FDA in focus:
2024 in review and 2025 outlook

DLA PIPER

Contents

Introduction

In 2024, the Food and Drug Administration (FDA) significantly invested in reorganizing its internal infrastructure and enhancing operations. These efforts aimed to address the complexities of a global supply chain, rapid innovation in product development and artificial intelligence (AI), and a strong focus on the safety and labeling of FDA-regulated products.

The Agency's 2024 USD7.2 million fiscal year budget, which funded wide-ranging programmatic, infrastructure, and operational changes, represented a significant increase from the prior year. Major changes to the structure of the FDA's Human Foods Program (HFP) and inspectorate, as well as substantial investments in optimizing clinical trial diversity, improving drug supply chain safety, harmonizing medical device quality with global standards, and increasing pay and staffing levels to expedite medical product review, illustrate the Agency's key priorities for 2024.

While FDA focused its proactive regulatory efforts on medical product innovation and food safety, enforcement trends remained largely unchanged in 2024. The Agency's 2024 enforcement activity suggests a continued focus on historical priority areas of manufacturing and quality, distribution of unapproved products, tobacco advertising and sales, and food safety. FDA's enforcement activities with respect to medical product advertising and promotion remained limited, with the Agency seemingly prioritizing Warning and Untitled letters involving novel products, new indications, or emerging or higher-risk therapeutic areas. The overall enforcement picture appeared to focus on cases the Agency perceived to be clear-cut wins or opportunities to expand or test authorities and remedies, such as responsible corporate officer liability under the Park Doctrine or economic restitution.

FDA also faced several significant judicial challenges to its authority that may influence how the Agency moves forward in 2025 and beyond. The end of *Chevron* deference ushered in by the US Supreme Court (SCOTUS) decision in the *Loper Bright* case (discussed in the *Enforcement and litigation* section below) may increase the number and frequency of challenges to FDA action under the Administrative Procedure Act (APA). It may also lead to more prescriptive statutory provisions with less room for interpretation, longer and more complex rulemaking processes, longer approval timelines, and additional guidance as FDA seeks to shore up regulatory decisions and preempt APA challenges based on *Loper Bright*.

2024 also marked notable leadership changes in key program areas, renewed focus on certain FDA advisory committees, and increased emphasis on transparency and combatting misinformation as a part of FDA's public health mandate. In 2024, FDA announced changes in leadership in key roles and areas such as a new Director for FDA's Center for Devices and Radiological Health (CDRH), the departure of FDA's Principal Deputy Commissioner, and many Office Directors in HFP. FDA also reorganized its field offices, which are primarily responsible for conducting inspections and coordinating import activities. This organization, along with the renaming and transformation of FDA's Office of Regulatory Affairs (ORA) into the Office of Inspections and Investigations, was designed to provide greater coordination of inspections, investigations, testing laboratories, and compliance functions across all regulated product areas.

The inaugural meeting of the newly formed Digital Health Advisory Committee and a flurry of new guidance documents covering a range of topics toward the end of 2024 and beginning of 2025 shed light on the Agency's 2025 priorities. The uptick in end-of-year guidance in 2024 and new guidance and proposed regulations in first month of 2025 may also reflect FDA's attempt to get ahead of anticipated changes in regulatory priorities or agency norms with a new administration in 2025. Recent terminations and significant reductions in staff across FDA centers and programs, combined with a series of Executive Orders (EOs) that will hinder the rule making process, will undoubtedly impact Agency operations and priorities in 2025.

Our report, *FDA in focus*, highlights key guidance documents and developments DLA Piper's FDA Regulatory team followed in 2024 with insights and perspectives on what may be to come in 2025.

Drugs and biologics

2024

FDA focused on optimizing and clarifying several existing programs for drugs and biologics, including orphan products, expedited approval pathways, and drug supply chain safety. Guidance documents related to gene therapy, platform technology for drug development, and biosimilars reflected the Agency's focus on shoring up existing programs to drive innovation in drug development.

Orphan products

Interpreting "same drug" remains an active battleground for orphan drugs. To incentivize pharmaceutical companies to develop drugs for rare diseases or conditions, the Orphan Drug Act (ODA) grants a seven-year market exclusivity for eligible drugs upon final FDA approval. During this time, FDA "may not approve another application . . . for the same drug for the same disease or condition." 21 U.S.C. § 360cc(a). The ODA did not specify the meaning of "same drug." Through regulation, FDA provides that, for small-molecule drugs, a subsequent drug is deemed the "same drug" as an already approved drug if it has the same active moiety and is not otherwise clinically superior to the already approved drug.

Recent litigation highlights the importance of these regulatory determinations, which rest on FDA's scientific assessment of the clinical benefits of one product versus another. These regulatory determinations can have significant implications for companies who have invested in the development of orphan drug products. *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC* involved a challenge to FDA's finding that one product intended for narcolepsy was "clinically superior" to another product. FDA made this finding despite the fact that the drugs at issue have the same active moiety and the same indication for use. FDA's finding of clinical superiority was based on a difference in the dosing schedule for the product (one nightly dose versus two nightly doses), which the Agency found to be a meaningful clinical benefit. The district court deferred to FDA's conclusion, holding that the Agency did not act arbitrarily and capriciously. The ongoing activity in this space underscores concerns that determinations of "clinical superiority" are nuanced, fact-specific, and subject to differences in interpretation between FDA and industry. For companies, early engagement with FDA on issues of the clinical benefit during the approval process may help to align expectations.

Expedited review pathways

In May 2024, FDA issued its "Platform Technology Designation Program for Drug Development" draft guidance, regarding implementation of the platform technology designation program under section 506K of the Federal Food, Drug, and Cosmetic Act (FDCA), discussed in detail in our client alert. This long-awaited draft guidance supports an expedited review pathway for products that receive a platform technology designation from the Agency. A platform technology is defined as a well-understood and reproducible technology, such as a nucleic acid sequence, molecular structure, mechanism of action, delivery method, vector, or any combination thereof. A platform technology:

- Can be incorporated into or used by a drug or biological product and is essential to the structure or function of the drug or biological product
- Can be adapted for, incorporated into, or used by one or more drug or biological products sharing common structural elements, or

- Facilitates the manufacture or development of drug or biological products through a standardized manufacturing production or manufacturing process or processes.

Platform technologies offer the potential to revolutionize drug development by creating greater efficiencies in manufacturing and regulatory review. Pharmaceutical and biologic companies are encouraged to review this guidance and consider whether they may be able to leverage platform technologies and the associated expedited review pathway.

Accelerated Approval program

The Accelerated Approval program remains under scrutiny following several high-profile drug withdrawals of products in key therapeutic areas such as Alzheimer's and sickle cell disease. The program was designed to allow for earlier approval of drugs that treat serious conditions and fill an unmet medical need based on a surrogate endpoint. A drug accepted for accelerated approval will be "conditionally" approved pending the results of the confirmatory trial. In theory, if the confirmatory trial does not show that the drug provides clinical benefit, FDA should revoke the approval and remove the drug from the market. However, critics of the program argue that drugs approved through the Accelerated Approval program are often marketed for years without completing or initiating the required confirmatory trial. In December 2024, FDA issued a draft guidance, "Expedited Program for Serious Conditions — Accelerated Approval of Drugs and Biologics." This is the first update since 2014, when the guidance was initially introduced. The 2024 draft guidance provides resources for sponsors using novel endpoints. Most importantly, the draft guidance provides information on timely conduct of confirmatory trials and provides an extensive procedure for withdrawal of accelerated approval. These measures were designed to ensure speedy approval for products intended to treat an unmet medical need without compromising the safety and efficacy of profile of the drugs.

Drug Supply Chain Security Act

Enacted in 2013, the Drug Supply Chain Security Act (DSCSA) requires parties in the prescription drug supply chain to use electronic interoperable tracking technology to enhance identification and removal of counterfeit or otherwise harmful drugs. FDA has previously provided serial delays in implementation and enforcement of the DSCSA, the most recent of which established November 27, 2024 as the new date for required compliance. The DSCSA continues to present implementation challenges to trading partners and other stakeholders engaged in the manufacturing, distribution, and dispensing of pharmaceuticals. Examples of challenges include capacity and resource constraints for both small and established trading partners, data retrieval and transmission issues, and difficulty incorporating exemptions and waiver processes into the verifying system, among others. Companies are encouraged to monitor this area for potential enforcement focus going forward, as further discussed in our client alert.

On October 9, 2024, upon receiving continued concerns from trading partners, FDA issued exemptions for certain trading partners, which allow additional time to meet enhanced drug distribution security requirements. The enhanced requirements focus on enabling secure tracing of product at the package level. These temporary exemptions were designed to provide additional time for trading partners to troubleshoot and ensure uninterrupted product distribution. As a result, the exemptions only apply to trading partners who have initiated their systems and processes, including electronic DSCSA data connections, to address challenges with data exchange, quality, and reliability. Similar to the implementation of DSCSA, the exemptions also will be phased in. The specific compliance deadlines depend on the roles of the entities.

- Manufacturers and repackagers: May 27, 2025
- Wholesale distributors: August 27, 2025
- Dispensers with 26 or more full-time employees: November 27, 2025

These exemptions are limited to the enhanced drug distribution security requirements. Trading partners are expected to meet other obligations and requirements under the DSCSA. In addition, FDA exempts small dispensers and certain small business dispensers' trading partners from certain requirements in section 582 of the FDCA until November 27, 2026. Exemptions include the requirements for dispensers to verify the product identifier and the transaction information and requirements related to ensuring that transaction statements are exchanged in a secure, interoperable, electronic manner. The special exemption allows additional time needed by small business dispensers to fully transition to interoperable, electronic product tracing at the package level under the DSCSA.

Other drug-related guidance

FDA issued several other drug-related guidance documents in 2024 on topics ranging from management of post-approval Individual Case Safety Reports (ICSRs), notice requirements for Active Pharmaceutical Ingredient (API) shortages, and data integrity for in vivo bioavailability and bioequivalence studies, to guidance on designing and conducting Risk Evaluation and Mitigation Strategy (REMS) assessments. The volume and diversity of topics covered underscore the breadth and scope of FDA's oversight as well as areas of focus for FDA in drug development. Of the many drug-related guidance documents issued, there were a few standouts we are currently discussing with drug developers, industry stakeholders, and others that could signal the Agency's likely focus in 2025.

