U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

September 11, 2017

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "Modernizing FDA's Regulation of Over-the-Counter Drugs"

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Wednesday, September 13, 2017, at 10:15 a.m. in 2322 Rayburn House Office Building. The hearing is entitled "Modernizing FDA's Regulation of Over-the-Counter Drugs." It will provide members an opportunity to better understand the current framework in place at the Food and Drug Administration (FDA) for regulating over-the-counter (OTC) drug products and to consider a bipartisan proposal to improve the OTC monograph process, one regulatory pathway used to bring such drugs to market.

II. WITNESSES

Panel I

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

Panel II

- Scott Melville, President and CEO, Consumer Health Products Association;
- Kirsten Moore, Project Director, Health Care Products, The Pew Charitable Trusts;
- Michael Werner, Partner, Holland and Knight, on behalf of the Public Access to SunScreens (PASS) Coalition;
- Bridgette Jones, Chair, American Academy of Pediatrics; and
- Gil Roth, President, Pharma and Biopharma Outsourcing Association.

III. BACKGROUND

An OTC (i.e., nonprescription) drug can be marketed if FDA approves a new drug application or if the drug conforms to a monograph, which is a set of standard specifications

(e.g., active ingredients, dosage strength, route of administration) established by FDA for each therapeutic category of product (e.g., antacids, cough/cold). If a specific product conforms to these specifications, FDA considers it to be generally recognized as safe and effective (GRASE) and it can be marketed without a product-specific application being approved by the agency.

FDA began evaluating twenty-six therapeutic categories of OTC drug products in 1972 and has yet to finalize monographs for each of them. Due in large part to the multi-phase public rulemaking process required even for changes to the monograph such as label warnings or new dosage forms, the current process is inefficient and does not enable product advancements to reach consumers quickly.

In 2016, FDA held a public meeting to gather stakeholder input on establishing a more flexible process funded by industry user fees. Based on negotiations between FDA and industry and informed by bipartisan, bicameral meetings over the past few months, Reps. Latta (R-OH), DeGette (D-CO), Guthrie (R-KY), Dingell (D-MI), Burgess (R-TX), and Green (D-TX) have developed a draft legislative proposal that would authorize this new and improved regulatory framework at FDA.[1]

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact John Stone of the Committee staff at (202) 225-2927.

[1] http://docs.house.gov/meetings/IF/IF14/20170913/106396/BILLS-115pih-OTCMonograph.pdf