Addressing Prescription Drug Abuse Requires Focus

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We are bombarded daily by the news of prescription drug abuse and its tragic consequences. The prevalence of our prescription drug abuse problem is confirmed by the daunting statistics: Some three million teens currently abuse prescription medications, according to the National Survey on Drug Use and Health. Inappropriate use of medicines is not limited to young people, however. More than 17 percent of adults over 60 admit to using prescription medications inappropriately. All in all, one in five Americans has used a prescription medication for non-medical purposes. These statistics only confirm that the medical community, including the FDA, needs to place more of a focus on this problem.

Law enforcement plays an important role in confronting criminal drug diversion, but erroneous prescribing, unintentional misuse, and intentional abuse of prescription medications are public health problems. The medical community and pharmaceutical companies must lead the efforts to craft public health solutions that preserve access to medications for patients who need them.

Pharmaceutical manufacturers are meeting this public health challenge. For example, opioid pain relievers - the most commonly abused medications - have been redesigned to deliver adequate pain relief and be less susceptible to abuse. New cannabinoid formulations show potential to treat patients suffering from cancer pain without exposing them to the risks of opioids. These innovations should be speeding through the FDA review process, but the FDA is facing its own challenges which have slowed the development, approval, and marketing of these medications.

To its credit the FDA has placed a priority on some of these innovations by granting accelerated approvals - a process that has recently come under fire in the cancer field because of its slow pace - yet novel pain medications have not hit the market, but have instead been inhibited further by new processes.

The FDA recently announced an expansion of requirements on many new and existing pain relievers. The agency is broadening its oversight beyond the safety and efficacy of the medications, now requiring manufacturers take responsibility for ensuring adequate prescriber training and patient assessment, education, and compliance through Risk Evaluation and Mitigation Strategies (REMS).

Improving the prescribing and use of pain relievers - all prescription drugs, in fact - is a necessity. It should rest in the hands of those with authority and experience on the matter: medical and pharmacy boards, professional societies, and patient advocacy organizations, among others. The FDA, in focusing its efforts on these matters, is being distracted from its core responsibilities: expediting the development of innovative medicines, and evaluating them with urgency to meet public health needs.

The FDA should return to basics. It should publish guidance for industry on the approval and labeling requirements for novel formulations. It should use its fact track and priority review

authority, and provide market exclusivity incentives, to encourage the development and hasten the availability of safer medications.

We are making progress. Law enforcement has stepped up its efforts on the Internet and is collaborating with the medical community at the state and local levels; Congressional representatives like Mary Bono Mack (R-CA-45) are taking a lead at finding policy solutions; Utah Department of Health's "Use Only As Directed" program decreased the number of prescription-related deaths in the state by 12.6 percent between 2007 and 2008. Even families through programs like the National Family Partnership's "Lock Your Meds" campaign are doing their part by educating others on properly storing their medicines.

If the FDA joins this effort by focusing its attention on making safer medications available to prescribers, it can make a real difference in the lives of patients with dire medical needs and, indeed, all of us affected by prescription drug abuse.

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