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2024 HEALTH REPORT

GOVERNMENT ACTIONS AFFECTING FOOD, DRUG AND MEDICAL DEVICE INDUSTRIES

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2024 FORECAST: GOVERNMENT ACTIONS AFFECTING FOOD, DRUG AND MEDICAL DEVICE INDUSTRIES

The food, drug and medical device industries comprise some of the most closely regulated sectors in the United States. The US Food & Drug Administration (FDA) actively exercises authority by constantly changing legislation and policies to keep pace with transformative technologies and emerging public health concerns. Issues such as artificial intelligence (AI), compounding, cannabis and national security are at the forefront of broadcast media and trade press, but they represent only a subset of regulatory focus areas potentially impacted this year.

Below we describe several actions, taking shape in 2024 by the federal government, that are expected to have broad impact within the food, drug and medical device industries. The summary below is intended to focus on those actions that are most highly anticipated and is not meant to provide an exhaustive overview of all federal regulations or guidance affecting these industries. Readers should keep in mind that individual states also promulgate regulations and guidance that could impact the sectors.

Artificial Intelligence

The FDA continues to recognize the growing need to provide additional guidance on the use of AI in medical products. Additionally, on March 28, 2024, the Biden administration issued its first set of binding, government-wide AI policies. All federal agencies must now (i) vet and verify that their AI tools are safe, (ii) publish an online list and risk assessment of their AI systems, and (iii) designate a chief AI officer to oversee all AI technologies used by that agency. These policies impact agencies regulating and administering healthcare that may use AI tools to help make diagnoses, detect health issues, flag patients for interventions, and perform other medical administrative functions such as health insurance risk assessments.

Additionally, on March 15, 2024, four of the FDA's medical-device centers and offices released a joint paper, titled "Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together," to discuss how the agency intends to approach the use of AI in the medical-product life cycle while balancing the promotion of innovation with the need to safeguard public health. The paper was issued by the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), and the Office of Combination Products (OCP) (collectively, the Centers), and it discusses agency actions such as public input, development of educational and technical assistance materials, and guidance and other future regulatory action.

The FDA has already released a number of publications, including a discussion paper on AI in drug manufacturing, the Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan, and the Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles. But the joint paper clearly signals that more guidance is coming. Notably, the inclusion of the OCP in the paper suggests that the FDA is cognizant that effective regulation of AI will require coordinating the jurisdictions of CDER, CBER and CDRH.

At the same time, the Centers acknowledge that this effort requires further development of the standards and tools used to evaluate AI systems and measure their performance. For example, CDER also has announced that it will be providing guidance on considerations for the use of AI to support regulatory decision-making for drugs and biological products. Also, in June 2024, the FDA released guiding principles for the transparency of machine learning-enabled medical devices in conjunction with Health Canada and the United Kingdom's Medicines and Healthcare Products Regulatory Agency.

Developers, investors, and users of AI-enabled medical products should begin considering their approach to AI to best position themselves to participate in shaping the FDA's ongoing approach to regulating AI in medical products and to comply with guidance as it develops.

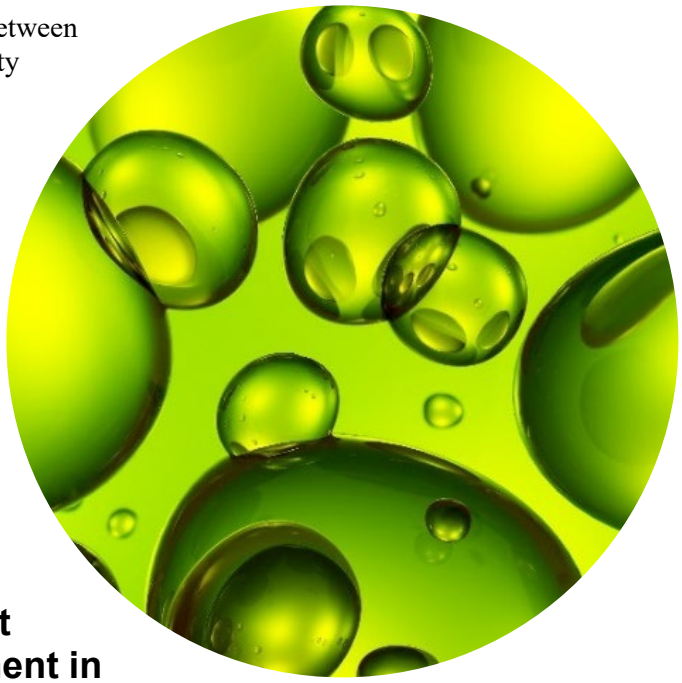
The joint paper, CDER announcement and medical device guiding principles suggest that the FDA will provide the opportunity for stakeholders across the medical-product life cycle to participate in shaping best practices and guidelines for monitoring AI-enabled medical products. Developers, investors, and users of AI-enabled medical products should begin considering their approach to AI to best position themselves to participate in shaping the FDA's ongoing approach to regulating AI in medical products and to comply with guidance as it develops.

