ACCESS TO PAIN TREATMENT AND PALLIATIVE CARE: A HUMAN RIGHTS ANALYSIS

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I. INTRODUCTION

The World Health Organization (WHO) estimates that each year, tens of millions of people suffer untreated moderate to severe pain, including 5.5 million terminal cancer patients and 1 million patients in the last phases of HIV/AIDS.[1]

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Most of this suffering is avoidable because pain medicines are inexpensive, safe, and easy to administer. In fact, as this paper argues, access to these medicines is a human right. However, availability of pain medicines in low- and middle-income countries is extremely poor, even in comparison to other essential medicines. In part, this is because strong pain medicines are subject to the international drug control regime. While restricting medical access to pain medicines is an unintended consequence of that regime, most governments have done little to ensure the availability of pain medicines. This failure is a breach of patients' international human rights.

II. PAIN, ITS TREATMENT, AND PALLIATIVE CARE

Chronic moderate to severe pain is a common symptom of cancer and HIV/AIDS, as well as many other health conditions.[2] A recent review of pain studies in cancer patients found that more than fifty percent of cancer patients experience pain,[3] and research consistently finds that sixty to ninety percent of patients with advanced cancer experience moderate to severe pain.[4]

Although no population-based studies of AIDS-related pain have been published, multiple studies report that sixty to eighty percent of patients in the last phases of illness experience significant pain.[5] The increasing availability of

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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 [hereinafter Briefing Note 2009].

2. Pain is also a symptom of various other diseases and chronic conditions, and acute pain is often a side effect of medical procedures. This paper, however, focuses primarily on chronic pain.

3. 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, 1437 (2007).

4. Charles S. Cleeland et al., *Multidimensional Measurement of Cancer Pain: Comparisons of U.S. and Vietnamese Patients*, 3 J. PAIN SYMPTOM MGMT. 1, 26 (1988); Charles S. Cleeland et al., *Dimensions of the Impact of Cancer Pain in a Four Country Sample: New Information from Multidimensional Scaling*, 67 PAIN 267, 270-72 (1996); Randall L. Daut & Charles S. Cleeland, *The Prevalence and Severity of Pain in Cancer*, 50 CANCER 1913, 1917 (1982); Kathleen M. Foley, *Pain Syndromes in Patients with Cancer*, *in ADVANCES IN PAIN RESEARCH AND THERAPY 59, 59-75* (Kathleen M. Foley et al. eds., 1990); Kathleen M. Foley, *Pain Assessment and Cancer Pain Syndromes*, *in OXFORD TEXTBOOK OF PALLIATIVE MEDICINE 310, 310-331 (D. Doyle et al. eds., 2d ed. 1999)*; Jan Stjernswärd & David Clark, *Palliative Medicine: A Global Perspective*, *in OXFORD TEXTBOOK OF PALLIATIVE MEDICINE* 1199, 1213 (D. Doyle et al. eds., 3d ed. 2003).

5. Kathleen M. Foley et al., *Pain Control for People with Cancer and AIDS*, *in* DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES 981, 982 (2d ed. 2003) [hereinafter Foley et al., *Pain Control*]; Francois Larue, et al., *Underestimation and Under-Treatment of Pain in HIV Disease: A Multicentre Study*, 314 BRITISH MED. J. 23, 23 (1997); Jerome Schofferman & R. Brody, *Pain in Far Advanced AIDS*, *in* ADVANCES IN PAIN RESEARCH AND THERAPY 379, 380-81 (Kathleen M. Foley et al. eds., 1990); Elyse J. Singer et al., *Painful Symptoms Reported by Ambulatory HIV-Infected Men in a Longitudinal Study*, 54 PAIN 15, 15-19 (1993).

antiretroviral treatment (ART) in middle- and low-income countries is prolonging the lives of many people with HIV; however, while people receiving ART generally have less pain than people without access to it, many continue to experience pain symptoms.[6] In fact, ART can itself be a cause of pain, especially neuropathic pain caused by damaged nerves.[7]

Moderate to severe pain has a profound impact on quality of life. It can lead to reduced mobility and consequent loss of strength, compromise the immune system, and interfere with a person's ability to eat, sleep, concentrate, or interact with others.[8] A WHO study found that people who live with chronic pain are four times more likely to suffer from depression or anxiety.[9] In addition, the physical and psychological effects of chronic pain can directly influence the course of disease and reduce patients' adherence to treatment.[10]

Pain also has social consequences for patients and their caregivers. These include the inability to work, reduced capacity to care for children or other family members, and decreased participation in social activities.[11] At the end of life, pain can even interfere with a patient's ability to bid farewell to loved ones and make final arrangements.

Most of the suffering caused by pain is avoidable because medicines to treat pain are safe, inexpensive, and easy to administer.[12] WHO's Pain Relief Ladder recommends the use of increasingly potent pain killers as pain becomes more severe.[13] These range from basic pain medicines (such as acetaminophen, aspirin, or ibuprofen) to strong ones (such as morphine).[14] Like morphine, all strong pain killers are opioids, which are extracts of the poppy plant (or similar synthetic drugs). WHO's Model List of Essential Medicines includes morphine in oral tablet, oral solution, and injectable formulations.[15] For chronic pain management,

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6. Peter Selwyn & Marshall Forstein, *Overcoming the False Dichotomy of Curative vs. Palliative Care for Late-Stage HIV/AIDS*, 290 J. AM. MED. ASSOC. 806, 808 (2003).

7. Marinos C. Dalakas, *Peripheral Neuropathy and Antiretroviral Drugs*, 6 J. PERIPHERAL NERVOUS SYSTEM 14, 16 (2001).

8. Frank Brennan et al., *Pain Management: A Fundamental Human Right*, 105 ANESTHESIA & ANALGESIA 205, 206 (2007) [hereinafter Brennan et al., *Pain Management*].

9. Oye Gureje et al., *Persistent Pain and Well-Being: A World Health Organization Study in Primary Care*, 80 J. AM. MED. ASSOC. 147, 149 (1998*); see also* Barry Rosenfeld et al., *Pain in Ambulatory AIDS Patients II: Impact of Pain on Psychological Functioning and Quality of Life*, 68 PAIN 267, 323, 326 (1996).

10. Rosenfeld et al., *supra* note 9, at 323, 326-27.

11. Randall L. Daut et al., *Development of the Wisconsin Brief Pain Questionnaire to Assess Pain in Cancer and Other Diseases*, 17 PAIN 2, 197-98 (1983).

12. WORLD HEALTH ORG., ACHIEVING BALANCE IN NATIONAL OPIOID CONTROL POLICY (2000), *available at* http://apps.who.int/medicinedocs/en/d/Jwhozip39e/ [hereinafter ACHIEVING BALANCE].

13. *WHO's Pain Ladder*, WORLD HEALTH ORG., http://www.who.int/cancer/palliative/painladder/en/ (last visited Nov. 4, 2010). This has been developed for cancer but is also referred to for other conditions.

14. *Id.*

15. WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 2 (2009),

WHO recommends oral morphine given at regular intervals around the clock.[16] Patients can easily take oral morphine in their own homes, avoiding the pain of regular injections. This is especially important for children and patients who are emaciated by cancer and HIV/AIDS.

In addition, basic oral morphine in powder or tablet form is not protected by any patent and can be produced very cheaply. In India, basic morphine tablets are sold for as little as 1.7 cents (US) each.[17] At this price, a typical daily dose of oral morphine would cost as little as 12 cents.[18] Nonetheless, in many countries, various factors make morphine much more expensive, as discussed in detail below.[19]

For patients with life-limiting illnesses like cancer or HIV, chronic pain treatment is often a part of broader palliative care services. Palliative care can be provided in parallel with curative treatment, but its main purpose is to ease suffering. In doing so, it aims to improve the quality of life of people who face life-limiting illness by relieving pain and other distressing symptoms, while also providing psychosocial support for patients and their families.[20] The WHO has emphasized that palliative care is particularly important in developing countries, where many cancer patients only seek medical attention when the disease is so advanced that it is beyond cure and causing severe pain.[21] For this reason, WHO has urged countries with limited resources to focus on developing home-based palliative care services.[22] Because oral morphine can be produced cheaply and is easily taken at home, utilizing it for home-based palliative care makes sense. In this setting, it can be provided by a visiting nurse or community health worker under the supervision of a doctor, making it a significant, cost-effective option.

