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Return of the UFA Riders: Congress Enacts Significant Changes to FDA's Drug, Device, and Cosmetic Authorities

Updated January 4, 2023
Food, Drugs, and Devices

On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act, 2023. In addition to funding the federal government through September 30, 2023, Division FF, Title III of the law, referred to as the Food and Drug Omnibus Reform Act of 2022 (FDORA),contains various policy riders that will reshape FDA's authority over drugs, medical devices, and cosmetics. These legislative changes were originally considered by the Senate HELP and House E&C Committees as they worked on reauthorization of FDA's prescription drug, medical device, generic drug, and biosimilar user fee programs, but committee leadership did not reach an agreement on the policy riders when Congress reauthorized those medical product user fee programs in September 2022.

A year-end deal on FDA policy is unusual, but has happened previously (e.g., the 21st Century Cures Act of 2016). Notably, the year-end deal includes a significant overhaul to FDA's cosmetics oversight—one of the so-called "super riders" that the Senate had advanced during its markup of the user fee reauthorization in June 2022. Nevertheless, Congress did not reach agreement around the other "super riders" as part of the year-end deal, so reforms related to diagnostics (i.e., the VALID Act) and dietary supplements will not advance at this time. Similarly, other proposals previously under consideration, such as amendments to address the *Catalyst Pharms., Inc. v. Becerra* case on orphan-drug exclusivity, are not part of H.R. 2617. We summarize the key FDA policy riders below.

Drug Reforms

Subtitles A, B, and F of FDORA implement the following key reforms to FDA's drug authorities:

Accelerated Approval: Section 3210 will amend section 506 of the Federal Food, Drug, and Cosmetic Act (FDCA), which authorizes FDA to grant accelerated approval drugs for serious or life-threatening diseases based on evidence that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or an intermediate clinical endpoint. FDORA requires that FDA, by the time of approval, specify conditions for any required postapproval study or studies that the sponsor must conduct, which may include enrollment targets, a study protocol, milestones, and a target completion date. The law authorizes FDA to require that such studies be underway before approval or within a specified time period after approval. FDA must post a rationale for any decision not to require a postapproval study in connection with an accelerated approval. FDORA will also streamline procedures for FDA to withdraw a drug approved under accelerated approval from the market by replacing the right to an informal hearing with an opportunity for an in-person meeting with the Commissioner or designee, a

written appeals process, a public docket and requirement for FDA to summarize and respond to public comments, and an opportunity for an advisory committee meeting if requested by the sponsor and no meeting has been convened previously on the topic. The law requires sponsors to report on postapproval study progress every 180 days. Section 3210 establishes new prohibited acts under section 301 of the FDCA for failure to conduct postapproval studies with due diligence or timely submit such reports. Section 3210 requires FDA to establish an intra-agency Accelerated Approval Council to address accelerated approval policy. The law also omits a parenthetical that had been in prior bills and referenced the potential for a sponsor to use real world evidence (RWE) to augment or support a postapproval study or studies. We understand that committee staff removed this parenthetical because of the risk that it could be misinterpreted as somehow limiting FDA to considering RWE only in situations where RWE is "supporting" or "augmenting" a postapproval study.

Drug vs. Device Determinations (*Genus*): FDORA responds to the D.C. Circuit's decision in *Genus Med. Techs. LLC v. United States Food & Drug Admin.*, 994 F.3d 631 (D.C. Cir. 2021), in which the court found that, if a product meets the statutory definition of "device," FDA lacks discretion to regulate that product as a drug. The law deems contrast agents and radioactive drugs, as well as OTC monograph drugs, to be drugs rather than devices.

Clinical Trial Diversity: FDORA requires sponsors to submit "diversity action plans" for most phase 3 or other "pivotal" studies of drugs that commence more than 180 days after publication of the final guidance on diversity action plans described below. The plan must outline the sponsor's goals for enrollment in the study, the sponsor's rationale for such goals, and an explanation of how the sponsor intends to meet such goals. FDA may waive the plan requirement due to disease prevalence, impracticality, or a public health emergency. FDA must issue or update guidance on the format and content of these diversity action plans "pertaining to" the sponsor's enrollment goals disaggregated by demographic subgroups including age group, sex, race, ethnicity, and, if appropriate, geographic location and socioeconomic status and an explanation of mechanisms the sponsor will use to enhance diversity, e.g., inclusion/exclusion criteria and diversity training for study personnel. The guidance also should address how sponsors "may" include information on their progress in meeting goals in regular reports otherwise required by FDA. The law will require FDA to hold public workshops on enhancing clinical trial diversity, to issue annual summary reports on its progress in increasing clinical trial diversity, to hold a public meeting on clinical trial flexibilities introduced during the COVID-19 pandemic, and to issue or revise guidance on decentralized clinical trials, the use of digital health technologies in clinical trials, and the use of seamless, concurrent, and other innovative clinical trial designs.

Real World Data and Real World Evidence (RWD/E): FDORA contains multiple provisions that could advance FDA's ongoing efforts to facilitate the use of RWD/E. For example, the law requires FDA to issue guidance on considerations for the use of RWD/E to support regulatory decision making, including with respect to RWD/E obtained as a result of the use of drugs and devices authorized for emergency use. The law also requires FDA to conduct public workshops related to development of endpoints for rare diseases, which may include discussions about the use of RWD/E to support the validation of efficacy endpoints, and requires the US Government Accountability Office to submit a report to Congress on FDA's policies, practices, and programs with respect to review of applications for drugs and biologics intended to treat rare diseases and conditions, including consideration of patient-experience data.

