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

May 16, 2017

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Subcommittee Markup of H.R. 1222, H.R. 2410, and H.R. ___

I. INTRODUCTION

The Subcommittee on Health will meet in open markup session on Thursday, May 18, 2017, at 10:00 a.m., in 2123 Rayburn House Office Building to consider the following:

- H.R. 1222, Congenital Heart Futures Reauthorization Act of 2017;
- H.R. 2410, Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2017; and,
- H.R. ____, FDA Reauthorization Act of 2017.

In keeping with Chairman Walden's announced policy, Members must submit any amendments they may have two hours before they are offered during this markup. Members may submit amendments by email to peter.kielty@mail.house.gov. Any information with respect to an amendment's parliamentary standing (e.g., its germaneness) should be submitted at this time as well.

II. LEGISLATION

A. H.R. 1222, Congenital Heart Futures Reauthorization Act of 2017

The Subcommittee plans to consider an amendment in the nature of the substitute (AINS) to H.R. 1222, introduced by Rep. Gus Bilirakis. Congenital heart disease (CHD) is the most common birth defect and the leading cause of infant mortality. Adults and children with CHD require specialized cardiac care and face a lifelong risk of permanent disability and premature death. H.R. 1222 enhances research and surveillance at the Centers for Disease Control and Prevention, awards grants to further study CHD, and directs the National Institutes of Health to report on their ongoing research efforts in this space. The AINS has changes that are technical in nature. The legislation reauthorizes appropriations of $4 million a year for FY2018-FY2022.

B. H.R. 2410, Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2017

Sickle Cell Disease (SCD) is an inherited blood disorder that primarily affects one in five hundred African-American births. As an inherited blood disorder, SCD causes blockages of small blood vessels leading to various health complications. H.R. 2410, introduced by Rep. Davis (D-IL) and Rep. Burgess (R-TX), reauthorizes the sickle cell disease prevention and treatment demonstration program. The legislation increases research, surveillance, prevention, and treatment for SCD, and emphasizes collaboration with community-based entities focusing on SCD. The legislation reauthorizes appropriations of $4.455 million a year for FY2018-FY2022.

C. H.R. ____, FDA Reauthorization Act of 2017

Introduced by Chairman Walden (R-OR), Ranking Member Pallone (D-NJ), Health Subcommittee Chairman Burgess (R-TX), and Health Subcommittee Ranking Member Green (D-TX), this bill updates and reauthorizes the FDA user fee programs for prescription drugs (Title I), medical devices (Title II), generic drugs (Title III) and biosimilar biological products (Title IV).

Title I: Prescription Drug User Fee Act (PDUFA VI) - Enhances patient-focused drug development, supports biomarker development and qualification, dedicates staff to assist in the development and review of rare disease drugs, sets clear timelines and improves guidance for drug and device combination products, and evaluates ways to modernize the clinical trial process.

Title II: Medical Device User Fee Amendments (MDUFA IV) - Enhances the patient voice in the device development process, supports the collection of real world evidence on the safety and effectiveness of devices, and improves the review process for "de novo" devices—low- to moderate-risk devices that are the first of their kind.

Title III: Generic Drug User Fee Amendments (GDUFA II) - Improves the fee structure to support small businesses, provides goal dates for all outstanding generic applications, and establishes priority review timelines.

Title IV: Biosimilar User Fee Act (BsUFA II) - Continues to build the biosimilars program, and supports guidance for product developers.

Title V-VI: Reauthorizes certain provisions of the Federal Food, Drug and Cosmetic Act (FFDCA) and provides technical changes to the 21st Century Cures Act.

III. STAFF CONTACTS

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