Congress Passes Food and Drug Administration Amendments of 2007

On September 20, 2007, Congress passed H.R. 3580, the Food and Drug Administration Amendments of 2007 ("FDAA"). The largest overhaul of FDA's safety authority since 1962, FDAA's core provisions are aimed at improving drug safety by strengthening FDA's authority to manage the full life cycle of a drug. The new amendments permit FDA to require: (1) postapproval studies and clinical trials; (2) risk evaluation and mitigation strategies ("REMS") for certain products; and (3) prereview of direct-to-consumer ("DTC") advertisements. FDAA also subjects manufacturers that violate the DTC and drug safety provisions to considerable civil penalties. For the full text of the bill, please click here.

Postapproval Studies and Clinical Trials

Currently, Phase IV postapproval studies and trials are voluntary. FDAA authorizes FDA to require postapproval studies and clinical trials in certain circumstances when necessary to assess or identify serious risks associated with a product. FDA may impose these postapproval requirements not only to products in the initial approval stages, but also to approved products for which new safety information is available.

REMS

REMS are risk management plans specifically tailored to enhance a product's safety. Designed by FDA in consultation with the manufacturer, a REMS may include: (1) elements to ensure effective communication of product risks; and (2) restrictions on distribution or use to ensure safe use of the product. To aid communication, FDA may require that patient-friendly information accompany the product at distribution and that the manufacturer disseminate information to health care providers outlining product risks and use protocols. FDA may also restrict the distribution or use of products associated with serious risks. Manufacturers themselves are required to monitor compliance by health care providers and patients with these safe use restrictions, which may include:

- Requiring prescribers to have specialized training;
- Permitting the dispensation of the product only in controlled settings, such as hospitals;
- Allowing the dispensation of the product only to patients with evidence of safe use conditions, such as laboratory test results; and
- Requiring patients who use the product to undergo monitoring or to be enrolled in a clinical trial.

FDA may require a REMS or any of the above requirements only upon a determination that it is necessary for the benefits of a product to outweigh its risks. FDA must consider a number of factors in making the determination, including the size of the patient population involved and the seriousness of the disease or condition to be treated. While FDA will require a REMS primarily for products in the initial approval stages, it may also require a REMS for previously approved products based on new safety information and for approved products already subject to restrictions on distribution or use.

Safety Labeling Changes

FDAA gives FDA new authority to require labeling changes for marketed drugs. The bill also contains new language on product liability, which can be argued to leave manufacturers potentially liable if they fail to make labeling changes, even if not required to do so by FDA.

Failure to Comply with Postapproval Requirements, REMS, or Labeling Changes

A product is deemed misbranded if fails to comply with a postapproval requirement, REMS, or labeling change. Such violations may result in civil penalties ranging from $250,000 for a single violation to $10 million in certain circumstances for multiple violations adjudicated in a single proceeding.

DTC Advertising

Prereview of Television Advertisements

The statute authorizes FDA to require prereview of DTC television advertising and also establishes a scheme whereby companies may submit DTC ads for review on a voluntary basis, accompanied by a user fee. FDA may require that a television advertisement contain specific disclosures about serious risks associated with the product, or in the case of drugs approved less than two years before dissemination of the advertisement, FDA may require disclosure of the approval date.

Additional DTC Requirements

DTC advertisements must contain: (1) a statement about side effects, contraindications, and effectiveness that is clear, conspicuous, and neutral; and (2) a statement that encourages the reporting of adverse events to FDA.

Civil Penalties for DTC Advertising

A person who disseminates a false and misleading DTC advertisement may be subject to a civil penalty of up to $250,000 for the first violation in a three-year period and up to $500,000 for subsequent violations in the three-year period.

Other Significant Provisions

In addition to the drug safety reforms outlined above, FDAA also contains the following significant provisions:

- Reauthorization of the Prescription Drug User Fee Act ("PDUFA");
- Marketing exclusivity for pediatric drugs; and
- Restrictions on the use of citizen petitions.

With the exception of the PDUFA fees, which will take effect at the discretion of the Secretary of Health and Human Services, the above provisions will take effect 180 days after enactment.

Contact Information

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