmaceutical supply chain would prove disastrous to access in a country with fewer resources and a more fragmented pharmaceutical delivery system. There are indeed varieties of permissible control.

We begin, in Part II, by describing the binding multilateral agreements that form the backbone of the international drug control system and the major institutional bodies responsible for enforcing them. In Part III, we present the regulatory requirements imposed by the drug control conventions. While others have done so in broad terms,[21] our contribution is a granular explanation of the steps the conventions require countries to take in the regulation of controlled substances organized along the supply chain. By illustrating possible applications at the national level, we emphasize that the controlling international conventions permit a variety of regulatory schemes. Examples are provided to illustrate how countries can ensure access to therapeutic opioids by deploying mechanisms and modalities of control tailored to their unique needs and resources. In Part IV, we note some of the ways that current laws and policies overly restrict access and discuss how these impediments perpetuate a negative cycle that makes access increasingly difficult over time. We also discuss why legal change is nearly always a necessary, but seldom a sufficient, component of successful reforms.

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studies of instances in which international organizations, national aid agencies and foundations have successfully assisted reform through a variety of mechanisms); Diederik Lohman et al., *Access to Pain Treatment as a Human Right*, 8 BMC MEDICINE 8 (2010), *available at* http://www.biomedcentral.com/content/pdf/1741-7015-8-8.pdf (surveying changes in Uganda and Vietnam). Since lack of knowledge among providers is often a side effect of overly restrictive laws, legal change often must be followed by intensive training efforts. *See* Jack G.M. Jagwe, *The Introduction of Palliative Care in Uganda,* 5 J. PALLIATIVE MED. 159 (2002); *Blueprint, supra* note 14, at 4, 6 (describing a system of international reform for opioid policy based on assessments of local needs and resources, partnership between local reform advocates and external groups with specialized technical expertise, and emphasis on sustainable change).

20. *See* Chiu et al., *supra* note 18, at 401-414 (explaining the Romanian experience with reforming laws and rules that regulate access to opioids).

21. *See, e.g.* Allyn L. Taylor, *supra* note 16; Cecilia Sepúlveda et al., *supra* note 16.

II. BACKGROUND AND FIRST PRINCIPLES OF INTERNATIONAL DRUG CONTROL

Although its roots go back to the early 1900s, most of the international system for regulating opioids was set in place a half century ago. This Part provides a brief explanation of the genesis and current state of the international legal framework and the institutional bodies that operate within it.

A. Brief Background and Current Controlling Law

Over the last century, a substantial body of international law has developed governing the regulation of controlled substances.[22] The first significant bilateral drug control efforts of the modern era can be traced to the Ten Year Agreement of 1907, a deal struck between China and India in which Britain agreed to reduce Indian opium exports by ten percent annually and China agreed to eliminate domestic production at the same rate.[23] This agreement was observed by both parties until a revolution broke out in China in 1911, at which point the Chinese government lost the ability to control internal opium production.[24]

While modern drug control efforts continue to utilize such bilateral and regional agreements, the international drug control system is now governed by comprehensive multilateral conventions enacted under the auspices of the United Nations.[25] The first substantial step towards the current system, originally termed the Hague Opium Convention but now referred to as the International Opium

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22. *See* I. Bayer & H. Ghodse, *Evolution of International Drug Control, 1945-1995*, 51 BULL. ON NARCOTICS 1, 1 (1999), *available at* http://www.unodc.org/pdf/bulletin_1999-01-01_1.pdf (detailing the history of drug control and identifying the international response to the evolving drug trade between 1945 and 1995). International concern about the negative effects associated with misuse of narcotic substances began to coalesce into drug control treaties in the early part of the 20th century with the development of agreements restricting the trade of opium. *See* WILLIAM B. MCALLISTER, DRUG DIPLOMACY IN THE TWENTIETH CENTURY: AN INTERNATIONAL HISTORY 16, 20 (2000) (noting that such efforts were often driven as much by financial and political considerations as by public health concerns); DAVID R. BEWLEY-TAYLOR, UNITED STATES AND INTERNATIONAL DRUG CONTROL, 1909-1997 (1999) (documenting evolution of drug policy with focus on US role).

23. *Agreement Between the United Kingdom and China Relating to Opium*, *China-U.K.*, *May 8, 1911*, 5 AM. J. INT'L L. 238 (Supp.: Official Documents, 1911).

24. MCALLISTER, *supra* note 22, at 24-25 (describing how the anti-opium crusade crumbled in China after the Manchu dynasty succumbed to revolution in 1911 and competing "[p]rofit hungry warlords encouraged, even compelled, opium production.").

25. *See, e.g.*, Office of Nat'l Drug Control Policy, *International Drug Control Cooperation*, *in* 1999 NATIONAL DRUG CONTROL STRATEGY (1999), *available at* http://www.ncjrs.gov/ondcppubs/publications/policy/99ndcs/iv-h.html (describing the *1996 Hemispheric Anti-Drug Strategy*, in which thirty-four countries agreed to broaden drug prevention efforts; cooperate in data collection and analysis, prosecutions, and extradition; establish or strengthen anti-money laundering units; and prevent the illicit diversion of chemical precursors); *see also* CLARE RIBANDO SEELKE & JUNE S. BEITTEL, MÉRIDA INITIATIVE FOR MEXICO AND CENTRAL AMERICA: FUNDING AND POLICY ISSUES 1 (2009), *available at* http://italy.usembassy.gov/pdf/other/R40135.pdf (describing the Mérida Initiative, a proposal for $1.4 billion in U.S. aid to Mexico and Central America to combat illicit drug trafficking and related activities).

Convention, was finalized in 1912.[26] Although only signed by twelve nations[27] and ratified by fewer, it went into force globally in 1919 through its incorporation in the Treaty of Versailles.[28] The League of Nations, which rose from the ruins of the First World War, assumed the task of overseeing international drug control, a task that its successor, the United Nations (UN), still performs.[29] The League created the Advisory Committee on the Traffic in Opium and other Dangerous Drugs, commonly known as the Opium Advisory Committee (OAC), the precursor to the UN Commission on Narcotic Drugs (CND).[30]

A revised Opium Convention, signed in 1925, set up a statistical reporting system to better permit the OAC to monitor opium demand.[31] In 1931, schedules for classification of controlled substances were set out by treaty and countries were required for the first time to estimate and report their needs for controlled drugs.[32] When supervision of the drug control system shifted from the League to the newly created United Nations in 1946,[33] responsibility for regulating the illicit drug market fell to the UN Economic and Social Council (ECOSOC). The Commission

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26. *See* United Nations, *The Beginnings of International Drug Control,* 35 U.N. CHRON. 8, 8 (1998) [hereinafter *The Beginnings*] (stating that the Hague Opium Convention was the first international convention to attempt to control a narcotic drug and was a direct result of the first attempt to internationally cooperate in drug control). The treaty bound signatories to "use their best endeavors to control, or to cause to be controlled, all persons manufacturing, importing, selling, distributing, and exporting morphine, cocaine, and their respective salts, as well as the buildings in which these persons carry such an industry or trade." Int'l Opium Convention art. 10, January 23, 1912, 38 Stat. 1912, 8 L.N.T.S. 187; *see also* Bayer & Ghodse, *supra* note 22, at 3.

27. Int'l Opium Convention, *supra* note 28 (listing the following signatories: Germany, the United States, China, France, the United Kingdom, Italy, Japan, The Netherlands, Persia, Portugal, Russia, and Siam).

28. MCALLISTER, *supra* note 22, at 37.

29. *See The Beginnings*, *supra* note 26, at 9 ("[T]he United Nations assumed the drug control functions and responsibilities formerly carried out by the League of Nations.").

30. William B. McAllister, *Conflicts of Interest in the International Drug Control System*, *in* DRUG CONTROL POLICY: ESSAYS IN HISTORICAL AND COMPARATIVE PERSPECTIVE 143, 145-46 (William O. Walker III ed., 1992).

31. *See The Beginnings*, *supra* note 26, at 8 ("The second International Opium Convention, concluded in 1925 and entered into force in 1928, introduced a statistical control system to be supervised by a Permanent Central Board."); Second Int'l Opium Convention, Feb. 19, 1925, 81 L.N.T.S. 317.

32. *See The Beginnings*, *supra* note 26, at 8 ("A Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, signed in Geneva in 1931, introduced a compulsory estimates system aimed at limiting the world manufacture of drugs to the amounts needed for medical and scientific purposes."); Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, July 13, 1931, 139 L.N.T.S. 301.

33. *See* Protocol Amending the Agreements, Conventions and Protocols on Narcotic Drugs Concluded at The Hague on 23 January 1912, at Geneva on 11 February 1925 and 19 February 1925, and 13 July 1931, at Bangkok on 27 November 1931 and at Geneva on 26 June 1936 art. II, ¶ 2, Dec. 11, 1946, 12 U.N.T.S. 179 [hereinafter 1946 Lake Success Protocol], *available at* http://treaties.un.org/doc/Treaties/1948/02/19480203%2010-47%20PM/Ch_VI_1p.pdf (transferring drug control duties from the League of Nations to the United Nations).

on Narcotic Drugs (CND) was later created by the ECOSOC as the central body for overseeing drug control policy, a position it still holds today.[34]

Until this time, the international law regulating drug control had developed mostly through accretion rather than amendment and harmonization. At the beginning of the 1950s, over half a dozen largely independent international instruments governed international trade in controlled substances. The 1961 Single Convention on Narcotic Drugs,[35] as amended in 1972, consolidated and superseded the thicket of earlier agreements[36] while broadening the scope of regulated substances.[37] The Single Convention, the major international drug control agreement currently in force, also clarified the duties of signatories to enforce its provisions and created the International Narcotics Control Board (INCB) to monitor and promote compliance.[38] The INCB consists of thirteen members, three of whom are nominated by the WHO while the rest are nominated by Parties to the Single Convention.[39] Members are elected by ECOSOC and serve in their individual capacities. The United Nations Office of Drugs and Crime (UNODC) was created in 1997 to establish a coordinated, comprehensive response to the interrelated issues of illicit drugs, crime, and terrorism.[40] The CND is still responsible for amending the Schedules of controlled substances, and its annual meeting serves as an important forum for the discussion of drug policy.[41] Membership consists of fifty-three states serving four year terms.[42] The INCB, CND and UNODC now all fall under the ECOSOC.[43]

Two other conventions also govern the international drug control system. The 1971 Convention on Psychotropic Substances was created to regulate drugs that are not covered by the Single Convention[44] such as buprenorphine, a drug often

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34. *See id.* at Annex (amending drug conventions to delegate authority to the Economic and Social Council of the United Nations).

35. Single Convention, *supra* note 10.

36. The 1936 Convention for the Suppression of the Illicit Traffic in Dangerous Drugs, Jun. 26, 1936, 198 L.N.T.S. 299, was not superseded for reasons that are unimportant here.

37. *See* Single Convention, *supra* note 10, at Schedules (classifying a broad range of drugs into four schedules).

38. *See id.* arts. 4, 5, 9.

39. *Id.* art. 9.

40. About UNODC, http://www.unodc.org/unodc/en/about-unodc/index.html (last visited Oct. 17, 2010).

41. Single Convention, *supra* note 10, art. 8; *see also* Convention on Psychotropic Substances (Feb. 21, 1971), art. 17, 32 U.S.T. 543, 1019 U.N.T.S. 175 [hereinafter Convention on Psychotropic Substances] (describing the functions of the Commission on Narcotic Drugs).

42. ECOSOC Res. 1991/49, U.N. DOC. E/1991/103/Add.1 (June 21, 1991). The fact that states, rather than individuals, serve on the CND means, at least in theory, that it is less independent from national pressure than the INCB, whose members serve in their individual capacities.

