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Skadden

The Nucleus: Life Sciences Enforcement and Regulatory Updates

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Circuit Split Widens Over AKS-Based FCA Causation Element

The Anti-Kickback Statute (AKS) continues to form the basis of hundreds of millions of dollars of annual recoveries for the government under the federal False Claims Act (FCA). In 2010, Congress amended the AKS to clarify that "a claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of" the FCA. Courts have recently divided, however, over the question of what standard a plaintiff must meet to demonstrate that claims submitted to the government "result[ed] from" an AKS violation in a manner sufficient to sustain an FCA claim.

Circuit Splits

The first federal appeals court to take up this question was the U.S. Court of Appeals for the Third Circuit. In *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89 (3d Cir. 2018), the Third Circuit stated that the phrase "resulting from" requires either "a direct causal link" between a kickback scheme and a claim for reimbursement, "no link at all or something in between." The Third Circuit decided that the AKS required "something in between." Because the legislative history of the 2010 AKS amendment revealed that the amendment was intended to broaden the government's prosecutorial authority rather than constrict civil liability with additional requirements of proof, the court ultimately concluded that an FCA claim arises out of an AKS violation if the government or relator proves that "a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." Thus, despite what might seem to be the plain language implication of the statutory phrase "resulting from," the Third Circuit concluded that the AKS requires proof of a "link" between the alleged kickback and a claim submitted for federal reimbursement, but not proof of but-for causation — *i.e.*, not proof that the item or service would not have been provided in the absence of the kickback.

The U.S. Court of Appeals for the Eighth Circuit, reviewing the same "resulting from" language that the Third Circuit considered in *Greenfield*, reached an opposing result. In *United States ex rel. Cairns v. D.S. Medical LLC*, 42 F.4th 828 (8th Cir. 2022), the court held that the 2010 amendment required the government or a relator to prove but-for causation, *i.e.*, "that a defendant would not have included particular 'items or services' but for the illegal kickbacks." The Eighth Circuit viewed the statutory text as unambiguous in mandating a but-for causation standard, and believed that neither the amendment's legislative history nor courts' interpretations prior to the AKS amendment altered its plain meaning.

Since the Third and Eighth Circuits diverged in *Greenfield* and *Cairns*, the split has widened. The U.S. Court of Appeals for the Sixth Circuit subsequently joined the Eighth Circuit in adopting the but-for causation standard in *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023).

Further complicating the issue, in circuits where the federal appeals courts have not yet considered the question, district courts have applied various standards, in some cases creating inconsistent authorities within their own circuits. For example, in the First Circuit, some district courts (*e.g.*, in *United States v. Teva Pharms. USA, Inc*., No. 1:20-cv-11548, 2023 WL 4565105 (D. Mass. July 14, 2023)) have applied the standard in *Greenfield*, relying on the First Circuit's apparently favorable citation to the decision in another context. However, another district court has held that *Greenfield* was wrongly decided and applied the *Cairns* but-for causation test instead (in *United States v. Regeneron Pharms., Inc.*, No. 1:20-cv-11217, 2023 WL 6296393 (D. Mass. Sept. 27, 2023)). The First Circuit has now certified interlocutory appeals in the *Teva* and *Regeneron* matters to address the applicable causation standard in order to resolve this division.

The approach adopted in *Cairns* and *Martin*, and the host of courts that have wrestled with the causation question since, suggest that courts may be willing to reevaluate the standards necessary for civil liability based on kickback allegations.