The BIOSECURE Act

Congress is considering legislation that aims to disrupt American ties with leading Chinese biotechnology companies. On March 6, 2024, an amended version of S.3558, introduced late last year, was referred for vote on the Senate floor. A very similar bill, H.R. 7085, was introduced in the House in January as The BIOSECURE Act and has yet to be considered by the House Committee on Oversight and Accountability. For convenience, we refer to the bills collectively as The BIOSECURE Act.

The BIOSECURE Act explicitly targets the BGI Group (BGI), China's largest genomics concern, and WuXi AppTec (WuXi), a Shanghai contract research and manufacturing firm whose American clients include pharmaceutical giants and biotech startups. The legislation would not only prohibit federal agencies from contracting with these companies or funding them through loans or grants, but would similarly restrict federal dealings with any third parties that persist in contracting for the targeted companies' technology or services. Organizations would need to sacrifice their connections with these companies to avoid forfeiting future US federal contracts and funding.

The House bill opens with five pages alleging partnership between BGI, WuXi, their affiliates, and Chinese military and security agencies. It states that the companies collect genomic and other biologic data to further Chinese government-led repression and surveillance and threaten US national security. BGI and WuXi have repeatedly denied these allegations as false, misleading and unfounded. They have denounced the bills as harmful efforts to restrict overseas competition in biotechnology. Nonetheless, in Congressional hearings, letters to federal agencies and elsewhere, these – and even more extreme allegations about the national security challenges posed by the targeted companies and Chinese biotechnology, more broadly – have gained traction in official Washington.



We broadly recommend that interested parties follow developments related to The BIOSECURE Act in Congress and at federal agencies and consider involvement in pertinent trade associations to grow more informed and politically active in this area.

Prospects for The BIOSECURE Act remain uncertain. Many major details would need working out before passage, including, the potential effects of the legislation on Medicare and other government health insurance programs. With the run-up to the 2024 elections underway, few observers expect bold initiatives from Congress. Meanwhile, the leading sponsors in both houses are retiring. Nonetheless, companies should take seriously the possibility that either Congress or executive agencies could move against China's biotechnology champions. Businesses that anticipate federal contracts and funding should give second thought to maintaining ties with BGI, WuXi and their affiliates. We broadly recommend that interested parties follow developments related to The BIOSECURE Act in Congress and at federal agencies and consider involvement in pertinent trade associations to grow more informed and politically active in this area.

Pharmaceutical Compounding

Pharmaceutical compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) has become a major area of focus of the FDA in recent years, especially with the rise in compounding of GLP-1 agonists. In a continuation of its move toward increased regulatory oversight of compounding, the FDA issued a proposed rule, Drug Products or Categories of Drug Products that Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, on March 20, 2024. In the proposed rule, the FDA seeks to form two lists: one for 503A compounding pharmacies and one for 503B outsourcing facilities. Any drug products or categories of drug products appearing on these lists will be prohibited from being compounded by the respective compounding facilities.