- **Charging for investigational drugs** – The issue of whether and to what extent companies may charge for investigational

drugs is an ongoing question for many developers and payors alike. In February 2024, FDA finalized a guidance entitled, "Charging for Investigational Drugs Under an IND: Questions and Answers." Revising the draft guidance of the same title issued in August 2022, and replacing the final guidance issued in June 2016, this guidance addresses frequently asked questions regarding implementation of FDA's regulation on charging for investigational drugs under an investigational new drug application (IND). With very few changes from the 2022 version, the guidance describes, among other topics, requirements and conditions related to charging for investigational drugs; defines extraordinary cost; and clarifies the definition of an independent certified public accountant. The guidance is organized to address questions related to charging in general, charging in clinical trials, charging for expanded access use, and cost recovery calculations. It reflects FDA's recognition of the significant costs associated with clinical trials, particularly those that involve new investigational uses of an approved drug. If sponsors plan to charge for investigational drugs, they need to submit a statement by an independent certified public accountant and a cost distribution plan in case of expanded access studies.

- **Compounded drugs** – After an unusually lengthy Office of Information and Regulatory Affairs (OIRA) review, FDA published a proposed rule in March 2024, entitled, "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." Under the proposal, all compounders, including both 503A and 503B facilities, would be prohibited from compounding drugs that present "demonstrable difficulties for compounding" (DDC). Such drugs would either be identified in a regulation or on a list that would be published by FDA. To reflect the differences in compounding standards, FDA proposed to create two DDC Lists, a 503A DDC List and a 503B DDC List. In determining whether drug products or categories of drug products present demonstrable difficulties, FDA proposed to consider the six criteria it previously published in 2016:

  1. Complex formulation
  2. Complex drug delivery mechanism
  3. Complex dosage form
  4. Bioavailability achievement complexity
  5. Compounding process complexity, and
  6. Physicochemical or analytical testing complexity.

  Under the proposed framework and following consultation with the Pharmacy Compounding Advisory Committee (PCAC), FDA is proposing to add three product categories of drug products to the DDC Lists, including oral solid modified-release drug products that employ coated systems (MRCS), liposome drug products (LDPS), and products produced using heat-melt extrusion (HME). According to FDA, there is no marketing of compounded drugs in the three proposed categories of human drug products. If finalized, the rule could limit the type of drugs can be compounded, including GLP-1s.

- **Real-world evidence** – With the Agency's increased focus on patient-reported outcomes and digital health, FDA has recognized that real-world data and evidence (RWD and RWE, respectively) can be a meaningful source of information about product safety and effectiveness. In March 2024, FDA issued a draft guidance entitled, "Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products." The draft guidance provides recommendations to sponsors who plan to use non-interventional studies to demonstrate the safety or the efficacy profile of drug and biological products. Examples of non-interventional studies include observational cohort studies, case-control studies, and self-controlled studies, among others. These categories of studies are often powered by RWD generated from registries, electronic health records (EHRs), digital and mobile applications, self-reported information, and other sources. The guidance describes when it may be appropriate to use RWE to make causal inferences and criteria to establish data fitness for use in generating RWE to support a labeling change or address a safety concern.
- In July 2024, as part of its Real-World Evidence program and to satisfy, in part, the mandate under the FDCA to issue guidance about the use of RWE in regulatory decision-making, FDA issued final guidance entitled, "Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products." This guidance is intended to provide

sponsors and other interested parties with considerations when proposing to use EHRs or medical claims data in clinical studies to support a regulatory decision for effectiveness or safety. After having reviewed a growing number RWD-based protocol submissions, the Agency formulated recommendations in this guidance to help sponsors better align their protocols for data source validation methods and expanded quantitative bias analyses in study design.

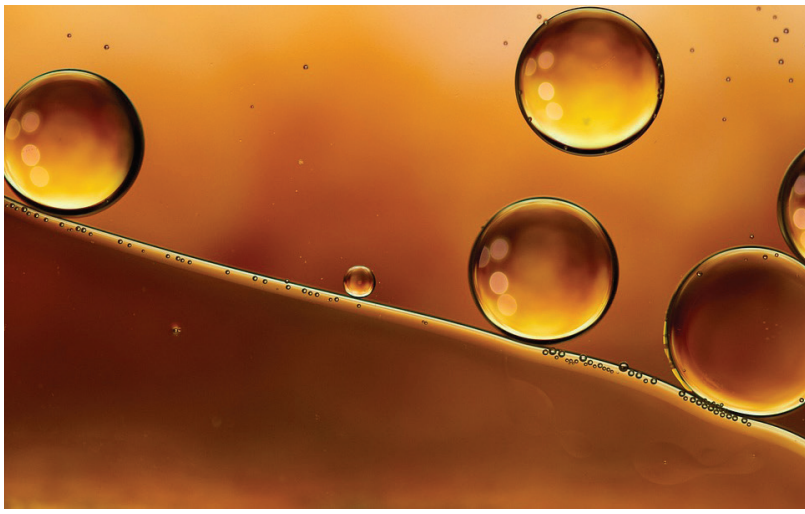
Over-the-counter drugs

Additional areas of focus for FDA include ensuring over-the-counter (OTC) drugs on the market are still considered effective and expanding access to OTC drugs. To that end, FDA has published an administrative order regarding phenylephrine and finalized its rule on OTC drugs with an additional condition for nonprescription use (ACNU). Currently, oral phenylephrine is widely used as a nasal decongestant active ingredient in many OTC monograph drug products. However, in November, FDA proposed to remove oral phenylephrine as an active ingredient that can be used in OTC monograph drug products for the temporary relief of nasal congestion after an Agency review of the available data determined that oral phenylephrine is not effective for this use – while the proposed order is based on effectiveness concerns, it does not implicate safety concerns. For now, companies may continue to market OTC monograph drug products containing oral phenylephrine as a nasal decongestant. Only an eventual final order will affect what products can be marketed.

In terms of rulemaking, two and a half years after FDA published its proposed rule (FDA-2021-N-0862), FDA has finalized its "Nonprescription Drug Product With an Additional Condition for Nonprescription Use" rule on Rx-to-OTC with ACNU switches. This final rule is intended to increase options for applicants to develop and market safe and effective nonprescription drug products, which could improve public health by increasing consumer access to nonprescription drug products, especially for chronic diseases. The final rule establishes requirements for a drug product that could be marketed as a nonprescription drug product with an ACNU that an applicant must implement to ensure appropriate self-selection, appropriate actual use, or both by consumers.

Generic drugs

In January 2024, FDA finalized its "Revising ANDA Labeling Following Revision of the RLD Labeling" guidance, which provides information on updating generic product labeling, current practices for monitoring reference listed drug labeling changes, and submitting new abbreviated new drug applications (ANDA) product labeling. This guidance, which finalizes a 2022 draft version, is the first finalized update to the policy on revising generic labeling since 2000. FDA also published a revised final guidance, "ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs," for ANDA applicants that seek to make



an amendment or request for final approval on a tentatively approved application. The updates reflect GDUFA III commitments, with the majority of changes relating to patent certifications and exclusivities. Both guidance updates are part of FDA's Drug Competition Action Plan (DCAP), an initiative through which the Agency aims to remove barriers to generic drug development and market entry, in an effort to spur competition and increase access to medicines for consumers.

Biosimilars

In July 2024, FDA issued its "Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products Questions and Answers" guidance in question-and-answer format. Under 21 C.F.R. § 601.12, applicants must inform FDA about each change in the manufacturing process from the approved biologics license application (BLA) and assess the effects of the change and demonstrate the lack of adverse effect of the change on the identity, strength, quality, purity, or potency of the product. The guidance provides recommendations for each reporting category, including prior approval supplement (PAS), Changes Being Effected in 30 Days (CBE-30)/Changes Being Effected (CBE-0) Supplements, and the delivery of an annual report as well as information necessary to establish comparability. The guidance also discusses the Chemistry, Manufacturing, and Controls (CMC) information required to support the approval of a supplement for a dosage form or a strength that has not previously been licensed under the 351(k) BLA.

In June 2024, FDA issued its "Considerations in Demonstrating Interchangeability With a Reference Product: Update" guidance, providing that its determination that a biosimilar is interchangeable will no longer necessarily require switching studies. A finding of interchangeability under the Biologics Price Competition and Innovation Act renders a biosimilar susceptible to being substituted at the pharmacy under many state laws. This regulatory change could effectively lower the regulatory burden for biosimilar applicants to meet this standard.

Biologics and human cells, tissues, and cellular and tissue-based products

In January 2024, FDA issued final guidance, entitled, "Human Gene Therapy Products Incorporating Human Genome Editing." This guidance provides recommendations to sponsors developing human gene therapy products that incorporate genome editing (GE) of human cells. The Agency's recommendations address information that should be included in an IND application, such as details related to product design, product manufacturing and testing, nonclinical safety assessment, and clinical trial design. The structure and content of the final guidance remains largely the same as in the draft version. However, the finalized document reflects various changes in response to industry comments, including clearer, more tailored terminology; information on efficacy endpoints and use of accelerated approval; broader language around techniques that can be used; component control strategy; and how to characterize potency.

At the end of April 2024, FDA published two draft guidance documents regarding cell and gene therapy, "Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products" and "Considerations for the Use of Human-and Animal-Derived Materials in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products." The first draft guidance provides recommendations for determining the appropriate cell safety testing to support an IND or a BLA. In the draft guidance, FDA states that the testing should be based on a risk analysis that considers the expansion potential of the cells, the reagents that are used to expand the cells in culture, and the number of individuals the cell-based medical product is capable of treating. The second draft guidance generally aligns with previous recommendations on strategies to manufacture finished products that are free from viral contaminants. However, this latest proposed guidance focuses on the introduction of human- and animal-derived materials during manufacturing (*eg*, feeder cells) and specifically excludes considerations of human cells used as starting material.

Cellular and gene therapy (CGT) research and development in the US continues to grow rapidly, with a number of products already approved and many more advancing in clinical development. In November 2024, as part of FDA's response to the Prescription Drug User Fee Act (PDUFA) VII commitment to increase efficiency in the development of CGT products, FDA issued its draft guidance, "Frequently Asked Questions — Developing Potential Cellular and Gene Therapy Products." This guidance is intended to provide industry with answers to frequently asked questions and commonly faced issues that arise during the development of CGT products and is intended to help facilitate the development of safe, effective, and high-quality products. The FAQs represent common questions directed to the Agency and span multiple disciplines, including regulatory review, CMC, pharmacology / toxicology (PT), clinical, and clinical pharmacology.

This year

In January 2025, FDA issued its "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act," an update to the prior January 2017 guidance. Additionally, FDA issued its first draft guidance on the use of artificial intelligence (AI) for the development of drug and biological products, "Considerations for the Use of AI to Support Regulatory Decision-Making for Drugs and Biological Product," which is expected to garner significant engagement from stakeholders during the comment period in the first quarter of 2025. The guidance provides recommendations on the use of AI intended to support regulatory decisions about a drug or biological product's safety, effectiveness, or quality. A culmination of feedback incorporated from various Agency outreach efforts over the course of the last couple of years, this guidance provides the eagerly awaited risk-based framework for sponsors to assess and establish the credibility of an AI model for a particular context of use and determine the activities needed to demonstrate that an AI model's output is reliable. The current administration may oversee significant changes in how FDA regulates certain products, including greater enforcement discretion over or deregulation of certain products (*eg*, stem cells, homeopathic products, and experimental or investigational treatments).