Meanwhile, district courts in the Ninth Circuit have applied three apparently different standards. One court has straightforwardly adopted *Greenfield. Kuzma v. N. Ariz. Healthcare Corp*., 607 F. Supp. 3d 942 (D. Ariz. 2022). Another has suggested that the causation element under the 2010 AKS amendment is met by proof "that Defendants' conduct was a substantial factor in bringing about the false claims and such claims were a foreseeable and natural consequence of its conduct" (*United States v. Orthopedic Alliance, LLC*, No. CV 16-3966 MWF, 2020 WL 8173025 (C.D. Cal. Nov. 19, 2020)). And a third court, observing that the Ninth Circuit has not yet decided the applicable standard, has held only that allegations of a "link" between the AKS violation and an alleged false claim are sufficient for an FCA complaint to survive a motion to dismiss — apparently a lower standard than the "link" required by *Greenfield*, in that the court held it was satisfied merely if the defendant's actions were taken "for the purpose of inducing" prohibited referrals (*United States ex rel. Everest Principals, LLC v. Abbott Labs., Inc.*, 622 F. Supp. 3d 920 (S.D. Cal. 2022)).

Implications for the Industry

The growing circuit split over the causation element calls into question the traditional assumption that FCA liability coincides as a matter of course with violation of the AKS. Undoubtedly the legal landscape is uncertain, and there is no clear sign that life sciences companies traditionally scrutinized under the AKS should expect any difference in that scrutiny moving forward. But the approach adopted in *Cairns* and *Martin*, and the host of courts that have wrestled with the causation question since, suggest that courts may be willing to reevaluate the standards necessary for civil liability based on kickback allegations. At a minimum, those cases will make the Department of Justice's (DOJ's)

pursuit of civil liability for kickbacks in the Sixth and Eighth Circuits more difficult, challenging a significant source of DOJ settlement and judgment awards. But broader adoption of the but-for causation standard could encourage DOJ to pursue criminal rather than civil remedies, and could therefore lead to an increase in AKS-based prosecutorial efforts. Regardless of how these trends develop, other circuits and the Supreme Court will likely be asked to weigh in on the debate in the near future.

As we await those decisions, the divided authority to date — and in particular the view held by some courts that a mere "link" is required between an alleged kickback and a claim submitted for federal reimbursement — underscores the need for entities dealing with federally funded health care programs to maintain scrupulous ongoing review and monitoring of both direct and indirect remuneration to patients and physicians. Regardless of the ultimate determination of the elements of the AKS, a company will best avoid liability if it can proactively identify and terminate dangerous conduct before that conduct becomes "linked" with a claim for federal reimbursement.

DOJ Enforcement

DOJ 2023 Life Sciences Fraud and Abuse Enforcement Activity: Year in Review

With 2023 in the books, it is now time to look back at the year's DOJ fraud and abuse enforcement matters involving life sciences companies and look ahead to what that enforcement activity might suggest about enforcement trends. Fifteen such DOJ-led settlements (of over $1 million each) occurred in 2023: eight involving pharmaceutical or device manufacturers and seven involving clinical laboratories.

The 2023 pharma and device settlements total was a slight increase from the six settlements in the segment in 2022. The overall number of pharma and device settlements, however, continued to be substantially lower than it was five years ago, when the total number of settlements each year generally hovered closer to 20. The types of drug and device resolutions were consistent with trends we have noted in recent years:

- The trend of device settlements outnumbering drug settlements continued in 2023, by a ratio of 2:1. This represents a marked reversal of the ratio from as recently as 2019, when two-thirds of the settlements involved pharma companies.
- The majority of pharma and device settlements — seven of the eight in 2023 — involved civil-only resolutions under the False Claims Act. Four of these involved FCA claims premised on alleged violations of the Anti-Kickback Statute resulting primarily from the provision of free items or services to physicians and patients. The remaining civil-only FCA resolutions similarly reflected well-known themes: distribution of knowingly defective or unapproved products, promoting products for medically unnecessary or unapproved uses, and pricing concerns.
- The press releases for seven of the eight pharma and device settlements reflect that they were initiated under the whistleblower, or *qui tam*, provisions of the FCA.

