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

January 12, 2018

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Subcommittee Markup

I. INTRODUCTION

The Subcommittee on Health will meet in open markup session on January 17, 2018, at 10:00 a.m. in 2123 Rayburn House Office Building to consider the following:

- H.R. 1876, Good Samaritan Health Professionals Act of 2017;
- H.R. 2026, Pharmaceutical Information Exchange Act; and
- H.R. __, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018.

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. EXPLANATION OF LEGISLATION

A. H.R. 1876, Good Samaritan Health Professionals Act of 2017

The Subcommittee held a legislative hearing on May 17, 2017, to review H.R. 1876, the Good Samaritan Health Professionals Act of 2017. This legislation, introduced by Rep. Marsha Blackburn (R-TN), would shield a health care professional from liability for harm caused by any act or omission if: (1) the professional is serving as a volunteer in response to a disaster and (2) the act or omission occurs during the period of the disaster, in the professional's capacity as a volunteer, and in a good faith belief that the individual being treated is in need of health care services. In 1997, Congress recognized that it was in interest of the Federal Government to encourage the contributions of volunteers through the passage of the Volunteer Protection Act (VPA, Public Law 105-19). The VPA provides civil liability protections to volunteers for acts of ordinary negligence that were committed while volunteering for a qualified nonprofit or governmental organization.[4] The VPA protects those offering medical services in emergencies to the extent that it encourages medical providers to join nonprofits or government entities.

[4] Health Resources and Services Administration. (2006). *Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) - Legal and Regulatory Issues* (p. 44). Department of Health and Human Services. http://www.publichealthlaw.net/Research/PDF/ESAR%20VHP%20Report.pdf

However, health practitioners who volunteer on their own are not protected from liability under the VPA.

B. H.R. 2026, Pharmaceutical Information Exchange Act

The Subcommittee held a legislative hearing on July 10, 2017, to examine medical product manufacturer communications. During the hearing, witnesses spoke to the importance of communication between manufacturers and entities involved in the selection of drugs or medical devices for coverage, reimbursement, or health care management decisions, such as public and private payors, and formulary or technology review committees.

H.R. 2026 would clarify how drug and medical device companies can share health care economic or scientific information with the previously described entities if it is based on competent and reliable scientific evidence and relates to an investigational use of a drug or device.

In order for information relating to an investigational use of an approved or cleared product to be provided under this statutory provision, the study or studies the manufacturer anticipates could be sufficient to support the approval of the new use must have been conducted; the manufacturer must intend that a supplemental application will be submitted to Food and Drug Administration (FDA) for such use; and the information must include a conspicuous and prominent statement describing any material differences between the information provided and the FDA-approved product labeling.

For information relating to an unapproved drug or device to be provided under this authority, such information must be based on competent, reliable scientific evidence, generated through clinical and pre-clinical data that will be relied on by the developer for FDA approval, clearance, or licensing.

C. H.R. __, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018

The Subcommittee held a legislative hearing on September 13, 2017, to examine the regulation of over-the-counter (OTC) drug products, and to consider this bipartisan proposal to improve the process by which these products are made available to consumers.

The legislation would amend the Federal Food, Drug, and Cosmetic Act to reform the OTC monograph framework. To help transition between OTC frameworks, the legislation includes, by reference, the OTC Review Final Monographs and Tentative Final Monographs (TFM) in the statute. To modernize and streamline the process, the legislation would create a system for future changes to Monographs through an administrative order procedure with the opportunity for development meetings or other consultations, submission of comments on proposed orders, and dispute resolution procedures. To enhance public health, the legislation would create a mechanism for faster safety label changes, and establish a pathway for innovations under Monographs. To support these reforms, the legislation would authorize a new user fee program subject to agreement between FDA and manufacturers on performance goals, reporting milestones, and financial specifications.

III. STAFF CONTACTS

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