ACCESS TO THERAPEUTIC OPIOIDS: A PLAN OF ACTION FOR DONORS, NGOS, AND GOVERNMENTS

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I. INTRODUCTION

Throughout the world, millions of people suffer pain caused by late-stage HIV/AIDS or cancer; millions more suffer the harms associated with addiction to illicit opioids, particularly heroin.[1] Medical best practice recognizes that

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therapeutic opioids are the only effective medication for most acute severe pain, as well as indispensible in palliative care.[2] Within this field, morphine and similar opioid medications are considered the "mainstay" in the treatment of moderate-to-severe intensity pain experienced by cancer and HIV patients.[3] Likewise, long-term pharmacotherapy (referred to here as Medication Assisted Treatment or MAT) has been proven to be an effective treatment for opioid dependence, one that also significantly reduces the risks of HIV/AIDS and other harms associated with injection drug use.[4] As a result, the World Health Organization (WHO) includes opioid medications that are commonly used to treat both pain and opioid dependence on its list of essential medicines.[5] According to the WHO, these medications should be "available within the context of functioning health systems at all times in adequate amounts [and] in the appropriate dosage forms."[6]

Despite the widespread recognition that opioid medications are necessary for medical treatment, a severe global inequality in access to these medicines persists. The United States, with 4.7% of the world's population, consumes nearly 55% of the world's morphine.[7] Poor and middle-income countries, where over 80% of the world's people live, consume only about 8%.[8] Similar disparities are found with

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‡ The Center for Health Law, Policy and Practice at the Temple University James E. Beasley School of Law is a member of the Drug Control and Access to Medicines Consortium, which also includes the Paint and Policy Study Group at the University of Wisconsin and the AIDS Project Management Group of Sydney, Australia. A contract with the United Knigdom's Department of International Development supported work on this article. The opinions and views expressed in this article are the authors', alone.

1. 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; *see also* 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; *see also* David S. Metzger, Helen Navaline & George E. Woody, *Drug Abuse Treatment as AIDS Prevention*, 113 PUBL. HEALTH REP. 97, 99 (1998).

2. Meredith Noble et al., *Long-term Opioid Management for Chronic Noncancer Pain*, 1 THE COCHRANE LIBRARY 1, 3 (2010), *available at* http://www.asipp.org/documents/Nobeletal.pdf.

3. William Breitbart, *Pain, in* A CLINICAL GUIDE ON SUPPORTIVE AND PALLIATIVE CARE FOR PEOPLE WITH HIV/AIDS 106 (Joseph F. O'Neill, et al. eds, 2003), *available at* http://hab.hrsa.gov/tools/palliative/contents.html.

4. *See* Metzger, *supra* note 1, at 100.

5. WORLD HEALTH ORG., THE SELECTION AND USE OF ESSENTIAL MEDICINES 78 (13th ed. 2003), *available at* http://whqlibdoc.who.int/trs/WHO_TRS_920.pdf.

6. *Id.* at 54; *see generally* WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES (2009), *available at* http://www.who.int/selection_medicines/committees/expert/17/sixteenth_adult_list_en.pdf.

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

8. INT'L NARCOTICS CONTROL BD., *supra* note 7; The United States, Canada, Australia, New Zealand, Europe and Japan combined consume nearly 92% of the world's supply of morphine. *Id.* Since much of this morphine is converted into other opioids, such as codeine, morphine is a good proxy for overall opioid consumption. *Id.*

MAT, which has become widespread in the developed world, but remains largely inaccessible in middle and low-income countries.[9] As efforts to improve HIV and cancer care in developing countries progress,[10] attention must be paid to the chronic lack of essential medicines for the care of pain and drug dependence.[11]

One significant source of this inequality of access lies in policy. In countries throughout the world, restrictive national policies emphasize drug control at the expense of ensuring access to essential opioid medicines.[12] This need not continue. International drug control bodies – the Commission on Narcotic Drugs, the United Nations Office on Drugs and Crime, and the International Narcotics Control Board – have traditionally encouraged an emphasis on drug control and neglected the issue of access.[13] However, the international conventions governing drug control unambiguously require states to balance control of illicit drug use with affirmative steps to ensure adequate access to opioids for medical and scientific use.[14] Over the past two decades, an informal coalition of dedicated international non-governmental organizations (NGOs) and United Nations programs have helped advocates in a number of countries expand access to therapeutic opioids. In recent years, both state parties to the drug control conventions and the international drug control organs have affirmed their support for access. With broad agreement in theory, all that now stands in the way of large-scale change at the international level is the lack of a unifying vision and a clear, adequately funded action plan.

This article is based on research commissioned by the United Kingdom's Department for International Development (DfID) that identified successful national opioid policy reform strategies. Based on the results of that work, we argue that moderate international investment can transform the current international consensus for improved therapeutic opioid access into meaningful

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9. PUBLIC HEALTH PROGRAM, OPEN SOCIETY INSTITUTE, BARRIERS TO ACCESS: MEDICATION-ASSISTED TREATMENT AND INJECTION-DRIVEN HIV EPIDEMICS 1 (2009), *available at* www.soros.org/initiatives/health/focus/.../barriers20090323.pdf [hereinafterBARRIERS TO ACCESS].

10. Paul Farmer, *Expansion of Cancer Care and Control in Countries of Low and Middle Income: a Call to Action*, 376 THE LANCET 1186, 1189 (2010), *available at* http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2810%2961152-X/abstract.

11. *See Painfully slow progress on palliative care*, 376 THE LANCET 206, 206 (2010), *available at* http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673610611245.pdf?id=4d037fefcb72946c:6ab6d4dd:12b7cebcf85:667f1286298514732.

12. *See* Evan Anderson & Corey Davis, *Breaking the Cycle of Preventable Suffering: Fulfilling the Principle of Balance*, 24 TEMP. INT'L & COMP. L.J. 329, 340-61 (2010) (explaining regulation of access to opioids).

13. *See* INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2009, U.N. Doc. E/INCB/2009/1 (2010) (The report devotes a significant amount of pages to the issue of drug control, yet it only devotes four pages to the issue of access for medical purposes).

14. Single Convention on Narcotic Drugs, as amended by the Protocol amending the Single Convention on Narcotics Drugs art. 2, Aug. 8, 1975, 18 U.S.T. 1407, 976 U.N.T.S. 105 [hereinafter Single Convention]; *accord* Convention on Psychotropic Substances pmbl., Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175.

reform. Part II makes the humanitarian case for national drug regulatory reform, describing the widespread medical need for opioid medicines and global inequity in their use. Part III provides a brief overview of the international law that obligates states to ensure adequate access to opioid medicines. It also discusses two kinds of impediments that national governments commonly face in improving access to opioid medicines. Part IV identifies three major elements of past successful national reform efforts. In addition, this section makes the case for funding and support to use these elements in a single, comprehensive intervention model for future drug policy reform. These sections make it clear that the NGOs, UN programs, and national champions committed to the cause know what changes are needed and how to initiate them. What they need now is the financial and political support of the world's donor nations.

II. THE NEED FOR OPIOID MEDICINES

In many countries, patients have little or no access to morphine and other clinically indicated pain medications.[15] Almost five million people suffer from untreated moderate to severe pain caused by cancer.[16] An additional 1.4 million people suffering from moderate to severe pain associated with AIDS also have no access to opioid medication.[17] These inequities will likely worsen with time – the WHO estimates that by 2020 there will be 15 million new cancer cases per year, with 60% occurring in the developing world.[18] In addition, HIV continues to infect over two and a half million people per year, the majority in sub-Saharan Africa, despite advances in the availability of antiretroviral therapy.[19] Of the people living now, at least 600 million individuals will see their health negatively affected by a lack of access to opioid medicines during their lifetimes.[20]

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15. Allyn L. Taylor, Lawrence O. Gostin & Katrina A. Pagonis, *Ensuring Effective Pain Treatment: A National and Global Perspective*, 299 JAMA 89, 89 (2008) (reporting severe under-treatment in more than 150 countries).

16. Willem Scholten, Helena Nygren-Krug & Howard A. Zucker, *The World Health Organization Paves the Way for Action to Free People from the Shackles of Pain*, 105 ANESTHESIA AND ANALGESIA 1, 2 (2007), *available at* http://www.anesthesia-analgesia.org/content/105/1/1.full [hereinafter ANESTHESIA AND ANALGESIA].

