



**“Please, do not make us suffer any more...”**

**Access to Pain Treatment as a Human Right**

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## Executive Summary

*“For two days I had agonizing pain in both the back and front of my body. I thought I was going to die. The doctor said that there was no need to medicate my pain, that it was just a hematoma and that the pain would go away by itself. I was screaming all through the night.”*

– An Indian man describing his stay in hospital immediately after a construction site accident in which he sustained spinal cord trauma.<sup>1</sup>

*“Cancer is killing us. Pain is killing me because for several days I have been unable to find injectable morphine in any place. Please Mr. Secretary of Health, do not make us suffer any more...”*

– A classified ad placed in a Colombian newspaper in September 2008 by the mother of a woman with cervical cancer.<sup>2</sup>

*“Physicians are afraid of morphine... Doctors [in Kenya] are so used to patients dying in pain...they think that this is how you must die. They are suspicious if you don’t die this way – [and feel] that you died prematurely.”*

– Physician at hospice in Kenya.<sup>3</sup>

In 1961, the world community adopted an international agreement—the 1961 Single Convention on Narcotic Drugs—that proclaimed “narcotic drugs...indispensable for the relief of pain and suffering” and instructed countries to make adequate provision to ensure their availability for medical needs. Today, almost fifty years later, the promise of that agreement remains largely unfulfilled, particularly—but not only—in low and middle income countries. In September 2008, the World Health Organization (WHO) estimated that approximately 80 percent of the world population has either no or insufficient access to treatment for moderate to severe pain and that every year tens of millions of people around the world, including around four million cancer patients and 0.8 million HIV/AIDS patients at the end of their lives suffer from such pain without treatment.

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<sup>1</sup> Human Rights Watch interview, Kerala, India, March 20, 2008. The name of the patient is withheld for reasons of privacy.

<sup>2</sup> The ad appeared in the newspaper El Pais in Cali, Colombia, on September 12, 2008.

<sup>3</sup> Human Rights Watch interview with Dr. Weru of Nairobi Hospice, Nairobi, Kenya, June 2007.

The poor availability of pain treatment is both perplexing and inexcusable. Pain causes terrible suffering yet the medications to treat it are cheap, safe, effective and generally straightforward to administer. Furthermore, international law obliges countries to make adequate pain medications available. Over the last twenty years, the WHO and the International Narcotics Control Board (INCB), the body that monitors the implementation of the UN drug conventions, have repeatedly reminded states of their obligation. But little progress has been made in many countries.

Under international human rights law, governments must address a major public health crisis that affects millions of people every year. They must take steps to ensure that people have adequate access to treatment for their pain. At a minimum, states must ensure availability of morphine, the mainstay medication for the treatment of moderate to severe pain, because it is considered an essential medicine that should be available to all persons who need it and is cheap and widely available. Failure to make essential medicines available or to take reasonable steps to make pain management and palliative care services available will result in a violation of the right to health. In some cases, failure to ensure patients have access to treatment for severe pain will also give rise to a violation of the prohibition of cruel, inhuman and degrading treatment.

There are many reasons for the enormity of the gap between pain treatment needs and what is delivered, but chief among them is a shocking willingness by many governments around the world to passively stand by as people suffer. Few governments have put in place effective supply and distribution systems for morphine; they have no pain management and palliative care policies or guidelines for practitioners; they have excessively strict drug control regulations that unnecessarily impede access to morphine or establish excessive penalties for mishandling it; they do not ensure healthcare workers get instruction on pain management and palliative care as part of their training; and they do not make sufficient efforts to ensure morphine is affordable. Fears that medical morphine may be diverted for illicit purposes are a key factor blocking improved access to pain treatment. While states must take steps to prevent diversion, they must do so in a way that does not unnecessarily impede access to essential medications. INCB has stated that such diversion is relatively rare.<sup>4</sup>

In many places, these factors combine to create a vicious cycle of under-treatment: because pain treatment and palliative care are not priorities for the government, healthcare workers do not receive the necessary training to assess and treat pain. This leads to widespread

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<sup>4</sup> International Narcotics Control Board, "Report of the International Narcotic Control Board for 2008," United Nations, 2009.

under-treatment and to low demand for morphine. Similarly, complex procurement and prescription regulations and the threat of harsh punishment for mishandling morphine discourage pharmacies and hospitals from stocking and healthcare workers from prescribing it, again resulting in low demand. This, in turn, reinforces the low priority given to pain management and palliative care. This low prioritization is not a function of low prevalence of pain but of the invisibility of its sufferers.

To break out of this vicious cycle, individual governments and the international community must fulfill their obligations under international human rights law. Governments must take action to eliminate barriers that impede availability of pain treatment medications. They must develop policies on pain management and palliative care; introduce instruction for healthcare workers, including for those already practicing; reform regulations that unnecessarily impede accessibility of pain medications; and take action to ensure their affordability. While this is a considerable task, various countries, such as Romania, Uganda and Vietnam, have shown that such a comprehensive approach is feasible in low and middle-income countries and can be successful. In pursuing steps to improve pain treatment, countries should draw on the expertise and assistance of the WHO Access to Controlled Medications Programme and INCB.

The international community should address the poor availability of pain treatment with urgency. The UN General Assembly Special Session on Drugs that will take place in Vienna in March 2009 is a unique opportunity to begin to do so. At the meeting, which will conclude a year-long review of the last ten years of drug policy, countries will set priorities for the next ten years of global drug policy. In Vienna, the international community should recommit itself to the mandate of the 1961 Single Convention for states to ensure adequate availability of controlled medicines for the relief of pain and suffering. For too long, the global drug policy debate has been strongly focused on prevention of the use and trade of illicit drugs, distorting the balance that was envisioned by the Convention. In March 2009, the international community should set ambitious and measurable goals to significantly improve access to opioid analgesics—pain medications made from opiates—and other controlled medicines worldwide over the coming ten years.

After March 2009, global drug policy actors, such as the UN Commission on Narcotic Drugs and INCB, should regularly review progress made by countries toward adequate availability of pain treatment medications, carefully analyzing steps taken to advance this important issue. Donor countries and agencies, including the Global Fund to fight AIDS, Malaria, and Tuberculosis and the U.S. President's Emergency Plan for AIDS Relief, should actively encourage countries to undertake comprehensive steps to improve access to pain relief

medications and support those that do, including through support for the WHO Access to Controlled Medications Programme. UN and regional human rights bodies should routinely remind countries of their obligation under human rights law to ensure adequate availability of pain medications.



## Background: Pain in the World Today

### Prevalence of Pain

Chronic moderate and severe pain is a common symptom of cancer and HIV/AIDS, as well as of various other health conditions.<sup>5</sup> A recent review of pain studies in cancer patients found that more than fifty percent of cancer patients experience pain symptoms<sup>6</sup> and research consistently finds that 60 to 90 percent of patients with advanced cancer experience moderate to severe pain.<sup>7</sup> The intensity of the pain and its effect vary depending on the type of cancer, treatment, and personal characteristics. Prevalence and severity of pain usually increase with disease progression.

Although no population-based studies of AIDS-related pain have been published, multiple studies report that 60 to 80 percent of patients in the last phases of illness experience significant pain.<sup>8</sup> Even though the increasing availability of antiretroviral drugs in middle and low income countries is prolonging the lives of many people with HIV, pain symptoms continue to be a problem for a significant proportion of these patients.<sup>9</sup> Several studies have found that between 29 and 74 percent of people who receive antiretroviral treatment experience pain symptoms.<sup>10</sup>

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<sup>5</sup> Pain is also a symptom in 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.

<sup>6</sup> M. van den Beuken-van Everdingen, et al., "Prevalence of pain in patients with cancer: a systematic review of the past 40 years," *Annals of Oncology*, vol. 18, no.9, Mar. 12, 2007, pp. 1437-1449.

<sup>7</sup> C. S. Cleeland, et al., "Multidimensional Measurement of Cancer Pain: Comparisons of U.S. and Vietnamese Patients," *Journal of Pain and Symptom Management*, vol. 3, 1988, pp. 1, 23 - 27; C. S. Cleeland, et al., "Dimensions of the Impact of Cancer Pain in a Four Country Sample: New Information from Multidimensional Scaling," *Pain* vol. 67, 1996, pp. 2-3 267 - 73; R.L. Daut and C.S. Cleeland, "The prevalence and severity of pain in cancer," *Cancer*, vol. 50, 1982, pp. 1913-8; Foley, K. M., "Pain Syndromes in Patients with Cancer," in K. M. Foley, J. J. Bonica, and V. Ventafridda, ed., *Advances in Pain Research and Therapy*, (New York: Raven Press, 1979), pp.59-75.; Foley, K. M., "Pain Assessment and Cancer Pain Syndromes," in D. Doyle, G. Hank, and N. MacDonald, eds., *Oxford Textbook of Palliative Medicine*, 2nd ed., (New York: Oxford University Press, 1999), pp. 310-31; Stjernsward, J., and D. Clark, "Palliative Medicine: A Global Perspective," in D. Doyle, G. W. C. Hanks, N. Cherny, and K. Calman, eds., *Oxford Textbook of Palliative Medicine*, 3rd ed., (New York: Oxford University Press, 2003), pp. 1199-222.

<sup>8</sup> Green, K., "Evaluating the delivery of HIV palliative care services in out-patient clinics in Viet Nam, upgrading document," London School of Hygiene and Tropical Medicine, 2008; Kathleen M. Foley, et al., "Pain Control for People with Cancer and AIDS," in *Disease Control Priorities in Developing Countries*, 2<sup>nd</sup> ed., (New York: Oxford University Press, 2003), pp. 981-994; Larue, Francois, et al., "Underestimation and under-treatment of pain in HIV disease: a multicentre study," *British Medical Journal*, vol.314, 1997, p.23, <http://www.bmj.com/cgi/content/full/314/7073/23> (Accessed April 2007); Schofferman, J., and R. Brody, "Pain in Far Advanced AIDS," in K. M. Foley, J. J. Bonica, and V. Ventafridda, eds., *Advances in Pain Research and Therapy*, (New York: Raven Press, 1990), pp. 379-86; E. J. Singer, C. Zorilla, B. Fahy-Chandon, S. Chi, K. Syndulko and W. W. Tourtellotte, "Painful Symptoms Reported by Ambulatory HIV-Infected Men in a Longitudinal Study," *Pain*, vol. 54, 1993, pp. 15 - 19.

<sup>9</sup> Selwyn, P. and Forstein, M., "Overcoming the false dichotomy of curative vs. palliative care for late-stage HIV/AIDS," *JAMA* vol. 290, 2003, pp. 806-814.

<sup>10</sup> Green, K., "Evaluating the delivery of HIV palliative care services in out-patient clinics in Viet Nam, upgrading document," London School of Hygiene and Tropical Medicine, 2008.

Experts believe that worldwide there are 24.6 million people who suffer from cancer annually, and that more than 7 million people die of it every year. Overall, 12 percent of all deaths worldwide are due to cancer.<sup>11,12</sup> WHO warns that these numbers will continue to grow over the coming years, with 30 million people projected to be living with cancer by 2020.<sup>13</sup> UNAIDS estimates that about 32 million people live with HIV worldwide, that some 4.1 million people are newly infected each year, and that almost 3 million die of the disease.<sup>14,15</sup>

## The Impact of Pain

Moderate to severe pain has a profound impact on quality of life. Scientific research has demonstrated that persistent pain has a series of physical, psychological and social consequences. It can lead to reduced mobility and consequent loss of strength; compromise the immune system; interfere with a person's ability to eat, concentrate, sleep, or interact with others.<sup>16</sup> The psychological consequences are also profound. A WHO study found that people who live with chronic pain are four time more likely to suffer from depression or anxiety.<sup>17</sup> The physical effect of chronic pain and the psychological strain it causes can even influence the course of disease. According to WHO, "[p]ain can kill..."<sup>18</sup>

Pain has social consequences for people experiencing it and often also for their care givers, who may face sleep deprivation and other problems as a result. These social consequences include inability to work, care for children or other family members, and participate in social activities.<sup>19</sup> Pain can also interfere with a dying person's ability to bid farewell to loved ones and make final arrangements.

