



THE COMMITTEE ON ENERGY AND COMMERCE

INTERNAL MEMORANDUM

February 7, 2012

To: Energy and Commerce Committee Members

From: Majority Staff

Re: Hearing on The Review of the Proposed Generic Drug and Biosimilars User Fees and Further Examination of Drug Shortages

On Thursday, February 9, 2012, at 10:00 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled “Review of the Proposed Generic Drug and Biosimilars User Fees and Further Examination of Drug Shortages.” At the hearing, the Subcommittee will examine issues pertaining to the proposed generic and biosimilars user fees and drug shortages.

I. WITNESSES

Panel I

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration

Panel II

Heather Bresch
Chief Executive Officer
Mylan, Inc.

David Gaugh
Vice President, Regulatory Sciences
Generic Pharmaceutical Association

William Greene, Pharm.D, BCPS, FASHP
Chief Pharmaceutical Officer, Pharmaceutical Services
Member, Pharmaceutical Sciences
St. Jude Children’s Research Hospital

II. BACKGROUND

At the hearing, the Subcommittee will hear testimony on the proposed generic drug user fee, biosimilars user fee and drug shortages. The following provides background.

Generic Drug User Fee

The proposed generic drug user fee would provide additional resources for the review and regulation of generic drugs. A generic drug is similar to a brand drug in the following ways: dosage form, strength, route of administration, active ingredient and intended use. In a generic drug application, which is known as an abbreviated new drug application or ANDA, the applicant generally does not submit clinical data on safety and effectiveness. Instead, the generic applicant proves that its drug is bioequivalent to the brand drug. The generic drug applicant must receive approval from FDA before marketing.

Under the proposed generic drug user fee agreement, FDA and industry agreed that industry would pay approximately \$1.5 billion over five years. The generics industry would pay this fee in return for more efficient and predictable review of generic drug applications and increased inspections of drug facilities. There would be two types of user fees: application and facility.

There are approximately 3,000 generic applications in the backlog, and one of the goals of the generic drug user fee would be to eliminate this backlog in five years. Another goal would ensure that FDA could inspect all drug facilities, domestic and foreign, at an increased frequency.¹

Biosimilars User Fee Agreement

FDA and industry also agreed to a proposed biosimilars user fee. This use fee applies to biosimilars, which are products approved under the abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed biological product. Under the proposed agreement, the following four types of fees would be authorized: application, product, establishment, and biosimilar product development. The first three would be set equal to the Prescription Drug User Fee Act (PDUFA) rate for each type of fee. The annual product development fee would be set at 10% of the PDUFA application fee for the respective year.²

Drug Shortages

Drug shortages have risen to unprecedented levels, more than tripling since 2005. These shortages adversely affect all segments of the healthcare system, including delaying, and forcing

¹ Please see the following for additional information:
<http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm282513.htm>

² For additional information on this user fee, please see the following information:
<http://www.fda.gov/ForIndustry/UserFees/ucm268124.htm>

changes to, treatment. These delays and changes in treatment have hurt patients across the country.

This hearing will build on the Subcommittee hearing held on September 23, 2011, entitled “Examining the Increase in Drug Shortages.” During the September 23 hearing, the Subcommittee examined the causes and effects of drug shortages in the United States health care system and received input on how to resolve this growing problem. The Subcommittee heard testimony from the following experts: Dr. Howard K. Koh, Assistant Secretary for Health, U.S. Department of Health and Human Services; Jonathan M. Kafer, Teva Health Systems; John Gray, Healthcare Distribution Management Association; Kevin J. Colgan on behalf of the American Society of Health-System Pharmacists; Mike Alkire, Premier, Inc.; Dr. W. Charles Penley on behalf of the American Society of Clinical Oncology; Richard Paoletti, Lancaster General Health; and Dr. Robert S. DiPaola, Cancer Institute of New Jersey, Robert Wood Johnson Medical School.

III. CONCLUSION

Should you have any questions regarding the hearing, please contact Clay Alspach or Ryan Long at (202) 225-2927.