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available at http://www.who.int/selection_medicines/committees/expert/17/sixteenth_adult_list_en.pdf [hereinafter ESSENTIAL MEDICINES 2009].

16. WORLD HEALTH ORG., CANCER PAIN RELIEF: A GUIDE TO OPIOID AVAILABILITY 22 (2d ed. 1996) [hereinafter CANCER PAIN RELIEF].

17. Scott Burris & Corey S. Davis, *A Blueprint for Reforming Access to Therapeutic Opioid Medications*, TEMP. UNIV. CTR. FOR HEALTH L. POL'Y & PRACTICE 1, 18 (2008), *available at* http://www.painpolicy.wisc.edu/internat/DCAM/Burris_Blueprint_for_Reform.pdf.

18. *See* Foley et al., *Pain Control, supra* note 5, at 988 (stating that in low and middle-income countries, a typical daily dose of morphine for patients in palliative care programs is sixty to seventy-five milligrams per day); *see also* Letter from Kathleen M. Foley to author (Jan. 23, 2009) (on file with author) (asserting that the average daily dose in industrialized countries tends to be higher as a result of, among other reasons, patients surviving longer and having an increased tolerance to opioid analgesics).

19. *See infra* text accompanying notes 88-97.

20. *Palliative Care*, WORLD HEALTH ORG., http://www.who.int/cancer/palliative/en (last visited Nov. 4, 2010).

21. WORLD HEALTH ORG., NATIONAL CANCER CONTROL PROGRAMS: POLICIES AND MANAGERIAL GUIDELINES 85-86 (2002), *available at* http://www.who.int/cancer/media/en/408.pdf.

22. *Id.* at 85, 91.

III. THE UNAVAILABILITY OF MORPHINE

Although morphine is an inexpensive essential medicine, its availability is limited in most developing countries and, therefore, most patients with severe pain do not get effective treatment.[23] In part, this is because morphine and other opioids are subject to the system of international drug control.

Treating a patient over time with an opioid can cause physical dependence, such that withdrawal symptoms occur if the opioid treatment is stopped abruptly. Physical dependence is a normal side effect that is treated by gradually reducing the dose of the medicine when it is no longer needed. It is distinct from dependence syndrome, commonly referred to as addiction, which is a pattern of behavior, such as compulsive use of drugs despite their known harm.[24] Addiction does not occur as a result of receiving opioids for pain treatment.[25]

Nonetheless, due to their potential for abuse, morphine and other opioids are regulated under the Single Convention on Narcotic Drugs ("Single Convention") and under national regulations.[26] This means that their manufacture, import and export, distribution, prescription, and dispensation can only occur with both government authorization and oversight by the International Narcotics Control Board (INCB), a body created by the Single Convention.[27]

The preamble to the Single Convention states 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."[28] The INCB has explained that the Convention "establishes a dual drug control obligation: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing illicit production of, trafficking in, and use of such drugs."[29] Sadly, it is evident that states are failing in the first part of this obligation. In 2009, at a session of the United Nations Economic and Social Council, the President of

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23. *See generally International Grants Programme*, HELP THE HOSPICES, http://www.helpthehospices.org.uk/our-services/international/internationalgrants/ (last visited Nov. 4, 2010) (offering grants to fund hospice and palliative care in developing nations) [hereinafter HELP THE HOSPICES].

24. STEDMAN'S MEDICAL DICTIONARY 23 (27th ed. 2000)

25. CANCER PAIN RELIEF, *supra* note 16, at 19; *International Statistical Classification of Diseases and Related Health Problems,* WORLD HEALTH ORG. (2007), http://apps.who.int/classifications/apps/icd/icd10online/.

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

27. *Id.* art. 5.

28. *Id.* at preamble.

29. INT'L NARCOTICS CONTROL BD., REPORT OF THE AVAILABILITY OF OPIATES FOR MEDICAL NEEDS ¶1 (1996), *available at* http://www.incb.org/pdf/e/ar/1995/suppl1en.pdf [hereinafter 1995 INCB REPORT]

the INCB stated that access to morphine and other controlled medicines is "virtually non-existent in over 150 countries."[30]

IV. BARRIERS TO ACCESS TO PAIN TREATMENT AND PALLIATIVE CARE

Barriers to access to pain medicines are well understood. They include "unnecessarily restrictive drug control regulations and practices, lack of functioning supply systems for controlled medicines, and fear among healthcare workers of legal sanctions for legitimate medical practice."[31] Many governments have no policies on pain treatment or palliative care and have not ensured that health care workers receive adequate education in these subjects. Although morphine should be inexpensive, in many countries it is not; low demand, inefficient distribution systems, and unnecessarily complex and restrictive regulations all combine to drive up the price.[32]

A. Excessively Restrictive Drug Control Regulations and Enforcement Practices

The Single Convention lays out three minimum criteria that state parties must observe when developing national regulations governing the handling of opioids. First, individuals must be authorized to dispense opioids by their professional license, or be specially licensed to do so.[33] Second, the movement of opioids may only occur between institutions or individuals so authorized under national law.[34] Finally, a medical prescription is required before opioids may be dispensed to a patient.[35] Governments may, under the Single Convention, impose additional requirements if deemed necessary.[36]

Indeed, many countries have regulations that go well beyond the requirements of the Single Convention. These countries have created complex procedures for procurement, stocking, and dispensing of controlled medications; such procedures include restrictive licensing requirements for health care providers prescribing medicines,[37] cumbersome dispensing procedures, and limitations on the formulation[38] and quantity of medicine that can be prescribed.[39] As a result, some drug control authorities or health systems adopt even more restrictive measures

30. Sevil Atasoy, Int'l Narcotics Control Bd., Statement by Professor Sevil Atasoy President of the International Narcotics Control Board (July 30, 2009).

31. Diederik Lohman et al., *Access to Pain Treatment as a Human Right*, 8 BMC MEDICINE 1, 2-5 (2010).

32. *Id.* at 5.

33. Single Convention, *supra* note 26, art. 30.

34. *Id.* art. 31.

35. *Id.* art. 30.

36. *Id.* art. 39.

37. *See* discussion *infra* notes 40-44.

38. *See* discussion *infra* notes 45-51.

39. *See* discussion *infra* notes 45-51; *see also Model Regulation Establishing an Interministerial Commission for the Coordination of Drug Control*, U.N. INT'L DRUG CONTROL PROGRAMME (2002), *available at* http://www.unodc.org/pdf/lap_imccdc_model-regulation.pdf [hereinafter Interministerial Commission].

than those required in the formal regulations. Although the diversion of medical opioids from their proper use is frequently cited as the explanation for such policies, the INCB has noted that diversion is relatively rare in practice[40] and WHO has observed that the right to impose additional requirements "must be continually balanced against the responsibility to ensure opioid availability for medical purposes."[41]

One example of a restrictive policy adopted by many countries is to limit the prescription of narcotic pain medicines to medical professionals who qualify for, and obtain, specific licenses.[42] Yet the 1961 Single Convention does not require healthcare workers to be specially licensed to handle opioids and WHO has recommended that "physicians, nurses and pharmacists should be legally empowered to prescribe, dispense and administer opioids to patients in accordance with local needs."[43]

Still, in many countries, doctors need a special license or registration to prescribe controlled medicines. In some countries that require a license, such as the United States, the process for obtaining one is simple and almost all doctors have one.[44] In others, obtaining the license requires considerable paperwork or even invasive screening of the doctor. For example, the Philippines require doctors applying for a license to submit urine for drug tests.[45] As a result of excessively complex licensing procedures in some countries, such as Morocco and the Philippines, few doctors obtain the required licenses.[46]

Other countries like Egypt, Montenegro, and Ukraine limit the right to prescribe opioids to doctors practicing in certain specialties, most commonly oncology, pain management, or anesthesiology.[47] Despite WHO's recommendation, few countries allow nurse prescribing. Uganda, the United Kingdom, and most states in the United States, however, allow nurses to prescribe controlled medicines in certain circumstances.[48] Nurse prescribing has the most

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40. INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTIC CONTROL BOARD FOR 2008, 22, U.N. Doc. E/INCB/2008/1 (2008) [hereinafter 2008 INCB Report].

