GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

January 16, 2018

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee Markup of H.R. 1876, H.R. 2026, and H.R. __, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018

On **Wednesday, January 17, 2018, at 10:00 a.m. in room 2123 of the Rayburn House Office Building**, the Subcommittee on Health will hold a markup of three bills: 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.

I. H.R. 1876, GOOD SAMARITAN HEALTH PROFESSIONALS ACT OF 2017

H.R. 1876, introduced by Rep. Blackburn (R-TN) and Rep. D. Scott (D-GA), would limit the civil liability of healthcare professionals who volunteer to provide health care services in response to a disaster. Healthcare professionals cannot be held civilly liable for harm arising out of their acts or omissions, if: 1) the professional is serving as a volunteer for purposes of responding to a disaster; and 2) the act or omission occurs during the period of the disaster, in the healthcare professional's capacity as a volunteer, and in their good faith belief that the individual being treated is in need of health care services. Protection from liability does not apply where there is willful or criminal misconduct, gross negligence, reckless misconduct, a conscious, flagrant indifference to the rights or safety of the individual harmed, or if the health care professional rendered the health care services under the influence of drugs or alcohol. The bill would also preempt state laws, except those providing greater protection from liability.

The Health Subcommittee held a hearing on this legislation on May 17, 2017.[1]

[1] Memorandum from Democratic Staff to Democratic Members of the House Committee on Energy and Commerce, Subcommittee on Health, Hearing on Examining Initiatives to Advance

II. H.R. 2026, PHARMACEUTICAL INFORMATION EXCHANGE ACT

A. Background

It is common for a medical product to be used in a way that is not consistent with its labeling, such as to treat another disease, or for a population not studied for purposes of approval. It is estimated that one in five prescriptions written are for off-label uses; and, such uses may even be recommended in certain clinical practice guidelines.[2] Off-label uses, however, can still have serious public health implications.

Under current law, drug and medical device manufacturers can disseminate certain medical and scientific information regarding unapproved uses of approved drugs and approved or cleared medical devices to health care professionals and entities. Such information must be truthful and non-misleading, and may include scientific and medical reference texts, clinical practice guidelines, and journal articles. If such information is disseminated in accordance with FDA guidance,[3] then the agency will not conclude that the manufacturer intends for the product to be used for an unapproved use. Manufacturers can also respond to unsolicited requests from health care professionals about unapproved uses so long as that response is truthful, balanced, non-misleading, and non-promotional, and relates to a specific request.[4] The 21st Century Cures Act further expanded the types of information manufacturers can share with payers and formulary committees regarding approved uses, to include health care economic data. FDA has sought to reexamine and clarify its policies related to off-label communication through public meetings and guidances.

The Health Subcommittee held a hearing on this issue on July 12, 2017.[5]

Public Health (May 17, 2017) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-examining-initiatives-to-advance-public-health-subcommittee).

[2] Department of Health and Human Services, Agency for Healthcare Research and Quality, *Off-Label Drugs: What You Need to Know* (http://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html).

[3] Food and Drug Administration (FDA), *Guidance for Industry Distributing Scientific and Medical Publications on Unapproved New Uses —Recommended Practices, Revised Draft Guidance* (Feb. 2014) (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf).

[4] FDA, *Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, Draft Guidance* (Dec. 2011) (https://www.fda.gov/downloads/drugs/guidances/ucm285145.pdf).

[5] Memorandum from Democratic Staff to Democratic Members of the House Committee on Energy and Commerce, Subcommittee on Health, Hearing on Examining Medical Product Manufacturer Communications (July 12, 2017) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-examining-medical-product-manufacturer-communications).