At present, the proposed rule suggests the inclusion of only three categories of drug products on both lists: (i) oral solid modified-release drug products that employ coated systems (MRCs), (ii) liposome drug products (LDPs) and (iii) drug products produced using hot melt extrusion (HMEs). Future drug products or categories of drug products will be added to the lists on a case-by-case basis following six criteria: (i) formulation complexity, (ii) drug delivery mechanism complexity, (iii) dosage form complexity, (iv) bioavailability achievement complexity, (v) compounding process complexity, and (vi) physicochemical or analytical testing complexity. The comment period closes on June 18, 2024. The implementation of these lists provides the FDA with a potential pathway for regulating a significant number of compounded drug products. It is likely that FDA oversight activities will only continue to increase, especially as semaglutide comes off the FDA shortage list in the near future.

It is also important to note that the Compounding Quality Center of Excellence 2024 Annual Conference will take place from August 21 – 23 in Rockville, MD. Attendees can expect sessions sharing varied perspectives on current good manufacturing practice (cGMP) requirements and top Form FDA 483 observations, among other topics. Register here.

Drug Importation

In recent years, US states have been exploring innovative avenues to address rising healthcare costs and ensure access to affordable medication for their residents. One idea gaining traction involves pursuing authorization from the FDA for importation programs under Section 804 of the FDCA to import prescription drugs from Canada. These Section 804 Importation Programs (SIPs), if approved, would enable states to import prescription drugs from Canada, often at significantly lower prices than those available in the United States.

After years of legal and other challenges to the rule, on January 5, 2024, the FDA authorized Florida's SIP proposal. While eight other states have laws that permit drug importation, and six of them are seeking FDA approval, this is the first time that the FDA has approved a state entity's importation of drugs from another country. Following Florida's example, Colorado and other states are moving forward with their own SIP plans.

Clinical Trial Regulation

The FDA continues to fine-tune various components of the clinical trial process through its regulation and guidance. In May 2023, the FDA issued guidance that provided recommendations for sponsors, investigators and other stakeholders regarding the implementation of decentralized clinical trials (DCTs) for drugs, biological products and devices. DCTs enable subjects to participate at locations and through methods that may be more convenient for them. DCTs also have the potential to expand access to more diverse subject populations that have historically been under-represented in study data and to improve trial efficiencies. Building on recommendations to facilitate trial decentralization issued at the beginning of the COVID-19 public health emergency, the issued guidance on May 2, 2023, recognized that, by enabling remote participation, DCTs may enhance convenience for trial participants, reduce the burden on caregivers, and facilitate research on rare diseases and diseases affecting populations with limited mobility or access to traditional trial sites. FDA's issuance of this draft guidance represents a broader recognition of the important role that digital health technologies (DHTs) may play in modernizing the conduct of research.

In February 2024, the FDA issued other draft guidance with recommendations for determining when to engage a data monitoring committee (DMC; also known as a data safety monitoring committee, or DSMC) for trial monitoring (discussed further here). DMCs are a group of individuals with relevant clinical, scientific, statistical or other expertise. This group regularly reviews human-subject data accumulating from a clinical trial and provides recommendations to the sponsor on whether to continue, modify or suspend the clinical trial for certain emergency research. The guidance also provides recommended procedures and other considerations for DMCs whose use has become more prevalent in clinical trials. Once the draft guidance is finalized, it will supersede the FDA's March 2006 guidance entitled Establishment and Operation of Clinical Trial Data Monitoring Committees.

Additionally, in March 2024, the FDA issued draft guidance on informed consent intended to help institutional review boards (IRBs), sponsors and investigators responsible for human subject research to comply with informed-consent regulations. The guidance provided recommendations for the current Department of Health and Human Services (HHS) regulations protecting human subjects, as well as certain proposed revisions to current FDA regulations for the protection of human subjects. The FDA continues its efforts to harmonize differences between HHS and its own human subject protection regulations and has issued a proposed rule to achieve such harmonization.

On April 15, 2024, the FDA announced the establishment of the CDER Center for Clinical Trial Innovation (C3TI). C3TI will serve as the central support hub for innovative approaches to clinical trials designed to improve the quality and efficiency of drug development and regulatory decision-making.