While the physical, psychological and social consequences of pain are measurable, the suffering caused by the pain is not. Yet, there can be little dispute about enormity of the misery it inflicts. People who experience severe but untreated pain often live in agony for

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<sup>11</sup> Parkin D.M., et al., "Global cancer statistics, 2002," *CA: A Cancer Journal for Clinicians*, vol.55, 2005, pp. 74-108.

<sup>12</sup> World Health Organization, "National Cancer Control Programmes: Policies and Managerial Guidelines, second edition," 2002, pp. vii, xii.

<sup>13</sup> Ibid, p. xii

<sup>14</sup> World Health Organization, "Achieving Balance in National Opioids Control Policy: Guidelines for Assessment," 2000, p. 1.

<sup>15</sup> UNAIDS, "Report on the Global AIDS Epidemic," May 2006, p. 8.

<sup>16</sup> Brennan F, Carr DB, Cousins MJ, "Pain Management: A Fundamental Human Rights," *Anesthesia & Analgesia*, vol. 105, No. 1, July 2007, pp. 205-221.

<sup>17</sup> Gureje O, Von Korff M, Simon GE, Gater R., "Persistent pain and well-being: a World Health Organization study in primary care," *JAMA*, vol. 80, 1998, pp. 147-51. See also: B. Rosenfeld, et al., "Pain in Ambulatory AIDS Patients. II: Impact of Pain on Psychological Functioning and Quality of Life," *Pain*, vol. 68, 1996, pp. 2-3, 323 - 28.

<sup>18</sup> WHO, "National Cancer Control Programme: Policies and Managerial Guidelines," 2002, p. 83.

<sup>19</sup> R. L. Daut, C. S. Cleeland and R. C. Flanery, "Development of the Wisconsin Brief Pain Questionnaire to Assess Pain in Cancer and Other Diseases," *Pain*, vol. 17, 1983, pp. 2, 197 - 210.

much of the day and often for extended periods of time. Many people interviewed by Human Rights Watch who had experienced severe pain in India, expressed the exact same sentiment as torture survivors: all they wanted was for the pain to stop. Unable to sign a confession to make that happen, several people told us that they had wanted to commit suicide to end the pain, prayed to be taken away, or told doctors or relatives that they wanted to die.<sup>20</sup>

## **Pain Management: Elements, Effectiveness, Cost**

According to WHO, “Most, if not all, pain due to cancer *could* be relieved if we implemented *existing* medical knowledge and treatments.”<sup>21</sup> The mainstay medication for the treatment of moderate to severe pain is morphine, an opioid that is made of an extract of the poppy plant. Morphine can both be injected and taken orally. It is mostly injected to treat acute pain, generally in hospital settings. Oral morphine is the drug of choice for chronic pain, and can be taken both in institutional settings and at home. Due to the potential for its abuse, morphine is a controlled medication, meaning that its manufacture, distribution and dispensing is strictly controlled both at the international and national levels.

The WHO Pain Relief Ladder is the basis for modern pain management. Originally developed for treating cancer pain, it has since been applied successfully to HIV/AIDS-related pain.<sup>22</sup> The ladder recommends the administration of different types of pain medications, or analgesics, according to the severity of the pain. For mild pain, it calls for basic pain relievers like acetaminophen (Tylenol), aspirin, or nonsteroidal anti-inflammatory drugs that are usually widely available and without prescription. For mild to moderate pain, it recommends a combination of basic pain relievers and a weak opioid, like codeine. For moderate to severe pain, it calls for strong opioids, like morphine. Indeed, WHO has held that for managing cancer pain, opioids are “absolutely necessary” and, when pain is moderate to severe, “there is no substitute for opioids” such as morphine.<sup>23</sup> The Pain Relief Ladder also recommends various other medications, known as adjuvant drugs, that serve to increase the effectiveness of analgesics or counter their side effects, including laxatives, anti-convulsants and anti-depressants.

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<sup>20</sup> Human Rights Watch interviews in March and April 2008 in the Indian states of Kerala, Andhra Pradesh, West Bengal, and Rajasthan.

<sup>21</sup> WHO, “Achieving Balance in Opioid Control Policy,” 2000, p. 1.

<sup>22</sup> O'Neill, J. F., P. A. Selwyn, and H. Schietinger, *A Clinical Guide to Supportive and Palliative Care for HIV/AIDS*, (Washington, DC: Health Resources and Services Administration, 2003).

<sup>23</sup> WHO, “Achieving Balance in National Opioids Control Policy.”

Pain medications vary greatly in terms of cost. Basic oral morphine in powder or tablet form is not protected by any patent and can be produced for as little as US\$0.01 per milligram.<sup>24</sup> (A typical daily dose in low and middle-income countries ranges, according to one estimate, from 60 to 75 milligrams per day).<sup>25</sup> Other pain medications, such as Fentanyl skin patches that gradually release the active substance, are very costly, and some protect by patent. Because oral morphine can be produced cheaply, providing pain management should be possible at the community level even in developing countries. However, a 2004 study by De Lima and others found that, for a variety of reasons (see below, under Cost), opioid analgesics, including basic oral morphine, tend to be considerably more expensive in both relative and absolute terms in low and middle income countries than in industrialized nations.<sup>26</sup>

Chronic pain management often comes as a part of broader palliative care services. Palliative care aims to improve the quality of life of patients and their families facing problems associated with life-threatening illnesses, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.<sup>27</sup> The World Health Organization recognizes palliative care as an essential component of a national response to HIV/AIDS, cancer and other diseases.<sup>28</sup> The organization estimates that,

despite an overall 5-year survival rate of nearly 50% in developed countries, the majority of cancer patients will need palliative care sooner or later. In developing countries, the proportion requiring palliative care is at least 80%. Worldwide, most cancers are diagnosed when already advanced and incurable.<sup>29</sup>

For those with incurable cancers, the only realistic treatment options are pain relief and palliative care.<sup>30</sup> Palliative care is often provided alongside curative care services.<sup>31</sup> While

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<sup>24</sup> Kathleen M. Foley, et al., "Pain Control for People with Cancer and AIDS."

<sup>25</sup> Ibid. This is an estimate for low and middle income countries. The average daily dose in industrialized countries tends to be higher. This is due, among others, to longer survival of patients and the development among patients of tolerance to opioid analgesics. Email communication with Kathleen M. Foley, January 23, 2009.

<sup>26</sup> De Lima L, Sweeney C, Palmer J.L, Bruera E., "Potent Analgesics Are More Expensive for Patients in Developing Countries: A Comparative Study," *Journal of Pain & Palliative Care Pharmacotherapy*, vol. 18, no. 1, 2004, pp. 59-70.

<sup>27</sup> WHO, "National Cancer Control Programmes: Policies and Managerial Guidelines," second edition, 2002, p. xv, xvi.

<sup>28</sup> Ibid., pp. 86-7.

<sup>29</sup> Ibid.

<sup>30</sup> Cited in WHO, *Achieving Balance in National Opioids Control Policy*, p. 3.

palliative care providers may offer inpatient services at hospices or hospitals, their focus is frequently on home-based care for people who are terminally ill or have life-limiting conditions, thus reaching people who otherwise might not have any access to healthcare services, including pain management.

## **Widespread Consensus: Pain Relief Medications Must Be Available**

For decades, there has been a consensus among health experts that opioid pain relievers like morphine and codeine must be available for the treatment of moderate and severe pain. Almost fifty years ago, UN member states articulated that consensus as follows when they adopted the 1961 Single Convention on Narcotic Drugs:

The medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and adequate provision must be made to ensure the availability of narcotic drugs for such purposes.<sup>32</sup>

The International Narcotic Control Board, the body charged with overseeing the implementation of the UN drug conventions, clarified in 1995 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.”<sup>33</sup>

The World Health Organization has included both morphine and codeine in its Model List of Essential Medicines, a list of the minimum essential medications that should be available to all persons who need them. WHO has also repeatedly stated that palliative care and pain treatment are an essential—not optional—component of care for cancer and HIV/AIDS. For example, in its guide on the development of national cancer control programs it observes

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<sup>31</sup> While there is increasing acceptance of the need for palliative care and pain treatment services for cancer patients, the focus on ensuring antiretroviral treatment to people living with HIV has detracted attention from palliative care needs of this group. In a March 2007 report, DFID noted that “dominant global and national policy on increasing access to treatment, and progress made in expanding access to ARVs, has added to the perception that palliative care is increasingly irrelevant. This is contrary to clinical evidence of the need for palliative care alongside treatment.... Not only do people on ARVs often need palliative care services, millions of people continue to die of AIDS and many could benefit from palliative care and pain treatment services.” DFID Health Resource Center, “Review of global policy architecture and country level practice on HIV/AIDS and palliative care,” March 2007, p. 16.

<sup>32</sup> Preamble of the 1961 Single Convention on Narcotic Drugs, [http://www.incb.org/incb/convention\\_1961.html](http://www.incb.org/incb/convention_1961.html) (accessed January 15, 2009).

<sup>33</sup> INCB, “Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995,” <http://www.incb.org/pdf/e/ar/1995/suppl1en.pdf> (accessed January 15, 2009), p.1.

that “a national disease control plan for AIDS, cancer and noncommunicable disorders cannot claim to exist unless it has an identifiable palliative care component.”<sup>34</sup>

Over the last twenty years, the INCB, WHO and other international bodies have repeatedly reminded countries of their obligation to ensure adequate availability of opioids for the treatment of pain.

- In 1986, the WHO recommended the use of oral morphine for treatment of long term pain.
- In 1989, INCB made a series of recommendations to states on the need to improve availability of opioid analgesics.<sup>35</sup>
- In 1994/5, it conducted a survey to identify obstacles to improving such availability and assess the response of member states to its 1989 recommendations.<sup>36</sup>
- In 1987 and 1996, the WHO issued guides to cancer pain relief with recommendations for countries on improving opioid analgesic availability.<sup>37</sup>
- In 1999, INCB devoted a chapter in its annual report to the issue.<sup>38</sup>
- In 2000, WHO developed a tool for governments and providers to use in evaluating national opioid control policies and recommendations on improving availability.<sup>39</sup>
- In 2007, in consultation with INCB, WHO established the Access to Controlled Medications Programme, which aims to address all identified impediments to accessibility of controlled medicines, with a focus on regulatory, attitude and knowledge impediments.<sup>40</sup>

In its annual reports, INCB routinely expresses concern about the poor availability of pain treatment medications in many countries and calls on member states to take further steps. Various other international bodies, such as the UN Economic and Social Council and the

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<sup>34</sup> WHO, “National Cancer Control Programme: Policies and Managerial Guidelines,” 2002, pp. 86-7.

<sup>35</sup> A copy of the report is on file with Human Rights Watch. The report is not on the INCB website.

<sup>36</sup> INCB, “Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995,” p. 1.

<sup>37</sup> WHO, *Cancer Pain Relief*, (Geneva: World Health Organization, 1987); WHO, *Cancer Pain Relief, Second Edition, With a guide to opioid availability*, (Geneva: World Health Organization, 1996).

<sup>38</sup> INCB, “Report of the International Narcotic Control Board for 1999, Freedom from Pain and Suffering.”

<sup>39</sup> WHO, *Achieving Balance in National Opioids Control Policy: Guidelines for Assessment*, (Geneva: WHO, 2000) WHO/EDM/QSM/2000.4, <http://www.painpolicy.wisc.edu/publicat/oowhoabi/oowhoabi.pdf> (accessed January 15, 2009).