17. *Id.*

18. Tan Ee Lyn, *Developing Nations to Bear Cancer Brunt*, REUTERS (Aug. 19, 2010), http://www.reuters.com/article/idUSTRE67I1GT20100819; *see* INFORMAL WORKING GROUP ON CANCER TREATMENT IN DEVELOPING COUNTRIES (CAN TREAT INTERNATIONAL), ACCESS TO CANCER TREATMENT IN LOW- AND MIDDLE-INCOME COUNTRIES 2 (Aug. 19, 2010), *available at www.axios-group.com/x/File/CanTreat-em-paper-new.pdf.*

19. UNAIDS, *2009 Report on the Global AIDS Epidemic*, 7-8, UNAIDS/09.36E/JC1700E (Nov. 2009), *available at* http://data.unaids.org/pub/Report/2009/JC1700_Epi_Update_2009_en.pdf.

20. ANESTHESIA AND ANALGESIA, *supra* note 15 at 2. For tragic stories illustrating the various legal and cultural barriers to care, *see* Eric L. Krakauer et al., *Opioid Inaccessibility and Its Human Consequences: Reports from the Field*, 24 J. OF PAIN & PALLIATIVE CARE PHARMACOTHERAPY 239 (2010) (discussing the difficulties encountered by people in low- and middle-income countries in obtaining opioids for medical purposes).

The number of worldwide injection drug users (IDUs) is estimated to exceed thirteen million.[21] MAT could help many of these individuals overcome their dependency.[22] Just as opioids are necessary for the treatment of moderate to severe pain, the science unequivocally indicates that the best and most appropriate therapy for dependence on heroin and other opioids is comprehensive treatment that includes MAT.[23] In industrialized countries, MAT is a standard option for those dependent on opioids, with more than 800,000 patients prescribed buprenorphine or methadone as of 2005.[24] These medications are prescribed to relieve cravings for illicit opioids like heroin.[25] This treatment, most often utilizing Methadone at appropriate doses, is associated with improvements in physical health, social health, and retention in substance abuse treatment programs.[26]

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.[27] A variety of studies indicate MAT has been shown to reduce use of illicit drugs, overdose deaths, needle sharing, and HIV transmission.[28] In 2005, the WHO recognized the importance of MAT by adding

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21. Carmen Aceijas et al., *Global Overview of Injecting Drug Use and HIV Infection Among Injecting Drug Users,* 18 OFFICIAL J. OF THE INT'L AID SOCIETY 2295, 2297 (2004).

22. U.S. DEP'T OF HEALTH AND HUMAN SERVICES, PUB NO. (SMA) 05-4048, MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION IN OPIOID TREATMENT PROGRAMS xvii (2005), *available at* http://www.naabt.org/documents/TIP43-buprenorphine-methadone-suboxone-opiate.pdf.

23. *See generally id.*; *see also* WORLD HEALTH ORG., SUBSTITUTION MAINTENANCE THERAPY IN THE MANAGEMENT OF OPIOID DEPENDENCE AND HIV/AIDS PREVENTION (2004), *available at* http://www.who.int/substance_abuse/publications/en/PositionPaper_English.pdf [hereinafter SUBSTITUTION MAINTENANCE THERAPY] (explaining that MAT is one of the most effective treatment options for opioid dependence and that provision of such therapy is an important treatment option in communities with a high prevalence of opioid dependence).

24. BARRIERS TO ACCESS, *supra* note 9, at 1.

25. Rolley E. Johnson et al., *A Comparison of Levomethadyl Acetate, Buprenorphine, and Methadone for Opioid Dependence*, 343 NEW ENGLAND J. OF MED. 1290, 1290-1297 (2000); *see also* Andy Gray, *Systematic Review of the Safety of Buprenorphine, Methadone, and Naltrexone* (Background document prepared for Technical Development Group for the WHO Guidelines for Psychosocially Assisted Pharmacotherapy of Opioid Dependence, Geneva).

26. *See generally* JOHN C. BALL & ALAN ROSS, THE EFFECTIVENESS OF METHADONE MAINTENANCE TREATMENT (1991).

27. BARRIERS TO ACCESS, *supra* note 9, at 1.

28. John R.M. Caplehorn et al., *Methadone Maintenance and Addicts' Risk of Fatal Heroin Overdose*, 31 SUBSTANCE USE AND MISUSE 177, 185 (1996) (indicating that opioid dependent patients are four times less likely to die if they receive methadone); David S. Metzger et al., *Human Immunodeficiency Virus Seroconversion Among Intravenous Drug Users In- and Out-of-Treatment: An 18-Month Prospective Follow-Up*, 6 J. OF ACQUIRED IMMUNE DEFICIENCY SYNDROME 1049, 1049 (1993) (noting that 22% of IDUs not receiving methadone during study period contracted HIV vs. only 3.5% of IDUs receiving methadone); Linda R. Gowing et al., *Brief Report: Methadone Treatment of Injecting Opioid Users for Prevention of HIV Infection*, 21 J. OF GENERAL INTERNAL MEDICINE 193, 193 (2006) (methadone maintenance patients show reduced injection, reduced needle sharing, reduced drug use, reduced risky sex behavior and reduced HIV incidence); BARRIERS TO ACCESS, *supra* note 9, at 1 (medication-assisted treatment

two of the most commonly used MAT drugs, methadone and buprenorphine, to its Model List of Essential Medicines.[29]

The international community increasingly recognizes the importance of these essential medicines and the shameful disparities in their global use. The World Health Assembly and the United Nations Economic and Social Council have recently adopted resolutions calling on all governments to take steps to ensure the availability of all essential medicines, particularly therapeutic opioid medications.[30] In June 2001, a special session of the UN General Assembly on HIV/AIDS provided milestones for implementing comprehensive care strategies that include palliative care.[31] Such measures are one of the few international guidelines available to national advocates.[32]

Earlier this year, the Commission on Narcotic Drugs (CND), one of the central policy-making bodies of the UN, drafted a resolution that expressly recognizes the need for access to controlled medicines.[33] At the same time, major donors, NGOs, physicians, and other advocates have emerged to push for increased access to therapeutic opioids and have been successful in a number of countries.[34]

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has been associated with decreased use of injecting drugs, increased retention in treatment for chemical dependence and increased adherence to HIV medication).

29. WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 21 (2005), *available at* http://whqlibdoc.who.int/hq/2005/a87017_eng.pdf.

30. Cancer Prevention and Control, World Health Org. Res. WHA 58.22, at 105 (2005), *available at* http://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_22-en.pdf; E.S.C. Res. 2005/25, U.N. Doc. E/2005/25 (July 22, 2005), *available at* http://www.un.org/docs/ecosoc/documents/2005/resolutions/Resolution%202005-25.pdf; *see also* U.N. E.S.C. Comm'n on Narcotic Drugs, Report on the Forty-Eighth Session, U.N. Doc. E/2005/28 (Mar. 19, 2004, Mar. 7-11, 2005, & Dec. 7-8, 2005), *available at* http://www.daccess-dds-ny.un.org/doc/UNDOC/GEN/V05/826/64/PDF/V0582664.pdf?OpenElement.

31. Declaration of Commitment on HIV/AIDS, G.A. Res. S-26/2, art. 56, U.N. Doc. A/RES/S-26/2 (June 25-27, 2001).

32. *See id.*

33. U.N. E.S.C. Comm'n on Narcotic Drugs, *Promoting Adequate Availability of Internationally Controlled Licit Drugs for Medical and Scientific Purposes While Preventing Their Diversion and Abuse*, 53d Sess., Mar. 8-12, 2010, U.N. Doc. E/CN.7/2010/L.6/Rev.1 (Mar. 10, 2010), *available at* http://www.unodc.org/documents/commissions/CND-Uploads/CND-53-RelatedFiles/ECN72010_L6Rev1EV1051780.pdf.

34. 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 in advocating for balanced access to therapeutic opioids); Paul Farmer, et al., *Expansion of Cancer Care and Control in Countries of Low and Middle Income: A Call to Action*, 376 THE LANCET 1186, 1188 (2010), *available at* http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2810%2961152-X/abstract (click "PDF (141 KB)" link in right-hand column for full text) (decrying lack of access to palliative care for cancer patients).

III. THE LEGAL OBLIGATION TO ENSURE ACCESS: UNAMBIGUOUS IN THEORY, UNFULFILLED IN PRACTICE

A. *Requirements under International Law*

The major treaties that govern controlled substances are the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol (Single Convention),[35] the 1971 Convention on Psychotropic Substances,[36] and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.[37] The Single Convention, which sets out the framework for international regulation of controlled substances and has attained nearly universal adherence,[38] requires that countries ensure adequate availability of opioid medications for medical and scientific purposes.[39] Additionally, the Convention on Psychotropic Substances recognizes that opioid medications are "indispensable" to proper medical care and treatment.[40] At the same time, these documents instruct states to regulate controlled substances in order to prevent illicit use.[41] This dual obligation to both ensure access and prevent diversion is frequently referred to as the Principle of Balance.[42]

Access to essential medicine is increasingly recognized as an implicit element of the right to health articulated in the International Covenant on Economic, Social, and Cultural Rights (ICESCR). The ICESCR recognizes that everyone has the right to "the enjoyment of the highest attainable standard of physical and mental

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35. Single Convention on Narcotic Drugs, as amended by the Protocol amending the Single Convention on Narcotics Drugs, Aug. 8, 1975, 18 U.S.T. 1407, 976 U.N.T.S. 105 [hereinafter Single Convention]

36. Convention on Psychotropic Substances, Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175 [hereinafter Convention on Psychotropic Substances].

37. Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, Dec. 20, 1988, 1582 U.N.T.S. 164, 28 I.L.M. 497 [hereinafter 1988 Convention] (entered into force Nov. 11, 1990).

38. Melissa T. Aoyagi, Note*, Beyond Punitive Prohibition: Liberalizing the Dialogue on International Drug Policy*, 37 N.Y.U. J. INT'L. L. & POL. 555, 577 (2005).

39. Single Convention, *supra* note 35, art. 9 para. 4.

40. Convention on Psychotropic Substances*, supra* note 36, at preamble.

41. *Id*. art. 5; Single Convention, *supra* note 35, art. 4(c).

42. *See* WORLD HEALTH ORG., NARCOTIC AND PSYCHOTROPIC DRUGS - ACHIEVING BALANCE IN NATIONAL OPIOIDS CONTROL POLICY 11-12 (2000), *available at* http://whqlibdoc.who.int/hq/2000/WHO_EDM_QSM_2000.4.pdf [hereinafter ACHIEVING BALANCE]. The principle of balance is ingrained in the international conventions that regulate controlled substances. *See generally id.* It was adopted by WHO in 2000 when it set out guidelines for assessing national opioid control policies so that drug control did not interfere in medical availability of essential medicines. *See generally id.; see also* David E. Joranson, *Improving Availability of Opioid Pain Medications: Testing the Principle of Balance in Latin America*, 5 INNOVATIONS IN END-OF-LIFE CARE 1 (2003), *available at* http://www2.edc.org/lastacts/archives/archivesJan03/printfeatureinn.pdf (discussing the history of the principle of balance); Karen M. Ryan, *The Pain & Policy Studies Group international Program*, 21 J. PAIN PALLIATIVE CARE PHARMACOTHERAPY 35, 35-37 (2007) (discussing the need for balanced opioid policy).

health."[43] It also obligates states to undertake minimum steps to ensure realization of the right to health.[44] According to the ICESCR, this means that states must take steps necessary for the "creation of conditions which would assure the availability of medical service and medical attention to every person in the event of sickness,"[45] including the right to be free from treatable pain.[46] But the ICESCR does not just require states to take affirmative steps to promote health; it also prohibits states from improperly limiting the ability of individuals to protect their own health.[47] Insufficient access to MAT can be seen as a significant limitation of that ability. This contention is bolstered by the fact that the WHO, UNODC, and UNAIDS all recognize the benefits of MAT and find that it is in line with international laws that govern narcotic drugs and psychotropic substances.[48]

The right to be free from pain is also increasingly recognized as included in international laws prohibiting torture and cruel, inhuman, and degrading treatment (CIDT).[49] The UN Special Rapporteur on Torture and CIDT has recognized that a government's failure to ensure adequate access to pain medicine may violate the right to be free from torture and CIDT.[50] Withholding medical treatment for drug dependency has been identified as causing severe abuse, amounting to CIDT in some cases.[51] Both torture and CIDT are prohibited in the major international

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43. International Covenant on Economic, Social, and Cultural Rights, art. 12, Dec. 16, 1966, 1966 U.S.T. 521, 993 U.N.T.S. 3, *available at* http://www2.ohchr.org/english/law/pdf/cescr.pdf [hereinafter ICESCR].

44. Frank Brennan, Daniel B. Carr & Michael Cousins, *Pain Management: A Fundamental Human Right,* 105 ANESTHESIA AND ANALGESIA 205, 213 (2007), *available at* http://www.anesthesia-analgesia.org/content/105/1/205.full (quoting ICESCR, *supra* note 42, art. 12).

45. ICESCR, *supra* note 43, art. 12(d).

46. Comm. on Econ., Soc. & Cultural rights, *The Right to the Highest Attainable Standard of Health: General Comment 14*, ¶ 25, U.N. Doc. E/C.12/2000/4 (Apr. 25-May 12, 2000), *available at* http://data.unaids.org/publications/External-documents-Restored/ecosoc_cescr-gc14_en.pdf [hereinafter *General Comment 14*]. General Comment 14 explains that the right to health includes, "attention and care for chronically and terminally ill persons, sparing them avoidable pain and enabling them to die with dignity." *Id.*

47. HUMAN RIGHTS WATCH, RHETORIC AND RISK: HUMAN RIGHTS ABUSES IMPEDING UKRAINE'S FIGHT AGAINST HIV/AIDS 72 (2006), *available at* http://www.hrw.org/en/node/11464/section/10; *see also General Comment 14*, *supra* note 43, ¶¶ 30-37.

48. SUBSTITUTION MAINTENANCE THERAPY, *supra* note 23 ¶¶ 20-23.

49. *See* Diederick Lohman, *Pain Relief: a Human Right*, NETWORK, (Dec. 4 2009), *available at* http://www.inctr.org/publications/images/newsletterv9n2.pdf; *see generally* Frank Brennan, Liz Gwyther &Richard Harding, *Palliative Care as a Human Right,* OPEN SOCIETY INSTITUTE PUBLIC HEALTH PROGRAM, Jan. 2008, *available at* http://www.soros.org/initiatives/health/focus/law/articles_publications/publications/pchumanright_20080101/pchumanright_20080101.pdf.

50. Diederik Lohman, Rebecca Schleifer & Joseph J. Amon, *Access to Pain Treatment as a Human Right*, 8 BMC MED. 1, 6 (2010) (citing *Z v. U.K.,* 4 EHRR 97 (2001)), *available at* http://www.biomedcentral.com/1741-7015/8/8.

51. R. Douglas Bruce & Rebecca Schleifer, *Ethical and Human Rights Imperatives to Ensure Medication-Assisted Treatment for Opioid Dependence in Prisons and Pre-trial Detention,* 19 INT'L J. DRUG POLICY 17, 17 (2008); *see also McGlinchey v. U.K.,* [2003] ECHR

human rights, humanitarian, and criminal law instruments,[52] as well as in regional instruments.[53] This makes the prevention of CIDT another reason to increase access to opioid medicines.

B. Legal Barriers at the National Level

Within countries, legal impediments to the availability of opioid medications generally fall into one or both of two broad categories: structural and regulatory. The first category represents an absence of infrastructure necessary to manage and allow access to drugs. There are two reasons why this absence may exist. First, it may exist because there are failures in the policy infrastructure that dictate the rules governing the manufacture, importation, distribution, and use of controlled medicines. Second, it may exist because there are failures in the administrative infrastructure that controls the personnel who manage permits and reports and perform other administrative tasks required to implement the policy.

The second category of barrier is comprised of legal regimes that thwart access through overregulation and the threat of harsh criminal sanctions. Many governments simply do not have the policies and legal mechanisms which are necessary to facilitate appropriate availability and access to opioid medications. Consequently, laws and health care policies that explicitly recognize the need for medical access can be useful to champions inside and outside of government and, like clear policies in any area, can help coordinate the provision of services. Yet, many developing and transitional countries have little or no policy infrastructure in place for pain and palliative care or MAT.[54]

For example, until 2006 Vietnam had no formal palliative care policy to guide the development of treatment services; a 2006 government report on scaling up universal access to HIV/AIDS services did not even include palliative care as an option.[55] In many countries, the best scientific and medical practices for using

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50390/99 (finding that the UK breached its Article 3 obligation for failing to provide adequate health care to a woman in detention, including failure to properly treat her withdrawal symptoms from heroin. The woman died in prison, and heroin withdrawal was identified as a contributor to her death.).

52. Universal Declaration of Human Rights, G.A. Res. 217A, art. 5, U.N. GAOR, 3d Sess., 1st plen. Mtg., U.N. Doc. A/810 (Dec. 10, 1948), *available at* http://daccess-ddsny.un.org/doc/RESOLUTION/GEN/NR0/043/88/IMG/NR004388.pdf?OpenElement (stating, "No one shall be subjected to torture or to cruel, inhuman, or degrading treatment or punishment."); International Covenant on Civil and Political Rights, G.A. Res. 2200A (XXI), art. 7, U.N. Doc. A/6316 (Dec. 16, 1966), *available at* http://www2.ohchr.org/english/law/ccpr.htm; Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, G.A. Res. 39/45, U.N. Doc. A/39/51 (Dec. 10, 1984), *available at* http://www2.ohchr.org/english/law/cat.htm.