On June 4, 2024, the FDA issued draft guidance on processes and practices applicable to bioresearch monitoring inspections (the agency's BIMO program). The guidance includes best practices for communication between the FDA and industry before, during, or after an inspection, and aims to clarify the types of records and information required to be provided. Comments are due by August 5, 2024.

Finally, in November 2024, the FDA intends to issue a final rule regarding informed-consent waivers in clinical trials. This regulation would permit an IRB to waive or alter certain informed-consent elements or to waive the requirement to obtain informed consent under limited conditions, for certain minimal-risk clinical investigations. This would support the development of new products to diagnose or treat diseases or conditions and harmonize with the HHS Common Rule waiver provision that has been adopted and successfully employed by other agencies. This regulation aims to enhance patient access to novel products by enabling researchers to conduct studies that significantly contribute to the advancement of diagnostic or therapeutic products for various diseases or conditions, including those targeting unmet medical requirements.

Laboratory-Developed Tests (LDTs)

On April 29, 2024, the FDA issued the long-awaited final rule around the regulation of laboratory developed tests (LDTs), which are *in vitro* diagnostic products (IVDs) that the FDA describes as intended for clinical use and are designed, manufactured and used within a single clinical laboratory that meets certain regulatory requirements. The final rule amends the FDA's regulations to make explicit that IVDs are devices under the FDCA, including when the manufacturer of the IVD is a laboratory. Along with this amendment, the FDA finalized its policy to phase out, over the course of four years, its general enforcement discretion approach for many LDTs. The agency also issued targeted enforcement discretion policies for certain categories of IVDs manufactured by laboratories.

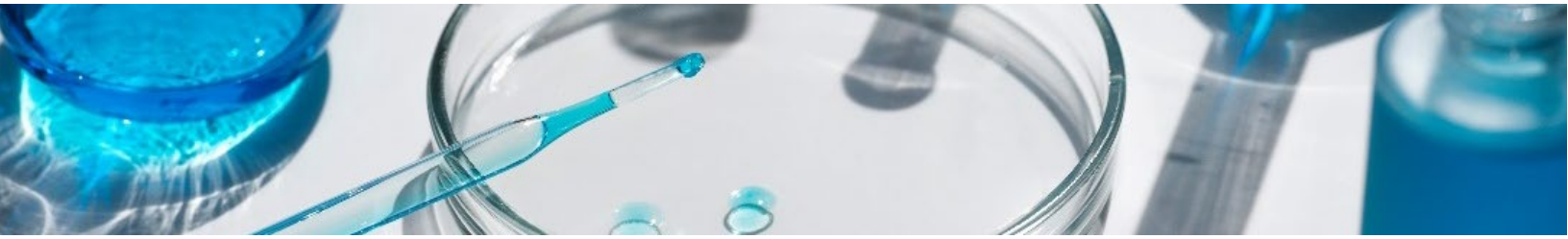
It has long been the FDA's position that the FDCA gives it authority to regulate LDTs as medical devices. Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required the laboratories offering such tests to comply with FDA regulatory requirements for medical devices. However, on September 29, 2023, the FDA published a modification to its regulations to explicitly state that IVDs are devices, including when the manufacturer of the IVD is a clinical laboratory.

The final rule is consistent with the proposed rule in many respects. However, in the final rule, the FDA substantially expanded its list of tests that will be eligible for some form of "grandfathering" (*i.e.*, continued enforcement discretion), including LDTs currently on the market, LDTs that obtain New York State approval and certain LDTs offered by integrated health systems for patients with unmet needs, with certain important limitations.

In addition to the final rule, the FDA provided two draft guidance documents, the first concerning the agency's enforcement discretion policy for certain labs offering unauthorized IVDs for emergency situations, and the second regarding the factors the agency is considering when developing a policy regarding enforcement discretion for certain IVDs during a public health emergency. These guidance documents are open to public comment through July 5, 2024. Dig deeper into McDermott's insights on the rule with our May 2024 webinar and *On the Subject*.