Combination products

2024

In its July 2024 draft "Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products" guidance, FDA outlined the purpose and content of a use-related risk analysis (URRA) and how a URRA can be used to determine human factors validation studies needs during product development or to support a marketing application for drug- and biologic-led combination products. According to the draft guidance, a URRA should include:

- A list of all tasks required for use of the product
- The potential use errors and harms that may occur with those tasks
- A determination of whether each task is a critical one
- Risk controls employed in the user interface design to mitigate use errors, and
- Evaluation methods that have or will be used to evaluate the effectiveness of risk controls.

The Agency notes that a URRA is important to help identify risks related to user interface design and measures implemented to reduce those risks.

Medical devices

2024

FDA focused on enhancing medical device manufacturing and quality, optimizing device innovation through expanded guidance on AI, regulation of laboratory developed tests (LDTs), post-market surveillance, and novel strategies to align device development to users and use cases beyond traditional hospital and in-patient settings.

In April 2024, CDRH launched the Home as a Health Care Hub to address medical device design, development, and lifecycle management considerations for home use. CDRH noted that the home is becoming an integral part of healthcare and health delivery as many individuals in the US do not have access to skilled nursing facilities or in-patient care. For many patients and other persons living with health conditions, most or all their healthcare is delivered at home through diagnostic and treatment devices, digitally enabled care coordination technologies, or home healthcare personnel. The initiative includes elements such as the Idea Lab, which is simulated home environment designed by FDA to help developers assess how current and future technology could function and integrate into a home environment. The Idea Lab also provides developers with access to fictional personas representing a range of people living with a disease or condition such as diabetes in specific home conditions, including affordable housing. The initiative includes access to a free software program that allows users to virtually enter the world of people living with a disease to visualize how their living conditions may impact how they interact with a medical device or other technology and how those living conditions and interactions influence elements of product design, including usability, human factors testing, and practical design elements such as the placement of power sources. The initiative signals FDA's increasing focus on patient-centered design and may influence future guidance, regulation, and policy considerations related to device safety and effectiveness.

In May 2024, FDA issued its final "Remanufacturing of Medical Devices: Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff" guidance. In the final guidance, in response to feedback on the May 2018 "FDA Report on Device Servicing," FDA added clarification around the distinction between "servicing" and "remanufacturing" activities. The Agency found that a majority of complaints and adverse event reports alleging inadequate "servicing" actually related to "remanufacturing" activities. The guidance addresses practical concerns related to the longstanding practice of third-party sellers refurbishing used devices and instances in which end users and original equipment manufacturers (OEMs) hire third parties or distributors to service and repair devices in the field. The secondary market for medical devices, particularly costly capital equipment, often raises questions regarding which parties are responsible for compliance with medical device requirements and the extent to which those requirements apply to certain servicing activities or refurbishments to old equipment. The Agency clarified that "servicing" activities return or maintain a device's safety and performance specifications and intended use, whereas "remanufacturing" significantly changes the device's performance, safety specifications, or intended use. Therefore, companies should assess whether their activities meet the definition of servicing or remanufacturing as this will trigger a specific set of post-market requirements under medical device regulation, such as registration and listing, compliance with the quality system regulation, and adverse event reporting. Companies should develop, or review and update, existing policies, contract provisions, and practices in light of the guidance.

In May 2024, FDA issued final rulemaking, "Medical Devices; Laboratory Developed Tests," which we discuss in detail in our DLA Piper client alert. As a follow-on to the final rule, in June 2024, FDA also issued its "Laboratory Developed Tests: Small Entity Compliance Guide: Guidance for Laboratory Manufacturers and Food and Drug Administration Staff," which, in key part, summarizes the five phases of compliance for *in vitro* diagnostics (IVDs) by category of product in Table 2. The LDT final rule is currently the subject of ongoing litigation, discussed in the *Enforcement and litigation* section below. The final rule, which will become effective for different categories of LDTs on a rolling basis starting in May 2025, may increase the safety, accuracy, and reliability of available tests. However, the increased regulatory burdens on laboratories may result in discontinuation of many tests, potentially impacting patient access to diagnostic options.

In response to FDA's March 2023 final rule to update mammography regulations in 21 C.F.R. Part 900, in August 2024, FDA issued a corresponding "Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide: Guidance for Industry and Food and Drug Administration Staff." The key changes under the Mammography Quality Standards Act (MQSA) addressed in the guidance include requirements for the content of mammography reports (including four categories for reporting breast tissue density), communication of results (patient lay summaries provided to patients), and medical outcomes audits (including the positive predictive value, cancer detection rate, and recall rate). Entities that are subject to the MQSA should refer to the guidance to ensure that their reports and records reflect the latest requirements.

As detailed here, in March 2024, CDRH published a draft guidance, "Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling," which applies to devices that produce tissue temperature change as an intended or unintended consequence of use. In light of FDA's recent proposed rule to ban electrical stimulation devices (ESDs) based on the potential for permanent tissue damage and other potentially significant safety impacts, the guidance provides considerations on how to adequately evaluate the thermal effects of a device and assess tissue effects in pre-market testing.

FDA's Voluntary Malfunction Summary Reporting System (VMSR) is an established program by which manufacturers may submit certain malfunctions related to devices under certain FDA product codes in a summary format on a quarterly basis. The August 2024 draft "Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers: Guidance for Industry and Food and Drug Administration Staff" is intended to explain the program's reporting conditions and how to make reports. The VMSR provides a streamlined and less burdensome approach for reporting malfunctions, and manufacturers should confirm whether their products are eligible to use the program in lieu of traditional, 30-day malfunction reports.

As discussed in detail in our client alert, in February 2024, FDA issued a final rule (see editorial correction here) amending its quality system regulations under 21 C.F.R. Part 820 to more closely harmonize these requirements with ISO 13485:2016, the international consensus standard for quality management systems. As discussed in detail here, the amended quality system regulations will be known as the quality management system regulation (QMSR) and puts greater emphasis on risk-based decision-making.

This year

While radical shifts in medical device policy are unlikely in 2025, recent staff reductions may impact the speed and extent to which CDRH can complete product reviews and execute core regulatory functions. FDA previously signaled that it might focus on updating outdated compliance policies and revising older guidance related to core requirements such as labeling, intended use, and preapproval promotion/selling activities. The Agency had also signaled its intent to focus on specific product categories such as 3D printed device activities at the point of care; clinical evidence considerations for digital mental health treatment devices, including Computerized Behavioral Therapy (CBT) devices; and consumer and OTC devices. LDTs are likely to be a focus as industry and FDA await the outcome of pending litigation on the LDT final rule. However, much of these efforts remain in question as the center is grappling with the impact of staff reductions on the sustainability and maintenance of basic operations.

Digital health

2024

In February 2024, FDA added the Digital Health Advisory Committee (DHAC) to its list of standing advisory committees. The DHAC's scope includes advice on scientific and technical issues related to digital health technologies, including AI and machine learning (ML), augmented or virtual reality, digital therapeutics, wearables, remote patient monitoring, software, and more. The DHAC held its first meeting in November 2024. The meeting focused on the regulatory, ethical, and practical challenges posed by the integration of Generative AI (GenAI) in medical devices. It also touched on how GenAI in the medical device context offers an opportunity to narrow the healthcare gap by bringing technology to those who need it most but who have limited access. Key topics included the need for specialized training for users, the role of human oversight in AI applications, and the potential for AI to exacerbate existing disparities in healthcare outcomes. The DHAC emphasized the importance of transparency, ongoing validation, and the development of robust post-market surveillance systems to ensure the safety and effectiveness of AI-enabled devices. The committee also discussed the need for the private and public sectors to work together to focus on validation of AI in medical devices. Key topics of discussion also signal topics of future guidance and areas of focus for premarket submissions, including explainability, trust, transparency, (user) training, (model) training, human in the loop vs. out of the loop, usability and stress testing, post-market monitoring, strategies and controls to mitigate risks associated with Gen AI applications, questions regarding the viability of the substantial equivalence pathway for AI medical devices, and the content of premarket submissions, among others. FDA issued a guidance on the topic of AI premarket submissions in January 2025 – see our discussion here.

In its March 2024 "Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act: Draft Guidance for Industry and Food and Drug Administration Staff," FDA clarifies the definition of "cyber device" for purposes of complying with cybersecurity requirements in premarket submissions. FDA considers a "cyber device" to include those that are or contain software, including software that is firmware or programmable logic. The guidance responds to cybersecurity mandates in the Food and Drug Omnibus Reform Act of 2022 (FDORA), which as enacted in 2022. FDORA added section 524B to the FDCA, which requires sponsors of premarket approval applications (PMAs), 510(k) clearances, and other medical device marketing applications to submit information to ensure that "cyber devices" meet cybersecurity requirements. Under section 524B, a "cyber device" is 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."

Key requirements under section 524B, as further outlined in the guidance, include:

- Submission of a post-market plan to monitor, identify, and address cybersecurity vulnerabilities
- Design, development, and maintenance of processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure
- Provision of a software bill of materials, and
- Compliance with other cybersecurity requirements FDA may promulgate via regulation.

FDA also issued guidance to address predetermined change control plan (PCCP) requirements in FDORA. Section 515C of the FDCA, describes requirements for PCCPs, which describe anticipated future modifications to a device and how the modifications will be assessed once the device is on the market. This is particularly relevant for AI/ML-enabled software devices that evolve, learn, and change after deployment based on user input. In August 2024, FDA issued its draft "Predetermined Change Control Plans for Medical Devices: Draft Guidance for Industry and FDA Staff," to describe guiding principles for PCCPs, components of a PCCP, and how to use an authorized PCCP to implement device modifications.

In December 2024, FDA issued its final guidance, "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions." The Agency previously issued a draft version of the guidance in April 2023. While the final guidance is largely the same as the draft version in substance, the Agency explicitly broadened the scope of the final guidance to include both AI/ML-enabled devices and device software functions.

