



THE COMMITTEE ON ENERGY AND COMMERCE

INTERNAL MEMORANDUM

March 5, 2012

To: Members and Staff, Subcommittee on Health

From: Majority Staff

Re: "FDA User Fees 2012: Hearing on Issues Related to Accelerated Approval, Medical Gas, Antibiotic Development and Downstream Pharmaceutical Supply Chain"

On Thursday, March 8, 2012, at 10:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled "FDA User Fees 2012: Hearing on Issues Related to Accelerated Approval, Medical Gas, Antibiotic Development and Downstream Pharmaceutical Supply Chain." The following provides background on the hearing.

I. WITNESSES

Panel I

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Panel II

John Maraganore, PhD.
Chief Executive Officer
Alnylam Pharmaceuticals

Jeff Allen, PhD.
Executive Director
Friends of Cancer Research

Barry Eisenstein, MD, FACP, FIDSA, FAAM
Senior Vice President
Scientific Affairs
Cubist Pharmaceuticals

John H. Powers, MD, FACP, FIDSA
Assistant Clinical Professor of Medicine
George Washington University School of Medicine

Michael D. Walsh
President
LifeGas
On behalf of:
Compressed Gas Association

Panel III

Shawn Brown
Vice President
State Government Affairs
Generic Pharmaceutical Association

Elizabeth A. Gallenagh, JD
Vice President
Government Affairs
General Counsel
Healthcare Distribution Management Association

Tim Davis, Pharm.D.
Beaver Health Mart Pharmacy
On behalf of:
National Community Pharmacists Association

Allan Coukell
Director
Medical Programs
Pew Health Group, The Pew Charitable Trusts

II. BACKGROUND

The hearing witnesses will testify on the following issues: FDA's accelerated approval process, medical gas regulation, antibiotic development, and the downstream pharmaceutical supply chain.

Accelerated Approval

FDA permits "accelerated approval" of drugs that offer meaningful therapeutic benefit over existing treatments for serious or life threatening diseases. Accelerated approval includes two different approval pathways. First, FDA will approve drugs based on a drug's impact on a surrogate endpoint reasonably likely to suggest clinical benefit. Second, FDA will approve drugs under prescribing or dispensing restrictions in order to address remaining safety issues.

FDA may condition approval under the accelerated approval pathway upon the completion of post-marketing studies. The pathway appears to have been successful for AIDS

and cancer drugs, but some believe that it has not been sufficiently utilized for other diseases, particularly rare diseases.

Medical Gas

The hearing also will include testimony on FDA's regulation of medical gas. The term "medical gas" includes the following gases: oxygen, nitrogen, nitrous oxide, carbon dioxide, helium and medical air. According to the Compressed Gas Association, the aforementioned gases comprise 99 percent of the medical gas prescriptions in the United States. Some believe that, because medical gases involve unique manufacturing and distribution processes, they do not fit well into FDA's current regulations for drugs, and, therefore, FDA may need to develop new, targeted regulations for medical gas.

Antibiotic Development

Antibiotics have been used in medicine since the discovery of penicillin, and they have yielded tremendous benefits for public health. Because most bacteria and other microbes multiply rapidly, they quickly evolve and develop resistance to antibiotics. This antibiotic resistance poses a severe threat to public health. Unfortunately, the nation's ability to counter this threat is limited because the antibiotics pipeline is almost bare. During the hearing, the Subcommittee will hear testimony on whether financial incentives and regulatory improvements at FDA would spur antibiotic development and thus improve the state of the antibiotics pipeline.

Downstream Pharmaceutical Supply Chain

The hearing also will include testimony on securing the downstream pharmaceutical supply chain, which includes manufacturers, distributors and pharmacies. In order to ensure that counterfeit or stolen drugs do not enter the supply chain and harm patients, States have passed laws that require, or will require, those involved in the downstream supply chain to keep pedigrees or transaction histories of drugs. Some believe these differing State requirements should be replaced with a uniform, practical and cost-efficient national policy.

III. CONCLUSION

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