Although the final rule runs more than 500 pages, a substantial number of questions remain unanswered, such as:

- Whether the FDA even has the legal authority to regulate LDTs and, if they do, how meaningful the FDA's expansion of grandfathering will be, as many of the grandfathering provisions only apply insofar as the test is not modified in a manner that would trigger the requirement for a new submission, effectively locking many LDTS in their current form;
- Whether the final rule changes the positions of industry or Congress on the proposed VALID Act – which would require the FDA to regulate *in vitro* clinical tests (IVCTs) – and, finally;
- What types of tests will be eligible for down-classification, as the final rule did not provide any additional details on which types of assays the FDA intends to down-classify.



Food

The food industry continues to evolve, and we will see new updates and guidance from the FDA in 2024. This year, we have already seen FDA movement with respect to food products. On February 12, 2024, the comment period closed for the FDA's Menu Labeling: Supplemental Guidance for Industry (Edition 2); Draft Guidance for Industry; Availability, and we expect that the FDA will finalize the guidance this year. Additionally, on March 5, 2024, the FDA released final guidance titled "Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry." The guidance is meant to help manufacturers and distributors of new dietary ingredients (NDIs) and dietary supplements navigate the process of submitting new dietary ingredient notifications (NDINs) to the FDA. The guidance finalizes Section V of the 102-page 2016 draft guidance and answers questions related to other sections of the draft guidance. The FDA indicated that the decision to separate the finalized versions of the 2016 draft guidance into discrete sections for ease of use is responsive to comments received on the draft guidance. As the FDA continues to review and analyze the remaining sections of the draft guidance, it will issue those sections as separate final guidance. Although it has been eight years since the FDA issued guidance on the dietary supplement notification and review process, the recently released guidance indicates a renewed focus on this topic.

Although it has been eight years since the FDA issued guidance on the dietary supplement notification and review process, the recently released guidance indicates a renewed focus on this topic.

In 2024, we expect to see the FDA continue to finalize regulations and implement programs under the Food Safety Modernization Act (FSMA), especially with the Food Traceability Rule compliance date of January 20, 2026 approaching. The Food Traceability Rule establishes traceability recordkeeping requirements, beyond those in existing regulations, for persons who manufacture, process, pack or hold foods included on the Food Traceability List. Such foods include certain cheeses, nut butters, shell eggs, and certain fruits and vegetables. (The full list of foods can be found here.) To read more about the final rule, see our previous discussion here, and for information on the proposed rule, see our discussion here.

We also expect per- and polyfluoroalkyl substances (PFAS) to remain a hot topic at the FDA. PFAS are "forever chemicals" that resist grease, oil, water and heat and that are in hundreds of products, including stain- and water-resistant fabrics and carpeting, cleaning products, paints and fire-fighting foams. Grease-proofing substances are also applied on paper and paperboard packaging to prevent the leaking of grease and oil, and to increase water-resistant properties. Substances containing PFAS were applied to fast-food wrappers, microwave popcorn bags, take-out paperboard containers and pet food bags, as well as other, similar types of packaging. In February 2024, the FDA announced that PFAS are no longer being sold by manufacturers for food contact use in the US market. The completion of the voluntary market phase-out of these substances used on food packaging paper and paperboard eliminates the primary source of dietary exposure to PFAS from authorized food-contact uses. The FDA said it is working towards a validated, analytical method that would allow it to monitor the market for these food-contact substances in food packaging.

MoCRA Implementation

DECEMBER 29, 2023

ADVERSE EVENT REPORTS
- Companies must submit an adverse event report to FDA and include a copy of the product label on or within 15 days from when a report is received
- Companies must submit, within 15 days of receiving, any new and material medical information related to a serious adverse event within 1 year of the initial report
- Companies are required to keep records related to reports for a period of 6 years (3 years for small businesses)

FRAGRANCE AND FLAVOR INGREDIENTS
- If requested, companies must submit a list of ingredients or category of ingredients in specific fragrances or flavors to FDA within 30 days

REGISTRATION
- Cosmetic manufacturer must register its facility if operational prior to MoCRA
- If operational after MoCRA, within 60 days of first engaging in activity or 60 days after December 29, 2023 (whichever is later)
- Biennial Renewal
- Notify FDA within 60 days of changes to information

