ABSTRACT. The purpose and activities of the Pain & Policy Studies Group (PPSG) at the University of Wisconsin are discussed, especially in its role as the World Health Organization Collaborating Center for Policy and Communications in Cancer Care. Issues relating to the need for balanced opioid policy, the International Narcotics Control Board, opioid availability, overly restrictive national laws and regulations, and specific examples of improvements that have resulted from work of the PPSG are described. doi:10.1300/J354v21n04_07

KEYWORDS. Opioid, availability, laws, regulations, International Narcotics Control Board, INCB, policy

The Pain & Policy Studies Group (PPSG), established in 1996, is part of the Paul P. Carbone Comprehensive Cancer Center within the University of Wisconsin School of Medicine and Public Health. The PPSG is the World Health Organization (WHO) Collaborating Center for Policy and Communications in Cancer Care, and its WHO terms of reference support its vision that pain management will be adequately available when and where it is needed so that people who suffer pain from cancer, AIDS, surgery, accidents and chronic conditions will have relief.

Karen M. Ryan, MA, is Associate Director for International Policy Research at the Pain and Policy Studies Group at the University of Wisconsin. Address correspondence to: Karen M. Ryan, Pain and Policy Studies Group, 406 Science Drive, Suite 202, Madison, WI 53711-1068 (E-mail: kmryan2@wisc.edu).

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from their pain, improved functioning and a better quality of life. Its mission is twofold:

- To promote ‘balance’ in international, national and state pain policies to ensure adequate availability of opioid analgesics and their appropriate medical use for patient care, while addressing, diversion and abuse.
- To support the global communications program to improve access to information about pain relief, palliative care, and pain policy.

In the face of ongoing global public health challenges that are both infectious and non-infectious in nature, access to essential pain medications is a humanitarian necessity, and is increasingly linked to human rights.1,2 The most effective pain medications for moderate to severe pain, such as that experienced by many late-stage cancer patients, are considered “essential medicines” by the WHO. These essential medicines include the opioid analgesics—morphine, fentanyl, hydromorphone, methadone, oxycodone and pethidine (meperidine). Opioid analgesics (legal term ‘narcotics’) are strong drugs, so they are strictly controlled under international treaties and national laws and regulations. Historically, many governments have created national narcotics-control policies that focus exclusively on drug control, that have little (if any) acknowledgment of the legitimate medical purposes of these important drugs, and that are full of provisions that may be so restrictive as to prevent, in effect, the medical use of opioid analgesics. This oversight was recognized in 1996 by the international drug control body, the International Narcotics Control Board (INCB), in Vienna, Austria, which called on governments to identify and make appropriate adjustments to undue restrictions in their national narcotics laws, regulations or administrative policies that might impede patient access to opioid analgesics.3

Other international organizations have recently echoed this call; in 2003, the Council of Europe declared that national legislation should make opioids accessible for medical use and that fear of abuse should not hinder access to pain relief.4 Furthermore in 2005 the United Nations Economic and Social Council urged the INCB and the WHO to examine the feasibility of a possible assistance mechanism that would facilitate the adequate treatment of pain using opioid analgesics.5

The PPSG accomplishes its policy work through a program of research, development, monitoring, evaluation and communications aimed at improving opioid availability; it provides technical assistance to diagnose regulatory problems, identify the need for changes in national and state policy, and monitor outcomes.

The PPSG participates in international and national conferences and strategy meetings for health professionals and government officials, and provides consultations to government and non-government organizations.

In addition, it helped to develop the WHO guidelines, ‘Achieving Balance in National Opioids Control Policy,’ an important policy tool that can be used to identify policy and administrative barriers to opioid availability. These guidelines, which introduced the principle of ‘balance,’ were drafted in 1999 by a team of global experts in palliative care, pain management and drug regulation, and issued in 2000 by the WHO. They are available in 22 languages at www.painpolicy.wisc.edu/publicat/00whoabi/00whoabi.htm. They provide the background to, and explanation of, how access to opioid analgesics should be integrated into the national narcotics policy, and have been used around the world to guide policy evaluation.

‘Balance’ is a principle that underlies the international narcotics treaties and national drug control laws and asserts that narcotic drugs (opioid analgesics) are indispensable for the relief of pain and suffering, and also have a potential for abuse; efforts to prevent abuse should not interfere with adequate availability of these drugs for medical and scientific purpose. The guidelines provide a 16-point checklist that can be used as a starting point to evaluate a country’s national policies.

The PPSG accomplishes its international communications work in several ways, including news alerts, two websites (www.WHOcancerpain.wisc.edu and www.painpolicy.wisc.edu) and through the publication of Cancer Pain Release, a quarterly WHO newsletter that provides health professionals, policy mak-
ers, and regulators throughout the world with updates on issues and developments in the field.

A recent project in Romania illustrates the work of the PPSG to improve opioid availability. Beginning in 2003, the PPSG worked collaboratively with healthcare colleagues and members of the Ministry of Health (MOH). After an invitation by a MOH palliative care commission, the PPSG performed a preliminary analysis of the 35-year-old law and regulations, and participated in several commission meetings to prepare formal recommendations that were submitted to the Minister of Health in July 2003.

In the following two years, the PPSG provided continuing assistance as the Romanians redrafted their law, which was adopted in November 2005. New regulations, issued in January 2007, were first drafted at a 2004 meeting in Madison, and greatly simplify the administrative process of prescribing opioid analgesics. An article describing this work appeared in *The Lancet.* Additionaly, the PPSG examines annual consumption of opioid analgesics as a measure of global treatment of pain. While such a measure provides a gross indication, it serves nonetheless, as an important comparative tool over time and among countries. In 2003, the INCB noted that just six countries accounted for 79 per cent of global morphine consumption, and that developing countries combined (with about 80 percent of the world population) accounted for just 6 percent. These important facts highlight the great disparity in patient access to pain medications. This disparity is also apparent in Europe in 2004, with per person morphine consumption for most countries in western Europe exceeding the European regional average, while that for countries in central and eastern Europe, and the former Soviet Union falls below the regional average.

In addition to Romania, several countries have made progress to rectify impediments in their national policies. However, much work remains to be done as many countries continue to experience serious impediments to patient access to pain medication.

Regulatory barriers represent just one obstacle among many that may prevent patient access to opioid analgesics. Improving a country’s regulatory environment, while often necessary, is usually not sufficient by itself to improve pain management. Clearly, there is an imperative to address other important barriers, such as inadequate public and professional education, and high medication cost. Recognizing this, the PPSG is pleased to play a continuing and collaborative role as one part of the larger picture to improve global access to pain management.

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