<sup>40</sup> Joint report by WHO and INCB, “Assistance Mechanism to Facilitate Adequate Treatment of Pain with Opioid Analgesics,” March 2, 2007, [http://www.who.int/medicines/areas/quality\\_safety/Joint\\_Report-WHO-INCB.pdf](http://www.who.int/medicines/areas/quality_safety/Joint_Report-WHO-INCB.pdf) (accessed January 12, 2009).

World Health Assembly, have also called on countries to ensure adequate availability of opioid analgesics.<sup>41</sup>

## The Pain Treatment Gap

“Most, if not all, pain due to cancer could be relieved if we implemented existing medical knowledge and treatments...There is a treatment gap: it is the difference between what can be done, and what is done about cancer pain.” – World Health Organization<sup>42</sup>

Despite the clear consensus that pain treatment medications should be available, approximately 80 percent of the world population has either no or insufficient access to treatment for moderate to severe pain and tens of millions of people around the world, including around four million cancer patients and 0.8 million end-stage HIV/AIDS patients, suffer from moderate to severe pain each year without treatment, according to the World Health Organization.<sup>43</sup> Approximately 89 percent of the total world consumption of morphine occurs in countries in North America and Europe.<sup>44</sup> Low and middle income countries consume only 6 percent of the morphine used worldwide<sup>45</sup>—while having about half of all cancer patients<sup>46</sup> and 95 percent of new HIV infections.<sup>47</sup> Thirty-two countries in Africa have almost no morphine distribution at all,<sup>48</sup> and only fourteen have oral morphine.<sup>49</sup> However, inadequate pain management is also prevalent in developed countries. In the United States, an estimated 25 million people experience acute pain as a result of injury or surgery, and between 70 and 90 percent of advanced cancer patients experience pain. Surveys of subjects ranging from children to elderly patients have shown that over one third

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<sup>41</sup> United Nations Economic and Social Council, Resolution 2005/25: Treatment of pain using opioid analgesics. (New York: UN General Assembly ECOSOC) 2005, <http://www.un.org/docs/ecosoc/documents/2005/resolutions/Resolution%202005-25.pdf> (accessed January 12, 2009). See also, among others, ECOSOC resolutions 1990/31 and 1991/43; and World Health Assembly, Resolution WHA 58.22 on Cancer prevention and control (Ninth plenary meeting, 25 May 2005 – Committee B, third report), [http://www.who.int/gb/ebwha/pdf\\_files/WHA58/WHA58\\_22-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_22-en.pdf) (accessed January 12, 2009).

<sup>42</sup> WHO, *Achieving Balance in Opioid Control Policy*, p.1.

<sup>43</sup> World Health Organization Briefing note, “Access to Controlled Medications Programme,” September, 2008. On file with Human Rights Watch.

<sup>44</sup> INCB, “Report of the International Narcotic Control Board for 2007,” E/INCB/2007/1, 2008, p. 19.

<sup>45</sup> International Narcotics Control Board, “Report of the International Narcotics Control Board for 2004,” United Nations, 2005.

<sup>46</sup> WHO, *National Cancer Control Programme: Policies and Managerial Guidelines*, 2002, p. 17.

<sup>47</sup> National institute of allergy and infectious diseases, NIH, DHHS, “HIV Infection in Infants and Children,” July 2004, <http://www.niaid.nih.gov/factsheets/hivchildren.htm> (accessed January 22, 2009); Fauci AS. “AIDS epidemic: Considerations for the 21<sup>st</sup> century,” *New England Journal of Medicine*, vol. 341, no. 1414, 1999, pp. 1046-1050.

<sup>48</sup> INCB, “Report of the International Narcotics Control Board for 2004,” United Nations, E/INCB/2004/1, 2005; INCB, “Use of essential narcotic drugs to treat pain is inadequate, especially in developing countries,” press Release, March 3, 2004.

<sup>49</sup> Email correspondence with Anne Merriman, January 24, 2009.

are not adequately treated for pain.<sup>50</sup> Lack of access to pain medication in pharmacies and fear of addiction on the part of both patients and providers are significant limiting factors in the United States.<sup>51</sup> Studies in Western Europe also document under-treatment of pain. A study of people living with HIV in France found that doctors underestimated pain severity in over half of their patients and under-prescribed both opioids and antidepressants.<sup>52</sup>

Up to 85 percent of people living with HIV have untreated pain, twice the proportion of people with cancer whose pain is untreated.<sup>53</sup> A study in the U.S. found that less than 8 percent of AIDS patients who reported severe pain were treated according to official treatment guidelines, and women, less-educated patients, and patients with histories of injection drug use were most likely to report inadequate treatment for pain.<sup>54</sup>

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<sup>50</sup> Foley, Kathleen M., "Ideas for an Open Society," *Pain Management*, vol. 3, no. 4, 2002, [http://www.soros.org/resources/articles\\_publications/publications/ideas\\_painmanagement\\_20021001/ideas\\_pain\\_management.pdf](http://www.soros.org/resources/articles_publications/publications/ideas_painmanagement_20021001/ideas_pain_management.pdf) (accessed January 15, 2009), p. 3.

<sup>51</sup> *Ibid.*, p. 4.

<sup>52</sup> Larue, Francois et al., "Underestimation and under-treatment of pain in HIV disease: a multicentre study," *British Medical Journal*, vol. 314, no.23, 1997, <http://www.bmj.com/cgi/content/full/314/7073/23> (Accessed April 2007).

<sup>53</sup> International Association for the Study of Pain, "Pain in AIDS: A Call for Action," *Pain*, vol. 4, no. 1, March 1996.

<sup>54</sup> Breitbart W, et al., "The undertreatment of pain in ambulatory AIDS patients," *Pain*, vol. 65, 1996, pp. 243-9.



## Pain Treatment, Palliative Care and Human Rights

### Health as a Human Right

Health is a fundamental human right enshrined in numerous international human rights instruments.<sup>55</sup> The International Covenant on Economic Social and Cultural Rights (ICESCR) specifies that everyone has a right “to the enjoyment of the highest attainable standard of physical and mental health.” The Committee on Economic, Social and Cultural Rights, the body charged with monitoring compliance with the ICESCR, has held that states must make available in sufficient quantity “functioning public health and health-care facilities, goods and services, as well as programmes” and that these services must be accessible. Because states have different levels of resources, international law does not mandate the kind of health care to be provided. The right to health is considered a right of “progressive realization.” By becoming party to the international agreements, a state agrees “to take steps... to the maximum of its available resources” to achieve the full realization of the right to health. In other words, high income countries will generally have to provide healthcare services at a higher level than those with limited resources. But all countries will be expected to take concrete steps towards increased services, and regression in the provision of health services will, in most cases, constitute a violation of the right to health.

But the Committee on Economic, Social and Cultural Rights has also held that there are certain core obligations that are so fundamental that states must fulfill them. While resource constraints may justify only partial fulfillment of some aspects of the right to health, the Committee has observed vis-à-vis the core obligations that “a State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations..., which are non-derogable.” The Committee has identified, among others, the following core obligations:

- To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups;
- To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs;
- To ensure equitable distribution of all health facilities, goods and services;

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<sup>55</sup> International Covenant on Economic, Social and Cultural Rights (ICESCR), G.A. res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, entered into force January 3, 1976, art. 11; also in the Convention on the Rights of the Child, G.A. res. 44/25, annex, 44 U.N. GAOR Supp. (No. 49) at 167, U.N. Doc. A/44/49 (1989), entered into force September 2 1990, art. 24.

- 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.<sup>56</sup>

## Pain Treatment and the Right to Health

As morphine and codeine are on the WHO List of Essential Medicines, countries have to provide these medications as part of their core obligations under the right to health, regardless of whether they have been included on their domestic essential medicines lists.<sup>57</sup> They must make sure that they are both available in adequate quantities and physically and financially accessible for those who need them.

In order to ensure availability and accessibility, states have, among others, the following obligations:

- Since manufacturing and distribution of controlled medicines like morphine and codeine are completely in government hands, states must put in place an effective procurement and distribution system and create a legal and regulatory framework that enables healthcare providers in both the public and private sector to obtain, prescribe and dispense these medications. Any regulations that arbitrarily impede the procurement and dispensing of these medications will violate the right to health.
- States must adopt and implement a strategy and plan of action for the roll out of pain treatment and palliative care services. Such strategy and plan of action should identify obstacles to improved services as well as steps to eliminate them.
- States should regularly measure progress made in ensuring availability and accessibility of pain relief medications.
- The requirement of physical accessibility means that these medications must be “within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as...persons with HIV/AIDS.”<sup>58</sup> This means that states

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<sup>56</sup> UN UN Committee on Economic, Social and Cultural Rights, “Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights,” General Comment No. 14, The Right to the Highest Attainable Standard of Health, E/C.12/2000/4 (2000), [http://www.unhcr.ch/tbs/doc.nsf/\(Symbol\)/40d009901358boe2c1256915005090be?Opendocument](http://www.unhcr.ch/tbs/doc.nsf/(Symbol)/40d009901358boe2c1256915005090be?Opendocument) (accessed May 11, 2006), para. 43. The Committee on Economic, Social and Cultural Rights is the UN body responsible for monitoring compliance with the International Covenant on Economic, Social and Cultural Rights.

<sup>57</sup> The 15<sup>th</sup> edition of WHO List of Essential Medicines, approved in 2007, [http://www.who.int/medicines/publications/o8\\_ENGLISH\\_indexFINAL\\_EML15.pdf](http://www.who.int/medicines/publications/o8_ENGLISH_indexFINAL_EML15.pdf) (accessed January 15, 2009), includes the following opioid analgesics: Codeine Tablet: 30 mg (phosphate); Morphine Injection: 10 mg (morphine hydrochloride or morphine sulfate) in 1-ml ampoule; Oral liquid: 10 mg (morphine hydrochloride or morphine sulfate)/5 ml., Tablet: 10 mg (morphine sulfate); Tablet (prolonged release): 10 mg; 30 mg; 60 mg (morphine sulfate).

<sup>58</sup> CESCR, General Comment 14, para. 12.

must ensure that a sufficient number of healthcare providers or pharmacies stock and dispense morphine and codeine, and that an adequate number of healthcare workers are trained and authorized to prescribe these medications.

- Financial accessibility means that, while the right to health does not require states to offer medications free of charge, they must be “affordable for all.”<sup>59</sup> In the words of the Committee:

Payment for health-care services...has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable to all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households.<sup>60</sup>

Countries also have an obligation to progressively implement palliative care services, which, according to WHO, must have “priority status within public health and disease control programmes.”<sup>61</sup> Countries must ensure an adequate policy and regulatory framework, develop a plan for implementation of these services, and take all steps that are reasonable within available resources to execute the plan. Failure to attach adequate priority to developing palliative care services within healthcare services will violate the right to health.

## **Pain Treatment and the Right to Be Free from Cruel, Inhuman and Degrading Treatment**

The right to be free from torture, cruel, inhuman and degrading treatment or punishment is a fundamental human right that is recognized in numerous international human rights instruments.<sup>62</sup> Apart from prohibiting the use of torture, cruel, inhuman, and degrading

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<sup>59</sup> Ibid., para 12.

<sup>60</sup> Ibid., para. 12.

<sup>61</sup> WHO, “National Cancer Control Programme: Policies and Managerial Guidelines,” 2002, p. 86.