41. CANCER PAIN RELIEF, *supra* note 16, at 56.

42. *See, e.g.,* Interview by Human Rights Watch with Dr. Francis Javier (Aug. 26, 2009) (on file with author).

43. CANCER PAIN RELIEF, *supra* note 16, at 56.

44. Interview with Don Schumacher, President and CEO, Nat'l Hospice and Palliative Care Ass'n (Feb. 8, 2010) (on file with author).

45. Javier interview, *supra* note 42.

46. *Id.*; Interview by Human Rights Watch with Professor Mhamed Harif (Jan. 21, 2010) (on file with author); Interview by Human Rights Watch with Dr Maati Nejmi, (Jan. 21, 2010) (on file with author).

47. Email from an Egyptian pain management specialist to Human Rights Watch (2010) (on file with author); N.I. Cherney 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 ANNALS OF ONCOLOGY 615, 618-619 (2010).

48. Schumacher interview, *supra* note 44; Interview with Dr. Bill Noble, Macmillan Senior Lecturer in Palliative Medicine, Sheffield University, U.K. (Dec. 14, 2009) (on file with author);

potential to improve access to controlled medicines in resource-limited settings where there are not enough doctors. In fact, the INCB has commended Uganda for its efforts to increase access to controlled medicines.[49]

Another common type of restrictive regulation is the requirement for special prescription forms for controlled medicines. WHO has observed that special multiple-copy prescription requirements "typically reduce prescribing of covered drugs by 50 percent or more."[50] The requirement to use special prescription forms can be particularly burdensome if doctors have to apply to receive the forms (as in Morocco) or have to pay for them (as in the Philippines, Denmark, Albania, and Estonia).[51] Problems accessing enough special prescription forms have been reported in Turkey, El Salvador, and Ukraine.[52] In some countries, opioid prescriptions must be approved by more than one doctor. One example is Ukraine, where "the decision to prescribe morphine must be made by a group of at least three doctors, at least one of whom must be an oncologist."[53]

The WHO has recommended that "decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, not by regulation."[54] Yet some countries, like Croatia, Estonia, and the Philippines, limit the total dose of morphine that can be dispensed in one prescription.[55] Many others limit the number of days that a prescription for controlled medicines can cover; extreme time limits include Belarus (three days), Greece, Lithuania, and Russia (five days).[56] Such regulations can "unduly interfere with medicinal availability" for pain relief.[57]

The practice in other countries demonstrates that such limitations are not necessary to prevent diversion. In many countries, including Austria, Finland, the Netherlands, Sweden, and the Czech Republic, opioid prescriptions can be valid for up to ninety days, while there is no limit in many countries, including Belgium, Denmark, Ireland, Norway, Switzerland, Poland, the United States, and Kenya.[58]

Cherney et al., *supra* note 47, at 624-25.

49. INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BD. FOR 2004, ¶196, U.N. Doc. E/INCB/2004/1 (2005) [hereinafter 2004 INCB Report].

50. CANCER PAIN RELIEF, *supra* note 16, at 57.

51. Nejmi interview, *supra* note 46; Interview by Human Rights Watch with Professor Lucas Radbruch (Feb. 4, 2010); Interview by Human Rights Watch with Professor Rolf-Detlef Treede (Oct. 12, 2009); Interview by Human Rights Watch with Dr. Henry Lu (Sept. 2, 2009); Cherney et al., *supra* note 47, at 619.

52. Interview by Human Rights Watch with Professor Serdar Erdine (Nov. 19, 2009); Cherney et al., *supra* note 47, at 619.

53. Lohman et al., *supra* note 31, at 4 (citing The Ministry of Health of Ukraine's Order No. 356).

54. CANCER PAIN RELIEF, *supra* note 16, at 58.

55. Lu interview, *supra* note 51; Javier interview, *supra* note 42; Cherney et al., *supra* note 47, at 620.

56. Cherney et al., *supra* note 47, at 620.

57. *Id.* at 622.

58. Schumacher interview, *supra* note 44; Interview by Human Rights Watch with Dr.

The INCB has recommended that national drug control laws recognize the indispensible nature of narcotic drugs for the relief of pain and suffering, as well as the obligation to ensure their availability for medical purposes.[59] However, in 1995, only forty-eight percent of the governments responding to a survey had laws reflecting the former and only sixty-three percent the latter.[60] It is not known exactly how many countries still do not use the relevant language in their legislation; even recent model laws and regulations on drug control from the United Nations (UN) Office on Drugs and Crime themselves do not contain these provisions.[61]

B. Fear of Legal Sanction

Legitimate prescribing can be chilled by either ambiguous standards regarding prescription and handling of opioids, or harsh punishment for mishandling. The INCB has said that the "vast majority of health professionals exercise their activity within the law and should be able to do so without unnecessary fear of sanctions for unintended violations."[62] Nevertheless, harsh sanctions (including mandatory minimum sentences) and prosecution of healthcare workers for unintentional mishandling of opioids has lead to fear among medical professionals. Ambiguous regulations coupled with poor communication by drug regulators about the rules for handling opioids has also caused concern among healthcare workers. Little research has been published regarding healthcare workers' fears of legal sanction, but one recent U.S. survey of criminal and administrative cases against physicians found that "the widely publicized chilling effect of physician prosecution on physicians concerned with legal scrutiny over prescribing opioids appears disproportionate to the relatively few cases in which convictions and regulatory actions have occurred."[63] The authors suggested that:

> [I]t seems likely that physicians react to frightening or inconsistent public policy statements. Likewise, they are sensitive to experience

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Zipporah Ali (Oct. 8 2009); Cherney et al., *supra* note 47, at 620.

59. Single Convention, *supra* note 26, at preamble.

60. 1995 INCB Report, *supra* note 29, at 5.

61. *See* U.N. OFFICE ON DRUGS AND CRIME, *Model Law on the Classification of Narcotic Drugs, Psychotropic Substances and Precursors and on the Regulation of the Licit Trade of Drugs* (2003), *available at* http://www.unodc.org/pdf/lap_civil_mod-leg_licit_trade_fr.pdf; *see also* Interministerial Commission, *supra* note 39; U.N. OFFICE ON DRUGS AND CRIME, *Model Drug Abuse Bill* (2000), *available at* http://www.unodc.org/pdf/lap_drug-abuse-bill_2000.pdf; PAIN & POLICY STUDIES GROUP, DO INTERNATIONAL MODEL DRUG CONTROL LAWS PROVIDE FOR DRUG AVAILABILITY? (2009), *available at* http://www.painpolicy.wisc.edu/internat/model_law_eval.pdf (arguing that current U.N. model laws do not provide sufficient guidance to governments in implementing drug availability under the Single Convention).

62. CENTER FOR HEALTH LAW, POLICY, & PRACTICE, A COMPENDIUM OF INCB STATEMENTS ON ACCESS TO MEDICINES 19 (Mar. 2009), *available at* http://www.painpolicy.wisc.edu/INCBCompendium.pdf.

63. D. M. Goldenbaum et al., *Physicians Charged with Opioid Analgesic-Prescribing Offenses*, 9 PAIN MED. 737, 745 (2008).

