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Beyond COVID: House Committee Advances Several FDA-Related Bills

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On Wednesday, July 15, the House Energy and Commerce (E&C) Committee advanced several bills to the House floor that demonstrate continued interest in health policy matters other than the COVID-19 pandemic.

The Fairness in Orphan Drug Exclusivity Act (H.R. 4712) introduced by Reps. Madeleine Dean (D-PA), Marc Veasey (D-TX), Buddy Carter (R-GA), and David McKinley (R-WV), addresses a loophole in the current orphan drug regulations. Orphan drugs are medications intended to treat rare diseases or drugs for which the manufacturer cannot expect to recover the costs of developing or marketing. Critics have argued that the Orphan Drug Act has a loophole that subverts competition, exemplified by the case of buprenorphine, a drug used to treat opioid addiction. In 2016, the Food and Drug Administration (FDA) granted drug manufacturer Invidior an additional seven years of market exclusivity for a new formulation of buprenorphine, blocking generic and competitors' formulations of the drug from entering the market. The FDA reversed its decision following public outcry in November 2019, but this bill aims to close the loophole and prevent similar situations in the future. It requires manufacturers to demonstrate that there is no reasonable expectation that they will recoup the cost of developing the drug within 12 years.

Senators Bill Cassidy (R-LA), Jeanne Shaheen (D-NH), and Tammy Baldwin (D-WI) introduced a companion bill to this legislation in February (which we blogged about here). The House E&C Committee adopted an amendment taking into consideration the sales of all drugs made by the manufacturer under the same orphan drug designation, which resolved some differences with the Senate bill. We are bullish on this becoming law now that the House and Senate are aligned. End-of-2020 health legislation or 21st Century Cures 2.0 could be a potential vehicle.

The E&C Committee also took legislative action to spur continuous pharmaceutical manufacturing by advancing the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act (H.R. 4866), introduced by Chair Frank Pallone (D-NJ) and Rep. Brett Guthrie (R-KY). This bill would direct the FDA to designate National Centers of Excellence in Continuous Manufacturing (NCEs), which would be higher education institutions that provide research, data, and leadership on continuous manufacturing. To qualify as an NCE, an institution would need to have physical and technical capacity for research and development of continuous manufacturing, proven capacity to design and demonstrate new, highly effective technology for use in continuous manufacturing, and the potential

to train a future workforce for research on and implementation of continuous manufacturing, among other requirements. The FDA would also be required to work with NCEs to create a national framework for continuous pharmaceutical manufacturing. The bill authorizes the appropriation of $80 million per year for NCEs for fiscal years 2021 to 2025. This bill complements other legislative and regulatory efforts to increase and improve US-based manufacturing, limit drug shortages, and make drug manufacturing more efficient.

The Committee also advanced these other bills related to FDA-regulated products:

- The Making Objective Drug Evidence Revision for New (MODERN) Labeling Act (H.R. 5668) gives the FDA authority to require drug companies to update their generic drug labeling.
- The Safeguarding Therapeutics Act (H.R. 5663) gives the FDA the power to seize and destroy counterfeit medical devices valued at an amount less than $2500 that are refused admission at the border.
- The Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2019 (H.R. 2117) requires the CDC to expand its collection of allergen information, amends the Food, Drug, and Cosmetic Act to include sesame as a major allergen, and grants the FDA the authority to add other foods to the list of major allergens.

These actions show at least one congressional committee is committed to continuing to work on health policy matters not directly related to the COVID-19 pandemic. This is important because COVID-19 may be in the picture for many more months or years and business as usual continues in many sectors, particularly those regulated by FDA. Despite its long to-do list, we remain optimistic and buoyed by the E&C Committee's recent actions that Congress will address other longstanding issues soon—such as medical device servicing—instead of waiting until the upcoming FDA user fee reauthorization cycle.

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