EDITORIAL

Hydrocodone Rescheduling Amendment And Pipeline Products on the Horizon

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Introduction

In 2010, more than 139 million prescriptions for hydrocodone were dispensed, making it the most frequently prescribed opioid in the U.S.[1] The 2010 National Survey on Drug Use and Health reports that 7 million individuals 12 years of age and older had abused prescription pain medications in the previous month.[2] In addition, the 2011 Monitoring the Future Survey reports that approximately 2%, 6%, and 8% of 8th, 10th, and 12th graders, respectively, had abused Abbott's Vicodin (hydrocodone/acetaminophen) in the previous 12 months.[3]

Pure hydrocodone medications are classified as Schedule II controlled substances;[4] however, combination hydrocodone products are designated as Schedule III controlled substances.[5] In this editorial, we discuss an amendment to reclassify hydrocodone-containing products as Schedule II controlled substances and the implications of this change to pharmacy practice. We also address hydrocodone extended-release pipeline products and their impact.

The Hydrocodone Reclassification Amendment

On May 24, 2012, the U.S. Senate passed the FDA Safety and Innovation Act (S. 3187) with an amendment to reclassify all products containing hydrocodone from Schedule III to Schedule II.[6,7] The companion bill, known as the FDA Reform Act of 2012 (H.R. 5651), was passed by the House of Representatives on May 30 without a mention of hydrocodone rescheduling.[8] Currently, the proposed hydrocodone amendment is under consideration for the final bill, which is expected to be signed by President Barack Obama this summer.[8] Senator Joe Manchin (D-W. Va.), one of the bill's supporters, hopes that the amendment will assist in combating prescription drug abuse. He discussed the problem of prescription drug abuse in his hometown of Farmington, West Virginia, referring to the experiences of students' families.[9]

Individuals who support this amendment believe that it might help decrease hydrocodone abuse through more stringent regulation of Schedule II controlled substances.[10] Under the amendment, refills of Vicodin prescriptions would be prohibited.[10] However, the American Pharmacists Association, Food Marketing Institute, International Academy of Compounding Pharmacists, National Association of Chain Drug Stores, and the National Community Pharmacists Association oppose the amendment because of concerns about decreased access for patients with legitimate prescriptions for pain and because of the additional burden that increased regulation would place on pharmacies.[11] These organizations issued letters to the Senate and House voicing their concerns.[11]

Hydrocodone Pipeline Products

Zogenix, Inc., has formulated an extended-release (ER) pure hydrocodone product, Zohydro, which utilizes the Spheroidal Oral Drug Absorption System (SODAS). In May, the New Drug Application (NDA) was submitted to the FDA.[12] If the NDA is approved, this would make Zohydro the first pure ER hydrocodone product. This formulation would contain 10 times the amount of hydrocodone found in Vicodin.[13]

SODAS contains a unique controlled-release profile with both immediate-release (IR) and ER properties to enable twice-daily dosing.[12,14] Teva Pharmaceuticals is currently studying a tamper-deterrent, ER hydrocodone product that might prevent abuse.[15] Many pharmaceutical companies have begun reformulating their opioid products with abuse-deterrent and tamper-resistant formulations to prevent abuse.[16] Purdue Pharma and Egalet, a Danish pharmaceutical company, are also competitors in this market.[15] There is concern regarding the potential for abuse of these products, and Senator Charles Schumer (D-N.Y.) voiced his opposition in a letter to the FDA.[13]

Conclusion

It is imperative that pharmacists stay abreast of the problem of prescription drug abuse. The hydrocodone amendment may lead to decreased abuse of substances such as Vicodin. If hydrocodone is reclassified as a Schedule II drug, studies would be needed to determine whether abuse has decreased. Pharmacists should make it a point to be aware of their state and federal laws regarding Schedule II controlled substances in light of changes that could occur if hydrocodone products are reclassified. Hydrocodone ER products in the pipeline have a potential for abuse, and pharmacists should determine whether these therapies are appropriate for their practice setting.

Note: Opioid products and abuse-deterrent technologies are also discussed in the Continuing Education Credit article beginning on page 412.

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continued on page 404

continued from page 399

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