43. *See* Cindy S.J. Fazey, *The Commission on Narcotic Drugs and the United Nations International Drug Control Programme: Politics, Policies and Prospect for Change*, 14 INT'L J. DRUG POL'Y 155, 159 (2003) (diagramming the UN Hierarchy).

44. *See* Int'l Narcotics Control Bd., *Convention on Psychotropic Substances 1971*,

used in Medication Assisted Treatment (MAT).[45] The 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances provides additional legal mechanisms for enforcing the 1961 and 1971 Conventions.[46] While the 1971 and 1988 Conventions help to shape the international drug control environment and are interesting in their own right, the amended Single Convention specifies the framework for the international drug control regime and remains the principal international treaty regulating opioids. Accordingly, it is the main regulatory instrument with which this paper is concerned.

B. The Dual Goals of International Drug Law

If a captain's only concern were the safety of his ship, as the saying goes, he would never leave port. Likewise, if international drug treaties were only concerned with preventing diversion into illicit trade, they would simply ban the use of all drugs with potential for abuse. Of course, the captain's goal is not only the safety of his ship, but also the timely delivery of his cargo. So it is with the international drug control regime, which aims to ensure that controlled substances are available in necessary quantities and timely delivered to those authorized to receive them, while at the same time minimizing the diversion of those substances into illicit trade.

As the INCB has noted, the "ultimate aim of the conventions is to reduce harm."[47] The convention's goal of reducing harm – from both inadequate access to controlled substances for medical and scientific needs and diversion into illicit trade – is achieved through adherence to the Principle of Balance.[48] This principle is simple: the health of the public is furthered by ensuring the availability of controlled drugs for medical and scientific purposes and reducing the diversion of these drugs into illicit trade.[49] In the words of the WHO, the Principle of Balance "represents a dual imperative of governments to establish a system of control to

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http://www.incb.org/incb/convention_1971.html ("This Convention establishes an international control system for psychotropic substances. It responded to the diversification and expansion of the spectrum of drugs of abuse and introduced controls over a number of synthetic drugs according to their abuse potential on the one hand and their therapeutic value on the other."). This Convention, confusingly, includes its own list of drug schedules, which are separate from the Single Convention schedules we address below. Convention on Psychotropic Substances, *supra* note 41. The convention came into force on August 16, 1976. It now has 183 state parties. *Id.* para. 16.

45. Convention on Psychotropic Substances, *supra* note 41, at Schedules.

46. United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (with annex), Dec. 20, 1988, 1582 U.N.T.S. 95, *available at* http://treaties.und.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-19&chapter=6&lang=en. The Convention focuses particularly on organized crime and clarifies the duties of parties in re extradition. *Id.* The convention entered into force on November 11, 1990 and currently has 184 state parties. *Id.*

47. INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2003, 12, U.N. Doc. E/INCB/2003/1 (2003).

48. ACHIEVING BALANCE, *supra* note 9, at 11, fig. 2.

49. *Id.* This Principle is directly derived from the treaty obligations of national governments, as laid out in the controlling treaties. *Id.* at 11.

prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability."[50] In the licit context, control is the means by which access is achieved: a properly functioning control system protects the end user from counterfeit or otherwise substandard medicine while at the same time providing a market for licit producers. Reduction of the illicit market protects users and states from harms associated with the illicit drug trade.[51] A control system that focuses disproportionately on preventing illicit traffic at the expense of access for permitted purposes fails under the Principle of Balance and therefore does not comply with either the spirit or the letter of international drug control conventions.[52]

The Single Convention repeatedly affirms the importance of ensuring access to controlled substances for medical and scientific purposes. The preamble recognizes that "the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering" and "adequate provision must be made to ensure the availability of narcotic drugs for such purposes."[53] While it directs the INCB to "endeavor to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical purposes," it also requires that the organization "ensure their availability for such purposes."[54] Similarly, the 1971 Convention declares that "the use of psychotropic substances for medical and scientific purposes is indispensable" and instructs that, "their availability for such purposes should not be unduly restricted."[55] All of the major international bodies involved with drug control acknowledge the primacy of Balance as a guiding principle.[56] Since 1989 U.N. agencies have repeatedly requested that governments

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50. *Id.* at 11, fig. 2. The Single Convention makes clear 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." Single Convention, *supra* note 10, at Preamble.

51. *See, e.g.,* Merrill Singer, *Drugs and Development: The Global Impact of Drug Use and Trafficking on Social and Economic Development*, 19 INT'L J. DRUG POL'Y 467 (2008) (discussing the health and social problems associated with the illicit drug trade).

52. *See* ACHIEVING BALANCE, *supra* note 9 (describing the purposes of international drug control conventions).

53. Single Convention, *supra* note 10, at 1; *accord* Convention on Psychotropic Substances, supra note 41, at 1. The Convention also directs a medical, rather than penal, response to drug abuse, requiring that signatories "give special attention to and take all practicable measures for the prevention of abuse of drugs and for the early identification, treatment, education, after-care, rehabilitation and social reintegration of" people suffering from drug addiction. Single Convention, *supra* note 10, art. 38. The parties also agree to "promote the training of personnel in the treatment, after-care, rehabilitation and social reintegration of abusers of drugs." *Id.*

54. Single Convention, *supra* note 10, art. 9(4).

55. Convention on Psychotropic Substances, supra note 41, at 1.

56. *See, e.g.,* ACHIEVING BALANCE, *supra* note 9 (discussing the importance of preventing illegal drug trafficking while ensuring availability of drugs for medical and scientific purposes); ECOSOC Res. 2005/26 (July 22, 2005), *available at* http://www.un.org/en/ecosoc/docs/2005/resolution%202005-26.pdf (indicating the demand for and supply of opiates used to meet medical and scientific needs). The World Health Organization (WHO) in 2004 "urge[d] Member States…to ensure the medical availability of opioid analgesics

examine their laws, regulations and health care systems to identify and rectify policies to ensure that opioid medications are adequately available for all medical and scientific needs.[57] In the past two years, the INCB introduced a section on access in its annual report. This year's annual report contains a Supplement dedicated to providing information to the international community about current availability of internationally controlled substances for medical requirements and impediments to access for those purposes.[58]

III. REGULATION ALONG THE OPIOID SUPPLY CHAIN: VARIETIES OF CONTROL

To achieve the dual objectives of the international drug control regime, the Convention sets forth general regulatory mandates as well as a small number of specific control requirements.[59] This section describes international requirements for each control point along the opioid supply chain.[60] To convey the variety of ways in which they can be implemented, we present examples drawn primarily from the diverse countries of Romania, Uganda and the United Kingdom.[61]

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according to international treaties and recommendations of WHO and the International Narcotics Control Board." World Health Org. *Cancer Control*, *Report by the Secretariat*, EB 114/3 (Apr. 1, 2004), *available at* http://apps.who.int/gb/ebwha/pdf_files/EB114/B114_3-en.pdf. The WHO has expressed concern about the disparity in opioid medication consumption, warning in 1996 that "in many countries, consumption of opioid analgesics remains extremely low in comparison to medical needs and many national governments have yet to address this important deficit." ACHIEVING BALANCE, *supra* note 9, at 4. The Executive Director of the U.N. Office on Drugs and Crime (UNODC) has called for placing public health at the centre of drug-control interventions. UNODC, MAKING DRUG CONTROL 'FIT FOR PURPOSE': BUILDING ON THE UNGASS DECADE, 13, U.N. Doc. E/CN.7/2008/CRP.17 (Mar. 7, 2008), *available at* http://www.unodc.org/documents/commissions/CND-Session51/CND-UNGASS-CRPs/ECN72008CRP17.pdf.

57. *See generally* Int'l Narcotics Control Bd., *Demand for and Supply of Opiates for Medical and Scientific Needs*, *in* INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 1989, 1, 15, U.N. Doc. E/INCB/1989/1 (1989); DRUG CONTROL & ACCESS TO MEDS. CONSORTIUM, A COMPENDIUM OF INCB STATEMENTS ON ACCESS TO MEDICINES (2009), *available at* http://www.painpolicy.wisc.edu/INCBCompendium.pdf (providing a collection of INCB statements from its annual report on access to essential opioids).

58. *See* INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD ON THE AVAILABILITY OF INTERNATIONALLY CONTROLLED DUGS: ENSURING ADEQUATE ACCESS FOR MEDICAL AND SCIENTIFIC PURPOSES, U.N. Doc. E/INCB/2010/1/Supp.1 (2010).

59. With few exceptions, specific requirements are limited to the movement of controlled substances in international trade. *See generally* Single Convention, *supra* note 10 (describing the role of the Convention).

60. Our focus in this paper is on opioids because of their role in the treatment of pain and addiction. However, the requirements we discuss apply to all substances controlled under the three conventions.

61. We chose Romania and Uganda because our partners at the Pain Policy Studies Group and other reformers such as Hospice Africa had worked with these countries on legal and policy reform of opioid regulation and therefore had access to English translations of many of the laws and regulations. We chose the United Kingdom to provide a contrast in size and socio-demographic composition. We systematically compiled the laws in the three countries and arrayed them in matrix organized by supply chain control point (e.g., "prescribing"). In

A. Infrastructure Requirements

The Single Convention sets forth three main infrastructural requirements.[62] First, countries must create a closed system in which opioids are available only as authorized by national authorities in accordance with international law.[63] Second, countries must estimate the country's projected annual need for opioids and track and report the consumption, manufacture, production, import, export, seizures and stock on hand of many of these opioids.[64] Finally, countries must regulate controlled substances according to their classification on schedules set out in the Single Convention.[65]

The first requirement sets out the default position of the international drug control regime: nearly all meaningful interactions with opioids are prohibited unless specifically permitted.[66] This requirement, though broadly defined, applies to nearly every level of the supply chain through the Convention's requirement that the possession of controlled substances be prohibited "except under legal authority."[67] A key but underappreciated characteristic of this closed system is that "legal authority" is undefined and, therefore, left almost entirely to the discretion of countries. For example, the Single Convention requires countries to license individuals who engage in cultivation and manufacture of opioids.[68] However, other than the vague requirement that licensed persons "have adequate qualifications for the effective and faithful execution of the provisions [of national drug control laws],"[69] the Convention provides no guidance about who may obtain licenses, for how long licenses should be valid, and so on. The Commentary provides no additional guidance, noting only that the provision prohibiting use

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subsequent iterations of the document, we have added provisions from different countries. This Matrix of drug control provisions is on file with the authors.

62. We use the term "infrastructural requirement" to refer to those overarching requirements that must be in place for the opioid supply chain, discussed below, to function.

63. Single Convention, *supra* note 10, art. 4. This requirement encompasses many levels, but it begins when opioids are either imported or cultivated. Countries are required to create a compliance body if they participate in cultivation. *Id.* arts. 23, 28. To participate in import or export of opioid materials, a competent national authority is required. *Id.* art. 31(5) ("Before issuing an export authorization the Parties shall require an import certificate, issued by the competent authorities of the importing country or territory and certifying that the importation of the drug or drugs referred to therein is approved, and such certificate shall be produced by the person or establishment applying for the export authorization.").

64. *Id.* art. 20.

65. *Id.* arts. 2, 4. These schedules can be conceptualized as tiers, with Schedule I on substances carrying the most restrictions and Schedule III the least. *Id.* art. 2. Schedule IV, somewhat confusingly, is a subset of Schedule I and should perhaps be thought of as Schedule I(a). *See id.* art. 2(5).

66. *See id.* art. 4 (explaining that opioids are only available in circumstances designated by the national government).

67. *Id.* art. 33. Possession, of course, is a requirement for nearly every other regulated activity. *Id.*

68. *Id.* arts. 23(2)(b), 29.

