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Subcommittee on Health Hearing
“Examining the Federal Government’s Response to the Prescription Drug Abuse
Crisis”
June 14, 2013

Prescription drug abuse is a serious and growing problem in America. The number of deaths due to unintentional overdoses with prescription drugs dwarfs the number of deaths from illegal drugs, and almost doubled between 2000 and 2007. According to the Centers for Disease Control and Prevention, there were over 16,650 deaths in 2010 due to overdose with prescription painkillers.

Although these drugs can cause harm if abused, they can also offer tremendous relief to patients, such as those with cancer or with chronic pain that responds poorly to other medications. The challenge, then, is to identify the means to prevent abuse while preserving access to these drugs by those who truly need them. I hope our witnesses today will provide information that can help us meet this challenge.

Clearly, there is no silver bullet, or any single simple approach that will solve the problem. However, there are a number of avenues that may be worth pursuing, many of which are reflected in the Administration’s prescription drug abuse plan.

First: Providers should be better educated on the use and potential abuse of these drugs, so they can be more effective in recognizing developing problems of abuse, and, in turn, more effective in educating and treating their patients. Studies show that even brief interventions by health care providers can be successful in reducing or eliminating substance abuse by patients who have begun abusing prescription opioids but have not yet become addicted to them.

There are a number of potential mechanisms that could enhance provider education. For example, Congress or possibly the Drug Enforcement Administration could include among the eligibility standards for DEA registration, a requirement that physicians receive adequate and appropriate training in the prescribing and use of controlled substances. FDA could also require that pharmaceutical companies develop educational materials and physician training programs as part of a Risk Evaluation and Mitigation Strategy (REMS) tied to opioid drug approval.

Second: We must educate patients on the risks of abuse of these drugs, and the need to properly store and dispose of them. According to a 2009 national survey by the Substance Abuse and Mental Health Services Administration, over 70% of people who abused these drugs got them from friends or relatives, rather than from drug dealers or over the internet. If we can reduce inappropriate access to these drugs, we can also reduce the incidence of their abuse.

A third approach involves efforts of drug companies to develop abuse-deterrent formulations of controlled drugs – making them difficult or impossible to crush or dissolve, for example, so they cannot be taken by inhalation or injection for an enhanced effect. FDA is supportive of such activities, and recently released a draft guidance to assist industry in developing new formulations of opioid drugs with abuse-deterrent properties. The guidance describes FDA’s current thinking about the studies companies would be expected to conduct to demonstrate the abuse-deterrent properties of a specific formulation, including the process by which FDA would evaluate such studies as well as the labeling claims FDA might approve based on the results.

This is a positive development and I applaud FDA for making this guidance a top priority. But I am concerned about the increasing evidence that brand companies are using abuse-deterrent technologies as a tool to thwart generic competition.

Indeed, the brand manufacturers of opioid drugs appear to be timing the release of their new abuse-deterrent formulations to coincide with the expiration of their patents and periods of marketing exclusivity. Upon FDA approval of the new formulations, the companies remove the old formulations from the market, claiming that they are no longer safe. If FDA agrees the brand formulations were removed for safety reasons, FDA is precluded from approving generic competitors without comparable abuse-deterrent formulations.

When a brand manufacturer’s new formulation truly deters abuse, there is no question FDA should not approve a generic version without comparable abuse-deterrent properties. In making that evaluation, however, FDA must be careful to ensure that the claimed abuse-deterrent properties are effective enough to justify a decision that the original version is no longer an acceptably-safe product.

To be clear: Abuse deterrence should not become a new “work-around” through which brand companies avoid generic competition. Instead drug manufacturers should engage in this area in accordance with both the letter and the spirit of the law. Towards that end, FDA should also provide guidance to companies on what they are expected to do to obtain approval of abuse-deterrent generic formulations.

No doubt, we need to address the growing problem of prescription drug abuse in this country. But we must do so through means that recognize and preserve the critical role opioid pain medications play in improving the quality of life of those with otherwise intractable and chronic pain. I hope our hearing today will enable us to make progress towards this goal.