This year

The rapid pace of digital health innovation will likely continue to drive policy and regulatory focus at FDA. Practical implications of new technologies such as GenAI are quickly outpacing existing medical device frameworks for hardware devices. In 2025, FDA may explore the applicability and viability of requirements related to predicate selection and substantial equivalence for AI-enabled devices. Industry is also awaiting additional guidance on applying medical device quality management and post-market safety requirements to software and AI-enabled devices. As noted in the *Drug and biologics* section above, FDA's January 2025 draft guidance on "Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products" represents a cross-functional approach to AI/ML and incorporates both feedback from Agency outreach to industry and insights gained from digital health policies in the medical device space. This is likely to be the first of many guidance documents that reflect FDA's cross-functional approach to addressing the expanding use cases for digital health and other AI across product areas.

Food and dietary supplements

2024

Human Foods Program reorganization

Food safety and dietary supplements continued to be a priority for FDA in 2024. FDA's new Human Foods Program (HFP) went into effect on October 1, 2024. The Agency implemented the program and associated reorganization to optimize communication and coordination as well as streamline processes. The reorganization combined the Center for Applied Food Safety and Nutrition (CFSAN) and the Office of Food Policy and Response into a single group working under the Deputy Commissioner for Human Foods. The reorganization created three new offices representing three main pillars of work: the Office of Microbiological Food Safety; the Office of Food Chemical Safety, Dietary Supplements & Innovation; and the Nutrition Center of Excellence (which include critical foods such as infant formula and medical foods). The reorganization also contains several cross-cutting offices, including the Office of Compliance & Enforcement, Office of Coordinated Outbreak Response, Evaluation & Emergency Preparedness, Office of Policy & International Engagement, and Office of Laboratory Operations & Applied Science. More streamlined decision-making and long-term accountability is the goal of this organization. In the short term, the program is still in a period of flux. While many permanent leadership positions have been filled, the change in administration may bring changes to leadership and policy directions. Consequently, it may be difficult to make significant policy decisions, and it may not always be clear where to turn for clear answers. That said, the changes to the field that consolidated compliance personnel in the centers will likely be beneficial to industry as compliance decisions will be centralized.

Regarding the reorganization of FDA's field component, the impact extends beyond foods and impacts all product centers. As noted in the *Introduction*, the Office of Regulatory Affairs (ORA) is now the Office of Inspections and Investigations (OII). OII will carry out traditional operational inspections and investigations across all commodity areas, with increased specialization for particular products. It will continue to oversee import operations and criminal investigations. However, most compliance officers and labs have been moved to their respective Centers and the HFP. That will likely result in more consistent compliance decisions since those decisions will be made by the Offices of Compliance within the associated Centers or HFP, making those offices the central place to discuss compliance issues.

Ingredients, safety, labeling, and disclosures

FDA issued several guidance documents and other initiatives related to food and dietary supplement topics ranging from ingredients and chemical safety to nutrient labeling and indirect food additives.

In September 2024, the Agency held a Public Meeting on the Development of an Enhanced Systematic Process for the Post-Market Assessment of Chemicals in Food. This meeting, discussed in detail in our client alert, continued the Agency's efforts to ensure the safety of the food supply, including with respect to food additives, GRAS ingredients, color additives, food contact substances, and contaminants. This issue remains a priority at the federal and state levels and continues to be the

subject of litigation. Companies are encouraged to monitor the reevaluation process as it may have a substantial impact on their products. Companies may also consider developing strategic plans to respond to this activity, including identifying opportunities to provide proactive input to the Agency, determining potential reformulations of products, reviewing supplier agreements, assessing the impact on global distribution of products, monitoring the impact on state requirements, and considering potential litigation risks that arise based on new information and statements by FDA.

The Agency also took a series of actions affirming its issuance of its 2022 "Indirect Food Additives: Adhesives and Components of Coatings; Paper and Paperboard Components; Polymers; Adjuvants, Production Aids, and Sanitizers" final rule that amended the food additive regulations to eliminate the use of 25 plasticizers in various food contact applications. The Agency rejected the objections of several public interest groups to expand the removal of these types of food contact substances in packaging, including diallyl phthalate. FDA determined that there was an insufficient basis to modify the 2022 final rule. However, the Agency has included phthalates on its List of Select Chemicals in the Food Supply Under FDA Review and has indicated that it is working on an updated safety assessment of the remaining authorized uses of phthalates, as discussed in detail in our client alert, so there may be additional action in the future.

State and federal regulators continued to focus on per- and polyfluoroalkyl substances (PFAS) in 2024. FDA announced its determination that 35 food contact notifications concerning certain PFAS are no longer effective because manufacturers have ceased production, supply, or use of those substances, which were used in paper and paperboard for grease proofing. This announcement followed an earlier announcement in February 2024 that this voluntary market phaseout was complete and these PFAS were no longer being sold. While FDA has been working with industry on voluntary efforts to remove PFAS from the food supply, states and plaintiff's attorneys have taken a more aggressive approach. Companies are encouraged to monitor their suppliers and review related supply agreements to ensure transparency into any prohibited PFAS materials in packaging.

Both FDA and USDA focused on labeling and nutrient disclosures in 2024. As discussed in our client alert, in December 2024, FDA issued its "Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy'" final rule updating the "healthy" nutrient content claim, which can be used on a voluntary basis by industry to highlight foods that are consistent with the Dietary Guidelines for Americans and the updated Nutrition Facts label. The updated criteria require a certain amount of food from recommended food groups (*eg*, fruits, vegetables, and dairy) and create limits for saturated, fat, sodium, and added sugars. The rule gives companies until February 25, 2028 to comply.

In December 2024, FDA and USDA issued a joint "Food Date Labeling Request for Information." This document requests stakeholder input on best practices and preferences for presenting "sell by," "best by," or "use by" dates. At this point, the agencies are seeking input on industry practices and preferences to help determine whether future action is needed.

To enhance transparency and clarity around US origin claims, in March 2024, USDA issued a "Voluntary Labeling of FSIS-Regulated Products With U.S.-Origin Claim" final rule regarding the voluntary "Product of USA" or "Made in the USA" label claim for meat, poultry, and egg products. Under the final rule, such claims can be made only when the products are derived from animals born, raised, slaughtered, and processed in the US. The claim will remain eligible for generic label approval, but it requires subject establishments to maintain documentation supporting the claim. Subject establishments and related products using the "Product of USA" claim must comply with the new final rule requirements by January 1, 2026.

Biotechnology plants received some attention from FDA in 2024. The Agency issued a guidance on "Foods Derived from Plants Produced Using Genome Editing," and it also introduced an inventory of voluntary premarket meetings for food from genome-edited plans, which will provide additional transparency for stakeholders around the plant, the developer, and intended use of the plant variety. In early 2025, FDA issued a draft guidance on "Labeling of Plant-Based Alternatives to Animal-Derived Foods suggesting continuing focus on technological innovation in food in 2025."

FDA also issued several documents regarding new dietary ingredients notifications (NDINs) including:

- "Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry" (March 2024) to assist industry in complying with the prenotification requirements
- "New Dietary Ingredient Notification Master Files for Dietary Supplements: Guidance for Industry" draft guidance (April 2024) providing information on Master Files, and
- "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues" (April 2024) providing information to determine whether a NDIN is required.

These documents are part of a larger effort on the part of the Agency to better understand the current dietary supplement landscape and, in particular, what dietary ingredients are being used by industry. In response to FDA's concerns and in anticipation of further FDA action, companies should review the ingredients in their products to ensure that all ingredients meet FDA safety standards.

In November 2024, the Food Safety and Inspection Service of the US Department of Agriculture (USDA/FSIS) issued a proposed rule that would establish final product standards to prevent raw chicken carcasses, chicken parts, ground chicken, and ground turkey products that contain any type of Salmonella at or above ten colony forming units (CFU) per gram per milliliter and any detectable level of at least one of the Salmonella serotypes that USDA identifies to be of public health significance from entering commerce. USDA also issued a determination that such products are adulterated within the meaning of the Poultry Products Inspection Act. A final rule would have significant impact on the poultry industry. Industry is encouraged to submit written comments within the extended comment period (by April 2025). There will also be opportunities to engage with the new administration and Congress on particular areas of concern prior to the issuance of any final rule.

Supply chain safety, imports, and supplier verification

As food and dietary supplement supply chains become more complex, FDA and other regulators continued to focus on imports and supply chain safety in 2024. The cinnamon applesauce recall highlighted FDA's focus on the need for robust supplier verification programs. FDA issued a Warning Letter to a manufacturer for not conducting a thorough hazard analysis and not conducting appropriate verification activities. FDA also alleged violations in the manufacturer's supplier program resulted in allegedly harmful levels of lead and chromium in certain products. In light of this, companies are encouraged to reassess their supplier verification program to ensure they are adequate and documented, whether they are implemented through the Preventive Controls, Foreign Supplier Verification Program, or Hazard Analysis Critical Control Point rules.

Also in 2024, FDA rewarded importers who have robust supplier controls. In November 2024, FDA issued its final guidance on FDA's Voluntary Qualified Importer Program (VQIP). This program was created under the Food Safety Modernization Act (FSMA) to provide a "green lane" for food imports that meet certain conditions, including demonstrating that the foreign supplier is certified under FDA's Accredited Third-Party Certification Program for foods. Those that participate in this fee for service program can help ensure that their products are not detained for further evaluation at ports of entry. This may provide a level of certainty that can be essential when importing fresh products or when the imported food is needed for production schedules.

This year

As in other product areas, it is difficult to predict what 2025 will look like. On the one hand, the new Administration indicated a deregulatory approach by reducing staff and issuing EOs that will slow down rulemaking, including an EO that requires agencies to identify 10 regulations (defined broadly to include guidance documents and other policy documents), before issuing a new regulation. On the other hand, Secretary Kennedy has indicated an increased focus on chemicals in food and nutrition policies. Prior to the change in administration, the agency forecasted a focus on food safety, chemicals, and supply chain safety, much of which aligns with Secretary Kennedy's priorities. Perhaps in anticipation on the change in administration, in the first few weeks of 2025, the Biden Administration issued several key guidance documents and proposed rulemakings on these and other topics that will likely drive the regulatory agenda for much of 2025. These documents focus on topics including chemicals, ingredients, and allergen labeling. Notably, FDA kicked off 2025 with a pair of allergen guidances, "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)" and "Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act."

With respect to chemicals, as discussed above, the Agency intends to advance its post-market reassessment of chemicals in food, resources permitting. For example, in early 2025, FDA issued a final guidance on "Action Levels for Lead in Processed Food Intended for Babies and Young Children." The Agency had indicated it would issue draft guidance documents on cadmium and arsenic in baby food. FDA had also promised to expand the use of new methods to evaluate and characterize exposure to PFAS. Because FDA did not publish the expected chapter 12 of the Food Safety Modernization Act Preventive Controls for Human Food specific to Chemical Hazards, this would likely be high priority in 2025. Industry has been looking forward to that guidance to help manage these hazards, particularly unavoidable environmental contaminants that have been the subject of both regulatory action and civil litigation. Given that there is no express federal preemption for chemical safety, we will continue to see states like California, New York, Washington, and others establishing requirements around ingredients and packaging for foods and other consumer products, particularly as FDA is slow to act in this area. This patchwork of state laws poses challenges for the industry as they must navigate different (and sometimes conflicting) requirements.