69. Single Convention, *supra* note 10, art. 34.

except under legal authority was intended to limit possession for "medical or scientific purposes," which does little to clarify the matter.[70]

The estimating, tracking and reporting system is designed to limit the total quantity of drugs produced domestically or imported to the amount needed for medical and scientific purposes.[71] Each signatory country is required to provide an annual estimate to the INCB of the national need for opioids.[72] That estimate, when confirmed by the INCB, becomes the annual amount that a country can import, manufacture and distribute.[73] Although this estimating and reporting system is an extremely important component of the international control system, there are no specific requirements for how countries should estimate domestic need.[74]

The Single Convention classifies all covered substances into four categories termed Schedules.[75] The placement of substances on these Schedules determines the regulations to which they are subject.[76] The default control requirements for drugs in all Schedules are those that apply to Schedule I,[77] which includes raw

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70. COMMENTARY ON THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961 art. 33 cmt. 1 (1973), *available at* http://www.unodc.org/documents/treaties/organized_crime/Drug%20Convention/Commentary_on_the_single_convention_1961.pdf [hereinafter COMMENTARY]. The Commentary notes: "The Conference was well aware that this requirement was very vague. It found it impossible, however, to use more specific terms, since the differing conditions in various countries and the divergent activities involved (manufacture, trade, distribution, agricultural cultivation) required the application of different technical standards." *Id.* art. 34(a) cmt. 2.

71. *See* Single Convention, *supra* note 10, art. 19.

72. *Id.*

73. *Id.*

74. Different processes may be better suited to different countries. For example, in some countries, insurance information could provide the basis for accurate estimates; in other countries prescription monitoring programs could provide useful information. Countries without such robust data can base the estimates on other information, such as the per capita estimates of another country that is similarly situated.

75. *See* Single Convention, *supra* note 10, art. 2 (describing the format of the Single Convention).

76. *See, e.g,. id.* art. 2(2) ("The drugs in Schedule II are subject to the same measures of control as drugs in Schedule I with the exception of the measures prescribed in article 30, paragraphs 2 and 5, in respect of the retail trade."). A country may place more restrictions on opioids than required by the conventions. However, any additional restrictions need to be carefully balanced against the need to preserve robust access for legitimate purposes. *Id.* art. 2(5)(b).

77. *Id.* art. 2(1). The Schedule I controls "constitute[s] the standard regime under the Single Convention." Commentary on the Single Convention on Narcotic Drugs, 1961, United Nations, New York, 1973; COMMENTARY, *supra* note 70, art. 2(1) cmt. 1. We discuss each of these requirements at the respective control points below. The schedule I controls require that records are kept of "the quantities of each drug manufactured and of each individual acquisition and disposal of drugs." Single Convention, *supra* note 10, art. 34(b). It also requires licenses for importers and exporters, and distributors. *Id.* arts. 31(3), 29(1), 30(1). Further, the Schedule I controls require: (1) prescriptions for the dispensation of drugs to individuals, *id.* art. 30(2); (2) countries to limit the amount of drugs that can be held by traders and distributors to "those required for the normal conduct of business," *id.*; (3) that drug retail labels show "the exact drug content by weight or percentage," *id.* art. 30(5); (4) limit use to "medical and scientific purposes," *id.* art. 2(5)(b); and (5) government authorization for the import and export of each shipment of

materials such as opium as well as most of the opioids used in palliative care and MAT.[78] Schedule II drugs are "subject to the same measures of control as drugs in Schedule I" with only a few exceptions.[79] One of these exceptions, that countries need not limit the amount of Schedule II drugs on hand to "those required for the normal conduct of business,"[80] can greatly increase access in remote locations where resupply is a lengthy affair and storage capacity is limited. Another exception, that prescriptions are not required for Schedule II substances, allows vastly increased access in areas where prescribers are few.[81] This is significant because Schedule II includes codeine,[82] by far the most widely used opioid in the world.[83] Schedule III "contains preparations which enjoy a privileged position under the Single Convention [and] are subject to a less strict regime than other Preparations."[84] Schedule IV is a supplementary schedule that contains a subset of drugs listed in Schedule I, which may be prohibited outright if doing so is "the most appropriate means of protecting the public health and welfare."[85]

Although the Single Convention places opioids into various schedules, there is no requirement that countries set up similar schedules – or any schedules at all. Countries are simply required to ensure that the level of domestic control complies with that required by the Single Convention.[86] This gives countries tremendous

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opioid precursors and opioids, *id.* art. 31(3).

78. INT'L NARCOTICS CONTROL BD., LIST OF NARCOTIC DRUGS UNDER INTERNATIONAL CONTROL 2 (2008), *available at* http://www.incb.org/pdf/forms/yellow_list/48thedYL_Dec_08E.pdf [hereinafter LIST OF NARCOTIC DRUGS].

79. Single Convention, *supra* note 10, art. 2(2).

80. *Id.* art. 30(6).

81. *Id.* The other exception, that the drug's label need not show the "exact drug content by weight or percentage," might impact locations without the ability to measure such specifics, but our review did not uncover instances where this was a barrier.

82. LIST OF NARCOTIC DRUGS, *supra* note 78, at 6.

83. INTL NARCOTICS CONTROL BD., NARCOTIC DRUGS: ESTIMATED WORLD REQUIREMENTS FOR 2008 77 (2007), *available at* http://www.incb.org/pdf/technical-reports/narcotic-drugs/2007/narcotic_drugs_2007_final.pdf ("Codeine [an opiate used to treat mild to moderate pain, as a cough suppressant and to treat diarrhea] has been one of the most largely consumed narcotic drugs in the world in terms of doses and the most commonly used narcotic drug in terms of the number of countries in which it is consumed."). Codeine is also used in many preparations placed in Schedule III. *See* LIST OF NARCOTIC DRUGS, *supra* note 78, at 7.

84. COMMENTARY, *supra* note 70, art. 2(4) cmt. 1. Many of the strict import and export rules discussed below do not apply to Schedule III substances, and only estimates of the quantities of drugs to be utilized for the compounding of preparations in the schedule and information on the amounts of drugs so used are required to be reported. Single Convention, *supra* note 10, art. 2(4).

85. Single Convention, *supra* note 10, art. 2(5). None of the opioids commonly used in palliative care or MAT fall in Schedule IV. *See id.* (listing those drugs covered by Schedule IV).

86. *Id.* This is an admittedly tricky arrangement to grasp. Consider, for illustrative purposes, morphine, which is a classified as a schedule I substance by the INCB. By virtue of its placement on schedule I, countries must require prescriptions for formulations that include morphine, notwithstanding the fact that countries classify it under their national systems as, among others, a

discretion to create classifications for drugs which facilitate the application of appropriate control mechanisms. Countries could, for example, create a schedule just for opioids (or classes of opioids) to provide more clarity about their regulation and the essential role they play in healthcare.[87] The variety of possibilities is shown by the different ways in which our three exemplar countries have chosen to schedule controlled substances.

Romanian law contains four drug schedules. Schedule I substances have no authorized medical use; Schedule II and Schedule III substances are subject to tight regulatory control but may be prescribed for any medical purpose; and Schedule IV contains drug precursors that do not have a medical purpose except during the manufacturing process.[88] Until recently, some types of morphine were classified as Schedule I substances, placing them in the same class as heroin and prohibiting their prescription and administration for any purpose.[89] In 2005, however, Romania overhauled its drug control statute and regulations.[90] Currently, morphine, pethidine, dihydrocodeine, opium, and methadone are Schedule II substances under the Romanian classification system and may be prescribed for any medical purpose.[91]

Uganda has created a control regime that contains a number of classes and sub-classes into which controlled substances are placed. In keeping with the Convention's scheduling regime, Uganda does not declare any drugs to have no permitted medical or scientific purpose. Morphine, pethidine, heroin and codeine are considered Class A drugs, the most heavily restricted.[92] Even so, the national drug law contains no restrictions on the conditions for which physicians may

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Schedule I substance (Canada), a Schedule II substance (United States), a schedule 8 substance (Australia), and a Class A substance (United Kingdom).

87. Some countries have created classes of drugs that are considered to have no medical application and that are therefore prohibited except for narrowly defined and specifically authorized purposes. For example, the United States has created a class of drugs that have "no currently accepted medical use in treatment." 21 U.S.C. § 812 (2010). The Single Convention does not list any such substances. Indeed, under international law, although some substances are permitted to be banned in some circumstances, no substances are considered not to have any medical or scientific application. While Schedule IV drugs may be subject to whatever "special measures of control" each Party deems necessary, no extra measures are specifically prescribed, and, in the absence of additional national controls Schedule IV substances are subject to the same controls as substances in Schedule I. Single Convention, *supra* note 10, art. 2(5).

88. Law 339/2005 Concerning the Legal Status of the Plants, Narcotics and Psychotropic Substances and Preparation published in the Official Gazette no. 1095/05.12.2005 app, *available at* http://www.dsclex.ro/legislatie/2005/decembrie2005/mo2005_1095.htm#l339 (Romanian Law).

89. *Cf.* Law 143/2000 published in the Official Gazette no. 362/03.08.2000 (listing morphine and oxycodone as Schedule I substances); *id.* (listing morphine and oxycodone as Schedule II substances and not including any morphine derivatives in Schedule I).

90. Law 339/2005 Concerning the Legal Status of the Plants, Narcotics and Psychotropic Substances and Preparation published in the Official Gazette no. 1095/05.12.2005 app. For a comprehensive discussion of reform in Romania, *see* Chiu et al., *supra* note 18.

91. Law 143/2000 published in the Official Gazette no. 362/03.08.2000.

92. National Drug Policy and Authority Act of 1993, ch. 206 scheds. (Uganda), *available at* http://www.ulii.org/ug/legis/consol_act/ndpaaa1993363/.

prescribe them.[93] Midwives are permitted to prescribe pethidine for relief of pain related to childbirth.[94] In 2004, the scheduling regime was amended to permit palliative care nurses and specially trained clinical officers to prescribe morphine for palliative care.[95]

In the U.K., controlled substances are classified into five schedules. Raw opium is classified in Schedule I, which contains drugs that have no authorized medical use.[96] However, morphine, heroin, opium in medicinal form, pethidine and dihydrocodeine are all classified as Schedule II drugs, making them available for use for any medical purpose.[97] Heroin's classification as a Schedule II substance is notable as this allows its use in MAT and analgesia.[98] Buprenorphine is classified as a Schedule III substance.[99] The distinction between the regulation of Schedule II and Schedule III substances mostly arises out of record keeping and storage requirements.[100] Schedules IV and V contain no opioids.[101]

B. Operational Requirements

We define operational requirements as the regulatory actions that countries must take at control points along the supply chain. Not every control requirement profiled below applies to every country since not every country cultivates, produces or manufacturers opioid medicines; some countries only import refined products.[102]

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93. National Drug Policy and Authority Act of 1993, *supra* note 92; Uganda Ministry of Health, Guidelines for Handling of Class A Drugs (March 2001) (on file with authors).

94. *See* National Drug Policy and Authority Act of 1993, *supra* note 92, at 13.

95. The National Drug Authority, Statutory Instrument Supplement No. 13; Statutory Instruments 2004 No. 24 (April 23, 2004) (on file with authors).

96. Dangerous Drugs: The Misuse of Drugs Regulations 2001, S.I. 3998, sched. 1 [hereinafter The Misuse of Drugs Regulations].

97. *Id.* at sched. 2.

98. *Id.* The United Kingdom's common use of heroin for many purposes, including pediatric pain care, illustrates the variation and underappreciated range of accepted use for opioids. *See* text accompanying notes 127-132.

