Drugs

Statement on Proposed Hydrocodone Reclassification from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research

[10-24-2013] Over the past several years, the U.S. Food and Drug Administration (FDA) has been carefully evaluating and weighing the appropriate use of opioid analgesic drug products. For the millions of American patients experiencing an acute medical need or living with chronic pain, opioids, when prescribed appropriately, can allow patients to manage their pain as well as significantly improve their quality of life.

However, in recent years, the FDA has become increasingly concerned about the abuse and misuse of opioid products, which have sadly reached epidemic proportions in certain parts of the United States. While the value of and access to these drugs has been a consistent source of public debate, the FDA has been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse.

In 2009, the U.S. Drug Enforcement Administration (DEA) asked the U.S. Department of Health and Human Services (HHS) for a recommendation regarding whether to change the schedule for hydrocodone combination products, such as Vicodin. The proposed change was from Schedule III to Schedule II, which would increase the controls on these products. Due to the unique history of this issue and the tremendous amount of public interest, we are announcing the agency's intent to recommend to HHS that hydrocodone combination products should be reclassified to a different and more restrictive schedule. This determination comes after a thorough and careful analysis of extensive scientific literature, review of hundreds of public comments on the issue, and several public meetings, during which we received input from a wide range of stakeholders, including patients, health care providers, outside experts, and other government entities.

By early December, FDA plans to submit our formal recommendation package to HHS to reclassify hydrocodone combination products into Schedule II. We anticipate that the National Institute on Drug Abuse (NIDA) will concur with our recommendation. This will begin a process that will lead to a final decision by the DEA on the appropriate scheduling of these products.

Going forward, the agency will continue working with professional organizations, consumer and patient groups, and industry to ensure that prescriber and patient education tools are readily available so that these products are properly prescribed and appropriately used by the patients who need them most.

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