> with, or lore about, investigations that were ultimately dismissed but which disrupted a medical practice and produced fear and possibly panic. Thus, the chilling effect may be, in part, related to public relations and communications problems on the part of regulators as well as to how law enforcement handles the full number of its investigations, not just those that lead to conviction or discipline. Thus, these data may be extrapolated to suggest that regulators and law enforcement may do well to improve how they craft their public messages to physicians and how they handle routine investigations of medical practice.[64]

Some scholars contend that doctors are obligated by medical ethics standards to treat patients' pain; withholding such treatment would result in charges of medical malpractice and/or criminal negligence.[65]

C. Failure to Ensure Functioning and Effective Supply Systems

Because the production, distribution and dispensation of controlled medicines are under exclusive government control, these medicines will simply be unavailable unless governments create effective supply systems. It is precisely these effective supply systems that many countries lack. In some countries, drug control regulations prevent supply systems from functioning. For example, in many Indian states, medical institutions need as many as five licenses in order to procure and stock morphine or other controlled medicines.[66] The procedure for acquiring the various licenses is complex; sometimes one of the licenses expires before the others can be obtained, leading to interruptions in supply and leaving patients with untreated pain.[67] In many other countries, effective supply systems have simply not been put in place. Resource limitations are one reason for this, but in many cases, lack of political will is the primary cause.[68]

In fact, this lack of political will inhibits the use of controlled medicines even when mandates for effective supply systems exist. The International Covenant on Economic, Social and Cultural Rights (ICESCR) obliges states to take steps to realize the right to the highest attainable standard of health, including "through international assistance and co-operation, especially economic and technical."[69] The UN Committee on Economic, Social and Cultural Rights (CESCR), the body charged with interpreting and monitoring compliance with the ICESCR, has stressed that a core obligation under the Covenant is providing essential medicines,

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64. Goldenbaum et al., *supra* note 63, at 745.

65. Lohman et al., *supra* note 31, at 5.

66. HUMAN RIGHTS WATCH, UNBEARABLE PAIN INDIA'S OBLIGATION TO ENSURE PALLIATIVE CARE 45 (2009) *available at* http://www.hrw.org/en/reports/2009/10/28/unbearable-pain [hereinafter UNBEARABLE PAIN].

67. *Id.*

68. Lohman et al., *supra* note 31, at 2; *see also* 2004 INCB Report, *supra* note 49, at 31 (stating that governmental political will is necessary in order to accomplish INCB initiatives).

69. International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), U.N. GAOR Supp. No. 16, U.N. Doc. A/6316, at 49 (Dec. 16 1966), 993 U.N.T.S. 3, *entered into force* Jan. 3, 1976, art. 12.

as defined by the WHO.[70] International assistance, from both donor countries and NGOs, has been essential to the dramatic increase in the availability of anti-retroviral medicines; there was a ten-fold increase in the number of people receiving ART in low- and middle-income countries between 2003 and 2008.[71] Some of this international assistance takes the form of economic and technical assistance to improve supply chains.[72]

For example, the Supply Chain Management System (SCMS) is funded entirely by the U.S. government through the President's Emergency Plan for AIDS Relief (PEPFAR).[73] SCMS "helps strengthen and build reliable, secure and sustainable supply chain systems [and] helps to reduce the price of essential medicines by working closely with clients to plan future procurement, pooling orders to buy in bulk, [and] establishing long-term contracts with manufacturers."[74] Although governments can purchase morphine from SCMS, only one, the Ethiopian government, has done so.[75] Other international assistance to improve supply chains or purchase medicines in bulk is available through the Global Fund to Fight AIDS, Tuberculosis and Malaria, and NGOs such as the IDA Foundation.[76]

To some extent, this dearth of political will stems from a lack of understanding regarding opioid pain relief needs and accessibility. A 2006 African Palliative Care Association survey found that in Kenya, Ethiopia, Tanzania, Uganda, and Namibia narcotics control board authorities noted opioids that they believed to be available in their respective countries, yet such opioids were unavailable via any service within those countries.[77] The palliative care providers surveyed also identified myriad problems with the regulatory systems.[78]

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70. U.N. Comm. on Econ., Soc. and Cultural Rts., *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 13 U.N. Doc. E/C. 12/2000/4 (Apr. 25-May 12, 2000) [hereinafter CESCR], *available at* http://data.unaids.org/publications/External-Documents-Restored/ecosoc_cescr-gc14_en.pdf.

71. WORLD HEALTH ORG., TOWARDS UNIVERSAL ACCESS: SCALING UP PRIORITY HIV/AIDS INTERVENTIONS IN THE HEALTH SECTOR – PROGRESS REPORT 54 (2009); *available at* http://www.who.int/hiv/pub/tuapr_2009_en.pdf.

72. *See, e.g., About Us*, SUPPLY CHAIN MANAGEMENT SYSTEM, http://scms.pfscm.org/scms (last visited Nov. 5, 2010) (describing an organization working to provide medicine more efficiently and at lower cost).

73. *Id.*

74. *Id.*

75. E-mail from Human Rights Watch to the United States Centers for Disease Control and Prevention (Mar. 16, 2010) (on file with author).

76. *See, e.g., Tuberculosis and Malaria, Procurement Support Services*, GLOBAL FUND TO FIGHT AIDS, http://www.theglobalfund.org/en/procurement/vpp/?lang=en (last visited Nov. 5, 2010) ("coordinated approach to provide support to countries to resolve procurement bottlenecks and supply chain management challenges and facilitate the timely access to pharmaceuticals and health products"); IDA FOUNDATION, http://www.idafoundation.org/we-are.html (last visited Nov. 5, 2010) (provides affordable pharmaceutical products to economically disadvantaged countries).

77. Richard Harding et al., *Pain-Relieving Drugs in 12 African PEPFAR Countries: Mapping Current Providers, Identifying Current Challenges and Enabling Expansion of Pain*

Sufficient political will to ensure the availability of controlled medicines has also been absent at the international level. The INCB has been commenting on the poor availability of controlled drugs for medical purposes and making recommendations to governments to address this for two decades, but its attention to medical supply has been scant compared to its focus on suppressing illicit use of controlled drugs.[79] The INCB also conducts country missions during which board members and government representatives discuss implementation of the U.N. Drug Conventions. The INCB's brief reporting on these missions indicates that availability of controlled drugs for medical purposes is raised on some missions, but not consistently across countries where availability is poor.[80]

There are signs that political commitment to improving the availability of controlled medicines is increasing. For example, the 2010 session of the Commission on Narcotic Drugs – the body of states party to the U.N. Drug Conventions – passed a resolution to promote the adequate availability of certain drugs for medical and scientific purposes.[81] The resolution endorses two recommendations from the INCB. One, that governments "promote access to and rational use of narcotic drugs," and two, that they "identify the impediments in their countries to the access and adequate use of opioid analgesics for the treatment of pain and to take steps to improve the availability of those narcotic drugs for medical purposes . . . ."[82]

D. Failure to Enact Pain Treatment and Palliative Care Policies

Like the obligation to provide essential medicines, CESCR has stated that another core obligation under the right to healthcare is to "adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population."[83] Although the WHO and leading experts on palliative care have stressed the importance of having a comprehensive strategy,[84] over thirty-three million people die each year without the benefit and pain relief of palliative care.[85] Many countries have even failed to add oral morphine and other opioid medicines to their list of essential medicines or to issue guidelines on pain management for healthcare workers.[86]

Control Provision in the Management of HIV/AIDS, AFRICAN PALLIATIVE CARE ASS'N 31 (2007), *available at* http://www.apca.co.ug/publications/PainRelief.pdf.

78. *Id.* at 29-31.

79. *See generally* 1995 INCB Report, *supra* note 29 (demonstrating generally that the INCB focuses on curbing illicit drug use and distribution).

80. *Id.* at 34-38.

81. CESCR, *Commission on Narcotic Drugs: Report on the Fifty-Third Session*, 12 U.N. Doc. E/2010/28, E/CN.7/2010/18 (Dec. 2, 2009 & Mar. 8-12, 2010) (Resolution 53/4: Promoting Adequate Availability of Internationally Controlled Licit Drugs for Medical and Scientific Purposes While Preventing Their Diversion and Abuse).