99. The Misuse of Drugs Regulations, *supra* note 96, at sched. 3.

100. Special registers must be used to record the dispensing of Schedule II substances and the registers must be kept for an indefinite time. The Misuse of Drugs Regulations, *supra* note 96, ¶¶ 19-20. Registries for Schedule III substances require less detail and need only be kept for 2 years after the last entry. The Misuse of Drugs Regulations, *supra* note 96, ¶¶ 22-24.

101. The Misuse of Drugs Regulations, *supra* note 96, at scheds. 4-5.

102. INT'L NARCOTICS CONTROL BD., NARCOTIC DRUGS: ESTIMATED WORLD REQUIREMENTS FOR 2010, 208-235, U.N. Doc. E/INCB/2009/2 (2010) [hereinafter INCB Narcotic Drugs Technical Report] In the most recent report, for example, the manufacture and consumption of morphine for the United States, United Kingdom, Romania and Uganda were as follows: U.S. (118,545 kg manufactured, 20,550 kg consumed); U.K. (95,024 kg manufactured, 1,925 kg consumed); Romania (0 kg manufactured, 32 kg tons consumed); Uganda (0 kg manufactured, 23 kg consumed). *Id.* at 313-379.

1. Import and Export

The Single Convention regulates import and export more stringently, and with more specificity, than any other activity in the supply chain. Import of opium or synthetic opioids is usually the first step in the opioid supply chain because relatively few countries cultivate poppy plants or produce opium for the manufacture of opioids.[103] Under the Convention, countries must:

- submit to the INCB names and addresses of the governmental authorities empowered to issue export and import authorizations or certificates;[104]
- designate one agency authorized to export cultivated poppy (if the country is a permitted exporter);[105]
- require licenses for private entities that import drugs in Schedules I, II, and III;[106]
- abstain from importing from countries that have not been producing opium prior to 1951 unless the country has been authorized by the INCB to export opium;[107]
- require a separate import or export authorization for each import;[108]
- present import certificates to the national authority of the export country before an export authorization for drugs in Schedules I, II and IV can be issued;[109]
- only honor import certificates that set forth (1) the name of the drug to be imported, (2) the drug's international name, (3) the amount, (4) the name and address of the import and exporter, and (5) the period for which the authorization is valid;[110]
- ensure that the export certificate accompanies the export, references the import certificate and a copy is submitted to the importing country;[111]
- state the quantity actually exported on the export authorization by the competent authorities;[112]
- note that import has been completed and the amount imported on the export authorization and return it to the exporting country;[113] and
- report all imports and exports of controlled substances to the INCB every quarter.[114]

According to the WHO, there are nine main steps in the import/export process:

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103. INT'L NARCOTICS CONTROL BD., *supra* note 102, at 208-235.
104. Single Convention, *supra* note 10, art. 18, ¶1(d).
105. *Id.* art. 23,¶ 1.
106. *Id.* art. 31, ¶ 3 (stating that the country need not license itself).
107. *Id.* art. 24,¶ 4.
108. *Id.* art. 31, ¶ 4.
109. *Id.* art. 31, ¶¶ 5, 15.
110. Single Convention, *supra* note 10, art. 31, ¶¶ 4, 16.
111. *Id.* art. 31, ¶¶ 6, 7.
112. *Id.* art. 31,¶ 7.
113. *Id.*
114. *Id.* art. 20, ¶ 1.

1. The entity wishing to import a substance controlled under the Single Convention applies to its regulatory authority for an import certificate.
2. The regulatory authority considers whether the entity is properly licensed and whether the drug and amount are within the national estimate; if approved, an original import certificate and one copy are issued.
3. The importer sends the original of the import certificate to the entity proposing to export the substance.
4. The exporter applies to its drug regulatory authority for an export certificate.
5. The regulatory authority in the exporting country checks that an import certificate has been issued and that the exporter is properly licensed; if the application is approved, an export certificate is issued.
6. The regulatory authority in the exporting country sends a copy of the export certificate to the regulatory authority in the importing country.
7. The exporter ships the drugs to the importer along with the originals of the export certificate and import certificate.
8. The shipment must pass a customs inspection.
9. The importer sends both certificates to its regulatory authority.[115]

This process, while cumbersome, is extraordinarily effective at preventing diversion of drugs during international transit. In fact, the INCB recently reported that "[i]n 2009, no cases were detected of diversion of narcotic drugs from licit international trade into the illicit traffic."[116]

2. Cultivation

The Single Convention requires countries that wish to cultivate poppy plants for the production of opium to designate one or more government agencies to ensure that cultivation complies with the Convention's requirements.[117] Countries that cultivate opium poppy for non-medical purposes (e.g., for culinary use) are required to report to the INCB the amount of exported poppy straw[118] and the location of areas where poppy plants are harvested.[119] International trade in poppy straw must also abide by the certificate and authorization process required for the

115. World Health Org., *Cancer Pain Relief: With a Guide to Opioid Availability* 53, 51-53 (2d ed. 1996), *available at* http://whqlibdoc.who.int/publications/9241544821.pdf [hereinafter *Cancer Pain Relief*].

116. INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2009, para. 51, U.N. Doc. E/INCB/2009/1 (2010). The fact that some countries import no opioids whatsoever, *id.*, raises the possibility that, for extremely resource poor countries, these requirements may curtail opioid access completely. This may be because these rules are too onerous in countries without highly developed administrative agencies or simply that technical assistance is needed to overcome barriers to the adoption of responsive regulatory infrastructure.

117. Single Convention, *supra* note 10, art. 23.

118. *Id.* art. 25, ¶ 3.

119. *Id.* art. 19, ¶ 1.

import and export of controlled substances.[120] Legal poppy cultivation is currently undertaken by at least nineteen countries, but only four produce raw opium, and only one (India) legally exports it.[121]

Of the three countries we examined, Romania and the U.K. currently cultivate opium poppies, but only the U.K. does so for the production of opium. In Romania, cultivation of poppy is authorized and regulated jointly by the Department of Health and the Ministry of Agriculture, Forests and Rural Development (AFRD).[122] Romania only cultivates poppies for poppy oil and poppy seeds; no medicinal opium is produced from Romanian poppy cultivation. Nevertheless, the country requires that cultivators be licensed and limits cultivation to quantities approved by the Department of Health on a yearly basis.[123] In Uganda, the Health Minister has the authority to provide, in consultation with the National Drug Authority, licenses for the cultivation of poppy plants.[124] However, Uganda grows no poppies, choosing to import manufactured opioids instead.

The U.K. recently entered the small ranks of countries that cultivate poppies for the production of opium.[125] In 2004-2005, a production failure at one of the two plants that manufacture diamorphine resulted in a national shortage.[126] There was also a sharp rise in the price of imported raw opium materials at the time.[127] Diamorphine, or heroin as it is commonly known, is used widely in the U.K., but few other places, for the treatment of pain.[128] For this reason, it is one of only two

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120. Single Convention, *supra* note 10, art. 25, ¶ 2-3.

121. Pierre-Arnaud Chouvy, *Licensing Afghanistan's Opium: Solution Or Fallacy?*, 2 CAUCASIAN REV. INT'L AFF. 101, 103-104 (2008) (Ger.), *available at* http://cria-online.org/Journal/3/Licensing%20Afghanistancs%20opium%20-%20solution%20or%20fallacy_by%20Couvy_done.pdf (listing the nineteen countries as: Australia, Austria, China, the Czech Republic, Estonia, France, Germany, Hungary, Japan, India, the Netherlands, Poland, Romania, Slovakia, South Korea, Spain, Macedonia, Turkey, and the United Kingdom). The other countries harvest opium poppies and produce a compound called concentrate of poppy straw. *Id.* at 104. *See also* INCB Narcotic Drugs Technical Report, *supra* note 102, at 73 ("India is the only licit supplier of opium to the world market, and most of the opium produced in India is destined for export.").

122. Law 339/2005 Concerning the Legal Status of the Plants, Narcotics and Psychotropic Substances and Preparation published in the Official Gazette no. 1095/05.12.2005 app. at 3.

123. *Id*. at 4.

124. The National Drug Policy and Authority Act, 1993, § 49 (Uganda), *available at* http://www.ulii.org/ug/legis/consol_act/ndpaaa1993363/.

125. Other countries that cultivated poppy plants for the production of opium between 2004 and 2008 are China, People's Republic of Korea, India, and Japan. INCB Narcotic Drugs Technical Report, *supra* note 102, at 177.

126. Rupert White, David Cox & Ben Charnaud, *Lessons from the UK Diamorphine Shortage*, 29 THE PSYCHIATRIST 316 (2005) (U.K.), *available at* http://pb.rcpsych.org/cgi/reprint/29/8/316.

127. Glenda Cooper, *Heroin Substitute Shortage Persists*, BBC NEWS, Feb. 19, 2007, http://news.bbc.co.uk/2/hi/health/6376713.stm.

128. *See, e.g.*, Michael Gossop et al., *The Unique Role of Diamorphine in British Medical Practice: A Survey of General Practitioners and Hospital Doctors*, 11 EUR. ADDICTION RES. 76 (2005) (Ger.), *available at* http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowPDF&ArtikelNr=83036&Ausgabe=230670&ProduktNr=22433&filename=83036.pdf. Several countries, including the

countries that manufactures diamorphine.[129] Part of the U.K.'s response to the shortage was to authorize farmers to cultivate poppy plants for a specially licensed private company to produce opioid medications, including diamorphine.[130] Notwithstanding some technical complexities and other curiosities,[131] this shows that domestic production is a permissible option for dealing with episodic opioid shortages.[132]

3. Production, Manufacturing, Storage, and Distribution

Production under the Convention refers to the process of separating raw opium from the poppy plant.[133] Manufacturing refers to the conversion of raw opium into opioids.[134] Under the Convention, countries are required to monitor the production of opium to prevent both diversion and the production of amounts that

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Netherlands, Germany, and Switzerland, permit its prescription to long-term addicts. *See* Carlos Nordt & Rudolf Stohler, *Incidence of Heroin Use in Zurich, Switzerland: A Treatment Case Register Analysis*, 367 LANCET 1830, 1830-34 (2006), *available at* http://www.cesda.net/downloads/lancet1.pdf (describing the effects of Switzerland's use of heroin replacement therapy in reducing the harms associated with injection drug use); Wim van den Brink et al., *Medical Prescription of Heroin To Treatment Resistant Heroin Addicts: Two Randomised Controlled Trials*, 327 BRIT. MED. J. 310 (2003), *available at* http://www.bmj.com/content/327/7410/310.full (reporting on the effective use of heroin in medication assisted treatment in the Netherlands); Uwe Verthein et al., *Long-term Effects of Heroin-Assisted Treatment in Germany*, 103 ADDICTION 960 (2008), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1360-0443.2008.02185.x/pdf (reporting on the use of heroin in medication assisted treatment in Germany). Trials have also been conducted in countries such as Spain and Canada. Benedikt Fischer et al., *Heroin-Assisted Treatment (HAT) a Decade Later: A Brief Update on Science and Politics*, 84 J. URB. HEALTH: BULL. N.Y. ACAD. MED. 552, 553-58 (2007), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2219559/pdf/11524_2007_Article_9198.pdf.

129. The other is Switzerland. INCB Narcotic Drugs Technical Report, *supra* note 102, at 84.

130. Rhodri Phillips & Barry Wigmore, *The Painkilling Fields: England's Opium Poppies that Tackle the NHS Morphine Crisis*, LONDON EVENING STANDARD, July 14, 2007, http://www.thisislondon.co.uk/news/article-23404311-the-painkilling-fields-englands-opium-poppies-that-tackle-the-nhs-morphine-crisis.do.