PRODUCT LISTING
- Cosmetic products must be listed if marketed prior to MoCRA
- If marketed after MoCRA, within 120 days of marketing the product in interstate commerce
- Update changes made to listing annually

LABEL: PROFESSIONAL USE
- Cosmetic product label must include professional use (where applicable)

TALC-CONTAINING COSMETICS
- FDA must propose regulations to establish and require standardized testing methods to detect asbestos in talc-containing cosmetics and issue final regulations 180 days after comment period closes

JUNE 29, 2024

FRAGRANCE ALLERGENS
- FDA is required to initiate rulemaking to identify fragrance allergens and issue a final rule no later than 180 days after comment period closes

DECEMBER 29, 2024

LABEL: FRAGRANCE ALLERGENS
- Cosmetic product label must declare each fragrance allergen

LABEL: CONTACT INFORMATION
- Cosmetic product label must include a domestic address and contact information to submit adverse event reports

GOOD MANUFACTURING PRACTICES (GMPs)
- FDA must establish rulemaking for GMPs

DECEMBER 29, 2025

GOOD MANUFACTURING PRACTICES (GMPs)
- FDA must issue the final rule for GMPs

PFAS IN COSMETICS
- FDA must publish on its website a report summarizing results of perfluoroalkyl and polyfluoroalkyl substances (PFAS) use in cosmetics and the safety of such use

At the end of 2023, the FDA set the stage for the implementation, in 2024, of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). In December 2023, the FDA issued its Guidance for Industry: Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing, which finalized the August 2023 Draft Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products. The final guidance assists stakeholders with cosmetic-product facility registration and product listing submissions, both of which are mandated by MoCRA. (MoCRA is discussed in depth in our prior OTS.)

The finalized guidance notes that the FDA intends to delay enforcement of facility registration and cosmetic product listing requirements until July 1, 2024. It also provides information on who is responsible for registering a facility and submitting the product listing information, what needs to be included for a facility registration and product listing, optional information the FDA requests be included with the product listing, and certain exemptions. Certain information, including product listing number and information from a facility registration – including the brand names manufactured or processed in the

KEY
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- FDA REQUIREMENTS

facility – will not be available for public disclosure. In the final weeks of 2023, the FDA announced the launch of the Cosmetics Direct Portal, which allows for the electronic submission of cosmetic product facility registration and cosmetic product listing using structured product labeling (SPL) format.

In December 2023, the FDA also provided Instructions for Serious Adverse Event Reporting for Cosmetic Products which updates its General Instructions for MedWatch Form 3500A to include cosmetic-specific information. This update is intended to assist the person responsible for completing the form with reporting a serious adverse event for a cosmetic product, which is mandated by MoCRA. (MoCRA includes a specific definition for a "serious adverse event," which is discussed in depth here.) MoCRA requires a responsible person to report a serious adverse event within 15 business days of the event occurrence and to include in the report a copy of the label on or within the retail package of the cosmetic product. Additionally, if the responsible person receives medical or other information about the event within a year of the initial report, they must submit the information to the FDA within 15 business days of receiving such information.

In 2024, the FDA will be busy implementing MoCRA requirements, and we will continue to see new updates and guidance.

In 2024, the FDA will be busy implementing MoCRA requirements, and we will continue to see new updates and guidance. In addition to delaying enforcement of facility registration and cosmetic product listing requirements until July 1, 2024, the FDA has also stated that it plans to provide additional information on the launch date for the electronic submission of serious adverse event reports for cosmetic products, an additional MoCRA requirement, in the coming months. The agency encourages the electronic submission of serious adverse event reports when available to help facilitate a timely and efficient submission.

Cannabis

We expect major milestones for cannabis regulation in 2024. At the start of the year, HHS issued its scientific review supporting recommendation to the US Drug Enforcement Agency (DEA) that cannabis be rescheduled from a Schedule I drug to a Schedule III drug. And, on May 16, 2024, the US Department of Justice proposed a rule to reschedule cannabis. Classifying cannabis as a Schedule III drug would have significant implications for state-legal cannabis businesses, including eliminating certain tax burdens for state-legal businesses and easing research restrictions. The rulemaking process will include a public comment period before any proposed scheduling change is finalized. Additionally, the Senate continues to labor over the SAFER Banking Act (SB 2860). If enacted, the SAFER Banking Act would ensure that state-legal cannabis businesses have access to banking services. Specifically, the SAFER Banking Act would protect banking institutions that provide services to state-licensed, regulated cannabis companies,

despite their federal illegality. Those services include access to mortgages, loans, low-cost bank accounts and other banking-related needs.