53. *See* European Convention for the Protection of Human Rights and Fundamental Freedoms, art. 3, 213 U.N.T.S. 222 (Nov. 4, 1950), http://www.conventions.coe.int/Treaty/en/Treaties/Word/005.doc (stating that "[n]o one shall be submitted to torture or to inhuman or degrading treatment or punishment").

54. *Blueprint*, *supra* note 34, at 2-3.

55. *See* MINISTRY OF HEALTH, SOCIALIST REPUBLIC OF VIET NAM, REPORT SCALING UP

opioid medications have progressed more rapidly than the legal structures governing them, leaving many antiquated administrative rules and practices in place.[56]

Even among countries that recognize the importance of therapeutic opioids in theory, the lack of governmental capacity and workable regulations controlling importation, production, and distribution can limit or close off supply. For example, the Single Convention requires States to annually report their previous year's consumption and to estimate their use for next year as a precondition to receiving approval to manufacture or import opioids.[57] Yet, some countries fail to report any estimates whatsoever, while others estimate and consume orders which are insufficient to satisfy their populations' needs.[58] Limited production or low-volume purchasing can raise the cost of opioid medications, which can then restrict access to a wealthy few.[59] The absence of coordinated policy can lead to supply interruptions, which can subsequently cause treatment interruption or sudden reductions in dosages to non-therapeutic levels.

For many years, India had only one factory that produced morphine and it experienced frequent interruptions in production.[60] As a result, Indian hospitals that were licensed to prescribe morphine were often unable to supply patients with necessary treatment.[61] Poor supply has also been a constant threat to new MAT programs needed to fight HIV/AIDS in Central Asia. In 2005, for example, methadone treatment was halted in Azerbaijan when clinics did not receive new supplies.[62] Similarly, in Kyrgyzstan, MAT patients had their doses sharply reduced

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TOWARDS UNIVERSAL ACCESS TO HIV/AIDS PREVENTION, TREATMENT, CARE AND SUPPORT IN VIET NAM (2006), *available at* http://www.unaids.org.vn/resource/topic/ua/ua_report_vietnam_10mar06_e.pdf; *see also* *Blueprint*, *supra* note 34, at 2.

56. WORLD HEALTH ORG., CANCER PAIN RELIEF: WITH A GUIDE TO OPIOID AVAILABILITY 41-45 (2d ed. 1996) (finding that legal restrictions and public and professional beliefs that ignore the latest scientific knowledge impede the proper use of opioids).

57. Single Convention, *supra* note 34, art. 20.

58. HUMAN RIGHTS WATCH, "PLEASE, DO NOT MAKE US SUFFER ANY MORE..." ACCESS TO PAIN TREATMENT AS A HUMAN RIGHT 20 (2009), *available at* http://www.hrw.org/sites/default/files/reports/health0309webwcover_1.pdf [hereinafter PLEASE, DO NOT MAKE US SUFFER]. Some countries do not submit estimates of needed opioids to the INCB, as required by international law, or they submit merely symbolic estimates. *Id.* Such underreporting causes the INCB to provide quotas for opioid use that cannot possibly meet the country's true level of need. *Id.*

59. *Id.* at 35-36. The basic opioid medicines for pain and drug treatment – morphine and methadone – are long past patent protection and can be manufactured at an extremely low cost. *Id.* at 36. They are sometimes expensive for buyers in developing countries because of the drugs' low volume, high regulatory compliance costs, and imbalances in negotiating power. *Id.* Generally, there is no reason for price to be a significant barrier to improved medicine access. *Id.* Indeed, greater demand and better cooperation among developing countries should help reduce the cost. *Id.* at 35-37.

60. *See* M.R. Rajagopal & David E. Joranson, *India: Opiod Availability – An Update*, 33 J. OF PAIN AND SYMPTOM MGMT. 615, 617 (2007).

61. *Id.* at 616-617.

62. BARRIERS TO ACCESS, *supra* note 9, at 2.

or were urged to stop treatment due to delays in the procurement and distribution of methadone.[63] These interruptions can have a devastating impact on both patient well-being and national efforts to prevent HIV. Because legal access to opioids can only occur through government-regulated channels, governments must have the policies and bureaucratic capacity necessary to support medical use. They must also enact legal mechanisms regulating supply.

The second category of barriers commonly found at the national level consists of laws that burden or even criminalize medically indicated opioid access. Sometimes the overly burdensome effect of laws governing opioid use is actually a result of efforts to prevent their illegal use. An example of this type of barrier is apparent in India, which passed a complex and harsh anti-drug act in 1985.[64] Under this act, even minor infractions could earn 10-year sentences.[65] Legal morphine use in India plummeted 97% after the law was passed.[66] Non-criminal regulations can also pose a significant barrier to opioid access. For example, Indian law requires five separate licenses for each shipment of morphine between states and requires the pills to be locked in two-key cabinets once they arrive.[67] In resource-poor countries, even these somewhat trivial bits of red-tape can immobilize health care agencies that have tiny budgets.

Drugs used for MAT are typically subject to all the same rules and barriers as those used for pain management. However, MAT may be subject to additional regulatory requirements because of its connection to illegal drug use and a prevailing belief that its use in drug dependency care must be strictly regulated.[68] In many countries, patients who seek MAT are deterred from treatment by regulatory barriers like waiting lists and restrictive initiation requirements.[69] As a result, changes to the protocol for entry into such treatment can have widespread positive effects on the number of people enrolled. In China, for example, the original entry criteria required that patients repeatedly "fail" treatment in compulsory detoxification facilities or forced labor camps prior to entry into a methadone program. In 2006, China relaxed these requirements and initiated a

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63. *Id.*

64. *See* Donald G. McNeil Jr., *In India, a Quest to Ease the Pain of the Dying*. N.Y. TIMES, Sept. 11, 2007, *available at* http://www.nytimes.com/2007/09/11/health.

65. *See id.*

66. *Id. See generally* 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 (detailing the reform experiences of China, India, Romania and Vietnam regarding pain treatment and opioid dependency).

67. McNeil, *supra* note 62.

68. *See* Rajagopal & Joranson, *supra* note 51, at 617 ("Through decades of strict regulation, medical professionals developed a fear of morphine . . . This attitude came out of exaggerated fears of addiction . . . and was reinforced by an unbalanced regulatory environment governing opiods.").

69. BARRIERS TO ACCESS, *supra* note 9, at 2.

strong pro-treatment campaign, leading to a sharp increase in patients who access methadone.[70]

Law enforcement practices can also reduce access to therapeutic opioids when laws are ambiguous or unsupported by police practices. For example, although the Malaysian government formally endorsed the establishment of MAT using methadone in 2005, police reportedly continued to raid treatment programs and arrest attendees.[71] In Kyrgyzstan, police have stationed themselves outside methadone clinics and have sometimes arrested patients or threatened to plant drugs on them unless they pay bribes.[72] In Odessa, Ukraine, buprenorphine patients report that police officers regularly extort money and threaten to plant drugs on them.[73]

All these legal impediments have been well-identified by researchers and health advocates. They have also been criticized by international drug control organizations. In addition, as case studies have shown, all these barriers can be effectively removed by committed champions armed with the data and resources necessary to mount a national campaign for reform. The policy problems that prevent access to therapeutic opioids are not just solvable in theory; they have been effectively addressed again and again. The next section details previous successes and what they teach us about making faster progress on a larger scale.

IV. TOWARDS REFORM: SPARKING AND SUSTAINING NATIONAL CHANGE

A. A History of Successful Reform: Balanced Laws, Sustainable Change

Successful and sustainable reform aimed at improving access to therapeutic opioids is as possible as it is necessary. In this part, we detail a systematic model for policy reform based on three basic elements, identified by a review of successful drug policy reform experiences: (1) mobilizing national advocates, politicians, and regulators through a needs assessment and the development of an action plan; (2) drafting regulatory reforms and building broad-based support; and (3) implementation and evaluation.

This model need not be followed exactly. Every country has its own unique needs, abilities, and timeframe.[74] Reform is not a fixed and invariant path;

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70. *Id*. at 3.

71. Gary Reid, Adeeba Kamarulzaman & Sangeeta Kaur Sran, *Malaysia and Harm Reduction: The Challenges and Responses*, 18 INT'L J. DRUG POL'Y 136, 139 (2007).

