Hearing of the House Committee on Energy and Commerce, Subcommittee on Health
"FDA User Fees 2012: How Innovation Helps Patients and Jobs"
April 18, 2012 – 10:15 am – Rayburn 2123

Background:
On April 18, the House Energy and Commerce Subcommittee on Health held a hearing on a package of bills that would reauthorize the prescription drug and medical device user fee programs, create user fee programs for generic drugs and biosimilars, reauthorize programs that encourage the development of drugs for children, enact administrative and regulatory reforms at the FDA, and address problems with drug shortages. The user fee programs are designed to provide the FDA with additional resources to handle applications to market drugs and devices in exchange for a commitment to meet certain performance standards. The intention is to substantially reduce the backlog of applications and provide companies with greater speed and predictability about the time to a decision. The hearing was held to consider the proposals within a discussion draft. The first panel included the top FDA officials leading the drug and device regulation and approval processes, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research, and Dr. Jeffrey Shuren, Director of the Center for Devices and Radiological Health. The second panel included stakeholders, including David Wheadon of PhRMA, Sara Radcliffe of BIO, David Gaugh of the Generic Pharmaceutical Association, Joseph Levitt, an attorney and negotiator for AdvaMed, and Allan Coukell of the Pew Health Group.

Discussion on Pharmaceuticals:
The major pharmaceutical issues addressed by members included concerns about drug shortages, the lack of new antibiotics in the drug pipeline, inspection of foreign drug manufacturers, and whether FDA should be required to track and report additional performance data.

Discussion Mobile Apps and Medical Software:
Dr. Shuren spoke about the underlying law, MDUFA, and issues related to the FDA's role in approving and regulating medical devices. Dr. Shuren expressed FDA's support for the reauthorization of MDUFA, emphasizing the commitment on the part of FDA to improve the predictability, transparency, and speed of the approval process. He cautioned against the addition of any new requirements, as they could divert critical resources from the review process and cause FDA to fail to meet its objectives under the MDUFA agreement.

The regulation of mobile apps and medical software, and FDA plans for regulation, and FDA collaboration with other government agencies with jurisdiction, was raised by Rep. Blackburn (TN). Dr. Shuren noted that FDA is trying to remain sensitive to technological advances in its handling of mobile apps and software. The FDA is working on guidance for the regulation of wireless devices, has released guidance on the regulation of clinical decision support systems, and is in discussions with other regulatory agencies (FCC) on the issue. Specifically, he noted that FDA focuses on safety and effectiveness and FCC focuses on issues regarding wireless spectrum. Rep. Blackburn asked for a list of primary activities of the FDA in this area. Dr. Shuren added that FDA recognizes that software is updated frequently and a requirement for re-approval for each update would be unduly burdensome. As such, FDA has currently opted not to exercise its regulatory authority for most medical software/mobile apps, and would not support statutory changes to the definition of a medical device to account for technological changes like mobile apps. Dr. Shuren agreed to provide a list while noting that the majority of apps will not be reviewed by FDA.

Rep. Black (TN) asked if Congress should update the law to clearly exclude software from regulation. Dr. Shuren responded that he believed that was not necessary, that updating the law could have broader implications, and that FDA could use existing public processes to decide which types of medical software could be exempted from regulation. Rep. Black asked if every software update would need approval. Dr. Shuren said that FDA would not need to approve every update, that only fundamental changes in technology would require approval, and that FDA's regulatory focus would be narrow.

Bakul Patel was identified as the point person at FDA for the agency's work in this domain.

Additional Discussion Concerning Medical Devices:

- FDA process for evaluating updates to existing medical devices and the 510(k) approval pathway
    - Currently, device manufacturers need to submit a new 510(k) application only when the device is updated in a manner that impacts its safety or effectiveness. The FDA has issued draft guidance to industry on 510(k) updates. However, Rep. Burgess (TX), Rep. Shimkus (IL), and Rep. Rodgers (MI) were concerned that the guidance was confusing to industry stakeholders and would lead to an unnecessary increase in 510(k) applications, thereby slowing the review process.
        - Dr. Shuren stressed that the development of guidance was a work in progress and that the FDA has been engaging with industry to
    - Rep. Burgess (TX) and Rep. Markey (MA) lamented a loophole in the review process that can lead devices to avoid 510(k) approval. If a new device is deemed "substantially equivalent" to an existing (predicate) device, the new device does not need to undergo the 510(k) approval process. In cases where a defect was later identified in a predicate device, new devices based on the defective technology (and thus deemed substantially equivalent) would automatically avoid the 510(k) process
        - It was not immediately clear whether these devices are considered "approved" by the FDA or if they remain in a grey-zone in which they remain on the market without official 510(k) approval. Rep. Burgess (TX) noted that substantial equivalence does not equate with clearance. Dr. Shuren responded that the FDA has limited options to regulate these devices (e.g. voluntary recall from the manufacturer, "adequate mitigation" of the defect including changes to labeling, and mandatory recall, a long and expensive process).
        - Dr. Shuren would not comment on whether he felt FDA should have statutory authority to more easily remove devices based on defective predicate technology from the market
- Post-market surveillance of medical devices (Rep. Capps (CA))
    - The FDA supports extension of the Sentinel Initiative to medical devices, but does not yet have the tools to do so. A unique device identifier is a key component, and legislation on the matter has been held up in OMB for some time.
- Investigational Device Exemption (IDE) process
    - IDE approvals allow devices that have not been cleared for market use to be used in clinical trials to evaluate safety and effectiveness. Rep. Pitts (PA) and Rep. Shimkus (IL) expressed concern that changes to FDA policy under MDUFA increase the requirements for IDE approval (by only approving those devices most likely to be cleared for the market), which could lead to companies conducting their clinical studies elsewhere (i.e. overseas). Dr. Shuren responded that the IDE process under MDUFA would be:
        - more consistent (e.g. by clarifying criteria and consequently preventing approvals from being held up by companies requesting approval for studies that were not relevant)
        - more effective (stricter criteria means more IDE devices will likely reach final approval and fewer resources will be spent investigating IDE devices that ultimately prove unsafe or ineffective)