Consistent with recent statements by DOJ that the department will focus on individual accountability, two of the medical device company resolutions in 2023 were paired with criminal charges against company executives. In the first, STIMWAVE LLC entered a nonprosecution agreement with forward-looking compliance obligations and agreed to a $10 million monetary penalty, while the company's former CEO was subsequently convicted in connection with an alleged scheme to create and sell a nonfunctioning dummy device for implantation into patients with chronic pain. In the second resolution, Dolor Technologies, Inc. entered a civil FCA settlement that required the company to make payments based on its ability to pay, while its former CEO pled guilty to misdemeanor charges of causing the introduction of misbranded and adulterated devices intended to treat migraine headaches that were neither approved nor cleared for that use.

In another interesting development, one of the device companies that entered into a civil FCA settlement in 2023 — BioTelemetry, Inc., which agreed to a $14.7 million resolution relating to allegedly submitting claims for a higher level of remote cardiac monitoring than medically necessary — also entered a $44.8 million FCA settlement in 2022 relating to allegedly billing for heart monitoring tests performed outside of the United States. While the two resolutions involve overlapping time periods, DOJ's 2023 press release did not refer to the 2022 resolution or suggest any concerns regarding recidivism, so it is possible that the two resolved matters were under investigation within DOJ at the same time.

In addition to pharma and device matters, DOJ also showed a continued focus on other life science industry segments in 2023. Most notably, seven of the 2023 settlements involved clinical laboratories. Of these, the majority — five of the seven — involved alleged AKS

As we consider what DOJ's 2023 enforcement activity might suggest about future enforcement trends, we anticipate that DOJ will continue to scrutinize arrangements involving the provision of product support to both patients and physicians.

violations, in some cases paired with allegations of medically unnecessary testing. The remaining two resolutions involved alleged overbilling for tests performed under Department of Defense contracts and alleged violations of the Medicare 14-Day Rule applicable to billing of tests performed after discharge from a hospital stay. The substantial number of resolutions involving diagnostic and genomic labs is consistent with a marked trend toward increased lab company enforcement in recent years.

The final 2023 settlement was likewise consistent with recent enforcement theories and involved a $31 million settlement with an electronic health record (EHR) technology vendor to resolve allegations under the FCA and AKS that the vendor falsely obtained meaningful-use certification for its software that, in fact, lacked required functionalities, and that the vendor also paid kickbacks to induce the use of its software. Notably, a number of cases involving EHR vendors have pursued these theories over the past five years.

While DOJ resolutions are necessarily a lagging indicator, as we consider what DOJ's 2023 enforcement activity might suggest about future enforcement trends, we anticipate that DOJ will continue to scrutinize arrangements involving the provision of product support to both patients and physicians. This may include both free and discounted items and services as well as the accuracy and completeness of coding advice. In addition, as therapies become increasingly bespoke, we anticipate that DOJ will continue to focus on the health care technology sector and manufacturers' arrangements with entities that help identify and maintain patients on therapy. We also expect to see continued resolutions involving diagnostic and genomic labs and EHR vendors, given the sustained activity in these spaces over the past five years.

FDA Enforcement

FDA Loses Another Tobacco Case: Does It Mean Anything for Other FDA Products?

In the last issue of *The Nucleus*, we highlighted the Food and Drug Administration's (FDA's) setback in *United States v. Vepuri*, 74 F.4th 141 (3rd Cir. 2023) as evidence of a growing trend: FDA is losing more cases in court, which is atypical for an agency that has historically benefitted from judicial deference to its scientific and regulatory expertise.

In January 2024, FDA absorbed another judicial blow — this time in relation to its review of Pre-Market Tobacco Product Applications (PMTAs) for electronic nicotine delivery systems (ENDS). In *Wages and White Lion Investments, L.L.C., d/b/a Triton Distribution and Vapetasia LLC v. FDA*, No. 21-60800 (5th Cir. 2024), the U.S. Court of Appeals for the Fifth Circuit held that FDA's denials of Triton's and Vapetasia's PMTAs for nontobacco flavored e-liquids were arbitrary and capricious under the Administrative Procedures Act (APA).