72. BARRIERS TO ACCESS, *supra* note 9, at 2.

73. BARRIERS TO ACCESS, *supra* note 9, at 2.

74. Burris & Davis, *supra* note 51, at 3 (explaining that countries experience a "cycle of policy learning" under which reform is achieved; the process of the cycle is not fixed, and reform is never reached the same way in any two countries). Romania, as detailed elsewhere in this issue, illustrates a "fast track" for pain reform that brought the country to the implementation phase in just a few years. Anderson et al., *supra* note 66, at 12-13. In other countries, like China, the elements of the model have been repeated several times over a decade and a half, with partial reforms and implementation problems feeding back into further advocacy, assessment and reform. Burris & Davis, *supra* note 51, at 3; *see also* Daniela Mosoiu et al., *Reforming Drug Control Policy for Palliative Care in Romania*, 367 THE LANCET 2110, 2110-2117 (2006)

however, this proposed model is a systematic approach to reform, distilled from the successful reform experiences of several low and middle-income countries.[75] The shared experiences of these very different countries suggest that any country undergoing national drug reform can benefit from a single framework based on the three essential stages of change. The intervention model we propose anticipates that each stage of reform will require approximately one year. We offer the approach not as a wholly original model, but rather as one drawn from actual experience. Our purpose is to demonstrate to major funders in global health that past success can be "packaged" and scaled up in a distinct intervention. Furthermore, experienced NGOs and international agencies can both predict such an intervention's cost and implement it successfully, since they have experience with all aspects of health reform.

1. Year One: Mobilization, Assessment, and Action Planning

Our research found that national reform begins with local champions who have the enthusiasm and the credibility to take the lead.[76] In most countries, these champions come from the health care field. They are often doctors who provide care to patients with cancer or HIV infection, or members of the drug treatment and harm reduction communities.[77] Sometimes they initiate this work on their own. More often they are identified by international advocates during regional workshops that are explicitly designed to identify countries that are ready for reform.[78] Government officials are also routinely invited to attend these workshops and are paired with these NGO champions based on the unassailable premise that reform is unlikely without government buy-in. These local champions and government allies are the catalysts for national reform.[79] Aided by funding, expertise, and technical assistance from outside organizations, these committed individuals assess the needs of their communities and build stakeholder ownership over the process.[80] Supporters of policy reform can assist national stakeholders by investing in a variety of capacity building mechanisms aimed at supporting the development and effective use of expertise.

(detailing a similar cycle during the reform process in Romania).

75. *See generally* Anderson et al., *supra* note 66 (analyzing reforms achieved in China, India, Romania, and Vietnam that involved pain relief and treatment of drug dependence).

76. *Id.* at 83.

77. *See generally Mission & History*, HARM REDUCTION COALITION, http://www.harmreduction.org/section.php?id=63 (last visited Oct. 6, 2010) ("The Harm Reduction coalition is a national advocacy and capacity-building organization that promotes the health and dignity of individuals and communities impacted by drug use.").

78. *See* Anderson et al., *supra* note 66, at 12 (stating that the WHO saw evidence that Romania was officially ready for reform after it held a three-day conference with Romanian physicians to discuss access to pain treatment; as a result, WHO then selected the country for further collaborative work.).

79. *Id.* at 83.

80. *Id.*

Regional palliative care coalitions, the WHO Access to Controlled Medicine Program (ACMP), the Open Society Institute (OSI), the Pain and Policy Studies Group at the University of Wisconsin (PPSG), and numerous other organizations have also played an important role in identifying and cultivating local champions.[81] Experience shows that, in many places, it is possible identify champions ready to act; it is also possible to cultivate and support new champions who can step up to leadership roles in the near future.[82]

Champions of reform, and their allies in government, next have to convince others that the problem is real and can be solved. Successful reformers have normally accomplished this by a process of assessment. This can take several forms, from investigative journalism to pilot programs or academic studies. Over many years, both the WHO's Guidelines for Assessment in Achieving Balance in National Opioids Control Policy and the Barriers to Opioid Availability Test (BOAT) developed by PPSG have been the starting point for identifying policy barriers to opioid access.[83] They have also been used elsewhere in much the same way.[84] These guidelines, which use a checklist approach to analyze the law on the books, have been used by country champions to assess national regulatory barriers and develop preliminary action plans.[85] Where resources allow it, countries increasingly use these empirical methods to define needs and policy barriers.[86]

For example, Vietnam used a rapid situation analysis (RSA) method in its reform efforts.[87] A Ministry of Health (MOH) working group administered RSA in five provinces across the country to better understand the availability of opioid analgesics and the role of laws and regulations as barriers to access.[88] These analyses contributed to a knowledge base for new palliative care guidelines that

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81. *See generally* Anderson et al., *supra* note 66 (identifying various governmental and non-governmental entities which contributed to and facilitated pain and drug-dependence treatment reform in China, India, Romania, and Vietnam).

82. *See* Anderson et al., *supra* note 66, at 32-33 (stating that in China, there were existing champions of reform made up of government officials and academics who recognized that preventative measures against HIV/AIDS were urgently needed; and there were also new champions who were identifies and prepared through the use of sponsored workshops).

83. ACHIEVING BALANCE, *supra* note 39, at 2; *see also* Joranson, *supra* note 39, at 5 (referring to two examples in Columbia and Mexico when the WHO guidelines were used to identify the need for barriers to opioid access).

84. Joranson, *supra* note 41, at 5.

85. *See generally* PAIN AND POL'Y STUDIES GROUP, AVAILABILITY OF MORPHINE AND PETHIDINE IN THE WORLD AND AFRICA WITH A SPECIAL FOCUS ON: BOTSWANA, LESOTHO, MOZAMBIQUE, NAMIBIA, SWAZILAND, ZIMBABWE (Feb. 27, 2008), *available at* http://www.painpolicy.wisc.edu/publicat/monograp/apca08.pdf.

86. Extensive literature exists documenting the use of RSA in a variety of contexts, including drug-related interventions. The method includes participant and direct observation, in-depth interviews, and focus groups. *See, e.g.,* DAVID MCCOY & LESLEY BAMFORD, HOW TO CONDUCT A RAPID SITUATION ANALYSIS A GUIDE FOR HEALTH DISTRICTS IN SOUTH AFRICA (1998), *available at* http://www.hst.org.za/uploads/files/rapid.pdf.

87. Anderson et al, *supra* note 66, at 76.

88. *Id.*

were made effective in 2006, resulting in improved opioid prescribing regulations by 2008.[89]

The RSA method has been used successfully to document need. However, it has also been used to secure the necessary support for reform from government sponsors. In India, a handful of NGO-run clinics began providing comprehensive treatment including MAT to IDUs in the early 1990s, but closed by 2002 because of a lack of funding.[90] In order to remedy this situation, RSA projects were conducted with funding from foreign donors. By combining survey and in-depth interviewing research, these analyses yielded the kind of solid data necessary to convince government officials that a national injection drug use problem existed.[91] Armed with data, the researcher-advocates held "dissemination workshops" with HIV-related NGOs, government officials, and local arms of AIDS control organs. While the data obtained from the RSA were largely as anticipated, the outcome of the dissemination workshops was "phenomenal," in the sense of increasing government awareness of the depth and the urgency of the IDU issue.[92]

Consistent with these examples, our research found that assessment techniques that involve stakeholders and government officials in the process of collecting and interpreting data increase the visibility of the process, the credibility of the results, and participant buy-in with regard to goals.[93] In our intervention model, we accordingly include a formalized community participatory assessment process called Rapid Policy Assessment and Response (RPAR).[94] RPAR was originally designed as a community participatory research method that would assess how laws and law enforcement practices influence HIV risks among drug users and sex workers.[95] It was also intended to support policy and practice change. DfID supported efforts by the Consortium for Drug Control and Access to Medicines (DCAM), a U.S. based consortium of pain and MAT experts, to develop an RPAR tool designed for therapeutic opioids.[96]

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89. Eric L. Krakauer, Nguyen Thu Phuong Cham & Lunong Ngoc Khue, *Vietnam's Palliative Care Initiative: Success and Challenges in the First Five Years,* 40 J. OF PAIN & SYMPTOM MGMT. 27, 28 (2010).

90. Anderson et al, *supra* note 66, at 78.

91. *Id* at 11-12.

92. *5 City Project*, SHARAN.NET, http://www.sharan.net/reports/5_city/impact1.zhtml (last visited Oct. 4, 2010). The 5 City Project aims to equip service providers and inform government responses to HIV. *Id.*

93. Anderson et al., *supra* note 66, at 83.

94. *Rapid Policy Assessment Response: Overview*, TEMPLE UNIVERSITY, http://www.temple.edu/lawschool/phrhcs/rpar.htm (last visited Oct. 4, 2010).

95. *Rapid Policy Assessment and Response: What is RPAR*?, TEMPLE UNIVERSITY, http://www.temple.edu/lawschool/phrhcs/rpar/index.html (last visited Oct. 4, 2010). RPAR was developed with support from the Open Society Institute and the National Institute of Drug Abuse (NIDA). *Rapid Policy Assessment and Response: History,* TEMPLE UNIVERSITY, http://www.temple.edu/lawschool/phrhcs/rpar/about/history.html (last visited Oct. 4, 2010).

