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New FDA Reform Legislation: Congress Gifts a "FDORA" for the Holidays

On December 29, 2022, President Biden signed the Consolidated Appropriations Act, 2023 (H.R. 2617), an omnibus appropriations bill to fund the U.S. government for fiscal year 2023. This 4,000-plus-page bill also contains important reforms relevant to the Food and Drug Administration ("FDA"), including the Food and Drug Omnibus Reform Act of 2022 ("FDORA") and the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (the "PREVENT Pandemics Act").

FDORA (pronounced, as we understand it, like the headwear most famously donned by Indiana Jones), in particular, is home to many provisions that were originally expected to be enacted earlier this year as part of FDA's user fee reauthorization process. Although Congress had historically used the user fee reauthorization legislation as a vehicle for attaching various FDA-related policy riders and amendments to the Federal Food, Drug, and Cosmetic Act (the "FDCA"), Congress was unable to reach agreement on such riders this year. This resulted in the September 2022 passage of a "clean" user fee reauthorization, as Ropes & Gray previously summarized. Many, but not all, of the policy riders left out of the user fee reauthorization legislation are now included in the December 2022 omnibus bill.

Among the most notable provisions within FDORA and the PREVENT Pandemics Act are requirements to encourage clinical trial diversity, reforms to FDA's accelerated approval processes, a long-awaited modernization of the FDA regulatory regime for cosmetics, and enhanced FDA oversight of infant formulas. This Alert summarizes the key provisions that were included in the omnibus bill as well as the provisions that were left out once again.

Key Provisions of FDORA and the PREVENT Pandemics Act

Key reforms to FDA's authority and matters within FDA's jurisdiction include:

Reforms Relevant to Medical Products Generally

- **Clinical Trial Diversity.** Several FDORA provisions encourage changes that will lead to greater diversity in the populations participating in clinical studies. Sponsors are now required to submit to FDA "diversity action plans" for certain late-stage trials for drugs and devices, unless otherwise waived or excepted. FDA is tasked with updating guidance on diversity action plans for clinical studies and hosting public stakeholder workshops focused on enhancing clinical study diversity. Additionally, within one year, the agency is to, as applicable, issue or revise guidances on the appropriate use of decentralized clinical studies in the development of drugs and devices, how digital health technologies can be best used in clinical trials, and how seamless, concurrent, and other innovative clinical trial designs can support expedited drug application development and review. Ropes & Gray has analyzed these diversity-related reforms and their implications in more detail in a separate Alert.

- **Bioresearch Monitoring ("BIMO") Inspections.** FDORA clarifies FDA's authority to conduct BIMO inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to FDA as well as other persons holding study records or involved in the study process. FDA is directed to issue draft guidance on this additional inspection authority within 18 months.

- **Pre-Approval Communications with Payors.** FDORA features a provision permitting both drug and device manufacturers to share certain information with payors, formulary committees, and similar entities regarding

investigational products and investigational uses of approved products. This statutory amendment essentially codifies FDA's policy on pre-approval communications with payors that it had previously issued in a non-binding guidance document in 2018, as Ropes & Gray previously reported.

- **Extension of Permitted Health Care Economic Information ("HCEI") Communications to Devices.** Since 1997, the FDCA has permitted drug manufacturers to communicate HCEI with payors, formulary committees, and similar entities under certain conditions. FDORA expands the scope of this provision to include devices in addition to drugs. FDORA essentially codifies FDA's position from its 2018 guidance document on payor communications in which FDA stated that its recommendations on HCEI communications were also generally applicable to device companies.

- **Clarification for Registration of Foreign Drug and Device Establishments.** The PREVENT Pandemics Act clarifies that foreign drug and device manufacturing establishments are subject to registration and listing requirements even if a drug or device undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States. FDA is directed to update its registration regulations, as appropriate, within two years to reflect this amendment.