The Decision

The appeal involved a consolidated review of a series of PMTAs that Triton and Vapetasia submitted in 2020 for nontobacco flavored, open-system ENDS products. FDA issued Marketing Denial Orders (MDOs) for each of the PMTAs on the grounds that the applications did not contain sufficient evidence — in the form of clinical trials or longitudinal studies — to demonstrate the benefit of nontobacco-flavored ENDS versus tobacco-flavored products. FDA concluded the absence of the studies was grounds to deny the PMTAs without further review, and therefore issued the MDOs without evaluating the other sections of the companies' applications, including their proposed marketing restrictions and the controls the companies had developed to inhibit youth access. The government's analysis occurred against the backdrop of its well-documented concerns relating to youth uptake of ENDS products, especially nontobacco-flavored versions.

The companies appealed the MDOs, arguing their PMTAs complied with FDA's repeated guidance on the types of evidence needed to secure approval. According to the petitioners, FDA clearly and repeatedly signaled to industry over several years that clinical trials and longitudinal studies would *not* be required to secure PMTA authorization. In sum, the companies accused FDA of moving the goalposts in the middle of the game — a refrain often leveled by unsuccessful applicants across all of FDA product centers that rarely gains traction in litigation.

In July 2022, a three-judge panel of the Fifth Circuit decided the appeal in favor of FDA, concluding that FDA had not created a detrimental reliance interest through its published guidance and public statements because the agency never expressly declared or guaranteed that applicants could meet their evidentiary burden through the submission of surveys or literature reviews alone. The Fifth Circuit panel also concluded FDA had not acted improperly in failing to evaluate the applicants' marketing restrictions and youth access measures because, at the time of the MDOs, the agency had already declared publicly that such restrictions were not effective controls against youth uptake of nontobacco-flavored vaping.

The companies sought rehearing *en banc* and, in January 2024, the en banc panel ruled against FDA by a vote of 10-6. In a strongly worded opinion, the court held that FDA had sent the industry on a "wild goose chase" and imposed new testing requirements without any notice, in violation of the APA.

The court essentially found that FDA had promulgated one set of rules for industry but then unfairly applied another during its internal reviews. The court grounded its decision in five separate public "instructions" FDA had provided to industry between October 2018 and January 2020. The court parsed the instructions — comprised of two guidance documents, two public meeting statements and a proposed rule — and concluded FDA had told the industry that clinical or long-term studies would *not* be required for PMTAs, that observational studies would suffice, that marketing plans would be "critical" to the success of PMTAs and that applicants should focus also on controls to restrict youth access, such as age verification plans.

The court concluded that the petitioners developed their PTMAs based on this guidance and submitted the applications to FDA for review in September 2020. Then, on August 26, 2021, while the PMTAs were pending review, FDA issued a press release announcing the *en masse* denial of 55,000 applications for flavored ENDS products and declared — for the first time, according to the court — that the agency *would* require randomized controlled trials or longitudinal cohort studies for nontobacco flavored applications. Following this announcement, Triton and Vapetasia petitioned FDA for additional time to conduct the studies. Without acknowledging this request, FDA issued the MDOs to both in mid-September 2021.

The court held that FDA's MDOs violated the APA on four distinct grounds:

i. An agency cannot invent post hoc justifications for its decision outside the administrative record.

ii. An agency must provide fair notice before the agency deprives a citizen of property.

iii. When an agency changes its position, the agency must display awareness of the change and explain it.

iv. Even when an agency acknowledges and explains a change in its position, the agency cannot fault a regulated entity for relying in good faith on the previous position.

The court concluded that FDA had an obligation under the APA to make an explicit announcement to stakeholders indicating that its prior policies and standards were being deliberately changed and explaining why the new position was better.

The fundamental problem, reasoned the court, was that FDA never gave the companies fair notice that they would need to conduct long-term studies on their specific flavored products. According to the court, FDA also never reviewed the same marketing restrictions and youth update controls it called for in its public statements.