PIE Act: Section 3630 of the law essentially codifies in statute the provisions of FDA's existing Guidance for Industry on Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities (June 2018) that permit manufacturers to provide information to payors and similar entities on unapproved products and unapproved uses of approved or cleared products in order to inform payor planning and coverage and reimbursement decisions prior to FDA approval or clearance.

Other Reauthorizations: The law also reauthorizes funding for various FDA drug programs whose funding had been set to lapse in December 2022, including, for example, the Best Pharmaceuticals for Children Program and the Critical Path Public-Private Partnership.

Medical Device

Subtitles A, C, and F of FDORA will introduce the following key reforms to FDA's device authorities:

Ensuring Cybersecurity of Devices: The law imposes new requirements for "cyber devices," which are devices that (A) include software, including software as or in a device; (B) have the ability to connect to the internet; and (C) contain any such technological characteristics that could be vulnerable to cybersecurity threats. Under new section 524B of the FDCA, starting 90 days after the effective date of the Act, premarket submissions for such devices must include plans to address postmarket cybersecurity vulnerabilities and exploits, information regarding processes to ensure devices are cybersecure, and a software bill of materials, as well as other information as FDA may require through regulation. The law also requires FDA to update a related guidance document within two years and periodically update public information on its website regarding improving cybersecurity of devices.

Banned Devices (*Judge Rotenberg Educational Center*): The law amends FDA's authority to ban medical devices under section 516 of the FDCA to overcome the holding of a recent court decision (*Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 394 (D.C. Cir. 2021)) that held FDA could not ban individual intended uses of an otherwise legally marketed device. As clarified in the law, FDA may ban individual intended uses of a device.

Predetermined Change Control Plans: The law allows, under new section 515C of the FDCA, that predetermined change control plans may be approved in premarket applications (PMAs) and supplements or cleared under 510(k) premarket notifications. If a predetermined change control plan is approved or cleared, then a supplemental PMA or a new 510(k) is not required for a change to a device that is consistent with such approved or cleared plan.

Small Business Fee Waiver: The law allows "small businesses" to apply for a waiver of the initial and annual establishment registration fees. A "small business" is defined as an entity that reported $1 million or less of gross receipts or sales in its most recent Federal income tax return for a taxable year. Starting October 1, 2024, FDA may grant a waiver of the registration fee if they find the establishment is a small business and paying the fee for such year represents a financial hardship to the establishment.

Clinical Trial Diversity: The diversity action plan requirements noted above extend to medical device investigations, unless those investigations are exempt from the investigational device exemption (IDE) requirements at 21 CFR Part 812. For significant risk device studies (for which

an IDE application is required), sponsors are required to submit diversity action plans with the IDE application. For non-significant risk device studies (for which an IDE application is considered approved, but not submitted), sponsors are still required to develop a diversity action plan, but instead of being submitted with an IDE application, the plan must be submitted in the marketing application for the device (whether a 510(k) premarket notification, de novo classification request, or premarket approval application).

PIE Act: As noted above, the PIE Act essentially codifies in statute the provisions of FDA's existing Guidance for Industry on Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities (June 2018) that permit manufacturers to provide information to payors and similar entities on unapproved products and unapproved uses of approved or cleared products in order to inform payor planning and coverage and reimbursement decisions prior to FDA approval or clearance. It also extends to medical devices the existing statutory provisions on the communication of healthcare economic information to payors and similar entities related to approved or cleared uses of the device. These provisions on the communication of healthcare economic information have existed for drugs since the enactment of the FDA Modernization Act of 1997, as amended by the 21st Century Cures Act of 2016, and provide an important safe harbor from FDA's traditional rules for advertising and promotion for eligible communications to payors and similar entities.

Other Reauthorizations: The law also reauthorizes various FDA device provisions that had been set to expire in December 2022, including, for example, the Humanitarian Device Exemption incentive, the third-party inspection and 510(k) review programs, and funding for the Pediatric Device Consortia Program, which is intended to help foster and guide the advancement of medical devices for pediatric patients.

Cosmetics Reforms

Subtitle E of FDORA, known as the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), fundamentally overhauls FDA's oversight of cosmetics. MoCRA adds significant new authorities to chapter VI of the FDCA—the first major change to FDA's cosmetics authorities since President Franklin D. Roosevelt signed the FDCA into law in 1938. MoCRA brings FDA's cosmetics regulation more in line with other areas that FDA regulates, notably over-the-counter (OTC) drugs, which often overlaps with the cosmetics category. We have issued a more detailed alert about MoCRA here.

What comes next?

Covington will host two webinars in January 2023 to examine the FDA-related provisions from this year-end legislation.

Session 1: Return of the UFA Riders: Changes to FDA Drug and Device Authorities in the Consolidated Appropriations Act, 2023

During this webinar, experts from PhRMA and Covington's Food, Drug and Device practice group will discuss these recent FDA reforms and assess key implications for industry stakeholders. The webinar also will cover the policies that did not make it into the year-end legislation and what that means for FDA.

Date: January 19, 2023
Time: 12 pm Eastern
Register Here

Session 2: Unpacking the Modernization of Cosmetics Regulation Act of 2022

Co-Hosted with the Personal Care Products Council (PCPC)

During this webinar, experts from the Personal Care Products Council (PCPC) and Covington's FDA regulatory team will discuss FDA cosmetics regulatory reform and assess key implications for cosmetics industry stakeholders.

Date: January 25, 2023
Time: 12 pm Eastern
Register Here

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices Practice:

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