Specific Drug and Biologic Reforms

- **Accelerated Approval Reforms.** FDORA includes numerous reforms to FDA's accelerated approval process for drugs and biologics. FDORA enables FDA to require, as appropriate, a postapproval study to be underway prior to granting accelerated approval. FDORA also expands the expedited withdrawal procedures already available to FDA to allow the agency to use expedited procedures if a sponsor fails to conduct any required postapproval study of the product with due diligence, including with respect to "conditions specified by the Secretary." It remains to be seen whether or how FDA will leverage these expedited procedures going forward. FDORA also expands the list of prohibited acts in the FDCA to include the failure of a sponsor of a product approved under accelerated approval to conduct with due diligence any required postapproval study with respect to such product or to submit timely reports with respect to such product. New accelerated approval provisions also aim to increase transparency for drugs approved through the accelerated approval process. If FDA determines not to require a postapproval study, FDA must publish the rationale on its website. Sponsors are also required to submit periodic progress reports regarding the progress of any postapproval study every 180 days, and FDA must publish the sponsor's progress reports on its website.

- **Designation Program for Advanced Manufacturing Technologies.** FDORA establishes a new program by which manufacturers can request that FDA designate a manufacturing method for a drug, including a biologic, as an "advanced manufacturing technology." A method or combination of methods is eligible for such designation if it incorporates a novel technology, or uses an established technique or technology in a novel way, that will substantially improve the manufacturing process for a drug while maintaining equivalent or providing superior drug quality, including by reducing drug development time or increasing or maintaining the supply of a drug on the shortage list or a drug that is life-supporting, life-sustaining, or of critical importance. The benefit to manufacturers of the new program is that FDA is required to expedite the development and review of applications for drugs that are manufactured using a designated advanced manufacturing technology. FDA is required to hold a public meeting and to issue guidance regarding the goals and implementation of this new program.

- **Designation Program for Platform Technologies.** The PREVENT Pandemics Act includes a similar designation program for "platform technologies" that have the potential to increase efficiencies in drug development. A platform technology is eligible for designation by FDA if (1) it is incorporated in, or utilized by,

an approved drug or biologic; (2) preliminary evidence demonstrates that the platform technology has the potential to be used with more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. Applications for drugs or biologics that use or incorporate platform technologies "may" be eligible for certain expedited development or review actions. Sponsors of applications or emergency use authorizations will also be allowed under certain circumstances to leverage data related to designated platform technologies previously submitted to FDA.

- **Exclusivity, Interchangeability, and Therapeutic Equivalence Reforms.** FDORA contains provisions that address generic drug and biosimilar competition. FDORA modifies provisions related to licensure of biosimilar or interchangeable biological products to note that FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product. It also modifies a provision of the FDCA related to exclusivity for new qualified infectious disease products to make it clear that the five-year exclusivity extension period for new qualified infectious disease products does *not* apply to biological products. Finally, FDA is also now required to consider therapeutic equivalence determinations for new drug applications submitted under section 505(b)(2) of the FDCA either at the time of approval or up to 180 days post approval upon the request of the sponsor.

- **Reports of Marketing Status for Biologics.** FDORA extends the existing requirement to submit certain marketing status reports for drugs to now also include biologics. Specifically, manufacturers will be required to notify FDA 180 days prior to withdrawing a licensed biologic from the market, and for newly licensed biologics, manufacturers will have to notify FDA if the biologic will not be available for sale within 180 days after licensure. FDORA also requires manufacturers to file a one-time report on the marketing status of their licensed biologics.

- **Changes to Generic Drug Labeling While Awaiting Approval.** Historically, if a reference listed drug ("RLD") sponsor made a change to the labeling of its "branded" drug, the labeling of a corresponding generic drug would need to be updated before FDA would approve an abbreviated new drug application ("ANDA") for that generic drug. FDORA provides wiggle room for such changes to generic drug labeling to occur shortly after ANDA approval if the labeling of the RLD changes while the ANDA is awaiting approval, as long as the changes are not made to the "Warnings" section of the RLD labeling.

- **Classification of Certain Products as Drugs.** FDORA clarifies that any contrast agent, radioactive drug, or over-the-counter monograph drug is to be classified as a drug and not a device. This provision was enacted in response to *Genus Medical Technologies, LLC v. FDA*, 994 F.3d 631 (D.C. Cir. 2021) in which Genus, a manufacturer of the contrast agent barium sulfate, asserted that its product should be regulated as a device rather than a drug. The appeals court sided with Genus, determining that FDA violated the Administrative Procedure Act via the approach the agency used to determine that barium sulfate and other contrast agents could be regulated as drugs. This ultimately resulted in FDA announcing that certain products that had been regulated as drugs would be switched to being regulated as devices instead. FDORA now reverses course back to the pre-*Genus* status quo for these products.