In reaching its conclusion, the court rejected FDA's defenses that the relevant public statements had been qualified and equivocal, that the FDA never disclaimed a need for robust scientific evidence in support of applications, and that the FDA reserved the right to modify its positions based on an evolving understanding of the science and regulatory risks. The court found these arguments unavailing, concluding that FDA never appropriately acknowledged or explained its change in position. The court concluded that FDA had an obligation under the APA to make an explicit announcement to stakeholders indicating that its prior policies and standards were being deliberately changed and explaining why the new position was better. According to the court, FDA's failure to do so violated the APA's "change-in-position" doctrine, regardless of whether the agency's prior public statements had been qualified to some degree. The court then found that the petitioners' reliance on FDA's prior statements in support of the PMTAs they submitted to the agency was not unreasonable. "[Administrative law]" said the court, "prohibits administrative agencies from saying one thing, pulling a surprise switcheroo, and ignoring the reasonable reliance interests engendered by its previous statements."

The decision sharpens a circuit split on the issue and underscores that not every court reads these facts the same way. Five circuits have sided in favor of FDA on challenges to MDOs for ENDS products based on the same change in policy, while the Fifth and the Eleventh Circuits have now ruled against the agency.[1] In at least two other instances, FDA has rescinded or stayed denial orders on its own after legal challenges were filed.[2] In doing so, the agency tacitly acknowledged a failure to fully address information or data pertaining to the denied applications in those cases.

Takeaways

For many outside the tobacco industry, the ENDS products cases seem to involve an isolated battle between companies that extol ENDS products as a safer alternative to combustible cigarettes and a public health agency deeply concerned about youth uptake of ENDS products and the role that flavored nicotine products play in youth initiation. Indeed, the facts in the *Triton/Vapetasia* case are unusual by FDA standards, in part because other product centers at FDA have long-standing, well-developed guidance programs informed by decades of product review and the interpretation of applicable statutory standards.

For those with business before other FDA centers, however, the cases are important and instructive as they fundamentally involve the question of how much deference will be given to FDA, regardless of the regulated product at issue. The *Triton/Vapetasia* case also surfaces at a time when courts seem more willing to side against FDA on matters of statutory interpretation and premarket review.

FDA continues to prevail in court much more often than not, and its success rate in cases challenging drug approvals on scientific grounds is staggeringly high. Suggesting FDA's recent struggles in the tobacco wars are a harbinger for the rest of the agency would be an overstatement. But the recent ENDS losses echo findings in other nontobacco cases that sided against FDA, including:

- *Vepuri*[3] (where the Third Circuit dismissed part of an indictment in a drug case on the grounds that FDA's interpretation of the new drug definition in the Federal Food, Drug, and Cosmetic Act (FDCA) was overly broad).
- *Catalyst Pharmaceuticals*[4] (where the Eleventh Circuit court rejected FDA's interpretation of the Orphan Drug provisions of the FDCA).
- *Alliance for Hippocratic Medicine*[5] (where the Fifth Circuit disagreed with FDA's expanded approval for mifepristone).
- The recent commercial speech cases — most notably *Amarin*[6] — where courts have sided against FDA's application of the FDCA on First Amendment grounds.

[1] *See, e.g., Bidi Vapor LLC v. U.S. Food & Drug Admin.*, 47 F.4th 1191 (11th Cir. 2022) (setting aside Denial Orders issued to Bidi Vapor, Diamond Vapor, Johnny Copper, Vapor Unlimited, Union Street Brands, and Pop Vapor Co. and remanding decision to FDA). The Fifth Circuit also ruled against FDA on related grounds in *R. J. Reynolds Vapor Co., et al. v. Food and Drug Administration, et al.*, No. 23-60037 (5th Cir. Mar. 23, 2023) (Dkt. No. 121-1) (staying MDO issued to Reynolds for its PMTA for nontobacco flavored ENDs).