We also anticipate developments and guidance with respect to food and color additives, food contact substances, and generally recognized as safe (GRAS) substances. In January 2025, FDA issued An order on the "Color Additive Petition

From Center for Science in the Public Interest, et al.; Request to Revoke Color Additive Listing of FD&C Red No. 3 in Food and Ingested Drugs." This order may be the first of many announcements on food and color additives in 2025. FDA also plans to complete a review of its pre-market review process for food and color additives, food contact substances, and GRAS substances. Given Secretary Kennedy's concerns in these areas, there will likely be renewed discussion GRAS reform, including proposals to eliminate self-affirmation of GRAS so that industry will be required to go through the GRAS notification process. However, there may be pushback from industry on this issue.

On the nutrition side, the Agency may focus on ways to decrease chronic disease, as that is also a priority of the new administration, as indicated in its EO, Establishing the President's Make America Healthy Again Commission. The Biden Administration kicked off 2025 with a "U.S. Surgeon General's Advisory on Alcohol and Cancer Risk," which may set the stage for additional policies focused on the connection between nutrition and disease. This may include new guidance on added sugars and new sodium reduction targets. FDA's 2025 proposed rule, "Food Labeling: Front-of-Package Nutrition Information," illustrates the Agency's continued emphasis on labeling, consumer information, and disclosures as a means of enhance consumer education and nutrition choices. There will also be attention given to "ultra processed" foods, which has been a target of Secretary Kennedy. This could result in new regulations and guidances aimed at the food industry. There will be opportunities for industry to engage with FDA on these issues, to help educate the Agency and its leaders on the significant impact removing some of these chemicals to a robust and affordable food supply. That said, and as discussed above with respect to FDA's reevaluation of chemicals in the food supply, companies are encouraged to consider additional steps to minimize risks to their business from a regulatory and litigation perspective.

Traceability and supply chain safety will likely receive continued attention in 2025. We may see continued pushback on the compliance date for the 2022 Food Traceability Rule. Industry is struggling to meet the January 2026 compliance date, but many producers and retailers are concerned that the complexity of the rule will create challenges to that goal. There may be legislative activity to move the compliance date and amend some of the requirements, and some are seeking to start with a pilot. Meanwhile, this remains a priority for the Agency in light of continued foodborne outbreak. Already this year, FDA issued a final guidance on "Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event." This and other forthcoming guidance suggest that FDA is prioritizing additional tools and resources to address foodborne outbreaks and sanitation programs and work toward implementation and will continue to engage with industry in 2025.

FDA will likely continue to target produce safety in the coming year, with a focus on pre-harvest agricultural water. The Agency is targeting the issuance of the final guidance for the 2015 Produce Safety Rule to assist industry in reducing foodborne outbreaks from produce.

The Agency stated its intention to advance the reinstatement of the Human Foods Advisory Committee, which was disbanded in 2017 and is set to be in place by 2026. FDA will use the advisory committee to obtain external experts' advice on challenging and emerging issues in food safety, nutrition, new and innovative food technologies, and other foods-related scientific, technical, and policy matters. Industry is encouraged to monitor notices to solicit members to ensure a balanced viewpoint. This committee could play an important role in critical decisions as food resources continue to be stretched thin.

With an administration that seems supportive of the dietary supplement industry, we may see more challenges to FDA's interpretations of regulatory requirements in this area. For example, the Agency has taken a strict of what is an "article that is approved as a new drug" in interpreting the clause in the FDCA that excludes certain ingredients in dietary supplements. The incentive to challenge the agency is likely bolstered by the *Loper Bright* decision (discussed in the *Enforcement and litigation* section below) that provides less deference to an Agency's interpretations of its statute. Much of what the Agency can do in the food and dietary supplement area will depend on funding, as this program has only limited user fees to support it. While the Agency has been committed to pre-market consultations for new ingredients and product development, its ability to offer such meetings and meet deadlines will likely be impacted by appropriations and a reduction in FDA staff.

Cosmetics

2024

As part of the Human Foods Program reorganization, the Office of Cosmetics and Colors was moved from CFSAN under the reorganization and now sits in the Office of Chief Scientist in the Office of the Commissioner.

FDA continued to implement the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). In 2024, several compliance dates kicked in, including registration and listing, reporting of significant adverse events to the Agency, labeling for professional use, and mandatory recall. In December 2024, FDA issued its "Registration and Listing of Cosmetic Product Facilities and Products" guidance, which provides detailed guidance on the submission of cosmetic product facility registrations and product listings.

The Office of Cosmetics and Colors was moved from CFSAN under the reorganization and now sits in the Office of Chief Scientist in the Office of the Commissioner.

In December 2024, FDA issued a proposed rule required by MoCRA, "Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products." The proposed rule specifies that manufacturers of talc-containing cosmetic products use both Polarized Light Microscopy (PLM) and Transmission Electron Microscopy / Energy Dispersive Spectroscopy / Selected Area Electron Diffraction (TEM / EDS / SAED) to test for potential asbestos contamination. If finalized, manufacturers would have to test representative samples of each batch or lot of talc-containing cosmetic product or on representative samples of each batch or lot of the talc ingredient used in the manufacture of cosmetic products. The proposed rule would allow manufacturer to rely on a certificate of analysis from the talc supplier, in lieu of its own testing, if the manufacturer qualifies the supplier by establishing and maintaining the reliability of the supplier's certificate of analysis through verification of the results of the supplier's tests.

This year

FDA did not meet the statutory deadline to publish mandatory GMPs under MoCRA in 2024. Therefore, the Agency will likely issue this proposed rule in 2025.

The increased focus on chemical safety will also likely spill over to the cosmetics area as FDA, states, and plaintiff's attorneys are focusing on ingredients used in consumer products.

Tobacco

2024

FDA's Center for Tobacco Products (CTP) ended 2023 by releasing its five-year strategic plan, in which CTP outlined its goals for regulations and guidance, product application review, enforcement, public education, and operational excellence. FDA took several steps in 2024 to advance these goals, and more work remains to be done as CTP continues to address a market filled with unregulated vapor products and a continued backlog of product applications submitted in September 2020. Nonetheless, CTP Director Brian King ended the year with a celebratory blog post, explaining that, under the recently released 2024 National Youth Tobacco Survey findings, "youth tobacco product use has dropped to its lowest level ever reported since the survey began a quarter century ago."

Regulation and guidance

In April 2024, the much-anticipated final rule that would create a product standard prohibiting menthol as a characterizing flavor in cigarettes was suddenly withheld, as HHS Secretary Xavier Becerra released a statement that the "rule has garnered historic attention and the public comment period has yielded an immense amount of feedback, including from various elements of the civil rights and criminal justice movement." Without saying more about the future of the final rule, the statement ended: "It's clear that there are still more conversations to have, and that will take significantly more time." While FDA has said in public appearances that the final rule is still a priority for CTP, the final rule was not featured on the Office of Management and Budget's Spring 2024 Unified Agenda of Regulatory and Deregulatory Actions.

In August 2024, FDA issued its final rule, "Prohibition of Sale of Tobacco Products to Persons Younger Than 21 Years of Age," making conforming changes after the federal minimum age for the sale of tobacco products was increased from 18 to 21 in 2019. Under the final rule, FDA increased the minimum age for age verification by means of photographic identification from 27 to 30 and increased the minimum age of individuals who may be present or permitted to enter facilities that maintain vending machines and self-service displays from 18 to 21.

In September 2024, FDA issued a revised "Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide (Revised): Guidance for Industry" intended to help small businesses understand and comply with FDA's 2020 final rule, "Required Warnings for Cigarette Packages and Advertisements." The 2020 final rule was subject to challenge in litigation, with FDA ultimately prevailing after SCOTUS denied a writ of certiorari in November 2024, leaving the US Court of Appeals for the Fifth Circuit's holding that the final rule did not violate the First Amendment to the US Constitution intact. Under FDA's "Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements," also issued in September 2024, FDA intends to exercise enforcement discretion and generally not enforce requirements of the final rule until December 12, 2025. Products manufactured prior to December 12, 2025 will have until January 12, 2026 to comply. The Agency updated its "Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised)*" guidance for those submissions.

Litigation

FDA's graphic health warnings final rule was not the only agency action subject to litigation. On December 2, 2024, SCOTUS heard oral argument in a challenge to FDA's denial of premarket tobacco product applications (PMTAs) for flavored e-cigarette products. While most circuits upheld FDA's decisions, the US Court of Appeals for the Fifth Circuit, sitting *en banc*, ruled against FDA, holding that FDA "sent manufacturers of flavored e-cigarette products on a wild goose chase" after FDA faulted the applicants for not providing longitudinal studies though FDA once said in guidance that such specific studies were not required. *Wages & White Lion Invs., LLC v. FDA,* 90 F.4th 357, 362 (5th Cir. 2024).

Enforcement

In June 2024, FDA, along with the US Department of Justice, announced the creation of a federal multi-agency task force focused on the illegal distribution and sale of e-cigarettes. Prior to this announcement, FDA and DOJ successfully seized mostly flavored, disposable e-cigarette products in California, along with issuing warning letters to various retailers for selling similar products that have not received FDA authorization. Since the taskforce was created, FDA has successfully conducted seizures of additional products, and in December 2024, FDA issued additional warning letters to over 100 retailers for selling similar products – a result of FDA's ongoing cooperation with state partners.

This year

Notwithstanding President Trump's campaign promises to "save vaping" and other potential impacts following the presidential transition, 2025 may bring additional product application decisions as CTP continues its review of PMTAs submitted by the September 2020 deadline imposed by the US District Court for the District of Maryland. However, it is possible FDA will wait to see the outcome of the current SCOTUS case before issuing any significant product application decisions. A decision in the SCOTUS case is expected in summer 2025.

FDA is also scheduled to release several proposed rules and final rules in 2025. These include:

- "Establishment Registration and Product Listing for Tobacco Products," RIN 0910-AH59
- "Administrative Detention of Tobacco Products," RIN 0910-AI05. The rule would permit FDA to administratively detain tobacco products observed during an inspection that Agency officials have reason to believe are misbranded or adulterated.
- "Requirements for Tobacco Product Manufacturing Practice," RIN 0910-AH91. The future of the final rule for the menthol cigarette product standard also remains to be seen in 2025.