B. Legislation

H.R. 2026, introduced by Rep. Guthrie (R-KY) on April 6, 2017, would allow drug and medical device manufacturers to share health care economic or scientific information with payors, formulary committees, and other similar entities about unapproved drugs and unapproved uses of drugs. There is no requirement that such information be truthful and non-misleading, and FDA would be prohibited from considering such action false or misleading, misbranding, or a violation of 505 of the Federal Food, Drug, and Cosmetic Act, or 351 of the Public Health Service Act. In order for information relating to an unapproved use of an approved drug to be provided, the manufacturer must have submitted a supplemental application or completed studies to support the supplemental application. The legislation does not require that the manufacturer provide further information or disclosures regarding the unapproved use of the drug.

III. H.R. _, OVER-THE-COUNTER MONOGRAPH SAFETY, INNOVATION, AND REFORM ACT OF 2017

A. Background

Over-the-counter (OTC) drugs are drug products that have been found to be safe and effective for use without the supervision of a physician, and can be purchased without a prescription.[6] Examples of OTC drugs include: antacids, antiperspirants, cough and cold products, ophthalmic products, dandruff products, and analgesics.[7] OTC drugs may be approved under a new drug application (NDA) similar to new prescription drugs, or they may be legally marketed without an application through conformance with an OTC drug monograph.

Today, FDA has an estimated 88 rulemakings in 26 therapeutic categories covering over 100,000 OTC drug products, making it one of the largest and most complex regulatory programs at the agency.[8] However, unlike other regulated product areas, there are no user fees associated with monograph products. The agency employs 30 full-time employees (FTEs) for the OTC monograph program, and in 2016, the program had a budget of $8.23 million. Due in large part to the small size of the OTC program, two areas in particular are consuming more than the majority of the FDA's monograph program's resources: namely, the current Sunscreen Innovation Act mandates and the recent consent decree on antiseptic rulemaking. Consequently, there is little capacity or financial resources for work associated with OTC monographs.[9] Further exacerbating these deficiencies and problems is the lengthy and very burdensome monograph

---

[6] FDA, *What are over-the-counter (OTC) drugs and how are they approved?* (https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194951.htm).

[7] FDA, *Overview of the Over-the-Counter Drug Monograph Process* (June 10, 2016) (https://www.fda.gov/downloads/Drugs/NewsEvents/UCM506382.pdf).

[8] *Id.*

[9] FDA, *The Over-the-Counter Monograph, Presented by Theresa Michele, MD, Director, CDER, DNDP* (2017).

process, which currently requires a rule-making process, and can take many years to finalize or change the monograph.

On June 7, 2017, the U.S. Department of Health and Human Services (HHS) transmitted to Congress recommendations to inform the development of an OTC Monograph User Fee Program. FDA has estimated that $22 million in fees collected under the OTC Monograph User Fee Program would be collected in FY 2018, and would gradually increase to $34 million in FY 2022.[10]

The Health Subcommittee held a hearing on this issue on September 13, 2017.[11]

B. Legislation

On September 11, 2017, Reps. Burgess (R-TX), Green (D-TX), Latta (R-OH), DeGette (D-CO), Guthrie (R-KY), and Dingell (D-MI) released the "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2017" discussion draft.

This discussion draft authorizes the OTC Monograph User Fee Program and includes a number of reforms to the current monograph process, including: transitioning OTC monographs from a rulemaking process to an administrative order procedure; expediting administrative order procedures for OTC monograph drugs that pose an imminent hazard to public health or are associated with serious adverse events requiring safety label changes; outlining a procedure for minor changes to an administrative order for an OTC monograph drug; providing two years of exclusivity for certain OTC innovative changes; and clarifying how sunscreens would be reviewed moving forward.

[10] Letter from Thomas E. Price, Secretary of Health and Human Services to Congressman Frank Pallone, Jr. and Congressman Greg Walden (June 7, 2017).

[11] Memorandum from Democratic Staff to Democratic Members of the House Committee on Energy and Commerce, Subcommittee on Health, Hearing on Modernizing FDA's Regulation of Over-the-Counter Drugs (Sept. 13, 2017) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-modernizing-fda-s-regulation-of-over-the-counter-drugs).