96. The Opioid Access RPAR is publicly available at *Rapid Policy Assessment and Response: Other Tools and Training*, TEMPLE UNIVERSITY, http://www.temple.edu/lawschool/phrhcs/rpar/tools/OtherTool.html (last visited Oct. 4, 2010).

Pilot programs also serve both as assessment and mobilization tools. Loosely defined, they may be nothing more than the programs run by champions themselves which can at least demonstrate feasibility. With more funding (and here government or international donor support has been crucial), formal pilot programs can refine a treatment model and overcome political objections to a controversial intervention. In China's move towards MAT, the absence of domestic data showing the feasibility and efficacy of MAT was a major barrier to reform.[97] A pilot project of eight MAT sites in five provinces demonstrated that MAT could achieve at least four important results in the Chinese setting: (1) reducing heroin usage; (2) reducing HIV-related high risk behavior; (3) reducing addiction-related crime; and (4) facilitating the rebuilding of social and family functions.[98] These findings were important in overcoming objections to the use of opioid medication in the treatment of opioid dependence and in addressing concerns of the law enforcement sector.[99] In addition, the success of the pilot programs addressed public misconceptions about MAT and assured IDUs that proper operation of MAT programs would not expose them to criminal punishment.[100]

Of course, there is a risk that pilot programs may be used by unwilling governments as a way to deflect international pressure while indefinitely delaying real program implementation. However, China's adoption of MAT for drug treatment provides an example of effective collaboration between international donors and national advocates.[101] In China, advocacy for increased MAT was primarily led by national advocates[102] with advice and strategic funding from international donors and agencies.[103] DfID; the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM); and others provided funding and technical assistance that helped domestic champions promote the public health aspect of MAT.[104] For example, in order to prepare Chinese advocates, international donors held scientific workshops with discussions on evidence-based medical interventions that targeted stigmatized groups.[105]

In the experience-based intervention model we present here, RPAR assessments (and feedback from any pilot programs) are used to develop action plans that are used to draft regulatory reforms and win support for their enactment. For example, in 2006 the PPSG hosted Vietnamese MOH officials at the

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97. Anderson et al., *supra* note 66, at 7.

98. Lin Pang et al., *Effectiveness of First Eight Methadone Maintenance Treatment Clinics in China*, 21 AIDS 103, 105-107 (Supp. 8 1984).

99. Anderson et al., *supra* note 66, at 34.

100. *Id.* at 25.

101. *Id.* at 34-37.

102. *Id.* at 37.

103. HEALTH POL'Y INITIATIVE, HIV ADVOCACY IN CHINA: STORIES FROM THE FIELD 2 (2009), *available at* http://www.healthpolicyinitiative.com/Publications/Documents/1009_1_HPI_Advocacy_1_Mengzi_1_14_10_web.pdf.

104. Anderson et al., *supra* note 66, at 7.

105. *Id.* at 32-33.

University of Wisconsin, where they identified a number of regulatory regime problems, supply chain issues, and reform needs in the realm of clinical practice governing therapeutic opioids.[106] Vietnamese officials and PPSG advisers "conducted a review of the existing Vietnamese laws and regulations to identify provisions relevant to improving palliative care and opioid medication availability and access."[107] They then identified provisions that were "supportive, conflicting, or ambiguous with regard to palliative care and opioid medication control . . . ."[108] MOH officials were then able to develop an action plan that addressed the key issues identified by the assessment processes.[109] Such issues included "provisions that linked opioid analgesics with so-called 'social evils,' restrictions on prescribing and dispensing opioid medications, overly-stringent professional restrictions and improper dosage . . . ."[110]

2. Year Two: Regulatory Change and Implementation Planning

The first phase of work will generally produce a clear picture of the regulatory reforms that a country needs, as well a coalition of governmental and non-governmental supporters working to implement these reforms.[111] In Year Two of the model, advocates work to enact changes.[112] In all the cases reviewed, collaboration between national reformers, international donors, and stakeholders was the key to achieving successful, sustainable reform.[113]

The PPSG is a leader in guiding a national coalition of stakeholders through the next step: removing policy barriers and planning implementation.[114] A key component of the PPSG's assistance is a fellowship program that trains health professionals and regulators in opioid medication control policy and policy change strategy.[115] Training includes evaluating national policy, preparing an action plan, and providing technical assistance during implementation.[116] For example, PPSG sponsored a weeklong visit to the University of Wisconsin by a five-member team from Romania in 2004.[117] Attendees included professionals from palliative medicine, oncology, pharmacy, pharmacology, law, and government drug

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106. Anderson et al., *supra* note 66, at 77.

107. *Id.* at 7.

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *See* Anderson et al., *supra* note 66, at 77-78 (explaining the overall process of assessing needs and crafting reform legislation for access to opioids).

113. *Id.* at 83-84.

114. *International Pain Policy Fellowship*, PAIN & POLICY STUDIES GROUP, http://www.painpolicy.wisc.edu/internat/IPPF/index.htm (last updated Sept. 14, 2010) (describing the components of the fellowship program).

115. *Id.*

116. *Id.*

117. Mosoiu et al., *supra* note 72, at 2114.

control.[118] The goal of the visit was to ensure that future Romanian regulations would amend overly restrictive licensing restrictions for prescribing opioid medications to outpatients.[119] Regulations drafted as a result of this visit made significant headway towards achieving this goal. They proposed that specialists would, for the first time, have independent prescribing authority, that prescription time would be increased to 30 days with no limit on dosage, and that the eligibility of patients based on diagnosis would be removed and non-specialists would be able to prescribe opioid analgesics after training.[120] The regulations drafted in the U.S. were brought to practitioners and other stakeholders in Brasov and Bucharest for further discussion. This process successfully defined the needed reforms and built support for enactment. The report and recommendations of these meetings formed the basis of Romania's reformed drug policy.[121]

PPSG also contributed to drug policy reform in India. The Indian Association of Palliative Care led an effort, with support from WHO and PPSG advisors, to conduct national workshops with principal stakeholders.[122] These meetings, which were co-sponsored by the Indian Ministry of Health and the WHO country office, revealed widespread confusion about the complex state rules governing the distribution and prescription of opioids.[123] State workshops highlighted the regulatory burdens imposed on access. These findings led the Health Secretary in Kerala to support simplification of that state's narcotics rules.[124] As a result, a new system of rules and policies was implemented.[125] After reform, the medical use of oral morphine increased significantly, with no evidence of diversion for illicit use.[126] The Kerala workshop was used as a model for sponsoring and conducting 13 more state workshops between 1998 and 2007, leading to additional policy changes.[127]

Vietnam provides another example. There the Ministry of Health responded to the assessment process by convening a group to draft comprehensive Guidelines on Palliative Care for Cancer and AIDS Patients.[128] These guidelines "integrated medical and ethical principles of palliative care, with focus on careful assessment and differential diagnosis of pain associated with cancer and AIDS."[129] In 2006, they were officially issued by the Vietnamese Ministry of Health.[130]

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118. *Id*.

119. *Id*.

120. *Id.* at 2114.

121. *Id*.

122. Anderson et al., *supra* note 66, at 9.

123. *Id*.

124. *Id*. at 10.

125. *Id*.

126. Rajagopal & Joranson, *supra* note 59, at 621.

127. *Id.* at 619-621 (discussing how thirteen states in India have simplified their narcotics rules through adoption of the recommended Government of India amendment or other policy changes).

128. Anderson et al., *supra* note 66, at 77.

129. *Id*.

130. *Id*.