The cannabis industry continues to innovate despite the lack of a federal regulatory framework. In January 2023, the FDA reaffirmed its position that the existing regulatory framework for foods and supplements is not appropriate for the incorporation of cannabis constituents such as cannabidiol (CBD). However, the agency expressed its concern around the issue, considering the number of CBD products that exist on the market. The agency announced that a high-level internal working group was being developed to explore potential regulatory pathways for CBD products. Their hope is to implement the kind of regulatory oversight needed to manage risks for this product category. Additionally, the agency announced that it is prepared to work with Congress on this matter. The FDA will continue to monitor the marketplace for products that seem to pose a more significant health concern. Until then, we remain in standby mode for the FDA's internal working group to establish rules, alongside Congress, that enable these consumer product companies to operate within an appropriate framework.

Gene Therapy

On April 18, 2024, the FDA released a memorandum of understanding with the US Department of Agriculture (USDA) that clarifies the roles and responsibilities of each agency in the regulation of intentional genomic alterations (IGAs) in animals. In particular, the FDA reviews and approves pre-market approval applications for IGAs in animals and intends to exercise enforcement discretion, whereas the USDA ensures the safety of food products and has authority to prevent and control diseases in livestock. Accordingly, on May 1, 2024, the FDA issued updated guidance on its regulatory process for IGAs in animals. The guidance was issued in two parts: (i) final guidance and (ii) draft guidance. The final guidance, GFI #187A, describes the FDA's risk-based approach toward regulating IGAs in animals based on level of mitigation and understanding of potential risks. The draft guidance, GFI #187B, describes the FDA's approval process, clarifying that the FDA is regulating IGAs in the animal and not regulating the animal itself.

The FDA plans to issue a proposed rule establishing requirements surrounding investigational animal cells, tissues, and cell- and tissue-based products (ACTPs) and current animal good-tissue practice for sponsors, firms, individuals and establishments that investigate, manufacture or market ACTPs regulated by the FDA. The proposed rule would also cover requirements surrounding donor eligibility and is planned for publication in January 2025.

Additionally, the FDA plans to revise regulations to permit limited exceptions to donor eligibility and donation suitability requirements for establishments that collect blood or blood components. The revisions aim to ensure the continued safety and supply of blood and protect donor health. Furthermore, the FDA plans to amend regulations concerning human cells, tissues, and cellular and tissue-based products (HCT/Ps) to require record submissions in advance of establishment inspections and to require participation in remote evaluations. The proposal seeks to streamline the FDA's oversight procedures over HCT/P establishments, which also can be expected to lead to increased oversight activities.

Glucose Monitoring

On March 5, 2024, the FDA granted clearance to market the first over-the-counter (OTC) continuous glucose monitor (CGM), a wearable technology that enables users to track their blood sugar levels in real time by measuring interstitial fluid just beneath the skin. Dexcom's Stelo Glucose Biosensor System (Stelo) is an integrated CGM (iCGM) designed for individuals 18 years and older who do not use insulin. Previously, CGMs were only available by prescription and were primarily designed for diabetes management. However, CGMs may offer a new avenue for wellness, proactive health monitoring and accessibility to chronic care management, all without a prescription.

> **The FDA's clearance of the first OTC CGM supports their commitment to encouraging innovation and advancing health equity by moving care and wellness into the home setting.**

OTC CGMs provide real-time data, allowing individuals to understand how their bodies react to workouts and meal plans and to monitor meaningful health data without a prescription. This information can guide nutrition choices, optimize workouts and prevent extreme blood sugar fluctuations. Moreover, OTC CGMs may be used as a preventative tool for those with pre-diabetes. The FDA's clearance of the first OTC CGM supports their commitment to encouraging innovation and advancing health equity by moving care and wellness into the home setting. It also paves the way for the clearance of future in-home OTC devices beyond diabetes management.