131. There is little written about this event and nothing in the peer-reviewed literature. It is curious that, according to a Home Office Spokesman, no license is required to cultivate poppies. Ian Bruce, *U.K. farmers Allowed to Cultivate Poppies for Morphine*, HERALD SCOTLAND, Sept. 3, 2008, http://www.heraldscotland.com/uk-farmers-allowed-to-cultivate-poppies-for-morphine-1.888681 (quoting a Home Office spokeswoman who stated: "[t]he poppies in question, papaver somniferum, can be grown without a license. The people who work to produce the drugs have to be licensed. We receive the information about the poppy farmers and how much they are growing from the pharmaceutical companies"). This appears to conflict with explicit language found in the Single Convention. *See* Single Convention, *supra* note 10, art. 23 ("Only cultivators licensed by the Agency shall be authorized to engage in such [opium poppy] cultivation."). We leave questions about this inconsistency to another day.

132. It is unclear whether it would be easier for a low resourced country to produce opium than to import it; all that can be noted – in the absence of instances in which countries have made that decision and subsequent evaluation have been conducted – is that it is in fact an option.

133. *See* COMMENTARY, *supra* note 70, art. 1, para. 1(t), U.N. Sales No. E.73.XI.1 (1973).

134. Single Convention, *supra* note 10, art. 1, ¶ 1(n).

exceed their yearly estimates submitted to the INCB.[135] The same principles apply to manufacturing.[136] The Convention also commands countries to abstain from producing opium if, in the country's opinion, doing so might result in illicit traffic.[137] Countries must also license manufacturers[138] and prohibit all unlicensed production and manufacture.[139] As with most domestic requirements, the Convention does not prescribe any operational requirements for filling these broad mandates, leaving great discretion in the hands of countries to craft law and policy that make sense given each country's unique needs and abilities.

Like many developing countries, Uganda neither produces nor manufactures opioids. Romania produces injectable morphine, hydromorphone, pethidine, and methadone tablets.[140] The U.K. both manufactures and imports opioids for medical use. Regulation of domestic movement and storage of controlled substances is left almost completely to the discretion of each country. In fact, the only specific requirement related to storage is that imported drugs may not be altered without the permission of "the competent authorities."[141] Similarly, a requirement that parties limit possession (a requirement for storage and shipping) of most controlled substances to those acting "under legal authority" is not further specified.[142] Discretion in these domains is limited ultimately only by the fundamental obligation to ensure that regulations permit access and limit diversion.

Countries sometimes fail to take advantage of this flexibility, and as a result access suffers. For example, Ugandan law specifies that most opioids must be stored in a locked, immovable container.[143] This seemingly innocuous requirement has impeded morphine availability because the locked boxes available in pharmacies are often too small to hold the size of the bottles in which morphine is routinely stored. Obtaining larger boxes is extremely difficult because pharmacies must purchase the boxes themselves, and government subsidies are not available.[144] Additionally, any overnight shipment of opioids has to be left in the protection of a police station, and carriers of opioids need special licenses issued by the government.[145] These restrictive measures have been successful in

135. Single Convention, *supra* note 10, art. 21 bis.

136. Single Convention, *supra* note 10, art. 21.

137. *Id.* art. 24, ¶ 1(b).

138. *Id.* art. 29, ¶ 1.

139. *Id.* art. 29.

140. Daniela Mosoiu et al., *Reform of Drug Control Policy for Palliative Care in Romania*, 367 LANCET 2110, 2113 (2006), *available at* http://www.painpolicy.wisc.edu/publicat/06lancet/lancet06.pdf.

141. Single Convention, *supra* note 10, art. 31, ¶ 13.

142. *Id.* art. 33.

143. The National Drug Policy And Authority Act, 1993, Seventh Schedule (Uganda), *available at* http://www.ulii.org/ug/legis/consol_act/ndpaaa1993363/.

144. Dorothy E. Logie & Richard Harding, *An Evaluation of a Morphine Public Health Programme for Cancer and AIDS Pain Relief in Sub-Saharan Africa*, 5 BMC PUB. HEALTH 82 (2005), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1232854/pdf/1471-2458-5-82.pdf.

145. Wholesale Supply Guidelines for Handling of Class A Drugs, 2001, § 1, § 8.

preventing diversion within the country – a 2003 review could not identify any cases of leakage occurring with morphine over twelve years of hospice and three years of government provision[146] – but they have also made it harder for opioids to be used for legitimate purposes.[147]

Romania requires wholesalers who store opioids to obtain licenses through a stringent application process.[148] A prospective distributor must provide: (1) a standard application; (2) a registration number; (3) a warehouse license; (4) a curriculum vitae of the pharmacists who may interact with the substances; (5) the criminal record of the pharmacists involved with the substances; and (6) a statement concerning measures taken to protect against diversion.[149] Distributors or those running storage facilities must apply for a new license every five years.[150]

The U.K. does not explicitly set forth formal requirements for companies that participate in the transportation or wholesale delivery of opioids. The legal authority exists for the Home Office to do so, but the U.K. government has chosen instead to regulate drug transporters on an ad hoc basis, consisting of individualized inspections.[151] Rather than setting out custody requirements in laws or regulations, the Home Office published a set of guidelines "that reflect the best of current practice."[152] The guidelines require the participation of a wide array of organizations and individuals involved in the pharmaceutical and shipping industries.[153] The guidelines are often framed as recommendations (e.g., the

146. Logie & Harding, *supra* note 144, at 82.

147. *Id.* The Uganda case-study provides yet another example of a country that has taken positive steps to increase access to therapeutic opioids for medical use, but continues to overly restrict them at many levels.

148. Decision 1.915/2006 Approving the Methodological Enforcement Regulations of the Provisions of the Law no. 339/2005 on the Juridical Regime of Plants, Substances, and Preparations with Narcotic and Psychotropic Contents published in the official Gazette no. 18/11/01/2007, art. 12, *available at* http://www.ana.gov.ro/eng/14.05.2007/Decision_1915_2006_en.pdf; Law 339/2005, Law 339/2005 Concerning the Legal Status of the Plants, Narcotics and Psychotropic Substances and Preparation published in the Official Gazette no. 1095/05.12.2005 app., art. 38(1)(a).

149. *Id.* art. 12.

150. *Id.* art. 13.

151. *See* HOME OFFICE, GUIDELINES FOR THE SAFE CUSTODY OF CONTROLLED DRUGS IN TRANSIT (2003), § 1 (U.K.), *available at* http://www.dhsspsni.gov.uk/pas-transit-guidelines-feb03.pdf/ [hereinafter HOME OFFICE GUIDELINES]. As Home Office guidance documents note: "[T]he power to make regulations . . . has been exercised in Misuse of Drugs (Safe Custody) Regulations 1973 together with subsequent amendments. In addition, there is power under Section 11 of Misuse of Drugs Act 1971 to serve a notice on the occupier of premises, where controlled drugs are stored, giving directions specifying the precautions to be taken for their safe custody. Wide use has been made of this power in relation to premises of companies producing and distributing controlled drugs. However, no regulations concerning the transport of controlled drugs have so far been made." *Id.* §§ 1.1- 1.2.

152. *Id*. § 1.5.

153. *See generally id.* For example, § 3.1 outlines the aspects that must be covered in procedures for moving controlled substances between different locations, including where responsibility rests, how far it extends, and whether and to whom it can be delegated; what should

"preferred option" is to store transport vehicles with low or medium risk drugs at secure locations rather than having the transporting driver sleep in the truck as customary).[154] The U.K. approach emphasizes self-regulation by the shipping industry with only affirmative encouragement by the U.K. Home Office, plus the threat of direct regulation if extensive evidence of diversion accumulates.

4. Dispensing and Administration

Under the Single Convention, "administration" is distinct from dispensing. Administration means that a medical practitioner injects the medicine into the patient or ensures that it is ingested in his presence.[155] The term "dispense" means to provide the drug to the patient, who may use it outside the medical practitioner's office or in his absence.[156] The term "use" covers administration as well as dispensing.[157]

Only two provisions of the Single Convention directly regulate the dispensing and administration of opioids. First, there is the general mandate – discussed above – that opioids (and other controlled substances) may not be possessed "except under legal authority."[158] Second, signatories must require prescriptions for Schedule I and IV drugs dispensed at the retail level.[159] The Single Convention is largely silent as to the appearance of medical prescriptions as well as to who can prescribe, in what amounts and for what period of time.[160] It does not even require that prescriptions be written. The Commentary provides only that oral prescriptions "should be subjected to restrictive conditions" and "limited to urgent cases."[161] Under the Convention countries *may* require that Schedule I prescriptions be written "on official forms to be issued in the form of counterfoil books by the competent governmental authorities or by authorized professional associations," but this is not required.[162] Prescriptions are not required for the retail trade or distribution of drugs on the Convention's Schedule II list.[163]While the Convention permits Schedule IV substances to be heavily restricted, it does not list any limitations on the use of controlled substances for legitimate medical and scientific purposes. Under the Convention, any controlled substance may be

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be recorded, when, and by who, and where records should be kept and for how long; reconciliation of records should be checked and who is to investigate and discrepancies; and when losses should be reported to the Home Office, who should report them, and at what point should the police become involved as a possible theft. *Id.* § 3.1.

154. HOME OFFICE GUIDELINES, *supra* note 151, § 5.1. However, some guidelines are expressed as commands (e.g., shippers transporting certain high risk drugs must be accredited consistent with special industry security standards) though it is unclear what the enforcement mechanism is for those that do not adhere. *See id.* § 6.6.

155. *See* COMMENTARY, *supra* note 70, at 339.

156. *Id.*

157. *Id*.

158. Single Convention, *supra* note 10, art. 33.

159. *Id.* art. 30(2).

160. Except that distribution must only occur under license. *Id*. art. 30.

161. COMMENTARY, *supra* note 70, art. 30(2)(b)(i) cmt. 3.

162. Single Convention, *supra* note 10, art. 30(2)(b)(ii).

163. *Id.* art. 30(6).

dispensed or administered for any medical purpose by persons who are licensed to do so under national law. The three countries we examined show some flexibility in opioid dispensing and administration. In Romania, doctors are permitted to prescribe, for any medical purpose, any drug in that country's Schedules II or III (which includes opium, pethidine, and dihydrocodeine).[164] In the U.K., doctors[165] and assistants under their supervision[166] can prescribe or administer, for any medical purpose, any drug placed in that country's Schedule II or III (which includes morphine, heroin, opium in medicinal form, pethidine and dihydrocodeine).[167] Midwives are authorized to possess and administer diamorphine, morphine, pentazocine and pethidine in the course of their practice.[168] In Uganda, doctors are permitted to prescribe opioids for any legitimate medical purpose. In 2004, after five years of advocacy, Uganda's prescribing regulations were amended to permit palliative care nurses and specially trained medical practitioners, known as clinical officers, to prescribe and supply morphine "for the management of pain and as part of the palliative care of patients suffering from severe pain and similar symptoms"– an extremely important change in a country with one of the lowest doctor-to-patient ratios in the world.[169] Several special courses have been designed to train these persons in proper methodology

164. Decision 1.915/2006, *supra* note 148, art. 32; Law 339/2005 Concerning the Legal Status of the Plants, Narcotics and Psychotropic Substances and Preparation published in the Official Gazette no. 1095/05.12.2005 app., art. 38(1)(a).

165. The Misuse of Drugs Regulations, *supra* note 96, art. 7 para. 1-3.

166. *Id.*

167. Misuse of Drugs Act, 1971 c. 38, § 7 (U.K.), *available at* http://www.statutelaw.gov.uk/legResults.aspx?LegType=All+Legislation&title=The+Misuse+of+Drugs+Act+1971&searchEnacted=0&extentMatchOnly=0&confersPower=0&blanketAmendment=0&TYPE=QS&NavFrom=0&activeTextDocId=1367412&PageNumber=1&SortAlpha=0. Until recently, individual licenses were needed to prescribe diamorphine, cocaine, dipipanone for MAT; in 2007 an amendment created a general license that authorizes prescription of these substances for MAT for anyone approved by the Department of Health.