In China, workshops and pilot programs in the first phase of reform provided a basis for wide-ranging discussions between Chinese and international advocates.[131] These discussions culminated in the development of a new legal framework to support the use of opioid medications in the treatment of opioid dependence.[132] This new framework included breakthroughs in formal policy and law enforcement practice.[133] The development of methadone treatment required specific regulatory changes, which in turn required cooperation across agencies charged with HIV/AIDS prevention, drug control, and pharmaceutical regulation.[134]

The Chinese government made significant headway toward these changes in 2004 when it mandated the departments of public security, health, and food and drug administration to coordinate MAT implementation in areas with high HIV/AIDS infection rates.[135] As a result of this directive, the departments created the infrastructure needed for cooperative policy-making.[136]

Both the Chinese and Vietnamese experiences demonstrate how important it is to properly implement new programs. The challenges can be substantial. It is not simply a matter of training health care providers to use opioids to care for both drug dependency and pain. A range of personnel, from pharmacists to police officers to drug control administrators, must learn about the legitimate uses of opioid medicines and their role in making the new practices work.[137] In our model, a major focus of the second year involves preparation for implementation. This requires identifying those who will need to be trained, how the training will be organized and funded, and what materials will need to be prepared in order to carry out the training.[138] To this end, DCAM has created or collected basic training tools in several languages and posted them on its website.[139]

3. Year Three: Implementation and Assessment

In the third stage of policy reform, the changes made to law "on the books" are tested "on the streets."[140] Effective implementation can be stymied by negative attitudes about opioids, uncertainty about the law, or simply a lack of awareness that the rules have changed. Providing care using opioids is not terribly difficult, but like any other form of health care, it requires specific knowledge of the medicine and a proper understanding of the malady to be treated. Health care

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131. *Id.* at 32-35.
132. *Id.* at 35-36.
133. *Id.*
134. Anderson et al., *supra* note 66, at 36-37.
135. *Id.* at 35.
136. *Id.*
137. Burris & Davis, *supra* note 33, at 46.
138. *Id.*
139. *See* DRUG CONTROL AND ACCESS TO MEDICINES CONSORTIUM, http://www.dcamconsortium.net (last visited Oct. 22, 2010).
140. Burris & Davis, *supra* note 33, at 46.

providers, including doctors, nurses, pharmacists, peer outreach workers, case managers, and counselors, will likely require training in order to effectuate the reforms.[141]

Training officials about medical opioids was not part of the original Romanian reform plan, but was added as the need became obvious.[142] This training included the sustained engagement of essential Romanian collaborators and the PPSG.[143] A local NGO prepared the curriculum and 40 trainers "ran courses, organized a strategic conference and established partnerships and agreements" with local health boards, government officials, physicians and pharmacist organizations.[144] In 2007, more than 80% of Romanian districts were trained.[145] In Vietnam, over 400 physicians were trained in palliative care in 2010 in order to implement the changes made in 2006.[146]

China's efforts to improve MAT access demonstrate the importance of healthcare providers in enabling reforms. In China, resource scarcity continues to shape the availability and quality of MAT services.[147] Even the rapid roll-out that has occurred there provides coverage to only a small fraction of the at-risk opioid dependent users.[148] One reported reason for the gap in availability is the limited manpower and high staff turn-over at the clinics.[149]

Negative perceptions of opioid use among health care workers and patients in China also continues to hamper efforts to increase medical opioids use. Further, because of the negative role of opioids in Chinese history, many members of the public still have exaggerated fears of opioid dependence.[150] In some cases, healthcare practitioners prescribe or administer inadequate doses of analgesics, only increasing the dosage when patients suffer intense pain.[151] Sometimes, administration of pain-management agents may be stopped as soon as side effects like vomiting appear.[152] Fear of opioid overdose and abuse results in restrictive policies and inadequate prescriptions of opioids.[153] Despite attempts to reform physician education and certification in China, ignorance regarding pain management still lingers among medical professionals and students.[154]

141. *Id.*; NEETA KUMAR, WORLD HEALTH ORG., NORMATIVE GUIDELINES ON PAIN MANAGEMENT 30 (2007), *available at* http://www.who.int/medicines/areas/quality_safety/delphi_study_pain_guidelines.pdf.

142. Burris & Davis, *supra* note 33, at 50.

143. *Id.*

144. *Id.* at 50-51.

145. *Id.* at 51.

146. Krakauer, Cham & Khue, *supra* note 87, at 27 (located in the abstract).

147. Anderson et al., *supra* note 66, at 39.

148. *Id.*

149. *Id.*

150. *Id.* at 31.

151. *Id.*

152. *Id.* at 39.

153. Anderson et al., *supra* note 66, at 39.

154. *Id.*

In several of the countries surveyed, MAT continues to be widely inaccessible despite legal reforms.[155] In general, MAT access is stymied by its cost, the duration of treatment, policies and practices to reduce diversion, and the lack of a national commitment to improving availability.[156] These issues require additional attention during the third stage of reform. For example, MAT in Romania is compromised by a lack of adequate treatment programs for opioid dependent individuals.[157] In India, while the government has very recently begun to officially fund MAT programs, it is still unclear whether any state sponsored centers have actually opened or even moved into the pipeline.[158] In Vietnam, the new MAT regulations were approved in 2008.[159] These provisions nominally provide greatly improved access to MAT, while clarifying regulatory mechanisms for diversion control.[160] However, the effect that the regulatory changes have had remains unclear.[161] Several pilot programs languish on the books without implementation.[162] Linking regulatory change to meaningful program scale-up will require additional advocacy, resources, and technical assistance.[163]

If they are guided by good monitoring and evaluation data, reformers can address not only the primary policies on controlled drugs, but also a range of secondary policies and practices that will influence how effective the new rules will be in practice. Even well thought-out laws may need to be accompanied by clarifying regulations. Further, they will almost always require education and training to be effectively realized. Monitoring the implementation of new policies is critical in order to gauge the effectiveness of reforms and understand additional measures. Unfortunately, assessing the extent to which opioid use has improved after the implementation of national reforms is often frustrated by substandard national monitoring and reporting.

For example, the Indian government's failure to consistently and timely report morphine use in the years following the initial reform have challenged ongoing reform efforts.[164] Despite the successful reform of Romania's drug control laws, reformers noted that one important element missing from the new rules was a clear

155. *See, e.g.*, *id.* at 31.

156. *Id.* at 54.

157. *Id.* at 70.

158. *Id.* at 54.

159. Anderson et al., *supra* note 66, at 81.

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.* at 81-82.

164. Rajagopal & Joranson, *supra* note 59, at 616 ("No system exists to obtain [morphine] consumption statistics from the states and to collate them at the national level." The single indicator of morphine consumption reported by the government is an indirect indicator.); INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2009, 14, 21, U.N. Doc. E/INCB/2009/1 (2010) (stating that India fails to timely report).

directive outlining the duties of the government in estimating the need for, and reporting the use of, opioid medications.[165]

Based on our review of successful national interventions, we have suggested a "standard" three-year intervention model. This model begins with assessment, coalition building, and the design of reforms, followed by drafting and enactment of new policies in concert with detailed planning for implementation. Finally, the model provides for a thoroughly evaluated implementation process with training for a range of agents essential to its success.

There is, of course, no "standard" country. Every nation is different in the nature of its laws, the condition of its health care system, and its cultural and political perception of opioid medicines. Our model must be used flexibly. But the bottom line is that experienced agents of change have proven that a few basic strategies can, with supporting resources, break down policy barriers to quality pain and drug-dependence care. The next section examines what those who control international aid and development resources can do to promote the wider use of these proven reform techniques.

B. A Proposal for Action: Next Steps for International Leaders

The general international consensus on the necessity of ensuring access to therapeutic opioids reflects many years of work at the international level. Research,[166] documentation of the problem,[167] and dedicated attention to the behavior of international drug control organizations[168] have all paid off. Still,

165. Anderson et al., *supra* note 66, at 81.

166. *See*, *e.g*., Rajagopal & Joranson, *supra* note 59, at 616 (noting that the PPSG's study of India's narcotics regulations and subsequent work with the Indian government resulted in the drafting of a narcotic regulation sent to state governments to amend their narcotic regulations); David E. Joranson & Karen M. Ryan, *Ensuring Opioid Availability: Methods and Resources,* 33 J.PAIN & SYMPTOM MGMT. 527, 527 (2007), *available at* http://download.journals.elsevierhealth.com/pdfs/journals/0885-3924/PIIS0885392407001121.pdf (describing the PPSG's development of "methods to evaluate and improve national policies that govern availability and access to the medicines [i.e., therapeutic opioids] that are essential for relieving severe pain throughout the world"); Sharon Stancliff, *Buprenorphine and the Treatment of Opioid Addiction,* THE PRN NOTEBOOK 28, 28 (Mar. 2004), http://www.prn.org/images/pdfs/294_stancliff_sharon.pdf (recognizing the importance of having treatment for opioid addicts readily available); David E. Joranson, *Improving Availability of Opioid Pain Medications: Testing the Principle of Balance in Latin America*, INNOVATIONS IN END-OF-LIFE CARE (2003), http://www.edc.org/lastacts/archives/archivesJan03/featureinn.asp (describing author's research and formulation of a model for evaluation and improvement of "anti-drug abuse policies so they do not interfere with the use of opioid analgesics for pain relief").

167. PLEASE DO NOT MAKE US SUFFER, *supra* note 57, at 9.

168. *See, e.g.,* DAMON BARRETT, INT'L HARM REDUCTION ASS'N, 'UNIQUE IN INTERNATIONAL RELATIONS'?: A COMPARISON OF THE INTERNATIONAL NARCOTICS CONTROL BOARD AND THE UN HUMAN RIGHTS TREATY BODIES 7 (2008), *available at* http://www.idpc.net/php-bin/documents/IHRA_UniqueIntRelations_EN.pdf (criticizing the INCB's role in "ensur[ing] adequate supplies of controlled drugs are available for medical and scientific uses, [ensuring] that the diversion of drugs from licit sources to illicit channels does not occur and [identifying and contributing] to correcting weaknesses in national and international

national aid services such as the United States Agency for International Development (USAID) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR); development banks such as the World Bank; and multilateral groups, such as the UNODC, the WHO, the International Narcotics Control Board (INCB), and UNAIDS have yet to agree on explicit goals for policy reform and access to care, or a joint strategy for achieving those goals. Going forward, joint, public commitment by these key international bodies is needed at two critical stages: the creation of explicit outcome goals for increasing access to essential opioid medicine and the funding of national reform efforts that are a precondition to meeting those goals.