82. *Id.* at 15.

83. CESCR, *supra* note 70, ¶43(f).

84. CANCER PAIN RELIEF, *supra* note 16, at 12.

85. Stjernswärd & Clark, *supra* note 4, at 1199.

86. Harding et al., *supra* note 77, at 20-21.

E. Lack of Training for Healthcare Workers

One of the largest obstacles to the provision of good palliative care and pain treatment services in many countries is the lack of training for healthcare workers. Misinformation about morphine is still extremely common among healthcare workers and knowledge of how to assess and treat pain is often very inadequate. As three experts in palliative care and pain management have written, "for too long, pain and its management have been prisoners of myth, irrationality, ignorance, and cultural bias."[87]

Common myths regarding palliative care are that addiction necessarily follows opioid treatment, pain is required for diagnoses, pain is unavoidable, and pain has only minor consequences. Each of these is inaccurate. Many studies have shown that opioid treatment rarely results in addiction, that most pain can be adequately treated, and that pain is not a requirement for diagnoses. Moreover, pain has considerable social, economic, and psychological consequences; it often prevents pain sufferers and their caregivers from living productive lives.[88]

Throughout much of the world, including some industrialized countries, the prevalence of these myths has lead to ignorance about the use of opioid medicines. This ignorance has resulted in a failure to provide healthcare workers with adequate training in palliative care and pain management. A Worldwide Palliative Care Alliance survey of healthcare workers in sixty-nine countries found that roughly eighty percent of workers in Latin America, approximately seventy percent in Asia and about forty percent in Africa had not received any instruction on pain management or opioids during their undergraduate medical studies.[89] In a separate survey by the African Palliative Care Association, most healthcare providers surveyed reported inadequate opportunities for training in palliative care and pain treatment.[90] Even in industrialized countries, instruction on palliative care and pain treatment remains inadequate; studies have shown that considerable numbers of healthcare workers had insufficient factual knowledge about pain management.[91]

F. Cost

Basic oral morphine can be produced cheaply. As mentioned above, in India morphine can be sold for as little as 1.7 cents per tablet.[92] Despite this, in many

87. Brennan et al., *Pain Management*, *supra* note 8, at 217.

88. *Id.*; ACHIEVING BALANCE, *supra* note 12, at 8; Brennan et al., *Pain Management*, *supra* note 8, at 206, 208.

89. Help the Hospices for The Worldwide Palliative Care Alliance, *Access to Pain Relief: An Essential Human Right*, 22 J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY 101, 119 (2008) (Report for World Hospice and Palliative Care Day 2007).

90. Harding et al., *supra* note 77, at 23-24.

91. Kimberly L. Pargeon & B. Jo Hailey, *Barriers to Effective Cancer Pain Management: A Review of the Literature*, 18 J. PAIN AND SYMPTOM MGMT. 358, 362 (1999).

92. *Id.*

countries morphine is much more expensive, making cost a barrier to access for many patients in need of chronic pain treatment.[93]

In one authoritative paper, experts estimated that generic morphine should cost no more than 1 cent per milligram, so that an average month's supply would cost US$9 to $22.5 per patient.[94] The real cost of morphine varies greatly between countries, from around this price to many times more expensive. A 2003 study found that the average retail cost of a monthly morphine supply ranged from US$10 in India to US$254 in Argentina.[95] Paradoxically, the study found that the median cost of a month's supply of morphine was more than twice as high in low- and middle-income countries (US$112) as in industrialized countries (US$53).[96] The study suggested that a number of factors might explain the discrepancy: medication subsidies by industrialized countries; industrialized government regulation of the price of opioids; taxes, licenses, and other regulatory requirements for importing and distributing controlled medicines; large overhead of local production; poorly developed distribution systems; and low demand.[97] Further, a 2007 report found that the promotion of non-generic and costly forms of opioid analgesics has made pain medicines more expensive in some countries,[98] as inexpensive formulations are withdrawn when more expensive opioids appear on the market.[99] The report cited India as one such country where, despite identical regulatory impediments, some hospitals only carry more expensive sustained-release morphine formulations or transdermal fentanyl, but not cheaper immediate-release morphine.[100]

A number of countries have successfully sought ways to create the capacity to locally produce basic oral morphine, in tablet or liquid form, at low cost. For example, in India, a small manufacturing unit has been set up at a hospital to produce low cost immediate-release morphine tablets from morphine powder.[101] Likewise, in Uganda, the government commissioned a facility to produce morphine solution for use by hospitals, health centers, and palliative care providers.[102] In Vietnam, the Ministry of Health may, pursuant to a new regulation governing opioid prescription, require state-owned pharmaceutical companies and

93. Pargeon & Hailey, *supra* note 91, at 362.

94. Foley et al., *Pain Control*, *supra* note 5, at 988.

95. *Id.* at 987.

96. Liliana De Lima et al., *Potent Analgesics Are More Expensive for Patients in Developing Countries: A Comparative Study*, 18 J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY 59, 63-64 (2004).

97. *Id.* at 66.

98. HUMAN RIGHTS WATCH, "PLEASE, DO NOT MAKE US SUFFER ANY MORE..." ACCESS TO PAIN TREATMENT AS A HUMAN RIGHT 35-36 (2009), *available at* http://www.hrw.org/sites/default/files/reports/health0309webwcover_1.pdf [hereinafter PLEASE, DO NOT MAKE US SUFFER].

99. Lohman et al., *supra* note 31, at 5.

100. PLEASE, DO NOT MAKE US SUFFER, *supra* note 98, at 36.

101. David E. Joranson et al., IMPROVING ACCESS TO OPIOID ANALGESICS FOR PALLIATIVE CARE IN INDIA, 24 J. PAIN & SYMPTOM MGMT. 152, 156-57 (2002).

102. Lohman et al., *supra* note 31, at 5 (referencing email from Human Rights Watch to Dr. Anne Merriman of Hospice Africa Uganda (Jan. 2009)).

others to produce both oral and injectable opioids.[103] As noted above, there are also several international organizations that work to improve access to medicines in developing countries.[104] These organizations accomplish this goal by improving supply chains, organizing countries to pool their procurement, or by providing medicines at cost. Although governments could work with these organizations to reduce the cost of morphine and other controlled medicines, as of yet, almost none have done so.

V. ADDRESSING BARRIERS TO ACCESS THROUGH COMPREHENSIVE REFORM

In most low- and middle-income countries, an assessment of the barriers to morphine access, coupled with the development of a plan of action, must be the first step in a comprehensive effort to increase access. To be successful, reforms must simultaneously address both supply and demand for morphine. Improving supply chains to increase morphine stocks will not improve patient access unless doctors are also adequately trained in pain treatment and palliative care. In undertaking these reforms, states can draw upon the expertise of the INCB, WHO, and other international organizations, such as the SCMS.

A number of countries have begun such efforts, with some success. Uganda and Vietnam, with the support of the international community, have made important progress in improving pain treatment and palliative care services for the population.[105] These countries have laid the foundation for replacing the vicious cycle of under-treatment of pain. Already, simpler drug control regulations and better knowledge among healthcare providers has led to increased demand for morphine, reinforcing the importance of pain management and palliative care.[106] This has also created greater awareness among healthcare workers and the public, but both still have a long way to go. Morphine consumption in both countries continues to be low, certain regulatory barriers remain, and large numbers of people suffering from moderate to severe pain still do not have access to adequate treatment.[107]

A. Uganda

In recent years, Uganda has significantly boosted its capacity for palliative care. There are now at least fifty facilities providing palliative care services, including morphine dispensation.[108] In order to reach more patients in need,

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103. Lohman et al., *supra* note 31, at 5 (citing email from Human Rights Watch to Kimberly Green, Family Health International Vietnam (2009)).

104. *See, e.g., supra* text accompanying note 71.