<sup>62</sup> International Covenant on Civil and Political Rights (ICCPR), adopted December 16, 1966, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, entered into force March 23, 1976, art. 7 provides, “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment”; Universal Declaration of Human Rights (UDHR), adopted December 10, 1948, G.A. Res. 217A(III), U.N. Doc. A/810 at 71 (1948); Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (Convention against Torture), adopted December 10, 1984, G.A. res. 39/46, annex, 39 U.N. GAOR Supp. (No. 51) at 197, U.N. Doc. A/39/51 (1984), entered into force June 26, 1987, article 16 provides that “Each State Party shall undertake to prevent in any territory under its jurisdiction other acts of cruel, inhuman or degrading treatment or punishment which do not amount to torture as defined in article I, when such acts are committed by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity”; Inter-American Convention to Prevent and Punish Torture, O.A.S. Treaty Series No. 67, entered into force February 28, 1987; European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment

treatment or punishment, the right also creates a positive obligation for states to protect persons in their jurisdiction from such treatment.<sup>63</sup>

As part of this positive obligation, states have to take steps to protect people from unnecessary pain related to a health condition. As the UN Special Rapporteur on Torture, Cruel, Inhuman and Degrading Treatment and Punishment wrote in a joint letter with the UN Special Rapporteur on the Right to Health to the Commission on Narcotic Drugs in December 2008,

Governments also have an obligation to take measures to protect people under their jurisdiction from inhuman and degrading treatment. Failure of governments to take reasonable measures to ensure accessibility of pain treatment, which leaves millions of people to suffer needlessly from severe and often prolonged pain, raises questions whether they have adequately discharged this obligation.<sup>64</sup>

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(ECPT), signed November 26, 1987, E.T.S. 126, entered into force February 1, 1989; 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 (1982), entered into force October 21, 1986.

<sup>63</sup> See for example the judgment of the European Court of Rights in *Z v United Kingdom* (2001) 34 EHRR 97.

<sup>64</sup> A copy of the letter is available at <http://www.ihra.net/Assets/1384/1/SpecialRapporteursLettertoCND012009.pdf> (accessed January 16, 2009).

## Obstacles to Provision of Pain Treatment and Palliative Care

There is no lack of information about the reasons why so many people who suffer from severe pain cannot get access to adequate pain treatment. In dozens of publications spanning several decades, the World Health Organization, the International Narcotics Control Board, healthcare providers, academics and others have chronicled the barriers in great detail.<sup>65</sup> A common theme of many of these publications is the failure of many governments around the world to take reasonable steps to improve access to pain treatment and palliative care services and to strike the right balance between ensuring availability of controlled medications for legitimate purposes and preventing their abuse.

In its 2007 Annual Report, the INCB repeated its previous calls for improvement:

The low levels of consumption of opioid analgesics for the treatment of pain in many countries...continue to be a matter of serious concern to the Board. The Board again urges all Governments concerned to identify the impediments in their countries to 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...<sup>66</sup>

To date, these calls have largely fallen on deaf ears. Because of countries' failure to act on the recommendations of WHO and INCB, many of the same obstacles that the organizations identified two decades ago remain today.

These barriers include the failure of many governments to put in place functioning drug supply systems; the failure to enact policies on pain treatment and palliative care; the existence of unnecessarily restrictive drug control regulations and practices; fear among healthcare workers of legal sanctions for legitimate medical practice; poor training of healthcare workers; and the unnecessarily high cost of pain treatment.

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<sup>65</sup> See for example, INCB, "Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995," p. 1, <http://www.incb.org/pdf/e/ar/1995/suppl1en.pdf> (accessed January 15, 2009); INCB, "Report of the International Narcotics Control Board for 1999"; INCB, "Report of the International Narcotics Control Board for 2007," <http://www.incb.org/incb/en/annual-report-2007.html>; WHO, "Achieving Balance in National Opioids Control Policy"; ECOSOC resolution 2005/25 on Treatment of pain using opioid analgesics (36th plenary meeting 22 July 2005), <http://www.un.org/docs/ecosoc/documents/2005/resolutions/Resolution%202005-25.pdf> (accessed January 16, 2009); World Health Assembly, Resolution WHA 58.22 on Cancer prevention and control (Ninth plenary meeting, 25 May 2005 – Committee B, third report), [http://www.who.int/gb/ebwha/pdf\\_files/WHA58/WHA58\\_22-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_22-en.pdf) (accessed February 2009).

<sup>66</sup> INCB, "Report of the International Narcotics Control Board for 2007," para. 97.

While there is no doubt that it will not be easy to overcome some of these barriers and implement comprehensive pain treatment and palliative care services, particularly for countries with limited resources, much progress could be made if governments took the action required of them by international human rights standards and the UN drug conventions. Indeed, the governments of countries like Romania, Uganda and Vietnam—each of which have adopted comprehensive approaches to improving availability of pain treatment—have shown that much can be done to comply with the basic standards required, even by countries with limited resources. While each of these countries still has much to do to make pain treatment and palliative care fully available they are all moving in the right direction.

### **Failure to Ensure Functioning and Effective Supply System**

Opioid analgesics are controlled medicines. As such, their manufacture, distribution and prescription are strictly regulated; these medications cannot be traded freely on the market. The 1961 Single Convention on Narcotic Drugs has created a system to regulate supply and demand. Every year, countries submit estimates of their need for morphine and other controlled medications to INCB, which then approves a quota for countries and authorizes producing countries to grow a specified amount of raw material. Once INCB has approved their quota, countries may then purchase morphine up to the approved amount. Each individual transaction across international borders must be authorized and registered by INCB. On a national level, special drug control agencies are responsible for communicating with INCB about the need for morphine, imports and exports, and for regulating and overseeing all domestic transactions involving controlled medications.

Under the UN drug conventions, countries have an obligation to ensure a functioning and effective supply system for controlled medications. The INCB has held that

...an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes.<sup>67</sup>

Such drug availability programs must be capable of ensuring that adequate amounts of morphine and other controlled medicines are available in the country at any given time, that an effective system of distribution is in place to provide healthcare providers and

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<sup>67</sup> INCB, “Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995,” p. 14.

pharmacies with a continuous and adequate supply of the medications, and that a sufficient number of pharmacies and health facilities stock them so that healthcare providers and patients around the country can reasonably gain access to them at need. As the World Health Organization has noted, good communication between health workers and drug regulators is crucial to meet these goals.<sup>68</sup>

Because the production, distribution and dispensing of controlled medicines is under exclusive government control, governments have a particularly strong responsibility to ensure their availability and accessibility. With medications that are not controlled, private actors, including healthcare providers, pharmaceutical companies and nongovernmental organizations, can produce or import medications themselves without limited or no government facilitation. That is not the case with controlled medications—if a government does nothing to ensure an adequate supply and a functioning distribution system, they will simply not be legally available.

Yet, many governments, particularly in low and middle income countries, have failed to put in place functioning and effective supply systems for controlled medicines. Indeed, judging by the fact that in dozens of countries almost no morphine is used, it appears that many do not have a functioning supply system at all. In 1999, the INCB noted that this is not just the result of resource limitations but also of “a lack of determination on the part of Governments and their services.”<sup>69</sup>

Research that the African Palliative Care Association (APCA) conducted in 2006 illustrates the lack of commitment of some African countries to ensuring availability of controlled medicines. The organization tried to conduct a survey among palliative care providers and drug control authorities in twelve African countries to identify challenges in implementation of palliative care and pain treatment services. The organization succeeded in securing the participation of drug control agencies in five of the twelve target countries in the survey.

The survey findings suggest a considerable disconnect between drug control authorities and the healthcare system. Three of the five drug control agencies—from Kenya, Tanzania and Ethiopia—stated that they believed the regulatory system worked well, even though morphine consumption in each of these countries is far below estimated need and the palliative care providers surveyed identified myriad problems with the regulatory system.<sup>70</sup>

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<sup>68</sup> WHO, “Cancer Pain Relief, Second Edition, With a guide to opioid availability,” 1996, p. 5.

<sup>69</sup> INCB, “Report of the International Narcotic Control Board for 1999, Freedom from Pain and Suffering,” p. 4.

<sup>70</sup> Harding R, et al., “Pain Relieving Drugs in 12 African PEPFAR Countries,” p. 31.

Furthermore, the survey suggested that drug control agencies in each of the five countries listed controlled medicines as available in healthcare settings when none of the palliative care providers actually had access to them. In its report, APCA wrote:

In every country without exception INCB competent authorities cited specific opioids that they believed to be available in-country that were never cited by any [palliative care] service within that country.<sup>71</sup>

### *Estimating National Need*

Many countries do not submit estimates for their need for controlled substances based upon careful assessment of population needs to the INCB, as required by the UN drug conventions. Some countries submit no estimate or estimates that are only symbolic in nature. For example, the West African nation of Burkina Faso estimated that it will need 49 grams of morphine in 2009.<sup>72</sup> Using Foley's estimate that the average terminal cancer or AIDS patient who suffers from severe pain will need 60 to 75mg of morphine per day for an average of about 90 days, this amount would suffice for about 8 patients. As a result, countries like Burkina Faso receive quotas from INCB for morphine that are so low that they cannot possibly ensure adequate availability of morphine for pain treatment in the country.<sup>73</sup>

Many other countries submit estimates that vastly understate the actual medical need for morphine. Often, these estimates are not based on actual need but on morphine consumption during the previous year. Some countries appear to simply reproduce the same estimate each year, regardless of demographic changes or true estimates of need.<sup>74</sup>

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<sup>71</sup> Ibid.

<sup>72</sup> Country estimates for 2009 can be found on the INCB website, <http://www.incb.org/pdf/e/estim/2009/Est09.pdf> (accessed January 13, 2009).

<sup>73</sup> Under the UN drug conventions, countries can request additional quota from INCB if the requested quota turns out to be insufficient. But countries that have poor systems for estimating their need are unlikely to submit supplementary requests.

<sup>74</sup> For example, Algeria, Iran, Namibia, and Thailand have all submitted the same round-number estimate for the last four years.



Figure 1. Morphine Estimates, Mortality, and Pain Treatment Need \*

Country	Cancer Deaths 2002 Estimate	AIDS Deaths 2005 Estimate	# of individuals expected to Need Pain Treatment in 2009	Estimated total morphine need in 2009 (kgs)	Estimate of morphine need provided by country to INCB for 2009 (kgs)	# of individuals estimate is sufficient for	Percentage of those needing treatment who would be covered by estimate
Countries that estimate almost no need for morphine							
Benin	13490	9986	15786	96	0.5	83	0.50%
Senegal	17625	5432	16816	102	0.6	99	0.60%
Rwanda	14196	21956	22335	136	0.8	132	0.60%
Gambia	2395	1430	2631	16	0.18	31	1.20%
Bhutan	727	<10 per 100,000	582	3.5	0.08	14	2.30%
Burkina Faso	23262	13067	25143	153	0.05	8	0.03%
Eritrea	6240	5959	7972	48	0.075	12	0.15%
Gabon	2071	4457	3886	24	0.088	14	0.40%
Swaziland	1837	17577	10258	62	0.5	82	0.80%
Selected other countries							
Egypt	62299	<10 per 100,000	49840	303	10	1646	3%
Philippines	78500	<10 per 100,000	62800	382	31	5103	8%
Kenya	50809	149502	115398	701	30	4938	4%
Russian Federation	217696	N/A	174157	1058	200	32922	15%
Mexico	92701	6321	77321	470	180	29630	38%

\*The purpose of this figure is to illustrate the gross inadequacy of estimates for medical need submitted to INCB by many countries. The projection for the numbers of people requiring pain treatment does not include persons with pain related to non-terminal cancer or HIV, acute pain, or chronic pain not associated with cancer or HIV. The true number of people who require pain treatment is much greater. The table only calculates morphine estimates. Some countries also use methadone or pethidine for pain control. The table is based on an estimate by Foley and others that 80% of terminal cancer patients and 50% of terminal AIDS patients will require an average of 90 days of pain treatment with 60 to 75 mg of morphine per day.<sup>75</sup> Country estimates were obtained from INCB website;<sup>76</sup> projections for annual cancer and AIDS deaths are based on the most recent cancer and AIDS mortality figures reported by WHO.<sup>77</sup> As the Pain & Policies Studies Group has pointed out, a population-based method for estimating the need for controlled medications “will likely overestimate the quantities that would be consumed when a country lacks the infrastructure and resources to distribute large quantities of medications.”<sup>78</sup> Without such infrastructure and resources, there is a very real potential that drugs could be wasted if large quantities are purchased and ultimately not consumed. Additionally, a potential for diversion exists if large amounts of drugs are held, unused, in stocks.