Finally, though originally identified in a March 2018 advance notice of proposed rulemaking, 2025 may also show progress for a tobacco product standard for a nicotine level of certain tobacco products. FDA has identified this rule as a "Long-Term Action", with an NPRM "to be determined."

Cannabis

2024

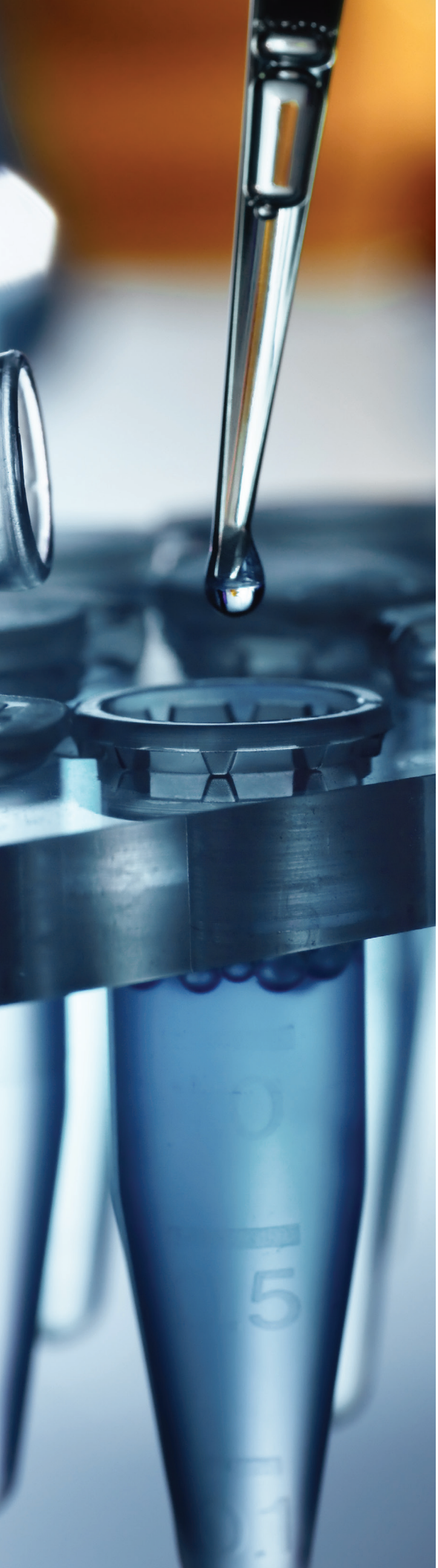
In May 2024, the Department of Justice (DOJ) issued a "Schedules of Controlled Substances: Rescheduling of Marijuana" proposed rule to reschedule marijuana from schedule 1 to schedule 3 and held a hearing to discuss the proposal. Should this rule become finalized, it would lessen restrictions on research and provide for tax advantages and access to banking institutions. See a detailed discussion here on for more details on what this means for industry.

While FDA has expressed a need for additional legislative authorities to regulate CBD and other cannabis products, the agency continues to take enforcement actions against products it believes pose a risk to public health, including Warning Letters against companies selling delta-8 THC products.

This year

It is unclear whether and how the new administration will prioritize cannabis issues. On the one hand, Robert F. Kennedy Jr. supports for full legalization of marijuana; however, Pam Bondi, Attorney General, has been an opponent of marijuana reform. While we will see continued movement toward rescheduling cannabis, we may not see a final rule or any practical effect in 2025.

We may see increased activity around delta-8 and delta-9 products, particularly those derived from hemp. Several states have been focused on tightening restrictions around intoxicating hemp products sold outside of any recreational cannabis framework.



Clinical trials

2024

In its January 2024 draft guidance, "Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products," the FDA provided updated recommendations on the presentation of demographic data in Investigational New Drug (IND) applications and New Drug Applications (NDAs). It also outlined the collection of race and ethnicity data in Biologics License Applications (BLAs) and medical device applications. In addition, the Safety and Innovation Act Section 907 Action Plan addressed methods to improve the completeness and quality of demographic data collection and reporting.

In June 2024, the FDA issued its "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies: Draft Guidance for Industry." The Diversity Action Plans aim to increase enrollment of subjects from historically underrepresented populations, thereby enhancing the strength and generalizability of clinical studies. The draft guidance outlines recommendations for the content of Diversity Action Plans, including:

- The sponsor's goals for enrollment,
- The sponsor's rationale for the goals, and
- The sponsor's strategy to achieve the goals.

The draft guidance also includes timelines for the submission of Diversity Action Plans based on the type of marketing application. These initiatives are intended to ensure that FDA-approved or cleared medical products are safe and effective for use in the general population, without causing delays in treatment or introducing new health risks.

In its February 2024 draft guidance, "Use of Data Monitoring Committees in Clinical Trials," FDA provides updated recommendation on data monitoring committees (DMCs), also known as data and safety monitoring committees (DSMCs) or independent data monitoring committees (IDMCs), including when they would be useful and policies and procedures that should be considered to guide their operation. While DMCs are not required except under limited circumstances in connection with emergency settings where an institutional review board approves a clinical trial without requiring informed consent, they may be useful where they can meaningfully assess continued exposure of subjects to investigational interventions, in therapeutic areas of limited experience, when subjects from a vulnerable population are participating in a trial, or if trial subjects are at risk of serious morbidity or mortality. They may also be useful in a single-arm trial.

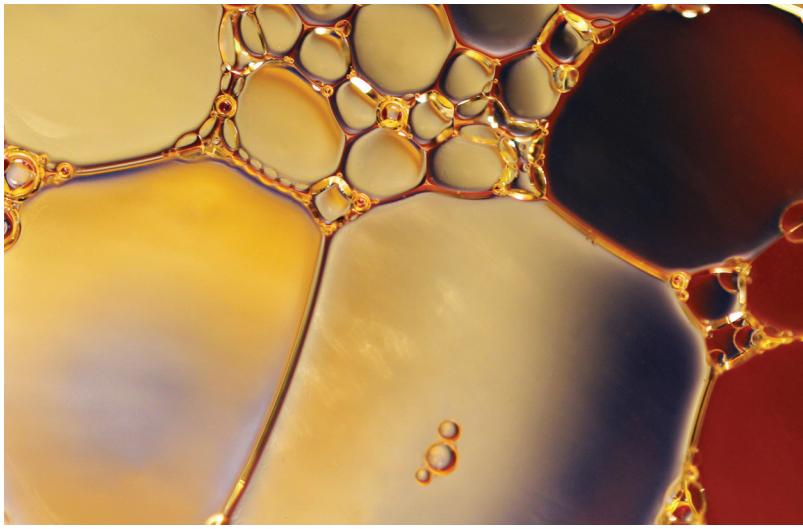
In its March 2024 draft guidance, "Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards," FDA provides recommendations on content, organization, and presentation of informed consent information in FDA-regulated clinical investigations that are also subject to the US Department of Health and Human Services Federal Policy for the Protection of Human Subjects (Common Rule). While the two sets of requirements are largely harmonized, the guidance provides practical guidance on how to present information to satisfy both while facilitating understanding for the trial subject.

The 21st Century Cures Act (Pub. L. No. 114-255) amended section 569C of the FDCA to include the concept of "patient experience data," which is data "intended to provide information about patients' experiences with a disease or condition." In the September 2024 "Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle: Draft Guidance for Industry, Food and Drug Administration Staff, and Other Interested Parties," FDA focuses on "patient preference information" (PPI) as a specific type of patient experience data. FDA encourages the submission of PPI with medical device marketing submissions, if available. In the guidance, FDA addresses how to outline the qualities of patient preference studies, provides recommendations on how to collect and submit PPI to FDA, and discusses FDA's inclusion of PPI in decision summaries and recommendations on inclusion of such information in device labeling. FDA acknowledges that PPI may be useful throughout the total product lifecycle, such as by improving understanding of the disease or condition, designing products to meet the needs of the patient end user, and assessing outcomes that are important or meaningful to patients.

In its September 2024 "Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice: Draft Guidance for Industry," FDA addresses "point of care trials" or "large simple trials," which are randomized controlled drug trials integrated into routine clinical practice. These trials may improve more representative enrollment by leveraging established healthcare institutions and clinical expertise. The draft guidance addresses the role of sponsors, healthcare institutions and healthcare providers, and clinical investigators as well as how sponsors can simplify trial designs for successful integration into clinical practice.

In September 2024, in response to a requirement in the Consolidated Appropriations Act, 2023, FDA also issued its final guidance, "Conducting Clinical Trials With Decentralized Elements," to support development of drugs and devices using decentralized clinical trials (DCTs). A decentralized clinical trial has trial-related activities at locations other than traditional clinical trial sites, *eg*, telehealth visits, and the use of DCTs has increased since the COVID-19 pandemic as a result of the expanded legal framework, infrastructure, and tools that enable them. Topics covered include DCT design and conduct, remote clinical trial visits and trial-related activities, digital health technologies, roles and responsibilities, informed consent and institutional review board oversight, investigational products, safety monitoring, and use of electronic systems when conducting DCTs.

In December 2024, FDA issued a draft "Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices" guidance addressing the types of protocol deviations sponsors should report to FDA and that investigators should report to sponsors and IRBs, respectively. The draft guidance also includes considerations for IRBs in evaluating protocol



deviations. In particular, FDA considers the following types of protocol deviations to be "important" and, therefore, reportable because they may significantly affect the reliability of study data or subject rights, safety, or wellbeing:

- Failure to conduct study procedures designed to assess subject safety or failure to adequately monitor subjects
- Administering concomitant treatments prohibited by the study protocol that may increase risks to subjects or impact interpretation of a device's safety and efficacy
- Failure to obtain informed consent or otherwise satisfy the requirements of 21 C.F.R. Part 50
- Failure to protect a subject's identifiable protected health information
- Failure to withdraw product administration from participants who meet withdrawal criteria
- Administration of the wrong treatment or incorrect dose or implantation of an incorrect device
- Failure to adhere to the protocol-specified randomization scheme
- Enrollment of a subject in violation of key eligibility criteria
- Failure to collect data to evaluate important study endpoints, or
- Premature unblinding for reasons other than those specified in a trial protocol.

This year

The current administration may determine to roll back clinical trial diversity plans and related initiatives. Companies that rely on Chinese manufacturing and research organizations may be required to sever ties or greatly reduce the scope of services obtained from Chinese companies. Further, there may be greater investment in and focus on the use of AI and other technological alternatives to traditional clinical trials.

