How User Fee Acts Affect Dentistry

Information on UFAs and the U.S. Off-Label Use Communications Debate

By Jeanie Kennedy

User Fee Acts (UFAs) are comprehensive U.S. Food and Drug Administration (FDA) bills that are passed by U.S. Congress every five years. Why should general dentists care? Because provisions attached to the agreements could be included that would affect drug shortages, off-label use issues, securing authorization for pediatric programs and language on the maintenance of radiological equipment.

The 2017 UFA Package

As federal dollars have become increasingly scarce, manufacturers of prescription and generic drugs, medical devices and biological products decided they would provide funds for the FDA in anticipation that their products could be reviewed more quickly. The first prescription drug user fee act (PDUFA) was created by Congress in 1992. The funding has helped expedite the drug-approval process, as well as product submissions in general.

The 2017 UFA package will include PDUFA VI, the medical device user fee act (MDUFA) IV, the biosimilar user fee act (BsUFA) II and the generic drug user fee act (GDUFA) II. Traditionally, UFAs have become a vehicle for other FDA-related legislation. While an effort has been made to minimize the addition of adjunct legislation this UFA cycle, bills will be added to the U.S. House and Senate drafts. If a bill is not controversial and is germane, it is usually added to the UFA package and reconciled in the conference committee.

The FDA UFA Bill Mark-Up Session

On July 12, 2017, the House of Representatives passed H.R. 2430 by voice vote. As of publication deadline, the Senate had not yet scheduled a vote on S. 934 but was expected to address it during the first two weeks of August. Votes are generally bipartisan in favor of the package with some 10 votes (total) against passage of the final omnibus bill. UFAs must be signed into law by the end of the fiscal year Sept. 30, 2017. The UFA package has always been signed into law prior to the deadline because the FDA could not function without the funding.

FDA's Collection of User Fees

Fees are now assessed for product applications, facility fees and product registration. According to H.R. 2430: FDA Reauthorization Act of 2017, as of May 18, 2017, base fee amounts for fiscal year 2018 are:

- Fees relating to drugs: $878,590,000
- Fees relating to devices: $183,280,756
- Fees relating to biologics: $45,000,000
- Fees relating to generic drugs: $493,600,000

Fees paid to the FDA do not ensure that the product will be approved; rather, they provide additional resources for agency staff to review products more swiftly. According to Avalere Health, a Washington, D.C.-based health care consulting firm, the estimated percentages of review budget paid by user fees is 68 percent for drugs, 30 percent for devices, 10 percent for biologics and 58 percent for generic drugs. Consumer groups consistently rail against the collection of user fees since they believe the FDA is beholden to the industry due to the large fee payments.

Off-Label Use Amendments

During the House Energy and Commerce Committee mark-up session, two amendments were introduced on the topic of off-label use. The term "off-label

use" refers to any use of approved drugs, licensed biologics, and approved or cleared medical/dental devices in any manner that is inconsistent with the FDA's approved labeling of the medical/dental product. Both amendments were withdrawn with a commitment to work on a bipartisan solution for Rep. Morgan Griffith's (R-Virginia) amendment in the future.[1] Some advocates of Griffith's amendment believe it would strike the appropriate balance between placing reasonable limits on manufacturers and allowing a productive, scientific exchange of data that would benefit patients.

Silver diamine fluoride (SDF) is one example of a dental product that is used off-label. While SDF is FDA-cleared as a Class II medical device only to reduce sensitivity in teeth for adults age 21 and older, it is often used by dentists to delay tooth decay, especially in children. Off-label use of SDF to delay or prevent cavities in children is supported by numerous studies and is generally permissible under U.S. federal law, despite a lack of FDA clearance for this use.[2] However, state regulations may vary on this matter, and it is important that you check with your state dental board before proceeding with off-label use of SDF to delay or prevent caries.

Debate exists in the United States as to whether the FDA should loosen its constraints on communications of off-label use of medical products. Several high-profile court cases centering on communications of off-label use have been won by manufacturers over the past few years. As a result, this prompted the FDA to hold an open public meeting in fall 2016 to discuss free-speech implications in off-label use communications.

FDA produced a memorandum in January 2017, titled "Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products." This summarized recent court challenges on speech restrictions regarding evidence of intended use, commercial free speech, content and speaker-based restrictions. The document is intended to solicit public feedback on free speech, while maintaining government interests in protecting the public's health.

Legal Developments

Decisions in several recent court cases have changed the landscape for findings in off-label issues. Truthful off-label promotional speech, the FDA's pursuit of misbranding provisions (for statements that were truthful and not misleading), and speech that is solely truthful and not misleading cannot be the basis for a misbranding charge for a manufacturer.[3-5] Additionally, a decision from the Ninth Circuit (*United States of America v. Michael Stanley Kaplan, MD*) appears to confuse the use of adulterated devices caused by unsanitary practices with the use of legally marketed off-label products.[6] Cases may be appealed to the U.S. Supreme Court, or the FDA may elect to alter their policies.

Why the Debate?

The cost of development of medical and dental products is high. The November 2010 study, "FDA Impact on U.S. Medical Technology Innovation," revealed that the average cost to bring a low- to medium-risk device (510(k)) from concept to clearance was close to $31 million. Higher risk (premarket approval) devices cost manufacturers approximately $94 million from concept to product approval. Moreover, FDA staff have sometimes taken a stringent interpretation on indications for use. ✦

References

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