<sup>75</sup> Kathleen M. Foley, et al., “Pain Control for People with Cancer and AIDS.”

<sup>76</sup> Available at [http://www.incb.org/incb/narcotic\\_drugs\\_estimates.html](http://www.incb.org/incb/narcotic_drugs_estimates.html) (accessed January 22, 2009).

<sup>77</sup> <http://www.who.int/whosis/en/> (search conducted February 2009).

<sup>78</sup> Pain & Policy Studies Group, “Increasing Patient Access to Pain Medicines around the World: A Framework to Improve National Policies that Govern Drug Distribution,” University of Wisconsin Paul P. Carbone Comprehensive Cancer Center, 2008. [http://www.painpolicy.wisc.edu/on-line\\_course/welcome.htm](http://www.painpolicy.wisc.edu/on-line_course/welcome.htm).

INCB has repeatedly reminded countries of their obligation to submit estimates based upon population need and has encouraged all countries to review their methods for preparing estimates so as to ensure that they actually reflect the need for controlled medications.<sup>79</sup>

### *Ensuring Effective Distribution*

Without an effective distribution system, accessibility of morphine to those who need it cannot be assured. As controlled medications may only be transferred between parties that have been authorized under national law, governments play a key role in putting in place such a distribution system. They must ensure that a sufficient number of pharmacies are licensed to handle morphine. They must also ensure that procedures for procuring, stocking and dispensing it are workable; in other words, they must strike the appropriate balance between ensuring pharmacies can obtain it without unnecessarily cumbersome or expensive procedures and preventing abuse.

Yet, in many countries few hospitals or pharmacies actually stock morphine. In some cases, this is due to government regulations that allow only specific institutions to stock the medication. The APCA study, for example, found that in Zambia only hospitals can stock morphine and that in Nigeria oral morphine is available only from one pharmacy, the National Drug Store.<sup>80</sup> Similarly, in Cameroon only one pharmacy prepares oral morphine.<sup>81</sup>

In some countries, excessively burdensome procedures for procurement, dispensing and accounting discourage health institutions from procuring morphine. In India, Human Rights Watch found that many hospitals do not stock oral morphine because they must obtain a number of different licenses for each order of morphine that is procured and these licenses are often very difficult to obtain. In Mexico City, a city of 18 million people, only nine hospitals and pharmacies stock morphine, apparently due to regulatory requirements around controlled medications.<sup>82</sup> Restrictions on licenses or cumbersome handling procedures that are not necessary for preventing abuse of these medications violate the right to health, and should be reformed. As countries are under the obligation to ensure adequate availability of opioid analgesics, they must take steps to ensure that a sufficient

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<sup>79</sup> INCB, "Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995," p. 8.

<sup>80</sup> Harding R, et al., "Pain Relieving Drugs in 12 African PEPFAR Countries," pp. 21 and 27. Since the APCA report was published, the National Agency for Food and Drug Administration Control has drawn up and approved a plan to decentralize national drug stores, which will eventually ensure availability of morphine outside Lagos.

<sup>81</sup> Email correspondence with Anne Merriman of Hospice Uganda and a leading palliative care doctor and advocate in Africa, January 24, 2009.

<sup>82</sup> Email correspondence with Liliana de Lima, Executive Director of the International Hospice and Palliative Care Association, February 11, 2009.

number of pharmacies or hospitals stock them. Recognizing this obligation, Vietnam adopted a new opioid prescription regulation in February 2008 which obliges district hospitals to stock opioids if no pharmacies in the district do.<sup>83</sup>

Where hospitals and pharmacies do stock morphine, problems with inefficient distribution systems are common. In India, for example, Human Rights Watch found that the excessively burdensome procurement procedures in many states can lead to stock-outs and delays in dispensing.<sup>84</sup> In Colombia, morphine has regularly been out of stock in the province of Valle del Cauca over the last several years, resulting in numerous patients being unable to obtain morphine to treat their pain. By contrast, other prescription medications have been widely available.<sup>85</sup> APCA's survey of palliative care providers in twelve African countries found "massive delays between scripts [physician prescription] and dispensing" due to problems with supply and distribution systems.<sup>86</sup>

## Failure to Enact Palliative Care and Pain Treatment Policies

A core obligation under the right to health holds that countries must "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." As part of this obligation, countries must develop a strategy and plan of action for the implementation of palliative care and pain treatment services. While these do not have to provide for the immediate implementation of the full range of services, they must set out a road map for their progressive implementation. There will be a strong presumption that any cost neutral steps will have to be taken immediately.<sup>87</sup>

In 1996, WHO identified the absence of national policies on cancer relief pain and palliative care as one of the reasons why cancer pain is so often not adequately treated.<sup>88</sup> In 2000, the organization noted that pain treatment continued to be a "low priority" in healthcare systems. In its 2002 book on cancer control programs, WHO noted that although governments around the world have endorsed the integration of palliative care principles into public health and disease control programs, "a yawning gap is evident between rhetoric

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<sup>83</sup> Email communication with Kimberly Green of Family Health International Vietnam, January 25, 2009.

<sup>84</sup> In many states in India, healthcare institutions and morphine manufacturers must obtain five licenses from several different government offices in both the importing and exporting state before they can procure morphine—a process that can take months.

<sup>85</sup> Human Rights Watch interview with Liliana de Lima, January 16, 2009.

<sup>86</sup> Harding R, et al., "Pain Relieving Drugs in 12 African PEPFAR Countries," p. 26.

<sup>87</sup> CESCR, General Comment 14, para. 43 (f).

<sup>88</sup> WHO, *Cancer Pain Relief, Second Edition, With a guide to opioid availability*, 1996, p.2.

and realization.”<sup>89</sup> Two leading experts on palliative care stress the importance of having a comprehensive strategy, pointing out that some policies have failed because they omitted community involvement in the provision of palliative care services.<sup>90</sup>

Yet, as these experts have observed, most countries do not have palliative care and pain treatment policies, whether as stand-alone policies or as part of cancer or HIV/AIDS control efforts.<sup>91</sup> In a 2007 report on palliative care and HIV/AIDS, the UK government’s Department for International Development found that palliative care was often not “integrated into health sector policies and National AIDS Frameworks.”<sup>92</sup>

Many countries have even failed to take relatively cost-neutral steps that are crucial to improving access to pain treatment and palliative care, such as adding oral morphine and other opioid-based medicines to their list of essential medicines or issuing guidelines on pain management for healthcare workers. For example, respondents to APCA’s 2007 survey of palliative care providers from four countries—Kenya, Namibia, Nigeria and Rwanda—reported that oral morphine was not on their country’s list of essential medicines.<sup>93</sup> According to Anne Merriman, a leading palliative care advocate in Africa, only fourteen African nations have oral morphine—all others only have injectable morphine, which is primarily used to treat acute pain in hospital settings.<sup>94</sup>

INCB has recommended that national drug control laws must recognize the indispensable nature of narcotic drugs for the relief of pain and suffering as well as the obligation to ensure their availability for medical purposes. Its 1995 survey found that the laws of 48 percent of responding governments contained the former and of 63 percent the latter.<sup>95</sup> Although it is not known exactly how many countries still do not have the relevant language in their legislation, it is telling that the model laws and regulations on drug control that the UN Office on Drugs and Crime has developed for the use of countries in developing national drug

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<sup>89</sup> WHO, *National Cancer Control Programme: Policies and Managerial Guidelines*, 2002, p. 86

<sup>90</sup> Stjernsward, J., and D. Clark, “Palliative Medicine: A Global Perspective,” 2003, p. 12.

<sup>91</sup> Ibid., p. 11; Downing J, Kawuma E., “The impact of a modular HIV/AIDS palliative care education programme in rural Uganda,” *Int J Palliat Nurs*, vol.14, no. 11, 2008, pp.560-8.

<sup>92</sup> DFID Health Resource Center, “Review of global policy architecture and country level practice on HIV/AIDS and palliative care” March 2007, p. 15.

<sup>93</sup> Harding R, et al., “Pain Relieving Drugs in 12 African PEPFAR Countries,” pp. 19, 21.

<sup>94</sup> These are Kenya, Tanzania, Uganda, Ethiopia, Nigeria, Cameroon, Zimbabwe, S Africa, Botswana, Namibia, Lesotho, Swaziland, Malawi and Zambia. Email correspondence with Anne Merriman.

<sup>95</sup> INCB, “Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995,” p. 5.

control laws and regulations themselves do not contain these provisions.<sup>96</sup> A new draft drug control law that is currently under consideration in Cambodia makes no reference to the fact that controlled medications are indispensable for the relief of pain and suffering or of the obligation to ensure their availability.<sup>97</sup>

## Lack of Training for Healthcare Workers

One of the biggest obstacles to provision of good palliative and pain treatment services in many countries around the world is a lack of training for healthcare workers. As Brennan and others put it, “for too long, pain and its management have been prisoners of myth, irrationality, and cultural bias.”<sup>98</sup> While misinformation about oral morphine remains extremely common among healthcare workers, knowledge about how to assess and treat pain is often absent or deeply inadequate. The combination of ignorance among healthcare workers with myths about opioids results in failure to treat patients, who are suffering from severe pain, with opioid analgesics.

Some of the most common myths hold that treatment with opioids leads to addiction—the most frequently cited impediment to the medical use of opioids in INCB 1995 study;<sup>99</sup> that pain is necessary; that it is essential for diagnosis; that it is unavoidable; and that it has negligible consequences. Each of these myths is inaccurate.<sup>100</sup> Numerous studies have shown that treatment of pain with opioids very rarely leads to addiction;<sup>101</sup> most pain can be treated well;<sup>102</sup> pain is not necessary for diagnosis;<sup>103</sup> and pain has considerable social, economic and psychological consequences as it keeps people who suffer from pain and often their caregivers out of productive life.<sup>104</sup>

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<sup>96</sup> See the Model Law on the Classification of Narcotic Drugs, Psychotropic Substances and Precursors and on the Regulation of the Licit Cultivation, Production, Manufacture and Trading of Drugs; the Model Regulation Establishing an Interministerial Commission for the Coordination of Drug Control; and the Model Drug Abuse Bill, <http://www.unodc.org/unodc/en/legal-tools/Model.html> (accessed January 24, 2009); A detailed analysis of provisions regarding controlled medications in the model laws and regulations can be found in a January 2009 report by the Pain & Policy Studies Group, entitled “Do International Model Drug Control Laws Provide for Drug Availability?” [http://www.painpolicy.wisc.edu/internat/model\\_law\\_eval.pdf](http://www.painpolicy.wisc.edu/internat/model_law_eval.pdf) (accessed February 6, 2009).

<sup>97</sup> A copy of the draft law is on file with Human Rights Watch.

<sup>98</sup> *Ibid.*, p. 217.

<sup>99</sup> 72 percent of governments participating in the survey cited concerns about addiction to opiates. INCB, “Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995,” p. 5.

<sup>100</sup> Brennan F, Carr DB, Cousins MJ, *Pain Management: A Fundamental Human Rights*, pp. 208, 209.

<sup>101</sup> WHO, “Achieving Balance in National Opioids Control Policy,” pp. 8, 9.

<sup>102</sup> *Ibid.*, p. 1.

<sup>103</sup> Brennan F, Carr DB, Cousins MJ, *Pain Management: A Fundamental Human Rights*, p. 208.