National advocates repeatedly cite the lack of clear and specific goals for adequate access as a barrier to reform. Reformers point to the lack of benchmarks that could be used to measure progress towards those goals.[169] Among its efforts to improve access to opioid medicines, the WHO's Access to Controlled Medications Programme (ACMP) has begun developing guidelines for HIV control, which include targets for MAT (e.g., 40% of IDUs in MAT is considered 'very good').[170] Experts from the ACMP, the Open Society Institute, and the PPSG have developed methods for assessing the gap between the national need for opioids in pain care and the amounts actually used. Although the UNODC and the INCB have taken much more notice of the issue in recent years, we still have not reached the point at which access is subject to regular and uniform analysis in the agency's annual reports, much less a bench-marking mechanism.

Better setting and tracking of goals is necessary for widespread reform, but it is not sufficient. The most pressing practical need continues to be funding for the reform process. Fortunately, enabling access to therapeutic opioids for pain relief and MAT for millions of patients in need can be achieved with only a modest level of international coordination and commitment. We estimate that costs associated with implementing the intervention approach we describe here range from U.S.$300,000 to $1 million per country for each three-year intervention cycle. Thus, in three years of reform, thirty countries might see successful reform for U.S.$30 million per year. This figure is small compared to the costs associated with other humanitarian efforts. For example, the GAVI Alliance, a public-private

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control"); Damon Barrett & M. Nowak, *The United Nations and Drug Policy: Towards a Human Rights-Based Approach*, *in* THE DIVERSITY OF INTERNATIONAL LAW: ESSAYS IN HONOUR OF PROFESSOR KALLIOPI K. KOUFA 449, 449 (Aristotle Constantinides & Nikos Zaikos eds., 2009) (criticizing the United Nations drug control system).

169. Burris & Davis, *supra* note 53, at 32.

170. WORLD HEALTH ORG., TECHNICAL GUIDE FOR COUNTRIES TO SET TARGETS FOR UNIVERSAL ACCESS TO HIV PREVENTION, TREATMENT AND CARE FOR INJECTING DRUG USERS 17 (Jan. 2008), *available at* http://www.who.int/hiv/idu/TechnicalGuideTargetSetting.pdf. The ACMP also works to raise awareness of barriers to opioid medicines, updates policy guidelines on how to achieve balanced national reform, and optimizes methods and tools to estimate national need for opioid and methadone. *Fact Sheet No. 336-Medicines: Access to Controlled Medicines (Narcotic and Psychotropic Substances)*, WORLD HEALTH ORG. (June 2010), http://www.who.int/mediacentre/factsheets/fs336/en/print.html.

partnership dedicated to improving access to vaccines and strengthening immunization programs internationally, estimates that it needs U.S.$7 billion in the next five years to support existing programs and new vaccines.[171]

One possible advantage in implementing the intervention described here is that successful reform in one country could catalyze and guide reform in others. The adoption of MAT by Chinese policymakers reportedly influenced Indian officials in their reform efforts.[172] Horizontal forms of technical assistance may also develop into more formal links between drug policy reformers. Champions in one country can become advisors to champions in other countries undergoing reform.[173] With this in mind, the PPSG and allied palliative care advocates have created an International Expert Collaboration (IEC) made up of palliative care experts with experience in national opioid availability issues. The members of the IEC provide valuable mentorship to the new reformers working with the PPSG.[174] This sort of a development could be extremely helpful to the diffusion of policy reform and medical best practices.

The problem of unequal access to essential opioids is becoming increasingly visible as a variety of stakeholders call for action. For example, the Global Task Force on Expanded Access to Cancer Care and Control in Developing Countries was formed to expand cancer control and treatment in low and middle-income countries. The Global Task Force has now joined long-time palliative care advocates, such as the Union for International Cancer Control, the International Association for Hospice and Palliative Care, the International Association for the Study of Pain, the Public Health Program of the Open Society Institute, and Human Rights Watch, as well as regional palliative care organizations such as the African Palliative Care Association and the European Association for Palliative Care (among others), in calling for the expansion of pain and palliative care services.[175]

In this field of stakeholders, there are other important signs of change which indicate that the time for unified action has arrived. In recent years, international organizations that have traditionally emphasized drug control have instead implemented policies that affirm the importance of access to essential opioids. In the past two years, the INCB introduced a section on access in its annual report.[176]

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171. *What We Need: GAVI's Funding Challenge for 2010-2015, Approximately US$ 4.3 billion,* GAVI ALLIANCE, http://www.gavialliance.org/about/resource_event/what/index.php (last visited Oct. 29, 2010).

172. Anderson, *supra* note 66, at 54; *see also* Tripti Nath, *Fighting AIDS: Oral Therapy for Injecting Drug Users*, THE TRIBUNE (India), July 16, 2007, *available at* http://www.tribuneindia.com/2007/20070716/nation.htm#4 (mentioning the influence of China's success with oral substitution therapy (i.e., MAT) on India's National AIDS Control Organisation).

173. Joranson & Ryan*, supra* note 152, at 530.

174. *Id.*

175. Farmer et al., *supra* note 10, at 1186.

176. *See generally* 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

The UNODC, in conjunction with the WHO and UNAIDS, recently published a step by step algorithm to assist East Asian countries in procuring opioids for MAT in compliance with the Single Convention.[177] These groups advise that "substitution 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."[178]

Dedicated action by international policymakers to guide national drug reform is urgently needed. Clear and coordinated messages from the UNODC and the INCB could influence national policymakers to undertake regulatory change. These bodies could also routinely include information about access in the annual INCB report and the UNODC World Drug Report. Additionally, the INCB should emphasize access to therapeutic medicines when reporting on country compliance and should highlight countries with high levels of untreated persons. Both the UNODC and INCB could coordinate their efforts better with the WHO's ACMP, which trains national regulators in reporting to the INCB.[179] They could also work more closely with NGOs. Finally, the UNODC and INCB could support ongoing efforts to include access obligations in international model laws and new national laws.

V. CONCLUSION

Poor access to therapeutic opioid medications condemns millions of people to severe, yet preventable, suffering. The use of therapeutic opioids in treating this pain is recognized as essential to good medical practice. Furthermore, international law requires that therapeutic opioids be made available for medical use and international bodies consistently support their use in medical practice. Despite this, both unbalanced policies and resource constraints continue to contribute to a lack of availability and medical access. A smart approach to reform can address both problems.

Although sometimes complicated by politics and inertia, the lack of access to opioid medications is a discrete, solvable problem. The experience of the past two decades demonstrates that reform is eminently achievable. The emerging international consensus on the need for opioid medications is itself a major policy

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statements from its annual report on access to essential opioids).

177. U.N. OFFICE ON DRUGS AND CRIME, A 'STEP-BY-STEP' ALGORITHM FOR THE PROCUREMENT OF CONTROLLED SUBSTANCES FOR DRUG SUBSTITUTION TREATMENT, Internal Doc. 3/2007 (Aug. 2007), *available at http://www.unodc.org/documents/hiv-aids/Step-by-Step%20procurement%20subs%20treat.pdf.*

178. SUBSTITUTION MAINTENANCE THERAPY, *supra* note 23, at 2.

179. *See generally The Access to Controlled Medications Programme*, WORLD HEALTH ORG., http://www.who.int/medicines/areas/quality_safety/access_to_cmp/en/index.html (last visited Oct. 30, 2010) (noting that the ACMP "train[s] civil servants responsible for submitting estimates" of opioid imports and exports); *Mandate of INCB*, INT'L NARCOTICS CONTROL BD., http://www.incb.org/incb/en/mandate.html (last visited Oct. 30, 2010) (describing the functions of the INCB).

success. The great needs now are clear goals and funding for strategies aimed at action on a national level.

The review of national reform efforts presented here demonstrates that certain elements are key in successfully reforming drug policy in order to improve access to controlled medicines. The three-year model described here reflects best practices from existing interventions and is a feasible framework for a broad-based coordinated reform effort. With proper financial and technical support, this model can be widely implemented by a network of experienced experts, champions, and reformers. By following this reform model, countries can fulfill the promise of their international obligations, leading to more rational policies regarding therapeutic opioids. Ultimately, this will put an end to the needless pain and suffering of an untold number of people.