

30 December 2005

Dear Colleague,

As 2005 comes to a close, I would like to extend my best personal wishes to you for a healthy and successful New Year--and offer a few reflections on the year past and ahead.

In the US, 2005 was characterized by a mix of policy setbacks, new information about the source of abused pain medications, and an important transition. Following the US Drug Enforcement Administration's (DEA) abrupt withdrawal from the interdisciplinary and balanced pain and regulatory education initiative known as the "FAQ", DEA reversed its own long-standing policy on issuing Schedule II prescriptions and communicated a new aggressive tone about investigations. These actions precipitated a nationwide retrenchment in care of pain patients and law-abiding physicians' concerns about being investigated have escalated. DEA requested comments on its actions; hundreds of comments were filed from healthcare professionals, associations, regulators and law enforcement officials all over the country; DEA's response is due early in 2006. We hope that DEA's statement will include a recommitment to a balanced approach to diversion control that specifically avoids interfering in medical practice and patient access to pain management, assurance to practitioners that DEA agents will use diversion indicators that cannot be confused with legitimate medical practice, clarification of the increasingly blurred lines between professional practice, unprofessional conduct and criminal conduct, reaffirmation that a series of original prescriptions for Schedule II medications is legal, endorsement of the Federation of State Medical Board Model Policy, and establishment of communication mechanisms that will allow, as years past, communication between DEA and practitioner, law enforcement, regulatory and patient groups.
<http://www.medsch.wisc.edu/painpolicy/DEA/index.htm>

In 2005, the PPSG published preliminary first-of-a-kind quantitative data about the amount of diversion of prescription drugs including opioid analgesics. We obtained data from federally-required reports which showed that in the last four years approximately 28 million dosages of prescription controlled substances were unlawfully diverted from the US drug supply chain into channels of illicit distribution and abuse. This tremendous quantity was based on reports from only 22 states; in 2003 alone, 5.8 million dosages of prescription opioid analgesics were diverted in this manner. Clearly, the reported increase in abuse of "prescription opioids" does not necessarily mean the opioids came from prescriptions. Twenty years ago, pharmacists terrorized by armed robberies convinced Congress to make theft of controlled substances from DEA-registered pharmacies a federal felony. Yet today, we know that thousands of incidents of theft and robbery resulting in diversion continue to occur every year, and we know nothing about the law enforcement response. A fair and balanced federal approach to prescription drug abuse must take into consideration all sources of diversion, including those criminal activities for which DEA-registered pharmacists and physicians are not responsible.

<http://www.medsch.wisc.edu/painpolicy/publicat/05jpsm/05jpsm.pdf>

2005 was also a year for important transitions. Patricia Good retired from the DEA. She understood pain management and was a clear voice within DEA for balanced law enforcement approaches to drug diversion and cooperation with the pain and palliative care fields. She will be missed.

In contrast with the confusion in Washington, the States continued to make steady progress to achieve more balanced policies governing the medical use of controlled substances for pain. We have previously reported that a number of states have adopted, amended or repealed policies sufficient to improve their grade for balanced pain policy.

<http://www.medsch.wisc.edu/painpolicy/publicat/05hlthpol/05hlthpol.pdf> In 2005, PPSG policy evaluation tools continue to be used by a number of organizations as road maps for achieving more balanced state pain policies.

On the international side, 2005 has been a year of important progress. The United Nations adopted new resolutions to address inadequate relief of pain in cancer and HIV/AIDS; all national governments have been asked to examine their laws and regulations for barriers to opioid availability; the World Health Organization and the International Narcotics Control Board have been requested to explore development of an assistance mechanism to support the work necessary to improve patient access to essential medicines, in particular the opioid analgesics.

<http://www.un.org/docs/ecosoc/documents.asp?id=863>

A collaborative project with the Ministry of Health Palliative Care Commission in Romania is coming to fruition. The project began in 2002 with a WHO workshop to assist Eastern European countries to identify and remove regulatory barriers to patient access to opioid pain medications. In November 2005, the Romanian Parliament adopted a new and modern drug control law replacing the laws of the Ceausescu regime which for decades restricted physicians from prescribing more than a 3-day supply of opioids; 10-15 day supplies were possible for cancer patients but only if they were "incurable," and not at all for patients with HIV/AIDS. Within six months the Ministry will adopt new regulations to implement the new law; the regulations have already been drafted by a team of Romanian experts during a visit to the PPSG. We are excited that 2006 may bring a new national drug policy that will strike a balance between control and availability, allow modern pain control practices in Romania and be an example for Eastern Europe and the Former Soviet Union. Look for a journal article soon.

2006 will mark the tenth anniversary for the PPSG. We look forward to announcing plans to expand our policy research and communications programs in the US and internationally, including improvements to the PPSG website at www.medsch.wisc.edu/painpolicy. We will continue to email you periodic updates and, as always, would look forward to comments you may have as we work toward our collective vision of relieving pain and suffering.

Best wishes for the New Year

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