

REDUCING PRESCRIPTION DRUG ABUSE

Non-medical use of addictive prescription drugs has been increasing throughout the United States at alarming rates. According to the National Survey on Drug Use and Health, in 2002, an estimated 6.2 million Americans reported past month use of prescription drugs for non-medical purposes. Nearly 14 percent of youth between the ages of 12 and 17 have used such drugs, which include pain relievers, sedatives/tranquilizers, or stimulants, for non-medical purposes at some point in their lives. Emergency room visits associated with narcotic pain relievers have increased 163 percent since 1995.

The President's National Drug Control Strategy engages Federal, state, and local officials; the medical community; and businesses working in the area of Internet commerce to prevent and stop the illegal sale, diversion, and abuse of prescription psychotherapeutic drugs.

The Strategy focuses on three core tactics for reducing prescription drug abuse:

- ☑ Business outreach and consumer protection
- ☑ Investigation and enforcement against the illegal sale and diversion of prescription drugs
- ☑ Education and training of physicians and consumers

☑ **Business Outreach and Consumer Protection:** The Food and Drug Administration (FDA) will work to ensure product labeling that clearly articulates conditions for the safe and effective use of controlled substances so that commercial advertising fully discloses safety issues associated with the drug's use. Specific examples include labeling that properly identifies patients for whom these products are appropriate and that recommends a "stepped care" approach to the treatment of chronic pain, in accordance with treatment guidelines.

- FDA will consider Risk Management Programs (RiskMAPs) during the approval process for Schedule II opiate drug products. RiskMAPs help ensure the safe prescription and use of these drugs through identification of appropriate patients and monitoring for adverse outcomes.
- FDA, the Drug Enforcement Administration (DEA), and the White House Office of National Drug Control Policy will work with physician organizations to encourage comprehensive patient assessment prior to prescription of opiate therapy. Identification of persons at risk for opiate abuse and addiction will help their medical caretakers to more effectively monitor for signs of abuse.
- Federal agencies are enlisting the support of responsible businesses affiliated with online commercial transactions. Such businesses include credit card companies, shippers, and Internet Service Providers (ISP). These legitimate businesses will be asked to alert law enforcement officials to suspicious or inappropriate activities, while ISP and credit card companies will be requested to require Internet pharmacies to display on their websites the physical street address of their primary business locations.

☑ **Investigation and Enforcement:** The Internet is one of the most popular sources of diverted prescription drugs. An increasing number of rogue pharmacies – or "pill mills" – offer controlled substances and other prescriptions direct to consumers online. These unscrupulous entities are often foreign-based and undermine state licensing systems, exposing consumers to potentially counterfeit, adulterated, and contaminated products.

- The FDA's Office of Criminal Investigations (OCI) and DEA work together on criminal investigations involving the illegal sale, use, and diversion of controlled substances, including illegal sales over the Internet. Both FDA and DEA have utilized the full range of regulatory, administrative, and criminal investigative tools available, as well as engaged in extensive cooperative efforts with local law enforcement groups, to pursue cases involving controlled substances.

Investigation and Enforcement (continued):

- DEA will deploy sophisticated web crawler/data mining technology to generate investigative leads that could lead to enforcement actions against illegal pill mills.
- ONDCP and DEA will work with state officials to expand the number of Prescription Monitoring Programs (PMPs) and to facilitate information sharing among jurisdictions. Currently, 20 states have PMPs to identify individuals who attempt to fill multiple prescriptions from numerous doctors ("doctor shopping"). This information can help reputable physicians and pharmacies prevent illegal diversion of controlled substances.
- FDA and U.S. Customs and Border Protection (CBP), with assistance from DEA, continue to do spot examinations of mail and courier shipments for foreign drugs to U.S. consumers to help FDA and CBP target, identify, and stop illegal and potentially unsafe drugs from entering the U.S. from foreign countries via mail and common carriers.

☑ **Education and Training:** One potential means of preventing diversion and abuse of prescription drugs is wider dissemination of continuing medical education programs for physicians and other health professionals regarding pain management. These programs will seek to balance the legitimate needs of patients against the risk of diversion and abuse.

- The DEA, with support from the FDA, is working to consult with medical associations to identify existing best practices in physician training in the field of pain management. The agencies plan to develop a mechanism to support the wider dissemination and completion of approved Continuing Medical Education (CME) courses for physicians who prescribe controlled substances. The curriculum will educate doctors on the appropriate medical use of opioids as well as the risks of abuse and addiction.
- ONDCP, DEA, and FDA will develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making direct purchases of controlled substances online. Currently, FDA, along with its sister agency, the Substance Abuse and Mental Health Services Administration (SAMHSA), have jointly developed a public service announcement campaign to better educate consumers on the abuse of prescription pain killers.

☑ **Protecting Safe and Effective Use of Medications:** Some estimate that more than 10 million Americans suffer from chronic pain. The efforts outlined in the National Drug Control Strategy to prevent and reduce the diversion and abuse of prescription drugs will help to ensure that patients have full and appropriate access to the medications that best meet their needs and that their healthcare providers are informed and trained to effectively manage pain while limiting potential for misuse, abuse, and addiction.