<sup>104</sup> *Ibid.*

Ignorance about the use of opioid medications is the result of a failure, across much of the world including in some industrialized countries, to provide healthcare workers with adequate instruction on palliative care and pain management. A survey by the Worldwide Palliative Care Alliance among healthcare workers in 69 countries in Africa, Asia and Latin America found that 82 percent of healthcare workers in Latin America and 71 percent in Asia had not received any instruction on pain or opioids in undergraduate medical studies. In Africa, the figure was 39 percent.<sup>105</sup> In a 2007 African Palliative Care Association survey, 33 out of 56 participating healthcare providers felt that there were insufficient training opportunities on palliative care and pain treatment. Twenty-one of the twenty-three providers that said that there was adequate opportunity for training were based in South Africa and Uganda, two countries where considerable training is available.<sup>106</sup>

Even in industrialized countries instruction on palliative care and pain treatment remains a considerable challenge. A 1999 review of literature regarding barriers to effective cancer pain management in industrialized nations found, for example, that considerable numbers of healthcare workers surveyed had insufficient factual knowledge about pain management.<sup>107</sup>

Under the right to health, governments must take reasonable steps to ensure healthcare workers have appropriate training on palliative care and pain management. As an integral part of care and treatment for cancer and HIV, two key diseases around the world, countries need to ensure that basic instruction on palliative and pain management is part of undergraduate medical studies, nursing school, and continuing medical education. Specialized instruction should be available for healthcare workers who pursue a specialization in oncology, HIV and AIDS and other disciplines where knowledge of pain management and palliative care is an integral part of care.

## **Excessively Restrictive Drug Control Regulations or Enforcement Practices**

The 1961 Single Convention on Narcotic Drugs lays out three minimum criteria that countries must observe in developing national regulations regarding the handling of opioids:

- Individuals must be authorized to dispense opioids by their professional license to practice, or be specially licensed to do so;

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<sup>105</sup> Vanessa Adams, "Access to pain relief – an essential human right," p. 28.

<sup>106</sup> Harding R, et al., "Pain Relieving Drugs in 12 African PEPFAR Countries," pp. 23-25.

<sup>107</sup> Pargeon K.L. and Haily B.J., "Barriers to Effective Cancer Pain Management: A Review of the Literature," *Journal of Pain and Symptom Management*, vol. 18, no. 5, November, 1999, p. 361.

- Movement of opioids may occur only between institutions or individuals so authorized under national law;
- A medical prescription is required before opioids may be dispensed to a patient.

Governments may, under the Convention, impose additional requirements if deemed necessary, such as requiring that all prescription be written on official forms provided by the government or authorized professional associations.<sup>108</sup>

However, as WHO has observed, “this right must be continually balanced against the responsibility to ensure opioid availability for medical purposes.”<sup>109</sup> Therefore, any regulations that unnecessarily impede access to controlled medications will be inconsistent with both the UN drug conventions and the right to health, which requires countries find a similar balance between ensuring availability for legitimate medical use and preventing abuse. WHO has developed guidelines for the regulation of health professionals who handle controlled medications that government can use to develop what WHO has called a “practical system.”<sup>110</sup>

Yet, many countries have regulations that are unnecessarily strict, creating complex procedures for procurement, stocking and dispensing of controlled medications. In some cases, drug control authorities or health systems go even beyond the strictures of regulations in their implementation and which limit access to those who need them. The effect of these unnecessarily strict regulations or implementation practices is that pharmacies and health facilities do not procure and stock opioids, that doctors do not prescribe them because of the hassle or fear of criminal sanction, and that prescription is so impractical that many patients cannot realistically obtain them on an ongoing basis.

One explanation for the existence of excessively strict regulations is the fact that many of these regulations were put in place before 1986, when WHO first recommended the use of oral morphine for long-term pain management.<sup>111</sup> Before that, most countries used only injectable morphine to treat acute pain, which is mostly used in hospital settings over short periods of time. As WHO has noted, “The science and best practices of opioids have

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<sup>108</sup> 1961 Single Convention on Narcotic Drugs, Article 30(2bii).

<sup>109</sup> WHO, *Cancer Pain Relief, Second Edition, With a guide to opioid availability*, 1996, p. 9.

<sup>110</sup> *Ibid.*, p. 10.

<sup>111</sup> WHO, “Achieving Balance in National Opioids Control Policy,” p. 6.

progressed more rapidly than the legal structures governing them, leaving many antiquated and overly restrictive legal policies.”<sup>112</sup>

Since the 1980s, WHO and INCB have repeatedly called on countries to review their drug control regulations and implementation practices, and make sure they do not unnecessarily impede the use of oral morphine. While INCB has repeatedly reminded states that they must continue to take steps to prevent diversion<sup>113</sup>—controlled medications being diverted for illicit use—it has also noted that:

Diversion of narcotic drugs from the licit trade into illicit channels remains relatively rare and the quantities involved are small in comparison to the large volume of transactions. That holds true for drugs in the international trade as well as in domestic wholesale circuits.<sup>114</sup>

Some countries have taken important steps in this regard. Uganda, for example, has approved nurse-based prescribing of oral morphine. Several countries have lifted restrictions on the amount of oral morphine that can be prescribed. Yet, in many countries problematic regulations continue to be in place. A number of common problems in these regulations include:

### *Overly Restrictive Licensing of Healthcare Institutions*

Some countries impose licensing procedures for pharmacies and healthcare providers that make it impossible or overly complicated for them to procure and dispense opioids. Palliative care providers that do not have inpatient facilities but offer home-based care services often have a particular difficulty getting licenses to dispense morphine, even though this is vital to their mission and they can provide a low-cost way of reaching large numbers of people in need of pain treatment. In its 2007 report, the African Palliative Care Association observed for example that:

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<sup>112</sup> Scott Burris and Corey S. Davis, “A Blueprint for Reforming Access to Therapeutic Opioids: Entry Points for International Action to Remove the Policy Barriers to Care,” (Centers for Law and the Public's Health: A Collaborative at the Johns Hopkins and Georgetown Universities, 2008), p.16.

<sup>113</sup> See for example INCB, “Report of the International Narcotics Control Board for 2007,” p. 19.

<sup>114</sup> INCB, “Report of the International Narcotic Control Board for 1990.”



Although in theory many countries permit importation and distribution of the drugs, it can be impossible in practice to obtain the necessary authority from regulation bodies to prescribe the drugs.<sup>115</sup>

Palliative care providers in Kenya surveyed by APCA noted, for example, that oral morphine is “mostly dispensed in hospitals and hospices so many patients [who are not in such institutions] do not get access.”<sup>116</sup> A 2007 report by the Worldwide Palliative Care Alliance quotes a healthcare worker as saying that

Palliative care doctors have a right to prescribe morphine but cannot obtain it if they work in a hospice which is not registered in the Ministry of Health as a medical organization.<sup>117</sup>

In India, regulations in some states make it practically impossible for palliative care providers to obtain a license to prescribe oral morphine, while in other states regulations establish a straight-forward procedure that has allowed palliative care providers to play a key role in making pain treatment available at the community level.<sup>118</sup>

Some countries allow only certain types of medical institutions to prescribe opioids. For example, in China, only hospitals above Level 2—hospitals in China are ranked from Level 1 to 3 depending on the jurisdiction they fall under—have the right to prescribe opioids, which means that hospitals in many cities and towns cannot dispense opioids and people may have to travel long distances in order to be able to obtain oral morphine.<sup>119</sup>

These licensing requirements significantly impede access to oral morphine. Countries need to ensure that all healthcare providers and pharmacies are either automatically licensed to procure, stock, and dispense by virtue of their registration as a healthcare institution, or have access to a rational and transparent procedure for obtaining a special license. There is no rational reason for denying palliative care programs that provide mostly home-based care services the right to prescribe and dispense oral morphine.

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<sup>115</sup> Harding R, et al., “Pain Relieving Drugs in 12 African PEPFAR Countries,” p. 8.

<sup>116</sup> Ibid., p. 26.

<sup>117</sup> Vanessa Adams, “Access to pain relief – an essential human right,” p. 21.

<sup>118</sup> Human Rights Watch research in the states of Kerala, Andhra Pradesh, West Bengal, and Rajasthan in March/April 2008.

<sup>119</sup> Evan Anderson, Leo Beletsky, Scott Burris, Corey Davis and Thomas Kresina, eds., “Closing the Gap: Case Studies of Opioid Access Reform in China, India, Romania & Vietnam” (Centers for Law and the Public's Health: A Collaborative at the Johns Hopkins and Georgetown Universities, 2008).

## *Licensing of Health Workers*

Many countries require special licenses for healthcare workers who want to prescribe opioids, and these licenses are often difficult to obtain. For example, the Worldwide Palliative Care Alliance reported in its 2007 report that in Mongolia, Peru, Honduras, Kyrgyzstan and a state in India only palliative care specialists and oncologists are authorized to prescribe oral morphine; that in the Philippines doctors must obtain two special licenses to be able to prescribe; and found that seventeen percent of locations (countries and sub-national regions) covered by the survey required special licenses that were hard to obtain.<sup>120</sup> At the 2008 Eastern European and Central Asian AIDS Conference, a Russian AIDS doctor told conference delegates that he could not treat a patient who suffered from severe pain because he was not licensed to prescribe morphine and that oncologists, who are, would not be able to provide her with morphine because she was not a cancer patient.<sup>121</sup>

While medical doctors in many countries can prescribe morphine by virtue of their professional license, this is not the case for nurses. This is a considerable problem in many middle and low income countries around the world where there are few medical doctors. For example, in Malawi there is only one doctor per 100,000 people.<sup>122</sup> In 2004, Uganda introduced nurse-based prescribing of oral morphine. According to its amended regulations nurses with a certificate in specialized palliative care are permitted to prescribe and supply certain types of opioid analgesics, including oral morphine.<sup>123</sup> Prior to 2004, many people in rural Uganda—where there is one physician per 50,000 people—did not have realistic access to medications for moderate to severe pain. INCB praised Uganda for this important step.<sup>124</sup>

Under the 1961 Single Convention on Narcotic Drugs, states do not have to require that healthcare workers obtain a special license to handle opioids. 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.”<sup>125</sup> As special licensing procedures impede accessibility of opioids for patients who need them, countries should strive as much as possible to allow healthcare workers to handle opioids by virtue of their

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<sup>120</sup> Vanessa Adams, “Access to pain relief – an essential human right,” p. 1.

<sup>121</sup> 2<sup>nd</sup> Eastern Europe and Central Asia AIDS Conference, May 3-5, Moscow.

<sup>122</sup> *Ibid.*, p. 22.

<sup>123</sup> Stjernsward, J., and D. Clark, “Palliative Medicine: A Global Perspective,” p. 11; Downing J, Kawuma E., “The impact of a modular HIV/AIDS palliative care education programme in rural Uganda,” *Int J Palliat Nurs.*, vol. 14, no. 11, Nov. 2008, pp. 560-8.

<sup>124</sup> INCB, “Report of the International Narcotic Control Board for 2004,” United Nations, 2005, pp. 32, 33.

<sup>125</sup> WHO, *Cancer Pain Relief, Second Edition, With a guide to opioid availability*, 1996, p. 10.

professional license or establish rapid rational and transparent procedures for obtaining special licenses.

### *Burdensome Prescription Procedures*

Some countries have established special prescription procedures for opioids that are cumbersome and discourage healthcare workers from prescribing them. A common example is the requirement to use special prescription forms and to keep multiple copies of the prescription. The WHO Expert Committee on Cancer Pain Relief and Active Support Care has observed that special multiple-copy prescription requirements “typically...reduce prescribing of covered drugs by 50 percent or more.”<sup>126</sup> Yet, countries ranging from Cote d’Ivoire to Ukraine require such special prescription forms.<sup>127</sup> In 1995, INCB found that 65 percent of countries that participated in its survey had special prescription procedures.<sup>128</sup>

Another common problem is that prescriptions by healthcare workers must be approved by their colleagues or superiors or that dispensing must be witnessed by multiple healthcare workers. In Ukraine, for example, decisions to prescribe morphine have to be made by a group of at least three doctors, one of whom must be an oncologist.<sup>129</sup> In South Africa, two nurses must observe the dispensing of opioids.<sup>130</sup> In Guatemala, every prescription must be authorized through an ink seal and a signature that are only issued in the central office of the Narcotic Control Agency.<sup>131</sup> In Colombia, the National Fund follows up every prescription with phone calls to the prescribing doctor.<sup>132</sup> In Vietnam, some hospitals mandate that all doctors and nurses return empty morphine ampoules to the chief pharmacist or otherwise be investigated for opioid diversion, even though Vietnam’s drug control regulations do not so require.<sup>133</sup>

Many of these special prescription procedures go well beyond what is required by the 1961 Single Convention and are unlikely to be necessary for preventing diversion. WHO has

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<sup>126</sup> Ibid.