Specific Medical Device Reforms

- **Cybersecurity Reforms.** Premarket submissions for devices that meet the definition of a "cyber device" must now include cybersecurity information, including a software bill of materials and a plan to address cybersecurity vulnerabilities. "Cyber device" is defined to mean a device that "(1) includes software validated, installed, or authorized by the sponsor as a device or in a device; (2) has the ability to connect to the internet; and (3) contains any such technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable

to cybersecurity threats." FDA may also identify devices or categories of devices that are exempt from the requirements. FDORA also amends the list of prohibited acts in the FDCA to include the failure to comply with the device cybersecurity requirements.

- **Device Facility Inspections**. FDORA grants FDA the authority to request medical device facility records "in advance, or in lieu of, inspections." The agency is also tasked with issuing guidance on this new authority within one year. FDA already had this records request authority for drug establishments and has regularly invoked it throughout the COVID-19 pandemic due to limitations on FDA's ability to conduct in-person inspections.

- **Device Bans for Specific Intended Uses.** The FDCA previously authorized FDA to ban a device intended for human use by regulation if FDA finds on the basis of all available data and information that such a device presents substantial deception or an unreasonable and substantial risk of illness or injury that cannot be corrected by labeling or a change in labeling. FDORA expands this authority to now allow FDA to ban specific intended uses. FDA historically has rarely exercised its authority to ban devices, but it remains to be seen how FDA will exercise its broader authority under FDORA.

- **Counterfeit Medical Devices.** Counterfeit medical devices (e.g., counterfeit masks, COVID-19 test kits, and other types of personal protective equipment) have posed a challenge during the COVID-19 pandemic, and the PREVENT Pandemics Act attempts to address this problem by expanding the scope of prohibited acts and penalties under the FDCA to include counterfeit acts for medical devices. Prohibited acts now include not only the act of counterfeiting itself but also knowingly making, selling, or dispensing, or holding for sale or dispensing, a counterfeit device.

- **Voluntary Notifications for Device Shortages.** The PREVENT Pandemics Act allows for voluntary notifications by manufacturers of certain devices (e.g., those that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery, or otherwise determined to be critical to the public health) regarding a permanent discontinuance in the manufacture of a device or interruption in the manufacture of a device that is likely to lead to a meaningful disruption in the supply of that device in the United States and the reasons for such discontinuance or interruption. If FDA concludes based upon such a voluntary notification that there is likely to be a shortage of the device, FDA will, as appropriate, prioritize and expedite inspections and marketing submission reviews for the device to help mitigate or prevent such shortage.

- **Miscellaneous Device Reforms.** Other device-specific reforms in FDORA include: a provision that would allow a *de novo* applicant for a home use COVID-19 test to streamline their marketing authorization submission; a requirement that if FDA relies on any data, analysis, or other information or findings provided by entities that have been funded in whole or in part by or otherwise performed under contract with FDA in regulatory decision-making with respect to devices, FDA shall request access to source data that underlies any data, analysis, or other findings upon which FDA seeks to rely and provide the source information to manufacturers in certain scenarios; and clarifications to requirements for certificates to foreign governments which certify that an exported device is a legally marketed device in the United States and is in compliance with the requirements of the FDCA.

Cosmetic Reforms

- **Modernization of Cosmetics Regulation.** Historically, FDA's regulation of cosmetics has been minimal relative to other categories of regulated products. This will change with the implementation of the Modernization of Cosmetics Regulation Act of 2022, a part of FDORA that strengthens FDA's oversight over cosmetics by introducing a comprehensive regulatory scheme that requires, among other things, facility registration and product and ingredient listing with FDA, serious adverse event reporting to FDA, compliance with certain

labeling requirements, and maintenance of records that adequately substantiate product safety. FDA is charged with issuing regulations to establish good manufacturing practices for cosmetics, as well as promulgating regulations on standardized testing for asbestos in talc-containing cosmetics. FDA is also granted mandatory recall authority for cosmetics. Most of the new requirements will take effect, at least as a statutory matter, one year after enactment.