105. PLEASE, DO NOT MAKE US SUFFER, *supra* note 98, at 38.

106. *Id.*

107. *Id.*

108. PALLIATIVE CARE ASS'N OF UGANDA, AUDIT REPORT OF PALLIATIVE CARE SERVICES IN UGANDA 7 (2009), *available at* http://www.theworkcontinues.com/document.asp?id=1526.

community services for home-based palliative care have been greatly strengthened.[109] Many patients can now receive palliative care in their own homes.

The Ugandan government has worked closely with palliative care organizations to expand access. In 1998, representatives of the Ugandan government, nongovernmental organizations, and WHO met at a conference entitled "Freedom from Cancer and AIDS Pain" to discuss ways to make pain treatment widely available.[110] A task force, including representatives of the Ugandan Ministry of Health and WHO, was formed to draft a national policy on palliative care, which the Ministry of Health incorporated into its Health Service Strategic Plan (HSSP) for 2000-2005, and the current HSSP II for 2006-2011.[111] The current strategic plan states that all hospitals and health centers should provide palliative care, that necessary medicines should be available, and that palliative care should be integrated into the curriculum of health training institutions.[112] It also emphasizes the need to strengthen referral systems and community-based palliative care.[113]

To implement the policy, a national palliative care team was established.[114] In 2004, the law was amended to allow nurses and clinical officers to prescribe morphine, once they have completed a nine-month palliative care course.[115] More than eighty nurses and clinical officers have graduated from the Clinical Palliative Care Course at Hospice Africa Uganda.[116] The Ministry of Health started importing oral morphine powder and providing oral morphine solution to public health facilities at no cost.[117] It has also published clinical guidelines on palliative care.[118] The country has gone so far as to reform its own narcotics control laws so that specially trained nurses can prescribe morphine.[119] As a result, the INCB has commended Uganda's efforts to improve access to pain treatment.

Despite this progress, many challenges remain in ensuring access to palliative care throughout Uganda. Some of the nurses trained in palliative care are not using their training because morphine is not available where they work.[120] In other places, hospital administrators are not supporting their efforts—for example, by

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109. Jack Jagwe & Anne Merriman, *Uganda: Delivering Analgesia in Rural Africa: Opioid Availability*, 33 J. PAIN & SYMPTOM MGMT. 547, 548-49 (2007).

110. Jan Stjernswärd, *Uganda: Initiating a Government Public Health Approach to Pain Relief and Palliative Care*, 257 J. PAIN & SYMPTOM MGMT. 259-60 (2002).

111. Jagwe & Merriman, *supra* note 109, at 548-49.

112. *Id.* at 549.

113. *Id.*

114. *Id.* (noting that the team is chaired by the Ministry of Health's Commissioner for Clinical Services, with other members representing the Ministry of Health, the WHO, the national AIDS control program, Makerere University, palliative care providers, the Palliative Care Association of Uganda and the African Palliative Care Association).

115. *Id.* at 549-50.

116. *Id.*

117. Jagwe & Merriman, *supra* note 109, at 549-50.

118. *Id.* at 548.

119. 22004 INCB Report, *supra* note 49, at 32-33.

120. PALLIATIVE CARE ASS'N OF UGANDA, *supra* note 108, at 17-25.

failing to assign them to care for patients with life-limiting disease.[121] Additionally, district health departments do not have defined palliative care budgets and inadequate distribution systems for morphine remain a problem.[122] Nonetheless, Uganda's progress in scaling up access to palliative care demonstrates what can be quickly achieved with limited resources and political will.

B. Vietnam

Since 2005, Vietnam has made considerable progress in expanding access to palliative and pain treatment services. This progress started with the creation of a working group on palliative care consisting of Ministry of Health officials, cancer and infectious disease physicians, and experts from NGOs supported by the PEPFAR.[123] This working group conducted a rapid situation analysis of the availability of and need for palliative care in Vietnam and then developed a national palliative care program based on its findings.[124] The rapid situation analysis found, among other things, that severe chronic pain was common among cancer and HIV/AIDS patients.[125] In addition, the availability of opioid analgesics and other key medications was severely limited, palliative care services were not readily available, and clinicians lacked adequate training.[126] Based on these findings, the working group recommended that national palliative care guidelines be developed, a balanced national opioid control policy be articulated, training for healthcare workers be expanded, and that availability and quality of palliative care services be improved at all levels.[127]

In September 2006, the Ministry of Health issued detailed Guidelines on Palliative Care for Cancer and AIDS Patients, which provide guidance to practitioners on palliative care and pain management.[128] In February 2008, it issued new guidelines on opioid prescription which have eased a number of key regulatory barriers.[129] For example, the new guidelines eliminate the maximum daily dose, allow prescriptions to be issued for thirty days instead of seven, and authorize district hospitals and community health posts to prescribe and dispense opioids.[130] The ministry also approved a package of training courses for practicing

121. PALLIATIVE CARE ASS'N OF UGANDA, *supra* note 108, at 56.

122. *Id.* at 56, 64.

123. KIMBERLY GREEN ET AL., PALLIATIVE CARE IN VIET NAM: FINDINGS FROM A RAPID SITUATION IN FIVE PROVINCES 3 (2006).

124. *Id.*

125. *Id.* at 4.

126. *Id.* at 4-5

127. *Id.* at 5-7.

128. PLEASE, DO NOT MAKE US SUFFER, *supra* note 98, at 44.

129. *Id.*

130. *Id.* While this is an improvement, patients and their families can only fill prescriptions for ten days at a time, after which their local commune must confirm in writing that the patient is still alive. *Id.* at 40.

physicians, while two medical colleges now provide undergraduate medical and nursing students with palliative care instruction.[131]

Yet, numerous challenges remain in Vietnam. Only a few hundred healthcare workers have received training, healthcare officials' understanding of palliative care remains limited, various regulatory barriers persist, and few pharmacies and hospitals stock oral morphine.[132]

VI. HUMAN RIGHTS ANALYSIS OF ACCESS TO PAIN TREATMENT AND PALLIATIVE CARE

Analysis of access to pain treatment as a human right is relatively new. Early analysis of the issue and calls for pain treatment to be recognized as a human right came from medical professionals working in pain management and palliative care.[133] Subsequently, the U.N. Special Rapporteur on The Right to the Highest Attainable Standard of Health, Anand Grover, and the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Manfred Nowak, both recognized that a failure to address barriers to palliative care can be a violation of human rights. They have jointly written that:

> Many countries do not recognize palliative care and pain treatment as priorities in health care, have no relevant policies, have never assessed the need for pain treatment or examined whether that need is met, and have not examined the obstacles to such treatment. . . . The failure to ensure access to controlled medicines for the relief of pain and suffering threatens fundamental rights to health and to protection against cruel, inhuman and degrading treatment. International human rights law requires that governments must provide essential medicines – which include, among others, opioid analgesics – as part of their minimum core obligations under the right to health.[134]

Human Rights Watch published its first report on access to pain treatment and palliative care in 2009.[135] Like the Special Rapportuers' report, the Human Rights Watch analysis focused on two main rights that barriers to access may violate: the

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131. PLEASE, DO NOT MAKE US SUFFER, *supra* note 98, at 40.

132. *Id.*

133. *Joint Declaration and Statement of Commitment on Palliative Care and Pain Treatment as Human Rights*, INT'L HOSPICE & PALLIATIVE CARE ASS'N AND WORLD WIDE PALLIATIVE CARE ALLIANCE, *available at* http://www.hospicecare.com/resources/pain_pallcare_hr/docs/jdsc.pdf; F. Brennan and M. J. Cousins, *Pain Relief as a Human Right*, IASP PAIN CLINICAL UPDATES, Vol. XII, No. 5, March 2004, *available at* http://www.hospicecare.com/resources/pdf-docs/pain_relief_as_a_human_right_pain_clinical_updates_2004.pdf; Frank Brennan, *Palliative Care as an International Human Right*, 33 J. PAIN & SYMPTOM MGMT. 494 (2007).