Advertising and promotion of medical products

2024

While advertising and promotion compliance remains a significant area of focus for FDA-regulated companies, FDA continued to take a more targeted approach to advertising and promotion policy and enforcement in 2024. The Office of Prescription Drug Promotion (OPDP) issued five untitled letters for violations such as failure to provide adequate risk information, overstating or misrepresenting the safety or efficacy of products, and failure to provide warning letters. By comparison, OPDP issued one warning letter and four untitled letters in the prior year. This year, CDRH and the Advertising and Promotional Labeling Branch of CBER did not issue any enforcement letters exclusively or primarily focused on advertising and promotion against firms. These numbers are consistent with the broader trend of more targeted FDA enforcement activity in the advertising and promotional space.

In April 2024, FDA issued its revised draft "Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers Guidance for Industry." In this draft guidance, FDA addresses, in a question-and-answer format, questions firms may have when developing promotional labeling and advertisements for prescription biologics products, including biosimilars and interchangeable biosimilar products. The key substantive updates from the 2020 draft guidance were the addition of two questions relating to interchangeable biosimilar products.

In July 2024, FDA issued its "Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers" draft guidance, which will replace the June 2014 "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices" draft guidance. The most notable change is the addition of specific examples of how firms can voluntarily correct misinformation about their products through "tailored responsive communications" (TRCs). These TRCs are voluntary, internet-based communications to address misinformation. While TRCs may be aimed at a class of products, the Agency does not require them to be specific to a firm's products. FDA notes that the guidance is limited to a firm's response to misinformation created or disseminated by a third party that suggests the firm's cleared or approved medical product should be used for an unapproved use (*ie*, off-label use). It does not extend to a firm's responses to statements describing opinions or value statements about a product, nor does it extend to representations about an individual patient's experience using a product (whether made by a patient or others). Broadcast advertisements are outside the scope of this guidance, even when streamed online.

FDA established a compliance deadline of November 20, 2024 for the final rule entitled, "Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format," which establishes five standards that the major statement must meet in order to satisfy the "clear, conspicuous, and neutral manner" requirement for broadcast advertisements in television and radio formats (CCN Final Rule). Drug manufacturers, packers, and distributors are subject to the CCN Final Rule and should ensure DTC prescription drug advertisements comply with the CCN Final Rule. The Agency provided an educational webinar on the CCN Final Rule in June 2024.

This year

In January 2025, FDA finalized its "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers" guidance, which remained substantially the same as the prior draft guidance.

We may see continued interest and scrutiny over advertising and promotion on social media platforms given their far-reaching impact. This year, three of the five untitled letters issued by OPDP involved social media influencers. Firms are encouraged to exercise judgment and caution when engaging online content creators and develop appropriate policies and controls to ensure these third-party endorsers understand and follow applicable regulatory requirements. We are also keenly monitoring the Agency's next moves under the new administration in light of the congressional letter issued to FDA in February 2024, urging the Agency to update its 2014 social media guidances and expand their enforcement activities. As companies start to employ and deploy AI tools and platforms for various advertising and promotion functions, there may be increased regulatory focus on the use of AI for prescription drug and medical product advertising, both in terms of the use of AI for targeted or customized marketing and in terms of appropriate disclosures regarding AI-generated content.

Enforcement and litigation

2024

In 2024, FDA focused on strengthening its inspection processes and clarifying the scope of its inspection authority as well as navigating several court rulings that challenge long-established norms regarding deference to agency decision-making. In February 2024, FDA issued an update to its July 2022 draft guidance, "Conducting Remote Regulatory Assessments Questions and Answers." The update provides additional information on authority for mandatory records requests. Specifically, recent updates to FDA's records request authority under section 704(a)(4) of the FDCA provide that this mandatory records request authority applies to drug and device establishments and to sites, entities, or facilities subject to BIMO inspections. FDA may increase use of this authority to make onsite inspections more efficient by allowing a pre-review of records or, in some cases, to completely replace onsite inspections.

Those in industry responsible for managing clinical studies are encouraged to review the guidance and consider what procedural or IT system changes may be needed to support a Remote Regulatory Assessment (RRA). For example, RRAs require the ability to share documentation electronically and hold video interviews remotely. Those individuals are also encouraged to reach out to clinical study sites to review whether those sites are prepared to support an RRA. Further, companies may want to develop procedures for how to manage RRAs.

In June 2024, FDA announced a draft guidance, "Processes and Practices Applicable to Bioresearch Monitoring Inspections." The draft guidance was issued to comply with FDORA, which directs FDA to issue guidance describing the processes and practices applicable to inspections of sites and facilities inspected under FDA's BIMO inspection program, to the extent not specified in existing publicly available FDA guides and manuals (*eg*, FDA's Regulatory Procedures Manual and RPM and Investigations Operations Manual). The draft guidance is intended to cover the types of records and information companies must provide, best practices for communication between FDA and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct.

The draft guidance provides clarity on FDA's expectations regarding communication before, during, and after the inspection. Specifically, before the inspection, FDA will notify the establishment in advance to ensure the availability of key personnel and records. During the inspection, the establishment should be prepared to provide FDA personnel with access to paper and electronic records. The draft guidance outlines that electronic systems should offer read-only access during inspections to maintain data integrity. After the inspection, FDA investigators hold a closeout meeting with the establishment's representatives after the inspection. If the inspection results in *non-compliance* observations (documented on a Form FDA-483), the establishment should respond in writing within 15 business days. FDA's draft guidance also recognizes the growing role of RRAs as an alternative or complement to onsite inspections. RRAs have become integral to FDA's oversight strategy, especially in light of global clinical trials and situations where travel is impractical.

In June 2024, FDA published its final "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection" guidance. This guidance defines the types of behaviors and circumstances FDA considers to

constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection for the purposes of section 501(j) of the FDCA.[1] The examples used in this guidance illustrate the most common situations that FDA has encountered in preparing for and conducting drug or device inspections as well as situations that FDA anticipates may occur, including FDA's efforts to take photographs during inspections and requests for records. Personnel responsible for inspection readiness training are encouraged to consider a review of current inspection SOPs and revise as needed.

The guidance provides a few new examples of what would be unacceptable to FDA and could lead to a determination that a product is adulterated pursuant to section 501(j) of the FDCA, such as interrupting operations in order to prevent the investigator from observing them, removing sections of records (*eg*, removing spreadsheet data columns, exporting only part of the electronic record that FDA is asking for, or locking a spreadsheet), or simply not providing electronic copies of records. The new final guidance includes a situation that might be acceptable, however, in which a facility limits photography in circumstances in which "the facility can document that taking photographs of any raw material or assembly would adversely affect product quality."

Enforcement resolutions

On March 26, 2024, Family Dollar Stores LLC, a subsidiary of Dollar Tree Inc., pled guilty to holding consumer products under insanitary conditions, specifically due to a rodent infestation at the company's West Memphis, Arkansas distribution center. Family Dollar was charged with one misdemeanor count of causing FDA-regulated products to become adulterated while being held under insanitary conditions. The company entered into a plea agreement and was sentenced to a fine and forfeiture amount totaling $41.675 million, the largest-ever monetary criminal penalty in a food safety case. According to the plea agreement, Family Dollar began receiving reports in August 2020 of mouse and pest issues with deliveries to its stores. The company admitted that, by January 2021, some of its employees were aware that the unsanitary conditions caused FDA-regulated products held at the warehouse to become adulterated in violation of the FDCA. Family Dollar continued to ship FDA-regulated products from the warehouse until January 2022, when an FDA inspection revealed live rodents, dead and decaying rodents, rodent feces, urine, odors, and evidence of gnawing and nesting throughout the facility. Subsequent fumigation of the facility resulted in the reported extermination of 1,270 rodents.

In June 2024, Magellan Diagnostics, Inc. (Magellan) pled guilty in federal court in Boston to criminal charges relating to its concealment of a device malfunction that produced inaccurately low lead test results for tens of thousands of children and other patients. As part of the criminal resolution, Magellan pleaded guilty to two counts of introducing a misbranded medical device into interstate commerce, in violation of the FDCA, and agreed to pay $21.8 million fine, $10.9 million in forfeiture, and a minimum of $9.3 million to compensate patient victims. Magellan also entered into a deferred prosecution agreement (DPA) which requires the appointment of an independent monitor for two years and compliance with a comprehensive corporate compliance program for the company to avoid prosecution on deferred conspiracy charges.

As a result of this matter, Magellan is subject to specific compliance program obligations. For example, Magellan must ensure that senior leadership provide "strong, explicit, and visible support and commitment to its corporate policy against violating the FDCA" and "demonstrate rigorous adherence by example." Notably, the DPA compliance measures extends forward to the acquisition of, or merger with, any new entities. In addition to this corporate resolution, Magellan's former CEO, Chief Operating Officer and Director of Quality Assurance and Regulatory Affairs were indicted in April 2023 and their criminal matters remain pending.

In March 2024, a federal court entered a consent decree of permanent injunction against Philips RS North America LLC (Philips Respironics) and related corporate entities; the CEO of Royal Philips, Philips Respironics' parent company; and several other corporate executives. With limited exceptions, the decree restricts the production and sale of Philips Respironics' sleep therapy devices, including CPAP and BiPAP machines, and other devices until the defendants have completed the repair, rework, replacement, and refund activities set forth in the Recall Remediation Plan, and are in compliance with requirements

[1] Section 501(j) states that a drug product is considered to be adulterated as a matter of law if the owner or operator of the facility where it was manufactured delayed, denied, obstructed, or refused an FDA inspection.

applicable to cGMP, reporting corrections and removals, and medical device reporting. In June 2021, Philips Respironics initiated a recall of certain ventilators and sleep therapy devices that contained polyester-based polyurethan (PE-PUR) foam, which was used for sound abatement but was later found to present a health risk to patients.

The consent decree is notable for many reasons, including that, as FDA noted, the consent decree "marks the first time a device company is providing a remediation payment option for a recalled device under a consent decree." The decree imposes testing requirements by an independent expert to assess Philips' plan for testing its replacement foam to ascertain whether Philip's testing plan will enable a determination that the replacement foam does not degrade during the labeled service life of the device and does not introduce any new or similar potential health concerns. While the implications or the Philips Respironics civil resolution are far-reaching, the civil resolution does not necessarily preclude further criminal enforcement. The case provides a cautionary tale regarding the costs of non-compliance and failure to correct quality deficiencies. Device manufacturers are encouraged to review this case for general awareness of the Agency's approach to enforcement of quality requirements. Manufacturers are also encouraged to invest in and assess its robust compliance program and proactive risk mitigation measures.

Judicial landscape and administrative law

Loper Bright Enterprises v. Raimondo **(June 28, 2024)**

On June 28, 2024, in a highly anticipated decision, SCOTUS in *Loper Bright Enterprises v. Raimondo,* 603 U.S. 369 (2024), overruled the *Chevron* deference doctrine, which required courts to afford deference to administrative agencies in interpreting statutes with which they were charged with enforcing.