168. NAT'L PRESCRIBING CTR., A GUIDE TO GOOD PRACTICE IN THE MANAGEMENT OF CONTROLLED DRUGS IN PRIMARY CARE (ENGLAND) 39 (3d ed. 2009), *available at* http://www.npci.org.uk/cd/public/docs/controlled_drugs_third_edition.pdf [hereinafter A GUIDE TO GOOD PRACTICE] (indicating that midwives are granted this authority through their participation in locally regulated partnerships).

169. Statutory Instrument Supplement No. 13; Statutory Instruments 2004 No. 24; *see also* Jack G.M. Jagwe, *The Introduction of Palliative Care in Uganda*, 5(1) J. PALLIATIVE MED. 160, 160-163 (2002) (Hospice Uganda was started in 1993 to provide palliative care services to patients living within a 20-kilometer radius from Uganda's capital, Kampala; in Uganda, 57% of the people cannot access health services.). There is one physician for every 19,000 Ugandans, and one nurse for every 5,000. Anne Merriman & Richard Harding, Commentary, *Pain Control in the African Context: The Ugandan Introduction of Affordable Morphine to Relieve Suffering at the End of Life*, 5 PHILOSOPHY, ETHICS, & HUMANITIES IN MEDICINE 10 (2010); Jack Jagwe & Anne Merriman, *Uganda: Delivering Analgesia in Rural Africa: Opioid Availability and Nurse Prescribing*, 33 J. PAIN & SYMPTOM MGMT. 547, 549 (May 2007) (giving detailed information regarding how change could come about).

for diagnosing and treating chronic pain.[170] Midwives are also permitted to administer pethidine[171] for pain treatment during the birthing process.

Each of the countries we examined also maintains numerous prescription requirements that may negatively impact access, and significant differences exist among the three countries regarding the writing and filling of prescriptions. In Romania, prescriptions must be issued in four copies: one to the patient, one for the pharmacy, one for the insurer and one kept in the prescription book of the physician who has filled in the prescription.[172] In addition, all prescriptions in Romania must be written on set prescription forms, which vary by color according to schedule of the prescribed substances.[173] Prescriptions for Schedule II preparations must be presented to the pharmacy no later than 10 days after the prescription day and for Schedule III preparations, no later than 30 days. After these deadlines, a new prescription is needed.[174] A prescription can include, at the most, three preparations, in maximum three dosage forms, and only the amount necessary for a 30-day treatment.[175]

In Uganda, all prescriptions must be indelibly written, dated and signed with the usual signature of a registered prescriber as well as the prescriber's name, qualification and address.[176] Additionally, the prescription must state the name and address of the patient and indicate the total amount of drug supplied, dose to be taken, and manner of application or use.[177] Although the Ugandan National Drug Law contains no limit on the duration of opioid prescriptions, pharmaceutical guidelines issued by the Ministry of Health specify that "prescriptions should be written for short periods and no more than one month's treatment at a time."[178] The name and signature of all medical staff authorized to prescribe Class A drugs must be on file with a pharmacy for that pharmacy to honor a prescription.[179] It is the responsibility of new medical personnel to give their name and signature to the pharmacy.[180]

In the U.K., a pharmacist cannot fill a prescription for a controlled drug except as specified in Schedule 4 or 5 unless it states the address of the patient,

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170. Anne Merriman, *Uganda: Current Status of Palliative Care*, 24(2) J. PAIN & SYMPTOM MANAGEMENT 252, 252-56 (2002).

171. Merriman & Harding, *supra* note 169, at 11 (more commonly known as meperidine or its brand name, Demerol, pethidine is a short-acting opioid).

172. Decision 1.915/2006, *supra* note 148, art. 21.

173. *Id.* art. 33.

174. *Id*. art. 36.

175. *Id.* art. 37.

176. *Id.* art. 36.

177. National Drug Policy and Authority Act 1993 (Ch. 206), (1993), S.I. 31/1999, § 20 (Uganda), *available at* http://www.ulii.org/ug/legis/consol_act/ndpaaa1993363/.

178. Prescriber's Guide (Prescription Requirements for Class A Drugs) Guidelines for Handling of Class A Drugs.

179. Uganda Ministry of Health, Guidelines for Handling of Class A Drugs, 28 (March 2001) (on file with authors).

180. *Id.*

which must be in the U.K.[181] In addition, the filler must have no reason to question its validity or must take reasonably sufficient steps to ensure validity.[182] It cannot be filled more than 13 weeks after the prescription date.[183] Formerly, all prescriptions in the U.K. had to be written entirely in indelible ink and dated and signed by the issuer, but recent legislation allows the use of electronic prescriptions.[184] Whether electronically generated or not, prescriptions must specify the total quantity in both words and figures of the controlled drug to be supplied and the strength of the preparation, as well as the total quantity in both words and figures of doses to be supplied.[185] The prescription must state the usage instructions, when appropriate.[186]

Although the laws of each country that we examined assume that most retail prescriptions will be filled by pharmacists at pharmacies, the Convention does not require either. In fact, the Single Convention neither defines "pharmacist" nor restricts who can dispense controlled substances.[187] As a result, it is entirely permissible under the Convention for a country to license persons other than pharmacists or prescribers to dispense opioids, and to allow for their dispensation at places other than pharmacies or physician's offices. Such a system, if properly implemented, could help increase access to opioids particularly in countries and areas where pharmacists are scarce.

IV. STUMBLING BLOCKS ALONG THE ROAD TO ACCESS

There are a number of seemingly intractable problems in the world. These problems are notable not only for the suffering and harm they render but for the cost and complexity involved in addressing them. Inadequate access to opioids is not one of these problems. Unlike the global campaign to reduce HIV/AIDS[188] or

181. The Misuse of Drug Regulations 2001, *supra* note 96, art. 16.

182. *Id.*

183. *Id.*

184. A GUIDE TO GOOD PRACTICE, *supra* note 168, at 47 (prescribers may issue computer-generated prescriptions for all drugs, with only the signature requiring the prescribers own handwriting).

185. *Id.*

186. The Misuse of Drugs Regulations 2001, *supra* note 96, art. 15.

187. *See generally* Single Convention, *supra* note 10, art. 1 (Article 1 of the Convention, which sets out definitions, does not define pharmacist).

188. Despite broad agreement that action is necessary, including the deployment of extraordinary resources, AIDS still kills approximately 2 million people per year. UNAIDS, 2008 REPORT ON THE GLOBAL AIDS EPIDEMIC, at 211-32, UNAIDS/08.25E/JC1510E (2008), *available at* http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp. In some instances, structural interventions such as syringe exchange programs (SEPs) can be used to address some of the root causes of HIV/AIDS such as transmission through injection drug use. *See* Scott Burris et al., *Racial Disparities in Injection-Related HIV: A Case Study of Toxic Law*, 82 TEMPLE L. REV. 1263 (2010) (reviewing the evidence supporting the use of SEPs in reducing the overall prevalence and racial disparities in HIV). However, to substantially reduce these harms and promote health at the global level, it is increasingly clear that more fundamental,

international efforts to address unclean drinking water, both of which require vast financial resources and a complex array of interventions,[189] the solution to untreated pain is simple, scalable and relatively inexpensive. Most opioids are cheap to produce[190] and easy to store and transport.[191] They can be safely dispensed by relatively low-level medical professionals and, when used correctly, have a very good safety profile.[192]

Why, then, is access so poor? As we note below, a number of inter-related causes combine to produce poor access. It is clear, however, that unbalanced law and policy is a driving factor, and that legal change at the national level is an important step in increasing access.[193] In the next part, we describe the two

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and difficult, social change is required. *See generally* WHO SOCIAL DETERMINANTS OF HEALTH, http://www.who.int/social_determinants/en (last visited Sept. 22, 2010); *see also* RICHARD WILKINSON & KATE PICKETT, THE SPIRIT LEVEL: WHY MORE EQUAL SOCIETIES ALMOST ALWAYS DO BETTER (2009) (noting that inequality within countries is a primary determinant of population health among poor and wealthy countries alike).

189. A recent WHO report suggested that providing clean water would cost forty-two billion dollars and involve complex choices in potential tension with economic development, a correlate of population health. Guy Hutton & Jamie Bartram, World Health Org., *Regional and Global Costs of Attaining the Water Supply and Sanitation Target (Target 10) of the Millennium Development Goals*, WHO/HSE/AMR/08/01 (2008), *available at* http://www.who.int/water_sanitation_health/economic/mdg_global_costing.pdf.

190. Liliana De Lima et al., *Potent Analgesics Are More Expensive for Patients in Developing Countries: A Comparative Study*, 18(1) J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY 59, 59-70 (2004) (making it clear that, where countries are willing to take the appropriate steps, therapeutic opioids can be made available at an affordable price and with a minimum of diversion. In China, where methadone is locally manufactured, the price of an average dose of the medication to patients is between US$ 0.66-1.30 per day.); *Blueprint, supra* note 14, at 17 (citing Daniel Wolfe, *Substitution Treatment in Developing/Transitional Countries with Injection-Driven HIV Epidemics: Availability and Barriers to Access* (IHRD, 2008)) (indicating that in India, morphine tablets cost 1.7 cents to produce); Daloni Carlisle, *Africans Are Dying of AIDS without Pain Relief,* 337 BMJ 1069 (2003) (explaining how one hospice in Uganda mixes its own liquid morphine so cheaply that a three-week supply costs less than a loaf of bread.).

191. U.S. FOOD AND DRUG ADMINISTRATION, ORAL MORPHINE MEDICATION GUIDE, *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/UCM199333.pdf (stating that morphine is stored at room temperature). Morphine does not require the cold chain which is the case for many other medicines; *see also* Rafik H. Bishara, *Cold Chain Management – An Essential Component of the Global Pharmaceutical Supply Chain,* 9(1) AM. PHARMACEUTICAL REV, 105, 105-109 (2006), *available at* http://www.americanpharmaceuticalreview.com/ViewArticle.aspx?ContentID=330 (noting that most vaccines need to be stored at cold temperatures which can dramatically increase the cost of interventions by requiring refrigerated trucks and storage).

192. Russel K. Portenoy, *Opioid Analgesics, in* PAIN MANAGEMENT: THEORY AND PRACTICE 248, 253-54 (1996) (suggesting that, unlike every other analgesic drug group, opioids do not cause visceral organ damage at any dose); A. Reed Thompson & James B. Ray, *The Importance of Opioid Tolerance: A Therapeutic Paradox*, 196(2) J. AM. COLL. SURG. 321, 321-24 (2003) (indicating that all side effects associated with long-term opioid use are reversible).

193. The INCB has recognized this by noting that:

the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which

components of imbalanced policy – unduly restrictive laws and insufficient legal support for access – and the impact these policies have on medical practice.

A. Strict Rules and Overcriminalization

Countries are required to balance efforts at reducing diversion with those aimed at ensuring access. Too often, however, countries fail to honor this mandate and formulate laws and regulations that are overly restrictive and have the effect of impeding medical and scientific use of opioids.[194] For example, many national laws limit the length of time that a patient can receive opioids during in-patient care, in some instances to as little as three days.[195] Similar requirements exist for dosing: before Romania reformed its opioid regulations, patients could only be administered sixty milligrams of morphine per day.[196] These overly strict laws often reflect inaccurate stereotypes about the risks involved with opioid use or archaic assumptions that pain is inevitable.[197] In other instances, laws are not facially problematic, but can stymie access when implemented in locally inappropriate ways.