134. *Letter to Chairperson of the Commission on Narcotic Drugs*, United Nations Special Rapporteur on the Prevention of Torture and Cruel, Inhuman, or Degrading Treatment or Punishment & Special Rapporteur on Right of Everyone to the Highest Attainable Standard of Physical and Mental Health, U.N. Doc. G/SO 214 (52-21) (Dec. 10, 2008), *available at* http://www.hrw.org/sites/default/files/related_material/12.10.2008%20Letter%20to%20CND%20fromSpecial%20Rapporteurs.pdf (last visited Nov. 6, 2010).

135. *See generally* PLEASE, DO NOT MAKE US SUFFER, *supra* note 98.

right to the highest attainable standard of health and the right to be free from cruel, inhuman, or degrading treatment.[136]

A. The Right to the Highest Attainable Standard of Health

The right to the highest attainable standard of health is found in the International Covenant on Economic, Social, and Cultural Rights (ICESCR) and several other human rights treaties.[137] State parties to ICESCR are obliged to 'take steps . . . to the maximum of its available resources, with a view to achieving progressively the full realization' of the right to health.[138]

The doctrine of progressive realization allows for the fact that different states have different resources available to provide health care services. In deciding whether a government is in violation of the right to health, its resources must be taken into account. However, as noted above, the CESCR (which interprets and monitors compliance with the ICESCR) has stated that there are certain "core obligations" which are "non-derogable," meaning that "a State party cannot, under any circumstances whatsoever, justify its non-compliance."[139] These include provision of essential medicines, which, as defined by WHO, includes morphine.[140]

Other core obligations that are relevant to addressing the barriers discussed above include obligations to ensure the right of access to health facilities, goods, and services on a non-discriminatory basis, especially for vulnerable or marginalized groups; obligations to ensure the equitable distribution of all health facilities, goods, and services; and obligations to adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population.[141] The committee has also described measures to treat and control epidemic and endemic diseases and the need to provide appropriate training for health personnel as obligations of "comparable priority" to the core obligations.[142]

The CESCR developed the doctrine of "respect, protect, fulfill" to emphasize that economic, social, and cultural rights give rise to both positive and negative

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136. PLEASE, DO NOT MAKE US SUFFER, *supra* note 98, at 14-15.

137. Convention on the Rights of the Child, adopted Nov. 20, 1989, G.A. Res. 44/25, Annex, 44 U.N. GAOR, Supp. No. 49, U.N. Doc. A/44/49, at 167 (Sept. 2, 1990); Convention on the Elimination of All Forms of Discrimination against Women, adopted Dec. 18, 1979, G.A. Res. 34/180, 34 U.N. GAOR, Supp. No. 46, U.N. Doc. A/34/46, at 193 (Sept. 3, 1981); International Convention on the Protection and Promotion of the Rights and Dignity of Persons with Disabilities, G.A. Res. 61/106, Annex, U.N. GAOR, 61st Sess., Supp. No. 49, U.N. Doc. A/61/49, at 65, *entered into force* May 3, 2008.

138. International Covenant on Civil and Political Rights, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. No. 16, UN Doc. A/6316, art 2.1 (Dec. 16, 1966) [hereinafter ICCPR].

139. CESCR, *supra* note 70, ¶47.

140. *Id.*; ESSENTIAL MEDICINES 2009, *supra* note 15, at 1.

141. CESCR, *supra* note 70, ¶43.

142. *Id.* ¶¶43, 44.

obligations for governments.[143] This includes both obligations to take action to realize and protect individuals' rights, as well as obligations to refrain from acts that would violate them.[144] Unlike other essential commodities, the manufacture, import, export, distribution, prescription, and dispensing of controlled medicines can only occur with government authorization. For this reason, the availability of controlled medicines will never be dictated solely by market forces. Instead, without government action, they will simply be unavailable. As a result, the Committee's doctrine means that governments have a clear obligation to take positive steps – such as putting in place functioning supply chains and ensuring that medical professionals have adequate training – to make controlled medicines available as an aspect of fulfilling obligations under the right to health.

On December 10, 2008, Human Rights Day, the U.N. General Assembly adopted an Optional Protocol to the ICESCR.[145] The Optional Protocol allows the CESCR to accept and give opinions on communications from individuals who claim that their rights under the Convention have been violated, as long as the state concerned has ratified the Optional Protocol.[146] Allowing the CESCR to receive individual communications brings its practice into line with the practice of the other treaty bodies and reflects evolving views about the justiciability of economic, social, and cultural rights.

The Optional Protocol states that:

> When examining communications under the present Protocol, the Committee shall consider the reasonableness of the steps taken by the State Part . . . and . . . shall bear in mind that the State Party may adopt a range of possible policy measures for the implementation of the rights set forth in the Covenant.[147]

The reasonableness standard has also been used by the South African Constitutional Court when adjudicating claims regarding economic, social and cultural rights.[148] For example, in the *Grootboom* case, the Court found that the government had not taken reasonable steps to provide housing to the plaintiff and others evicted from an informal settlement.[149]

The reasonableness standard can be applied to determine whether the barriers to access to pain treatment described above are violations of the right to health. A failure to take any steps at all to ensure access to an essential medicine, or failure to take low-cost steps such as developing policies and making use of available international assistance, will almost always be unreasonable. In determining

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143. CESCR, *supra* note 70, ¶33.

144. *Id*.

145. Optional Protocol to the Int'l Covenant on Economic, Social and Cultural Rights, G.A. Res. 63/117, art. 1, U.N. Doc. A/RES/63/117 (Dec. 10, 2008), *available at* http://www2.ohchr.org/english/bodies/cescr/docs/A-RES-63-117.pdf.

146. *Id.*

147. *Id.* art. 8.4.

148. *Republic of South Africa v. Grootboom* 2001 (1) SA 46 (BCLR), *available at* http://www.saflii.org/za/cases/ZACC/2000/14.html (ordering the government of South Africa to provide certain accommodations for the applicants).

149. *Id.*

whether measures designed to prevent diversion of controlled medicines to illicit supply are unreasonable one must consider that, according to the INCB, such diversion is relatively rare.[150] The goal of preventing diversion must be balanced against the need for ensuring medical supply of controlled medicines for pain treatment; the reasonableness of any drug control measures must then be judged accordingly. Measures beyond those necessary to prevent diversion and restrict medical access to controlled drugs should be held unreasonable and thus, a violation of the right to health.

At least one court has applied a similar analysis to the question of morphine access.[151] In 1998, a man petitioned the Delhi Supreme Court on behalf of his mother, who had severe cancer pain but was unable to obtain morphine because of complex narcotics regulations.[152] The court found in favor of the plaintiff and directed government agencies to adopt "rational" narcotics rules and ensure morphine availability.[153] However, because the government has failed to adequately implement the ruling, the plaintiff has filed a similar case with India's Supreme Court.[154]

B. Pain Treatment, Palliative Care, and the Right to be Free from Cruel, Inhuman or Degrading Treatment

The prohibition of cruel, inhuman or degrading treatment is found in the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT) and other human rights instruments.[155] The Committee Against Torture, the treaty body that interprets the CAT, has stated that cruel, inhuman or degrading treatment or punishment "may differ [from torture] in the severity of pain and suffering and does not require proof of impermissible purposes."[156] In other words, governments may violate the CAT when they fail to take steps to prevent cruel, inhuman or degrading treatment or punishment, regardless of whether any government official had malicious intent. The Committee Against

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150. 2008 INCB Report, *supra* note 40, at 22.

151. UNBEARABLE PAIN, *supra* note 66, at 55-56.

152. *Id.*

153. *Id.*

154. *Id.*

155. Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, G.A. Res. 39/46, Annex 39, U.N. GAOR, Supp. No. 51, UN Doc. A/39/51, at 197 (Dec. 10, 1984); Universal Declaration of Human Rights, G.A. Res. 217A (III), U.N. GAOR, 3d Sess., U.N. Doc A/810 (Dec. 10, 1948); ICCPR, *supra* note 138, at 52; Inter-American Convention to Prevent and Punish Torture, *entered into force* Feb. 22, 1987, OAS Treaty Series No. 67, reprinted in 25 I.L.M. 519 (1987); European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment, ETS 126 (1987); African [Banjul] Charter on Human and Peoples' Rights, adopted June 27, 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58, art. 5 (1982), *entered into force* Oct. 21, 1986.