Since the original ruling in *Chevron U.S.A., Inc. v. Natural Resources Defense Council. Inc.*, 467 U.S. 837 (1984), courts had employed a two-step test to review an agency's construction of a statute it administers. At step one, the court would ask "whether Congress has directly spoken to the precise question at issue." If the meaning of the statute was "unambiguously expressed," then "that [was] the end of the matter because the agency and the court would have to adhere to that. At step two, "if the statute [was] silent or ambiguous with respect to the specific issue," the court would then ask "whether the agency's answer [was] based on a permissible construction of the statute." The second step embodied the *Chevron* deference as it called for courts to resist "imposing their own construction of the statute" and instead called for courts to defer to an agency's reasonable construction in the absence of clear congressional intent.

Writing for the majority in *Loper Bright*, Chief Justice John Roberts found that the Administrative Procedure Act required the overruling of *Chevron* in commanding courts to decide all questions of law when reviewing any agency action. According to the Court, there is a "best reading" of each statute, which is the "one the court, after applying all relevant interpretive tools, concludes is best."

The impact of the *Loper Bright* case will be far-reaching, given the extent of regulations that govern corporations and individuals in the US. There are, however, some limits to its impact. First, the Court acknowledged that some statutes contain an express delegation of authority to an agency to interpret and implement particular provisions; these delegations of authority are still subject to deference, so long as the agency is acting within the scope of the lawful delegation. Second, the Court explained that prior court decisions upholding specific agency interpretations of statutes under *Chevron* are not automatically vacated. Over time, as new challenges are litigated, the outcomes of those cases may be different, but, for the time being, the prior cases have not been overruled. Third, the Court ruled that courts may consider the "persuasive power" of an agency's views, even if those views no longer effectively determine the "best reading" of a statute.

FDA, like many other agencies, has relied on *Chevron* deference to defend agency decision-making in APA challenges. *Chevron* principles also form the basis of FDA's internal evaluations of policy and regulatory decisions. The *Loper Bright* decision will undoubtedly influence FDA's approach to final decisions, particularly those that implicate significant programs or product-specific approval decisions. Companies may wish to recalibrate their internal processes for determining whether to challenge regulations, particularly in those areas where the underlying statute is silent or unclear on issues critical to implementation or enforcement. In the absence of clear and lawful delegation of interpretive authority to the agency in question, pursuing challenges to such regulations in the future will no longer require overcoming presumptive deference to the agency's determination. Rather, companies have to show only that the agency did not apply the "best reading" of the statute.

Corner Post, Inc. v. Board of Governors, FRS **(July 1, 2024)**

On July 1, 2024, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System,* 603 U.S. 799 (2024), SCOTUS held the statute of limitations for challenging agency action under the Administrative Procedure Act does not start running until the particular plaintiff has been harmed by the agency action. The lawsuit was a challenge to a 2011 regulation of the Federal Reserve Board setting the maximum fees that large banks can charge merchants for a debit-card transaction. The question before SCOTUS was limited to whether the case was properly dismissed because of the statute of limitations. The legal

question under review was whether a challenge to the validity of a rule must be brought within six years of the rule's issuance, or instead, as SCOTUS held, within six years of when the rule first injures the particular plaintiff challenging the rule.

Beyond the particular case, the decision has wider significance by establishing that federal regulations more than six years old can still be challenged for procedural defects in their enactment. This decision means that new businesses can be created for the purpose of challenging government regulations that would otherwise have been protected by the statute of limitations. Longstanding business with new products may also be in a position to argue harm commenced at the time the regulation became applicable to the product at issue, permitting lawsuits challenging agency regulations well beyond six years after the date of issuance.

***Securities and Exchange Commission v. Jarkesy et al.* (June 27, 2024)**

Discussed in detail in our DLA Piper client alert, on June 27, 2024, *Securities & Exch. Comm'n v. Jarkesy et al.*, 603 U.S. __ (2024), SCOTUS ruled that the Securities and Exchange Commission (SEC) cannot use its administrative courts, instead of Article III federal district courts, to decide securities fraud claims seeking civil money penalties (CMPs). SCOTUS held that the Seventh Amendment "entitles the defendant to a jury trial when the SEC seeks civil penalties . . . for securities fraud."

The Court first concluded that the SEC's antifraud provisions "replicate common law fraud," thereby requiring that a jury hear such claims. Second, the Court concluded that the public rights exception to a defendant's jury trial right did not apply to SEC antifraud claims, because such claims did not fall within "any of the distinctive areas involving governmental prerogatives where SCOTUS has previously concluded that a matter may be resolved outside of an Article III Court, without a jury."

This case has implications for FDA-regulated entities facing CMP assessments under FDA's administrative CMP provisions, which allow the Agency to assess CMPs for a range of statutory violations, including sale of tobacco products to minors, violations of Medical Device Report (MDR) requirements, and certain violations of drug advertising and promotion requirements, among others. Almost immediately after SCOTUS's decision in *Jarkesy*, litigants have filed several lawsuits against FDA to challenge its authority to impose CMPs for violations of the FDCA. In one example, *Huff and Puffers v. FDA*, No. 8:24-cfv-02110 (C.D. Cal., filed Sept. 27, 2024), FDA had imposed CMPs against a vape manufacturer for its alleged sale of unauthorized vape tobacco products which were thus alleged to be adulterated and misbranded under the FDCA. Relying on *Jarkesy*, Huff and Puffers (H&P) sought a declaration that the FDCA's CMP provisions violate the Seventh Amendment, a declaration that the administrative proceeding against H&P violates the Seventh Amendment, an order requiring FDA to dismiss the administrative complaint against H&P, an order prohibiting FDA from adjudicating civil money penalties generally and against H&P specifically.

These cases could provide greater clarity on whether and to what extent the "public rights" exception continues to permit the adjudication of certain administrative issues. The majority and dissenting *Jarkesy* opinions discuss and debate the history of the adjudication of certain "public rights" without a jury. Whether a civil penalty for violation of the FDCA is sufficiently different from an SEC fraud penalty and can be upheld as a remedy concerning a "public right" remains to be seen.

The H&P case signals potential evolution of defensive strategies in response to FDA CMP cases, where companies may increasingly consider Seventh Amendment arguments, along the lines sustained in *Jarkesy*.

***FDA v. Alliance for Hippocratic Medicine* (June 13, 2024)**

As discussed in detail in our DLA Piper client alert, on June 13, 2024, in *FDA v. Alliance for Hippocratic Medicine,* 602 U.S. 367 (2024), SCOTUS reversed and remanded the decision of the US Court of Appeals for the Fifth Circuit that would have severely restricted FDA-approved use of mifepristone to terminate pregnancies.

This year

LDT litigation

In May 2024, the American Clinical Laboratory Association and one of its members, HealthTrackRx, filed a lawsuit against FDA in the US District Court for the Eastern District of Texas to challenge the Agency's regulation of LDTs. The case specifically contests FDA's ability to regulate LDTs. The case is before federal District Court Judge Sean D. Jordan and has been consolidated with another case filed by Association for Molecular Pathology. Together, the matter is likely to be one of the first FDA-related cases to be decided under the new *Loper Bright* regime. In its brief, FDA argues the FDCA allows FDA to regulate LDTs, which the brief calls "IVD [*in vitro* diagnostic] test systems made by laboratories," and it reiterates policy arguments made in the preamble to the final rule, including that LDTs are "no longer simple, well-characterized tests" and that they are "in widespread use beyond the laboratory that designed them." Plaintiffs' reply briefs focus on the definition of a "device," the major questions doctrine, the Centers for Medicare & Medicaid Services' (CMS) authority to regulate LDTs under the Clinical Laboratory Improvement Amendments (CLIA), and FDA's lack of authority to regulate the practice of medicine. It remains to be determined whether the Trump Administration is likely to take a different approach to LDT oversight.

2025 outlook

The new administration is contemplating potentially monumental changes to federal agency leadership that could drastically affect the way the government operates. These changes include the confirmation of Robert F. Kennedy, Jr. as Commissioner of the Department of HHS and the nomination of Dr. Marty Makary, who previously opposed COVID-19-related mandates, as FDA Commissioner. These and other leadership changes will likely significantly impact FDA's strategic priorities and regulatory agenda. Food safety, vaccine safety and the use of AI/ML will likely drive FDA's policy agenda in 2025. We may see greater focus on the use of FDA's regulatory authorities related to generic drugs and biosimilars to influence ongoing discussions regarding drug prices. Strategic initiatives of the prior leadership such as combatting misinformation regarding FDA-regulated products may be deprioritized in favor of new pathways for expanded use of alternative medicines, homeopathic products, cannabis, and psilocybin.

Perhaps in anticipation of shifts or shakeups in regulatory focus and priorities, many of FDA's end-of-year guidance and early-2025 policy announcements focus on food safety issues and drug development. Notably, however, FDA issued the long-awaited proposed rule on "Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products" on January 15, 2025. If finalized, the rule would limit the allowable levels of nicotine in cigarettes and certain other combusted tobacco products to align with FDA's goal of making these products minimally or nonaddictive.

Both FDA and industry have been bracing for change. Many of these changes have been swift with far-reaching impacts. Notably, several centers within FDA have been impacted by employee layoffs and terminations. Many affected FDA employees include recently hired product reviewers, scientific officers, and statisticians, whose positions were funded by industry user fees. CDRH, for example, lost several employees who were hired under medical device user fee mandates to ensure timely review of marketing applications, safety monitoring, and other initiatives. The impacts of these staff reductions will undoubtedly impact the execution of core regulatory functions and processes. Significant legislative and policy changes may take more time, and the processes for change are still guided by longstanding statutory and regulatory norms such as the APA rulemaking requirements, good guidance practice regulations, and FDA's User Fee reauthorizations program, which is often the vehicle for major legislative amendments to the FDCA.

In the interim, new leadership may seek to use existing FDA authorities and processes such as Information Requests, inspections, and public meetings to gather information about current operations and industry practices. Therefore, companies are encouraged to assess the available Agency tools for information gathering, when and how they are used, and the benefits and risks of proactive engagement with FDA on key issues that may impact their commercial strategies and operations. In addition, because the pace of EOs, announcements and inquiries will likely increase in 2025, proactive monitoring and strategic planning around proactive engagement and the timing of regulatory submissions will likely take on greater significance in 2025.

About us

DLA Piper is a global law firm with lawyers located in more than 40 countries throughout the Americas, Europe, the Middle East, Africa, and Asia Pacific, positioning us to help companies with their legal needs around the world.

dlapiper.com

Feb 27 2025 | MRKT0026338 FDA Year in Review 2024_v6LM