Infant Formula Reforms

- **Enhanced Oversight of Infant Formula.** In direct response to the 2022 U.S. infant formula crisis, FDORA establishes within FDA's Center for Food Safety and Applied Nutrition a new Office of Critical Foods to oversee, coordinate, and facilitate activities related to infant formulas and certain medical foods. FDORA also shortens the window of time relating to the premarket submission requirement for new infant formulas from 90 to 30 days in periods of shortage, requires manufacturers to notify FDA of product discontinuance or supply interruption within five business days, and relaxes certain foreign import rules. It requires FDA to develop, with input from the Department of Agriculture and other relevant departments and agencies, a national strategy on infant formula to increase supply chain resiliency, ensure product access, and protect against future contamination and other causes of shortages. It also requires FDA to notify Congress within 24 hours of any infant formula recall, to list on its website appropriate substitutes to certain products in shortage, and to assess supply challenges and market competition in the United States.

Key FDA Reforms Left Out of the Legislation

Just as notable as the FDA-related reforms enacted as part of the omnibus bill are some of the riders that were again left on the cutting room floor. These include:

- **The VALID Act.** The appropriate role of FDA oversight of laboratory developed tests ("LDTs") has been a perennial feature of congressional discussion, and the Senate's original user fee reauthorization bill included the Verifying Accurate Leading-edge IVCT Development Act of 2022 (the "VALID Act"). The VALID Act would have conferred FDA oversight authority over a new category of medical device products known as in vitro clinical tests ("IVCTs"), including both LDTs and in vitro diagnostics. Though trade press reports indicate that tweaks to the specific language of the VALID Act were discussed in the days and weeks leading up to passage of the omnibus bill, no version of the VALID Act was anywhere to be found in FDORA or the rest of the omnibus bill. With iterations of the VALID Act having previously failed at least three times in Congress, this latest failure leaves the future of LDT reform once again uncertain in the new Congress.

- **Product Listing for Dietary Supplements.** The Senate's original user fee reauthorization bill also featured lengthy provisions establishing product listing requirements for dietary supplements. The proposal would have required dietary supplement manufacturers, distributors, and packers to list product information with FDA, including the supplement's ingredients, any required warnings, notice and safe handling statements, allergen statements, and any health claims or structure/function claims. FDA additionally would have been tasked with providing a unique listing number for each listed supplement and directing resources to conduct facility inspections for high-risk facilities, suppliers, and dietary supplement types.

- **Orphan Drug Exclusivity Reforms.** FDA has historically interpreted grants of orphan drug exclusivity ("ODE") to block approval of the same drug for only the use or indication actually approved, which may be narrower than the entire disease or condition for which a drug is orphan-drug designated. However, the recent decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299, 1307 (11th Cir. 2021) found that the statutory phrase "same disease or condition" is not ambiguous and that the district court had erred in deferring to FDA's interpretation of the statutory language. Legislative proposals to override the *Catalyst* decision were included in

earlier user fee reauthorization proposals in both the House and Senate, but they were not included in the omnibus bill. Meanwhile, FDA has seemingly been operating in a post-*Catalyst* holding pattern; FDA has not publicly recognized new orphan drug exclusivity for any product approved since November 2021. With no congressional fix forthcoming, it remains to be seen how FDA will move forward.

Next Steps

Life sciences industry stakeholders, especially manufacturers of medical products, cosmetics, and infant formulas, should carefully review FDORA and the PREVENT Pandemics Act to assess any immediate and longer-term impacts on their operations. While many of the provisions in FDORA and the PREVENT Pandemics Act call for implementation and interpretation by FDA through regulations or guidance documents that will necessarily play out over the coming months and years, other provisions could have immediate impact. Companies will need to be nimble in digesting and responding to these new developments. Stakeholders should also continue to monitor the potential for additional FDA reform legislation in Congress, which is highly uncertain with Republicans taking control of the House.

Ropes & Gray will continue to monitor developments in these areas. If you have any questions, please contact any member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray advisor.