156. U.N. Comm. Against Torture, *General Comment No. 2: Implementation of Article 2 by State Parties*, ¶10, U.N. Doc. CAT/C/GV/2 (Jan. 24, 2008), *available at* http://www.unhcr.org/refworld/docid/47ac/78ce2.html.

Torture has stated that the CAT requires state parties to take "effective preventative measures" and "eliminate any legal or other obstacles that impede the eradication of torture and ill-treatment."[157]

The UN Special Rapporteur on Torture and Other Cruel, Inhuman and Degrading Treatment or Punishment stated in his February 2009 report to the Human Rights Council that "de facto denial of access to pain relief, when it causes severe pain and suffering, constitutes cruel, inhuman or degrading treatment or punishment."[158]

Human Rights Watch argues that not every case where a person suffers from severe untreated pain is cruel, inhuman, or degrading treatment or punishment.[159] Rather, the prohibition is only violated when the following conditions are met:

- The suffering is severe and meets the minimum threshold required under the prohibition against torture and cruel, inhuman, or degrading treatment or punishment;
- The state is, or should be, aware of the level and extent of the suffering;
- Treatment is available to remove or lessen the suffering but no appropriate treatment was offered; and
- The state has no reasonable justification for the lack of availability and accessibility of pain treatment.[160]

Human Rights Watch applied these criteria to the access to pain treatment in India, arguing that the Indian government's failure to take reasonable measures to offer pain treatment or palliative care amounted to a violation of the CAT.[161] Specifically, the report cited India's failure to earmark funds for palliative care or require all regional cancer centers to develop palliative care services.[162]

C. Conclusion

Since palliative care's emergence as a discreet medical discipline in the 1960s, its practitioners have led a movement for increased access to controlled medicines, particularly in developing countries.[163] Despite the numerous challenges, especially in resource-limited settings, these practitioners have

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157. *General Comment No. 2*, *supra* 156, ¶¶4, 25.

158. Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishmen, *Promotion and Protection of All Human Rights, Civil Political, Economic, Social and Cultural Rights, Including the Right to Develop*, U.N. Doc. A/HRC/10/44, ¶72 (Jan. 14, 2009).

159. UNBEARABLE PAIN, *supra* note 66, at 60.

160. *Id.* at 60-61.

161. *Id.* at 61.

162. *Id.*

163. AFRICAN PALLIATIVE CARE ASS'N, http://www.apca.org.ug/ (last visited Nov. 6, 2010) (developed to promote and support affordable and culturally appropriate palliative care network throughout Africa); INT'L CHILD. PALLIATIVE CARE NETWORK, http://www.icpcn.org.uk (last visited Nov. 6, 2010) (working to provide hospice and palliative care to children in developing world); WORLDWIDE PALLIATIVE CARE ALLIANCE, http://www.thewpca.org (last visited Nov. 6, 2010); INT'L ASS'N FOR HOSPICE AND PALLIATIVE CARE, http://www.hospicecare.com (last visited Nov. 6, 2010).

significantly increased morphine access. Organizations focusing specifically on access to controlled medicines have also emerged.[164]

However, a lack of pain treatment and palliative care in low- and middle-income countries persists. This could be viewed simply as tragedy: lamentable, dreadful, and perhaps even inevitable. Indeed, this appears to be the attitude throughout much of the world, where available palliative care services are provided by hospices, often run by religious groups, and supported only by charity.[165] Through compassion and hard work, these institutions have eased the suffering of hundreds of thousands of people, but their services reach only a small fraction of those in need. Meanwhile, a fundamental and common medical condition – the experience of pain – has been largely ignored by governments, cast off as the responsibility of others.

A human rights analysis rejects the idea that suffering from treatable pain is inevitable and that the provision of cheap, effective pain medicine must remain a matter of charity. Human rights conventions obligate governments to identify health needs and to adopt national health policies that include detailed plans for realizing the right to health. Under these conventions, States must ensure the appropriate training of doctors and other medical personnel. Additionally, human rights bodies have specifically placed the onus on governments to attend to and care for chronically and terminally ill persons suffering pain.

A human rights analysis also provides a structured framework for addressing potential conflicts in government obligations and interests. Governments have legitimate reasons, and specific obligations, to address illicit narcotics trafficking and use. However, human rights norms mandate that this goal cannot be pursued at the expense of obligations to provide patients with access to pain medicines. The various government ministries charged with addressing different aspects of these obligations must work towards a larger common goal.

Concepts such as progressive realization and "respect, protect, fulfill" encourage identification of specific steps that governments can take in addressing barriers to pain treatment and palliative care. These steps include reforming narcotics control legislation, improving drug supply systems and medical education, and integrating palliative care into the public health system. Thus, a

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164. *See* UNIV. OF WISC. PAIN & POLICY STUDIES GROUP (last updated Oct. 25, 2010), http://www.painpolicy.wisc.edu/ (last visited Aug. 6, 2010); *Access to Analgesics and to Other Controlled Medications*, WORLD HEALTH ORG., http://www.who.int/medicines/areas/quality_safety/access_Contr_Med/en/index.html (last visited Aug. 6, 2010).

165. *See*, *e.g.*, Help the Hospices, *supra* note 23; *see also Palliative Care Initiative*, THE DIANA, PRINCESS OF WALES MEMORIAL FUND, http://www.theworkcontinues.org/landing.asp?id=3 (last visited Nov. 6, 2010) (independent, grant-giving charity working to ensure availability of palliative care in sub-Saharan Africa); *About Us*, ST. CHRISTOPHER'S HOSPICE, http://www.stchristophers.org.uk/page.cfm/Link=2/t=m/goSection=4 (last visited Nov. 6, 2010) (charity that must raise two-thirds of its £14M annual income to provide palliative care services to those in need).

human rights analysis encourages addressing the problem of lack of access to palliative care in a systemic way, which would improve access for the population as a whole.

By conceiving of those suffering from untreated pain as rights-holders to whom governments owe obligations, a human rights analysis encourages patients, families, and doctors to hold governments accountable for lack of access to pain medicines. The human rights perspective also provides an idiom to express this accountability. Patients may assert their rights against the government informally, through protests or letters, or in domestic courts where laws allow for arguments made in terms of human rights. International human rights law also provides forums in which these claims can be made. For example, in response to a submission by Human Rights Watch, the Committee Against Torture specifically raised the issue of lack of access to pain medicines in Cameroon, asking the government to describe its policies and action plans for improving access to palliative care, including morphine.[166] The adoption of the Optional Protocol to ICESCR will go one step further, allowing individuals to assert violations of the right to health against governments.

As the human rights movement has grown, new groups have adopted the language of rights. Through this process, more types of suffering have been analyzed in terms of human rights law and recognized as human rights issues. Conceiving of the palliative care deficit as a human rights issue is therefore a natural progression. However, like many other human rights problems, the causes of the lack of access to pain treatment are complex and interrelated. Simply conceiving of the lack of pain treatment as a human rights issue will not eliminate all barriers that patients in severe pain face. Both regulatory reform and cultural change are needed. A comprehensive approach, with sustained effort over several years, will be required before reform efforts are translated into better patient access. A human rights analysis places the onus of undertaking this reform effort upon the actors best able to implement systemic change – national governments. At the international level and in some countries, that process is already underway.

166. U.N. Comm. Against Torture, Apr. 26-May 14, 2010, *List of issues to be taken up during the consideration of the fourth periodic report of Cameroon,* ¶33, U.N. Doc. CAT/C/CMR/Q/4 (Jan. 18, 2010), *available at* http://www2.ohchr.org/english/bodies/cat/docs/CAT.C.CMR.Q.4.pdf