<sup>127</sup> Harding R, et al., “Pain Relieving Drugs in 12 African PEPFAR Countries,” p. 19.

<sup>128</sup> INCB, “Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995,” p. 9.

<sup>129</sup> The Ministry of Health of Ukraine, Order # 356, pp. 3-9.

<sup>130</sup> Harding R, et al., “Pain Relieving Drugs in 12 African PEPFAR Countries,” p. 20.

<sup>131</sup> In March 2009, a new regulation will come into force in Guatemala that abolishes these requirements. Personal communication with Dr. Eva Duarte, January 23, 2009.

<sup>132</sup> Scott Burris and Corey S. Davis, “A Blueprint for Reforming Access to Therapeutic Opioids: Entry Points for International Action to Remove the Policy Barriers to Care” (Centers for Law and the Public’s Health: A Collaborative at the Johns Hopkins and Georgetown Universities, 2008), p.18.

<sup>133</sup> Ministry of Health of Vietnam, “Palliative Care in Viet Nam: Findings of A Rapid Situation Analysis in Five Provinces,” June 2006, p. 36.

recommended that “if physicians are required to keep records other than those associated with good medical practice, the extra work incurred should be practicable and should not impede medical activities.”<sup>134</sup> Requirements that do not need meet those criteria will violate the right to health.

### *Prescription Limitations*

Regulations in some countries impose limitations on the dose of oral morphine that can be prescribed per day or unnecessarily restrict the number of days that it can be prescribed and dispensed for at once. These restrictions impede access to adequate pain management. 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.”<sup>135</sup>

The 1995 INCB survey found that 40 percent of countries participating set a maximum amount of morphine that could be prescribed at one time to a hospitalized patient, and 50 percent did so for patients who lived at home.<sup>136</sup> INCB noted that some governments had set the maximum amount “as low as 30 milligrams” – or approximately half the average daily dose in low and middle income countries.<sup>137</sup> WPCA reported in 2007 that Israel limits morphine prescription to 60 milligrams per day for non-cancer patients.<sup>138</sup> It is unclear how many other countries maintain dosage limitations today. Dosage limitations make no medical sense as patient need varies considerably from person to person, and some people require very large doses to achieve adequate pain control. They are therefore not consistent with the right to health.

The 1995 INCB report found that 20 percent of countries participating in the survey imposed a maximum length of time that a hospitalized patient could receive morphine, and 28 percent of governments had such restrictions for patients at home. In some cases, patients could only receive morphine for three to seven days at once and sometimes that was not renewable.<sup>139</sup> Although no comprehensive overview of countries that impose these kinds of limitations today is available, they continue to be widespread. WPCA reported in 2007 that Honduras and Malawi do not allow morphine to be dispensed for more than three days at a

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<sup>134</sup> WHO, *Cancer Pain Relief, Second Edition, With a guide to opioid availability*, 1996, p. 10.

<sup>135</sup> *Ibid.*, pp. 10, 11.

<sup>136</sup> INCB, “Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995,” p. 9.

<sup>137</sup> Kathleen M. Foley, et al., “Pain Control for People with Cancer and AIDS,” p. 988.

<sup>138</sup> Vanessa Adams, “Access to pain relief – an essential human right,” p. 22.

<sup>139</sup> INCB, “Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995,” p. 9.

time.<sup>140</sup> In China, prescriptions can only be given for seven days at a time.<sup>141</sup> In Israel, prescriptions can only be given for ten days at a time unless the doctor confirms that the patient lives far away from a pharmacy.<sup>142</sup>

While there are good reasons, including preventing diversion, for certain limitations on the length of time medications can be dispensed, the kinds of restrictions mentioned above make it impractical or impossible for many patients to have continuous access to them. Many patients live far away from pharmacies or healthcare centers and repeated travel is a considerable burden because of expense and difficulty of travel for people who are ill. It also puts a drain on healthcare workers who are already overworked in many parts of the world. Any limitations on the amount of time morphine can be described or dispensed for should be reasonable—the limitations should be necessary for preventing abuse and not result in the medication becoming practically inaccessible for people who need them—otherwise they will violate the right to health. In recent years, an increasing number of countries have relaxed the length of time for which oral morphine can be prescribed at once, with many settling on about a month. These countries include Romania (from 3 to 30 days), France (from 7 to 28 days), Mexico (from 5 to 30 days), Peru (from 1 to 14 days), and Colombia (from 10 to 30 days).<sup>143</sup>

## Fears of Legal Sanction

In some countries, a key reason for the low consumption of opioid medications is fear among healthcare workers that they may face legal sanctions for prescribing them. INCB has recommended that

health professionals...should be able to...[provide opiates]...without unnecessary fear of sanctions for unintended violations [including]...legal action for technical violations of the law...[that]...may tend to inhibit prescribing or dispensing of opiates.<sup>144</sup>

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<sup>140</sup> Vanessa Adams, “Access to pain relief – an essential human right,” p. 22.

<sup>141</sup> Evan Anderson, Leo Beletsky, Scott Burris, Corey Davis and Thomas Kresina, eds., “Closing the Gap: Case Studies of Opioid Access Reform in China, India, Romania & Vietnam” (Centers for Law and the Public's Health: A Collaborative at the Johns Hopkins and Georgetown Universities, 2008), pp. 7, 30.

<sup>142</sup> Vanessa Adams, “Access to pain relief – an essential human right,” p. 22.

<sup>143</sup> *Ibid.*, p. 39.

<sup>144</sup> INCB, “Demand for and Supply of Opiates for Medical and Scientific Needs,” United Nations, 1989, p. 15.

Almost fifty percent of countries participating in the 1995 INCB survey cited such fear as an impediment to medical use of opioids.<sup>145</sup> In APCA's survey of national drug control authorities, four out of five cited fears among healthcare professionals as one of the key reasons for low use of opioid medications. The drug control authority in Kenya stated that "due to the punitive nature of the 1994 Act, most providers have shied away from selling opioids."<sup>146</sup>

Ambiguity in regulations, poor communication by drug regulators to healthcare workers about the rules for handling opioids, the existence of harsh sanctions are some of the reasons for this persistent fear among medical professionals, and, in some countries, actual prosecutions of healthcare workers for unintentional mishandling of opioids. In China, for example, regulations that were adopted in 2005—and have significantly improved accessibility of opioids—hold that healthcare workers can prescribe opioids for "reasonable need" but the rules do not clearly define reasonable.<sup>147</sup> In INCB's 1995 survey some countries reported that failure to comply with laws and regulations governing opiate prescribing could result in a 22-year prison sentence. Almost fifty percent of participating countries reported mandatory minimum sentences, some as high as 10 years in prison.<sup>148</sup> In some cases, these are sentences for unintentional mistakes in handling opioids, not for drug dealing.

In the United States, many physicians are reported to fear unjustified prosecution or sanctioning for prescribing opioids for pain and, consequently, tend to under-prescribe.<sup>149</sup> While a recent survey of criminal and administrative cases between 1998 and 2006 found that the number cases had grown from 17 in 1998 to 147 in 2006, the study also concluded 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."<sup>150</sup> The authors suggested that

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

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<sup>145</sup> INCB, "Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995," p. 5.

<sup>146</sup> Harding R, et al., "Pain Relieving Drugs in 12 African PEPFAR Countries," p. 30.

<sup>147</sup> Evan Anderson, Leo Beletsky, Scott Burris, Corey Davis and Thomas Kresina, eds., "Closing the Gap: Case Studies of Opioid Access Reform in China, India, Romania & Vietnam" (Centers for Law and the Public's Health: A Collaborative at the Johns Hopkins and Georgetown Universities, 2008), pp. 7, 29.

<sup>148</sup> INCB, "Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995," pp. 9, 10.

<sup>149</sup> Goldenbaum et al., "Physicians Charged with Opioid Analgesic-Prescribing Offenses," *Pain Medicine*, vol. 9, no. 6, 2008.

<sup>150</sup> Ibid.

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. These phenomena deserve greater study.<sup>151</sup>

Unfortunately, the U.S. Drug Enforcement Administration's public message to physicians who prescribe opioids has been ambiguous. After initially supporting a series of Frequently Asked Questions (FAQ) for physicians about the use of pain management medications that had been developed by a panel of clinicians and regulators, including DEA officials, it abruptly pulled the FAQ from its website in August 2004, creating confusion over what acceptable prescribing practices are.<sup>152</sup> It has not been re-posted since.

While countries have a right—and an obligation under the drug conventions—to take legal action against medical professionals who dispense opioids for non-medical uses, criminalizing unintentional mistakes in opioid prescription is not consistent with the right to health. Furthermore, countries must ensure that regulations are unambiguous and that complete information about them is readily available for healthcare providers.

## Cost

Cost is a frequently cited impediment to improving access to pain treatment and palliative care services, particularly for low and middle income countries. Under the right to health, governments do not have to offer medications such as oral morphine free of charge. However, they must strive to ensure that they are “affordable to all.” In some countries and for certain sections of countries' populations that will mean that it must be provided at no or very little charge. In any case, governments must take all reasonable efforts to ensure that medications are available at a reasonable price that is affordable for patients.

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<sup>151</sup> Ibid.

<sup>152</sup> Brennan F, Carr DB, Cousins MJ, “Pain Management: A Fundamental Human Rights,” p. 209.

Basic oral morphine should be very cheap. Cipla in India makes 10 mg morphine tablets that sell at US\$0.017 cents each.<sup>153</sup> Foley and others estimate that generic morphine should not cost more than US\$0.01 per milligram.<sup>154</sup> An average month's supply of morphine would cost US\$9 to 22.5 per month per patient.<sup>155</sup>

In reality, however, morphine is often much more expensive. A study by De Lima and others found that the average retail cost of a monthly morphine supply in 2003 ranged from US\$10 in India to US\$254 in Argentina. The study found that 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).<sup>156</sup> The study suggested that a number of factors might explain the discrepancy: the fact that most industrialized countries subsidized medications while low and middle income countries did not; that several industrialized governments regulated the price of opioids; taxes, licenses and other costs related to import of finished product; large overhead of local production; poorly developed distribution systems; low demand; and regulatory requirements that drive up cost.<sup>157</sup>

A 2007 report of the Worldwide Palliative Care Alliance also found that the promotion of non-generic—and costly—forms of opioid analgesics has made pain treatment medications unaffordable in some areas. It stated that “when expensive formulations of opioids appear on the market, inexpensive immediate-release morphine often becomes unavailable” as pharmaceutical companies withdraw basic oral morphine from the market. It cited India as an example of a country where in some places hospitals have costly sustained release morphine or transdermal fentanyl but no immediate release morphine, even though the regulatory barriers are the same for both.<sup>158</sup>

Governments have an obligation to explore ways to ensure that basic morphine is available at low cost to people who are in need of pain treatment. A number of countries have successfully sought ways to create capacity for local production of basic oral morphine, in tablet or liquid form, at low cost. For example, in the state of Kerala in India, a small manufacturing unit has been set up at a hospital that produces low cost immediate release

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<sup>153</sup> Scott Burris and Corey S. Davis, “A Blueprint for Reforming Access to Therapeutic Opioids: Entry Points for International Action to Remove the Policy Barriers to Care” (Centers for Law and the Public's Health: A Collaborative at the Johns Hopkins and Georgetown Universities, 2008), p.18.