In many places, overregulation makes prescribing onerous for patients and prescribers.[198] Many countries in Europe require triplicate prescriptions forms, which are cumbersome to fill out and sometimes difficult to obtain.[199] In

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drug control laws and regulations are interpreted or implemented and legislators sometimes enact laws which not only deal with the illicit traffic itself, but also impinge on some aspects of licit trade and use, without first having adequately assessed the impact of the new laws on such licit activity. Heightened concern with the possibility of abuse may also lead to the adoption of overly restrictive regulations which have the practical effect of reducing availability for licit purposes. Int'l Narcotics Control Bd., *Demand for and Supply of Opiates for Medical and Scientific Needs*, *in* INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 1989, 1, 15, U.N. Doc. E/INCB/1989/121 (1989); *see also* M.R. Rajagopal & David E. Joranson, *India: Opioid Availability- An Update,* 33(5) J. PAIN SYMPTOM & MGMT. 615, 617 (2007) (noting that insufficient access in India has been "reinforced by an unbalanced regulatory environment governing opioids").

194. *See, e.g.*, Neil MacDonald, *Educational Programs in Pain and Palliative Care*, 8(6) J. PAIN & SYMPTOM MGMT. 348, 348-52 (1993) (These barriers ''usually include draconian regulations that do little to hold back the illicit drug traffic but sharply limit the access of . . . patients to adequate analgesia'').

195. INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2005, U.N. Doc. E/INCB/1995/Supp1 (1996) (finding that "[t]wenty percent of governments impose a maximum length of time that a hospitalized patient can receive morphine . . . Twenty-eight percent of governments determined a maximum duration of morphine treatment for a patient at home." This maximum was as low as 3-7 days in some cases, although it was occasionally possible to renew the prescription.).

196. Daniela Mosoiu et al., *Reform of Drug Control Policy for Palliative Care in Romania,* 367 THE LANCET 2110, 2115 (2006).

197. *See* INCB Narcotic Drugs Technical Report, *supra* note 102 (describing the international use of narcotic drugs).

198. N. I. Cherny et al., *Formulary Availability and Regulatory Barriers to Accessibility of Opioids for Cancer Pain in Europe: A Report from the* ESMO/EAPC *Opioid Policy Initiative*, 21(3) ANNALS OF ONCOLOGY 615, 615 (2010).

199. *Id.* at 619 (noting that duplicate or triplicate forms are required in most of Europe and

Bucharest, Romania, to provide MAT as an inpatient service a physician needs three copies of a specially stamped form with an authorization issued to the patient by the County Directorate for Public Health and the city.[200] Strict limits on the dose and duration of prescriptions create significant impediments to care.[201] Requiring patients to refill prescriptions after a few days or weeks can create an insurmountable obstacle for patients in remote areas or for those who suffer from a disabling condition, which is not infrequent for pain sufferers. Yet these restrictions are commonplace. In South Africa, for example, there is a 30 day limit to prescriptions, resulting in considerable hardship for rural patients;[202] in Colombia, opioids cannot be prescribed for more than ten days.[203] In China, licensed physicians may issue prescriptions for a maximum of a 3-day supply of injectable opioid medications or a 7-day supply of oral medications.[204]

Unnecessarily onerous recordkeeping requirements can also dampen access to opioids by discouraging businesses from becoming involved with the delivery and distribution process.[205] Many countries require pharmacies to keep a record of each transaction, to keep those records in a locked receptacle and to keep them available for inspection for a number of years.[206] Such objectively reasonable requirements may lead small pharmacies not to stock opioids.[207]

Widely-sweeping anti-trafficking campaigns can also cause problems for medical access. The threat of criminal sanction chills widespread adoption of opioid medicines in a number of ways. In 1985, India passed a complex and harsh

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that "[d]ifficulty in accessing the required prescription forms was reported in Bulgaria, Moldova, Russia, Montenegro, Macedonia, Albania, Lithuania, Tajikistan and Ukraine. In Latvia, Estonia, Albania and Denmark, physicians need to purchase the prescription forms").

200. *Id.*

201. *See* Cherny et. al., *supra* note 198, at 620 (noting that in the Ukraine, prescriptions may only provide a one day supply of medicine).

202. Susan L. Beck, *A Systematic Evaluation of Opioid Availability and Use in the Republic of South Africa*, 6(4) J. PHARM. CARE PAIN SYMPTOM CONTROL 5, 11 (1998) (reporting on a study that found that some of the sampled respondents found the 30 day limit to be a barrier to care because it necessitated returning to the hospital or doctors which is difficult for patients that live rural areas).

203. Sophie M. Colleau, *Barriers to Cancer Pain Control in Latin America and Their Impact on Patient Care*, 9 CANCER PAIN RELEASE 2 (1996), *available at* http://whocancerpain.wisc.edu/index?q=node/283.

204. Anderson et al., *supra* note 19, at 8.

205. *See* Cherny et al., *supra* note 198, at 615 ("In many countries, excessively zealous or poorly considered laws and regulations to restrict the diversion of medicinal opioids for the relief of pain. Often the logistics of the treatment of pain with opioids is so burdensome or complex for physicians, nurses and pharmacists as to be a major disincentive to involvement.").

206. For example, the regulations governing Class A drugs in Uganda state that "All [pharmacy] records should be kept in an immovable, locked cupboard for five years from the date of last entry." Guidelines for Handling Class A Drugs, *supra* note 178, at 23.

207 Opioids are required to be kept in the same containers, and investigators have reported that lack of the containers keeps some pharmacies from stocking opioids. Dorothy E. Logie & Richard Harding, *An Evaluation of a Morphine Public Health Programmed for Cancer and AIDS Pain Relief in Sub-Saharan Africa*, 5 BMC PUB. HEALTH 82 (2005), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1232854/pdf/1471-2458-5-82.pdf.

anti-drug act creating 10 year sentences for even minor drug-related infractions.[208] Legal morphine use in India plummeted 97% after the law was passed.[209] Physicians and pharmacists in many countries are reluctant to prescribe and distribute opioid medicines not only due to the burden of administrative details, but also for fear of making a mistake in good faith that could result in criminal punishment.[210]

MAT often faces these same obstacles, and more. Waiting lists, restrictive initiation requirements and limited access are common barriers.[211] Law enforcement activities pose another barrier to MAT in many places. Police in many countries have been reported to arrest or harass MAT patients, particularly where the legal status of MAT is unclear or police are poorly trained.[212]

B. Inadequate Support for Access

Access does not happen by itself. The closed system of regulation will be a barrier to access unless access is permitted and encouraged by governmental and non-governmental actors. The absence of such government support and programming aimed at ensuring adequate access to therapeutic opioids is one of the major barriers to adequate treatment.[213] The absence of programming and sparse or non-existent educational requirements in palliative care and MAT, and

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208. Donald G. McNeil, Jr., *In India, A Quest to Ease the Pain of the Dying,* N.Y. TIMES, September 11, 2007, *available at* http://www.nytimes.com/2007/09/11/health/11pain.html.

209. *Id.*

210. *See* M.M. Seidenberg & O. Willis, *Prosecution of Physicians for Prescribing Opioids to Patients*, 81(6) CLINICAL PHARMACOLOGY & THERAPEUTICS 903, 905 (2007) (finding that fear of prosecution "inhibits doctors from prescribing appropriately high doses of opioids to patients who need them"); B. Jung & M.M. Seidenberg, *The Risk of Action by the Drug Enforcement Administration Against Physicians Prescribing Opioids for Pain*, 7 PAIN MED. 353, 353 (2006) ("Fear of government actions against physicians for prescribing opioids for their chronic pain patients is a cause for under-treatment of pain."); Art. 387(1), C. Pen. (2005) (Rom.) (superseding article 312 of the Criminal Code of 1969, making it a crime for a physician to unnecessarily prescribe a narcotic drug); *see also* Art. 6(1) & 7, Law No. 143 of 26 July 2000 (Rom.) ("Administration of high risk drugs to a person in violation of law shall be punished with imprisonment for a term of 6 months to 4 years.").

211. *Blueprint, supra* note 14, at 17 (citing Daniel Wolfe, *Substitution Treatment in Developing/Transitional Countries with Injection-Driven HIV Epidemics: Availability and Barriers to Access* (IHRD, 2008).

212. *Id*.

213. *See, e.g. Cancer Pain Relief*, *supra* note 115, at 42 (noting that lack of government support for pain care is a barrier to access); World Health Organization, *National Cancer Control Programme: Policies and Managerial Guidelines* 86 (2nd ed. 2002), *available at* http://www.who.int/cancer/media/en/408.pdf (noting that there was a wide gap between the rhetoric and the reality when integrating palliative care principles into public health and disease control programmers); Thomas Lynch et al., *Barriers to the Development of Palliative Care in the Countries of Central and Eastern Europe and the Commonwealth of Independent States,* 37 J. PAIN AND SYMPTOM MGMT. 305, 312 (2009) (identifying lack of governmental involvement and support as a key barrier to palliative care in many countries in the region).

disparities in how resources are allocated between preventing diversion and promoting access reflect of inadequate government support for access.

National drug control laws often lack language articulating access to opioids and other controlled substances as an important policy objective. Some countries simply fail to report estimated need to the INCB,[214] and so are unable to produce or import opioids at all.[215] Others provide unrealistically low estimates.[216] A UNODC survey revealed that less than half of surveyed countries had laws that stated that opioids were essential to pain care and only 63% mentioned the obligation to maintain access to controlled substances for medical purposes.[217] Some countries even frame drug control entirely as an issue of criminal law.[218] While there is reason to be skeptical of the power of preambular language,[219] clear statements of legislative intent can be influential both normatively and, in some places, legally.[220]

Affirmative statutory law recognizing the need to provide access to essential medicines is important, but it is far from enough. Government support and programming is also needed. National spending on diversion-prevention reaches into millions and in some instances billions of dollars annually.[221] Yet, most countries devote only a tiny fraction of that amount to activities supporting medical and scientific use. In contrast to the leviathan-like reach of interdiction agencies, palliative care and chronic pain seldom have an institutional champion that can work to increase access to opioids. Pain is often forgotten or taken as an inevitable phenomenon, rather than identified as a remediable policy objective.[222]

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214. INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2009, 23-30, U.N. Doc. E/INCB/2009/2 (2010) (Noting that a number of countries did not return estimates to the INCB for 2010. These countries include Congo, Côte d'Ivoire, Guinea, Liberia and Niger.).

215. Single Convention, *supra* note 10, arts. 20, 21.

216. INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2000, 2, U.N. Doc. E/INCB/2000/1 (2000) (declaring that "most developing countries lack the resources and expertise required for determining medical needs and adjusting drug supply to meet those needs").

217. INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 1995, 1, 5, U.N. Doc. E/INCB/1995/Supp1 (1996).

218. *Id.*

219. *See e.g.*, Dan Himmelfarb, *The Preamble in Constitutional Interpretation*, 2 SETON HALL CONST. L.J. 127 (1991-1992) (noting that in the United States, for example, preambular language is interpreted differently across jurisdictions but is seldom viewed as persuasive or controlling).

220. *See e.g.*, Anne Winckel, *The Contextual Role of a Preamble in Statutory Interpretation*, 23 MELB. U. L. REV. 184, 186 (1999) (indicating the interpretive influence given to preambulular and introductory sections of law in Australia).

221. OFFICE OF NAT'L DRUG CONTROL POL'Y, NATIONAL DRUG CONTROL STRATEGY: FY 2010 BUDGET SUMMARY (2009), *available at* http://www.whitehousedrugpolicy.gov/publications/policy/10budget/fy10budget.pdf (indicating that the Unites States spent over $15 billion in 2010 directly on combating illicit drugs).