Biologics Regulations

In a final rule effective March 13, 2024, the FDA codified its existing practice of requiring biologics license applications (BLAs) not to reference drug master files (DMFs) for drug substance, drug substance intermediate, or drug product information. DMFs allow manufacturers to incorporate proprietary information from another manufacturer in their own applications via reference. The FDA has longstanding policies against the referencing of DMFs in BLAs. However, the rule clarified that biological products originally approved under a new drug application (NDA) that referenced DMFs can continue to do so. As the rule reflects the current practice of the FDA, it is unlikely that its codification will disrupt activities of manufacturers.

cGMP Proposed Rules

The FDA plans to issue a number of proposed rules in 2024 surrounding the current good manufacturing practices (cGMP) for various activities. First, the FDA plans to issue, in November 2024, a proposed rule setting the minimum cGMP requirements for outsourcing facilities compounding human drug products. As mentioned above, this continues the FDA's trend toward increased oversight of compounded drugs. Second, the FDA plans to amend the cGMP requirements for positron emission tomography (PET) drugs to remove the reference to the outdated chapter in the United States Pharmacopeia and to streamline requirements such that they apply to all PET drugs, including investigational and research PET drugs. Third, the FDA plans to remove cGMP requirements for manufacturers/processors of animal and human food to provide written assurances that hazards will be controlled (although documentation that the hazard was not controlled must still be provided).

Enforcement Outlook

FDA officials, in a December 2023 enforcement conference hosted by the Food and Drug Law Institute (FDLI), provided details regarding priorities entering 2024. For example, the Office of Product Evaluation and Quality (OPEQ) at CDRH stated that it will continue to focus on Corrective and Preventive Actions (CAPAs), with an increased focus on going after repeat violators of inspections. OPEQ further stated that a finalized rule updating the FDA's Quality Management System Regulation to "harmonize 21 CFR 820 to the ISO 13485 standard" is currently under review with the Office of Management and Budget (OMB).

The Office of Compliance and Biologics Quality (OCBQ) in CBER noted a focus on amniotic fluid-derived products, stating that an amendment to current HCT/Ps is in the works, and on noncompliance with ClinicalTrials.gov, as corroborated by the FDA Commissioner Robert Califf's blog post issued on December 4, 2023. CDER emphasized that failure to maintain cGMP and the marketing of unapproved products remain priority areas of focus.

Notably, in its FY 2024 budget request, the FDA requested an expansion to its mandatory recall authority under the SUPPORT Act to cover all human and animal drugs. At present, the FDA's mandatory recall authority is limited to controlled substances, outside of which the FDA depends on companies to voluntarily withdraw products when requested. The budget further focuses on pandemic preparedness and requests enhanced authorities related to shortages of drugs, medical devices and foods. The FY 2024 Justification of Estimates for Appropriations Committees also suggests that current levels of inspection will be continued or increased in the coming year.

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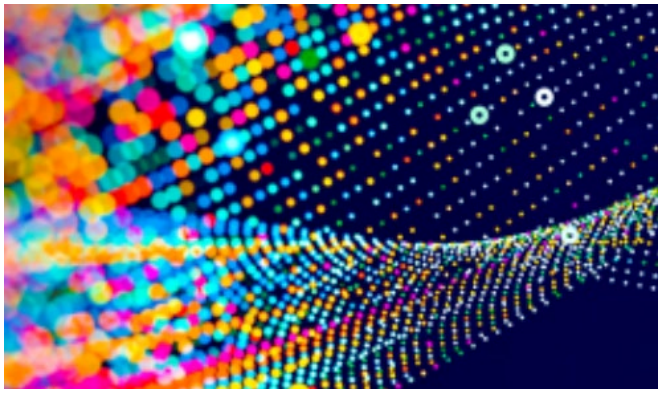
Save the date for our life sciences boot camp series:

- September 11, 2024
  Chicago
- October 1, 2024
  Boston

Join us at one of our upcoming healthcare and life sciences events.



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