<sup>154</sup> Kathleen M. Foley, et al., “Pain Control for People with Cancer and AIDS,” p. 988.

<sup>155</sup> Ibid.

<sup>156</sup> De Lima L, Sweeney C, Palmer J.L, Bruera E., “Potent Analgesics Are More Expensive for Patients in Developing Countries: A Comparative Study,” *Journal of Pain & Palliative Care Pharmacotherapy*, vol. 18, no. 1, 2004, p. 63.

<sup>157</sup> Ibid., p. 66

<sup>158</sup> Vanessa Adams, “Access to pain relief – an essential human right,” p. 26.



morphine tablets from morphine powder that is purchased from a factory at Ghazipur.<sup>159</sup> In Uganda, the ministry of health commissioned charitable procurement and manufacturing facility to produce morphine solution which could be distributed to hospitals, health centers and palliative care providers. Before deciding on this option, the ministry of health had approached commercial manufacturers but these were not interested in producing morphine solution due to lack of profitability.<sup>160</sup> In Vietnam, a new opioid prescription regulation allows the ministry of health to mandate state and para-state pharmaceutical companies to produce oral and injectible opioids.<sup>161</sup>

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<sup>159</sup> Joransen DE, Rajagopal MR, and Gilson AM, "Improving access to opioid analgesics for palliative care in India," *Journal of Pain and Symptom Management*, vol. 24, no. 2, 2002, pp.152-159.

<sup>160</sup> Vanessa Adams, "Access to pain relief – an essential human right," p. 37.

<sup>161</sup> Email communication with Kimberly Green of Family Health International Vietnam, January 25, 2009.

## Breaking Out of the Vicious Cycle of Under-Treatment

Comprehensive steps to address all barriers simultaneously are needed in countries where a vicious cycle of under-treatment exists. Governments have the responsibility to lead this process. They need to develop plans for the implementation of palliative care and pain treatment, adopt relevant policies, introduce instruction for healthcare workers, and ensure adequate availability of morphine and other opioid medications. The WHO, INCB, and donor community must assist in these efforts.

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.<sup>162</sup> But both still have a long way to go. Morphine consumption in both 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. But the steps these countries have taken are laying the foundation for replacing the vicious cycle of under-treatment of pain with a positive cycle in which simpler drug control regulations and better knowledge among healthcare providers leads to increased demand for morphine, reinforcing the importance of pain management and palliative care and leading to greater awareness among healthcare workers and the public.

### Uganda

Uganda, an East African country of about 31 million, has made considerable progress in tearing down barriers that have traditionally impeded the ability of people to access pain treatment medications. In 1998, Ugandan government officials, representatives of non-governmental organizations, and WHO sat down together at a conference entitled “Freedom from Cancer and AIDS Pain” to discuss ways in which pain treatment could be made available to the population. At the meeting, participants agreed to take a series of simultaneous steps to deal with key barriers:

- The Ministry of Health and WHO were to develop a national palliative care policy, and cancer and AIDS pain relief policies.
- Although Hospice Africa Uganda had taught palliative medicine in the medical, nursing and pharmacy schools and to practicing post graduate health professionals

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<sup>162</sup> Uganda and Vietnam are not the only countries that have made such progress. Other countries include, among others, Mongolia and Romania.

since 1993, the Government initiated meetings which resulted in the endorsement of a 9-month full time course training at Hospice Africa Uganda, to increase the number of prescribers.

- The drug control authority was to develop new drug regulations, update the essential drug list, conduct estimates of the medical need for morphine, and request an increased national allowance from INCB.

In addition, a commitment was made to ensure coordination of palliative care activities for AIDS and cancer, to set up multidisciplinary clinics for cancer patients, to increase awareness of palliative care among the population, and to identify a demonstration project in Uganda's Hoima District where Little Hospice Hoima, a branch of Hospice Africa Uganda was already active.<sup>163</sup>

In its five-year Strategic Health Plan for 2000-2005, the government stated that palliative care was an essential clinical service for all Ugandans, becoming the first nation in Africa to do so. It also added liquid morphine to its essential drug list, adopted a new set of Guidelines for Handling of Class A Drugs for healthcare practitioners—also a first in Africa—and, in 2003, authorized prescribing of morphine by nurses who have been trained in palliative care.

By early 2009, 79 nurses and clinical officers had received training on pain management and been authorized to prescribe oral morphine; several thousand healthcare workers had attended a short course on pain and symptom management; and 34 out of 56 districts in Uganda had oral morphine available and in use. Despite this impressive progress, many challenges remain, including ensuring availability of oral morphine throughout Uganda; keeping it affordable; preventing stock-outs; and training all relevant healthcare workers.<sup>164</sup>

## Vietnam

Since 2005, Vietnam, a country of 84 million people, 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. This working group, which consisted of ministry of health officials, cancer and infectious disease physicians, and experts from NGOs supported by the US President's Emergency Plan for AIDS Relief, decided to conduct a rapid situation analysis to assess the availability of and the need for palliative care in Vietnam,

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<sup>163</sup> Stjernsward J., "Uganda: Initiating a Government Public Health Approach to Pain Relief and Palliative Care," *Journal of Pain and Symptom Management*, vol. 24, no. 2, August 2002.

<sup>164</sup> Email correspondence with Dr. Anne Merriman of Hospice Africa Uganda, January 2009.

and to subsequently develop a national palliative care program based on its findings.

The rapid situation analysis found, among others, that:

- Severe chronic pain was common among cancer and HIV/AIDS patients;
- Availability of opioid analgesics and other key medications was severely limited;
- Palliative care services were not readily available to the population; and
- Clinicians lacked adequate training.<sup>165</sup>

Based on these finding, the working group recommended that national palliative care guidelines be developed, a balanced national opioid control policy be developed, training for healthcare workers be expanded, and that availability and quality of palliative care services be improved at all levels.

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. In February 2008, it issued new guidelines on opioid prescription which have eased a number of key regulatory barriers. For example, the maximum daily dose has been abolished; prescriptions can now be issued for 30 days, rather than 7;<sup>166</sup> and district hospitals and commune health posts are now authorized to prescribe and dispense. The ministry has also approved a package of training courses for practicing physicians and two medical colleges now offer instruction on palliative care to undergraduate medical and nursing students.

Yet, numerous challenges remain as only a few hundred healthcare workers have received training so far, understanding of palliative care among healthcare officials continues to be limited, various regulatory barriers persist,<sup>167</sup> and few pharmacies and hospitals stock oral morphine.

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<sup>165</sup> Green K, Kinh LN, Khue LN., “Palliative care in Vietnam: Findings from a rapid situation analysis in five provinces,” (Hanoi: Vietnam Ministry of Health, 2006).

<sup>166</sup> 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.

<sup>167</sup> For example, patients must fill their prescription within one day, otherwise it becomes invalid. This is burdensome under any circumstances but particularly as few pharmacies and hospitals in Vietnam stock oral morphine.

## Recommendations

The pain treatment gap is an international human rights crisis that needs to be addressed urgently both at the international and national level. Therefore, Human Rights Watch makes the following recommendations:

### To governments around the world

#### *General*

- Establish, where this has not yet been done, a working group on palliative care and pain management. This working group should include all relevant actors, including health officials, drug regulators, healthcare providers, nongovernmental palliative care providers, and academics, and develop a concrete plan of action for the progressive implementation of pain treatment and palliative care services.
- Assess both the availability of and the need for pain management and palliative care services.
- Develop a comprehensive plan of action that addresses the various barriers that impede availability of pain management and palliative care, including government policy, education, and availability of medications.
- Invite the WHO Access to Controlled Medications Programme to assist them in implementing the above recommendations.
- National human rights commissions or ombudsman offices should, where possible, investigate obstacles to availability of pain management and palliative care services, and request that their governments take urgent measures to address them.

#### *Ensuring an Effective Supply System*

- Submit, in a timely fashion, realistic estimates for the need of controlled medications to the INCB.
- Ensure an effective distribution system for controlled medications. While procurement, transportation and stocking regulations should be able to prevent potential abuse, they should not arbitrarily complicate these processes.
- Countries must ensure that in each region at least a minimum number of pharmacies and hospitals stock morphine.

### *Developing and Enacting Pain Management and Palliative Care Policies*

- Recognize human rights obligation to provide effective/adequate palliative care programs.
- Develop official policies on pain management and palliative care, including as part of cancer and HIV/AIDS control programs;
- Develop practical guidelines on pain management and palliative care for healthcare workers;
- Include oral morphine and other essential pain treatment medications in national lists of essential medicines;
- Ensure that drug control laws and regulations recognize the indispensable nature of opioid and other controlled medications for the relief of pain and suffering, as well as the obligation to ensure their adequate availability;

### *Ensuring Instruction for Healthcare Workers*

- Ensure adequate instruction for healthcare workers, including doctors, nurses, and pharmacists, at both undergraduate and postgraduate level.
- Instruction should also be offered to those already practicing as part of continuing medical education.

### *Reforming Drug Regulations*

- Review drug control regulations to assess whether they unnecessarily impede accessibility of pain medications. Healthcare providers should participate in conducting this review.
- If regulations are found to impede access, they should be amended. Recommendations of WHO and healthcare providers should lay at the foundation of revised drug control regulations.
- Requiring special licenses for healthcare institutions or providers to handle morphine should be avoided as much as possible. In other cases, transparent and simple procedures should be established for obtaining such special licenses.
- Special prescription procedures for controlled medications should be avoided as much as possible. Where they are nonetheless in place, they should be minimally burdensome.
- Limitations on the amount of morphine that can be prescribed per day should be abolished.
- Unnecessary limitations on the amount of morphine that can be prescribed or dispensed at once should be abolished.

### *Ensuring Affordability of Medications*

- Countries should seek to ensure the affordability of morphine and other opioid analgesics.

### **To global drug policy makers**

- Restore the balance between ensuring availability of controlled medications and preventing abuse, as provided for by the UN drug control conventions, in global drug policy debates. Access to controlled medications should be a central and recurring agenda item at the Commission on Narcotic Drugs and other meetings on global drug policy.
- At the UN General Assembly Special Session on Drugs in March 2009, countries should make improving availability of pain treatment medicines, and controlled medications generally, a priority. They should set ambitious and measurable goals to significantly improve access to these medicines worldwide over the coming ten years.
- After March 2009, relevant international agencies, such as the Commission on Narcotic Drugs and INCB, should regularly review progress made by countries toward adequate availability of pain treatment medications, carefully analyzing steps taken to advance this important issue.
- INCB should significantly increase its efforts to encourage and assist states in improving availability of opioid analgesics.
- UNODC should amend the model laws and regulations it has developed to include recognition of the indispensable nature of narcotic drugs and psychotropic substances for medical and scientific purposes, and the obligation for states to ensure their availability.

### **To WHO, UNAIDS, and the donor community**

- WHO should continue to treat access to controlled medications with urgency through its Access to Controlled Medications Programme.
- Donor countries and agencies, including the Global Fund to fight AIDS, Malaria, and Tuberculosis and the U.S. President's Emergency Plan for AIDS Relief, should actively encourage countries to undertake comprehensive steps to improve access to pain relief medications and support those that do, including through support for the WHO Access to Controlled Medications Programme.
- UNAIDS should work with governments to identify and remove obstacles to availability and accessibility of pain management and palliative care services.

## **To the global human rights community**

- UN and regional human rights bodies should routinely remind countries of their obligation under human rights law to ensure adequate availability of pain medications.
- Human rights groups should include access to pain treatment and palliative care into their work, including by submitting shadow reports to UN treaty bodies, providing information to the UN Special Rapporteurs on the Highest Attainable Level of Health and on Torture, Cruel, Inhuman and Degrading Treatment and Punishment, to the Human Rights Council.



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