222. For example, until 2006 Vietnam had no formal palliative care policy to guide development of treatment services. SOCIALIST REPUBLIC OF VIET NAM, SCALING UP TOWARDS UNIVERSAL ACCESS TO HIV/AIDS PREVENTION, TREATMENT, CARE AND SUPPORT IN VIET NAM

C. Impact on Medical Practice: Fear, Stigma, and Ignorance

Overemphasis on diversion prevention and inattention to impediments to therapeutic access has had a powerful influence on the culture of medical practice, both on the part of physicians and patients.[223] Cultural norms and stigmas concerning opioid medicines, pain and drug dependency can suppress the use, and even the discussion, of therapeutic opioids in health care systems. Patients and their families are often afraid of opioid medicines.[224] As a Colombian physician explained, *"A big percentage of our patients are scared of opioid addiction despite explanations and educative campaigns . . . [A]lmost one hundred percent of patients are frightened of becoming addicted to morphine."*[225] Negative attitudes and myths about opioid medications are often shared by health care providers.[226]

(2006). In India, where 1.6 million people suffer from cancer pain, clinics dispensing morphine are so scarce that some patients live 500 miles from the nearest center. McNeil, *supra* note 208.

223. *See* Ethan A. Nadelmann, *Global Prohibition Regimes: The Evolution of Norms in International Society,* 44 INT'L ORG. 479 (1990) (noting that these influences flow directly from the current regime's overemphasis on diversion prevention).

224. Charles S. Cleeland et al., *Cancer Pain Management by Radiotherapists: A Survey of Radiation Therapy Oncology Group Physicians*, INT'L. J. OF RADIATION ONCOLOGY, BIOLOGY & PHYSICS, 203, 203 (2000) (noting that 72% of oncologists reported "patient reluctance to take analgesics" as a barrier to pain management).

225. Interview by OLEC with Jairo Moyano, April, 7, 2004, *available at* http://www.eolc-observatory.net/global_analysis/colombia_opioid.htm. These concerns are misguided. Although abuse and addiction are always possible outcomes of long-term opioid treatment, research shows that these instances are relatively rare and typically treatable. Russell K. Portenoy, *Opioid Therapy for Nonmalignant Pain: Current Status*, *in* 1 PHARMACOLOGICAL APPROACHES TO THE TREATMENT OF CHRONIC PAIN: NEW CONCEPTS AND CRITICAL ISSUES: PROGRESS IN PAIN RESEARCH AND MANAGEMENT 247, 247-87 (Howard L. Fields, John C. Liebeskind, eds., 1994); Bridget M. Kuehn, *Opioid Prescriptions Soar: Increase in Legitimate Use as Well as Abuse*, 297 JAMA 249 (2007), *available at* http://jama.ama-assn.org/cgi/reprint/297/3/249; Jan Stjernswärd, *Palliative Care: the Public Health Strategy*, 28 J. PUB. HEALTH POL'Y 42 (2007), *available at* http://jama.ama-assn.org/cgi/content/full/297/3/249. While tolerance and physical dependence are common effects of opioid use in chronic pain patients, they are not the same as, and should not be confused with, addiction. *Cf.* Karen L. Sees & H. Westley Clark, *Opioid Use in the Treatment of Chronic Pain: Assessment of Addiction*, 8 J. PAIN SYMPTOM MGMT. 257 (1993), *available at* http://www.ncbi.nlm.nih.gov/pubmed/7963767 (noting that while tolerance and physical dependence are common effects of opioid use in chronic pain patients, they are not the same as, and should not be confused with, addiction); M. R. Rajagopal, David E. Joranson, & Aaron M. Gilson, *Medical Use, Misuse, and Diversion of Opioids in India*, 358 LANCET 139 (2001), *available at* http://www.painpolicy.wisc.edu/publicat/01lancet/lancet1.pdf (reporting on 1,723 patients followed in Calicut, India, who were treated for pain with oral morphine over two years failed to identify any instances of abuse, indicating that in properly monitored opioid patients, such addiction occurs infrequently).

226. Luo-Ping Ger et al., *Physicians' Knowledge and Attitudes Toward the Use of Analgesics for Cancer Pain Management: A Survey of Two Medical Centers in Taiwan*, 20 J. OF PAIN & SYMPTOM MGMT. 335, 335 (2000), *available at* http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T8R-41JTP1D-5&_user=1543922&_coverDate=11%2F30%2F2000&_rdoc=1&_fmt=high&_orig=search&_origin=search&_sort=d&_docanchor=&view=c&_searchStrId=1525806835&_rerunOrigin=google&_acct=C000053639&_version=1&_urlVersion=0&_userid=1543922&md5=9b469ba280d3f53131f4c3ab5c34156d&searchtype=a (The majority of Taiwanese physicians surveyed "displayed

Clinicians often unwittingly bring a number of barriers to their clinical encounters with patients, including insufficient knowledge, negative attitudes toward prescribing opioid medications, inadequate assessment skills and the fear that patients will become addicted.[227] These attitudes and misperceptions can contribute to unequal provision of care along racial and ethnic lines.[228]

Doctors in developing countries often have beliefs about narcotics that prevailed in Western medical schools decades ago — that narcotics "are inevitably addictive, carry high risks of killing patients and must be used sparingly, even if patients suffer."[229] Where opioid medications are not available at all, medical providers may not have received any training in their use; they also may not be aware of proper diagnosis of pain and the indicated treatment. Inadequate training, however, is not limited to developing countries. Until recently, medical schools in Japan taught that narcotics should be used sparingly.[230] When asked about their

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significantly inadequate knowledge and negative attitudes toward the optimal use of analgesics and opioid prescribing…").

227. Myr Glajchen, *Chronic Pain: Treatment Barriers and Strategies for Clinical Practice*, 14 J. AM. BOARD FAM. PRACT. 211, 211 (2001), *available at* http://www.jabfm.org/cgi/reprint/14/3/211.pdf ("Lack of knowledge about opioids, negative attitudes toward prescribing opioids, and inadequate pain-assessment skills combine to create major barriers to pain relief."); Francois Larue et al., *Oncologists and Primary Care Physicians' Attitudes Toward Pain Control and Morphine Prescribing in France,* 76 CANCER 2375, 2375 (1995), *available at* http://www.ncbi.nlm.nih.gov/pubmed/8635046 (noting 76% of primary care physicians and 50% of medical oncologists report being reluctant to prescribe morphine for cancer pain); Sharon M. Weinstein *et al.*, *Physicians' Attitudes Toward Pain and the Use of Opioid Analgesics: Results of a Survey from the Texas Cancer Pain Initiative*, 93 SOUTH MED. J 479*,* 479 *(2000),* available at *http://www.ncbi.nlm.nih.gov/pubmed/10832945* ("Overall, a significant number of physicians in this survey revealed opiophobia (prejudice against the use of opioid analgesics), displayed lack of knowledge about pain and its treatment, and had negative views about patients with chronic pain"); William Breitbart et al., *Clinicians' Perceptions of Barriers to Pain Management in AIDS*, 18 J. OF PAIN & SYMPTOM MGMT. 203, 203 (1999), *available at* http://www.ncbi.nlm.nih.gov/pubmed/10517042 (A survey of AIDS health care providers indicated that the most frequently endorsed barriers to pain management were those regarding lack of knowledge about pain management or access to pain management experts, and concerns regarding potential substance abuse or addiction); Bhushan Bhamb et al., *Survey of Select Practice Behaviors by Primary Care Physicians on the use of Opioids for Chronic Pain,* 44 CURRENT MEDICAL RESEARCH & OPINION 1859, 1859 (2006), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1959337/pdf/nihms28635.pdf (reporting that a survey of primary care physicians found concerns about addiction and abuse to be the number one and two concerns respectively, regarding opioid therapy).

228. Vence L. Bonham, *Race, Ethnicity, and Pain Treatment: Striving to Understand the Causes and Solutions to the Disparities in Pain Treatment*, 29 J. L. MED. & ETHICS 52, 52 (2001), *available at* http://www.painandthelaw.org/aslme_content/29-1/bonham.pdf (noting that "racial and ethnic minority populations are at a higher risk for olioanalgesia, or the ineffective treatment of pain"); Kathryn E. Lasch, *Culture, Pain, and Culturally Sensitive Pain Care*, 1 PAIN MGMT. NURSING 16, 20 (Supp. 1) (2000), *available at* http://www.ncbi.nlm.nih.gov/pubmed/11710145.

229. Donald G. McNeil, *Drugs Banned, Many of World's Poor Suffer in Pain*, N.Y. TIMES, Sept. 10, 2007, *available at* http://www.nytimes.com/2007/09/10/health/10pain.html.

230. Donald G. McNeil, *Japanese Slowly Shedding Their Misgivings About The Use of Painkilling Drugs,* N.Y. TIMES, Sept. 10, 2007, *available at* http://www.nytimes.com/2007/09/10/health/10painside.html.

training in pain management, 88% of U.S. physicians surveyed reported that their medical school education in pain management was poor and 73% reported that residency training was fair or poor.[231] In another survey, 76% of physicians cited their own sense of low competence in patient assessment as the major barrier to effective pain management.[232] Reluctance to prescribe opioid medications was cited by 61% of the respondents as the second most important barrier.[233]

The socio-cultural impact of overly restrictive laws and under-supportive policies perpetuates a vicious cycle: poor access leads to less use, and less use leads to lack of medical training and stigma, further reducing use and leading to unrealistically low estimates. Low national estimates limit importation or manufacture, which leads to less supply, less access and so on.[234] But while burdensome legal impediments sustain a negative feedback loop, positive reform can turn the cycle towards healthier ends. Broadening access can help to change perceptions about opioid therapy and improve practitioner knowledge about the risks and benefits of opioids in clinical practice. But the benefits can also flow the other way: better informed patients and medical practitioners are better advocates for appropriately balanced regulation and the reform needed to realize it.[235] Although inertia challenges meaningful reform, small improvements in drug control laws, policies or attitudes can break down barriers to access and catalyze changes in cultural and social norms surrounding the appropriate medical use of opioids.

V. CONCLUSION: BREAKING THE CYCLE

The stated purpose of the international drug control system is to protect and promote public health by ensuring access to therapeutic opioids for medical and scientific purposes while preventing diversion and illicit use. Because each aim is indispensible to health, the legal framework for drug control is predicated upon the principle of Balance, which is supported, at least on paper, by all the relevant international drug control entities. The paradox of international drug control is that unbalanced laws, policies and practices remain widespread.

In recent decades, a broad coalition of governmental and non-governmental actors has been carrying out an array of activities aimed at breaking the cycle of untreated pain that persists in so many corners of the globe. A smaller, but no less

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231. Jamie H. Von Roenn et al., *Physician Attitudes and Practice in Cancer Pain Management. A Survey from the Eastern Cooperative Oncology Group*, 119 ANNALS OF INTERNAL MED. 121, 124 (1993), *available at* http://www.ncbi.nlm.nih.gov/pubmed/8099769.

232. Charles F. Von Gunten & Jamie H. Von Roenn, *Barriers to Pain Control: Ethics and Knowledge,* 10 J. PALLIATIVE CARE 52- 54(1994), *available at* http://www.ncbi.nlm.nih.gov/pubmed/7531235.

233. *Id.*

234. Scott M. Fishman et al., *Regulating Opioid Prescribing Through Prescription Monitoring Programs*, 5 PAIN MED. 309 (2004), *available at* http://www.ncbi.nlm.nih.gov/pubmed/15367312.

235. *See Blueprint*, *supra* note 14, at 11 (noting that in places with heavy regulation practitioners never learn to use opioid medication and share unfounded doubts about their value).

dedicated group has focused on making opioids more available for MAT. In this issue, Chiu and colleagues provide a model for thinking about how the work of these disparate groups can be best harnessed to achieve needed reform.[236] This paper supports that model by showing the considerable flexibility that countries have in achieving balanced opioid policy while remaining compliant with international obligations.

236. *See* Chiu et al., *supra* note 18.