[2] *See* "FDA Rescinds Previously Disclosed Marketing Denial Order for Turning Point Brands' Vapor Products," *Business Wire* (Oct. 11, 2021); *see also*, FDA press release "FDA Denies Authorization to Market Juul Products" (June 23, 2022).

[3] *United States v. Vepuri*, No. 22-1562 (3d Cir. 2023).

[4] *Catalyst Pharmaceuticals, Inc. v. Becerra,* No. 20-13922 (11th Cir. 2021).

[5] *Alliance Hippocratic Medicine v. FDA*, No. 23-10362 (5th Cir. 2023).

[6] *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

While many scientific and regulatory issues in the food and medical product space are well-settled, many others, like the treatment of ENDS, are the subject of new thinking, new guidance and new interpretation. Some current examples include the regulation of artificial intelligence, self-correcting software, cell-cultured meat, laboratory developed tests, clinical trial design, HCT/Ps (human cells or tissues intended for transfer into a human recipient), patient-reported outcomes, and real-world evidence. The level of deference given to FDA's interpretations in these areas will substantially impact regulated parties.

The FDA may appeal the *Triton/Vapetasia* case to the Supreme Court, and the case could resolve in FDA's favor. But the fact remains that federal district and appellate courts appear more willing than ever to second-guess FDA on matters of science and statutory interpretation. At the same time, the Supreme Court is also poised to decide a *Chevron* case this term, which could invite more of this second-guessing in the years ahead if the Court makes sweeping pronouncements about the deference owed — or not — to regulatory agencies under the APA. At a minimum, we expect FDA-regulated entities seeking to challenge FDA to try to find grounds to bring those disputes in the Fifth or Eleventh Circuits. Accordingly, questions of venue have taken on new importance in FDA cases, and the tobacco decisions are a reminder that, at least in those circuits, courts are prepared to act if they perceive overreaching, even from an agency as vital to the public health as FDA.

FDA Regulatory

Importation of Prescription Drugs From Canada

On January 5, 2024, FDA authorized the state of Florida's Section 804 Importation Program (SIP), which is the first major step in allowing the state's Agency for Health Care Administration (AHCA) to import certain prescription drugs from Canada. This is the first such program authorized in the United States, despite efforts by at least six other states to seek similar approvals. The SIP is authorized under a final rule that FDA issued in 2020 to implement language in the Medical Prescription Drug Improvement and Modernization Act of 2003 (MMA). The MMA amended Section 804 of the Federal Food, Drug, and Cosmetic Act to allow for importation of prescription drugs from Canada, but only if the secretary of the Department of Health and Human Services (HHS) first certifies that such importation would "pose no additional risk to the public's health and safety" and would "result in a significant reduction in the cost of covered products to the American consumer."

For years, HHS — under both Republican and Democratic administrations — declined to make the necessary certifications under Section 804, which led to no action under the law for nearly two decades. FDA's October 2020 rulemaking signaled a new willingness to consider potential SIP applications, and AHCA submitted its initial SIP application in November 2020. In August 2022, AHCA sued FDA, accusing the agency of unreasonably delaying action on AHCA's SIP application. FDA planned to make a decision on the application by October 2023, and after several revisions and much dialogue, in January 2024, ultimately authorized AHCA's request for a period of two years.

Obstacles Remain

FDA's authorization of Florida's SIP is a landmark decision in the long-running drama over drug importation, but many steps remain before implementation of the program, and challenges are expected.

Under the terms of the SIP regulation, AHCA must now submit a Pre-Import Request to FDA for each drug it proposes to import. A request must be submitted at least 30 days before the scheduled date of entry for each drug and must include, along with other information, a detailed testing plan to show that the product complies with applicable standards and specifications. No drug may be admitted into the United States under the SIP unless and until FDA has approved the corresponding Pre-Import Request.

At the same time, Health Canada has voiced concerns about the SIP. Shortly after FDA authorized the AHCA proposal, Health Canada announced that it is "taking all necessary action to safeguard the drug supply and ensure Canadians have access to the prescription drugs they need" and that "bulk importation will not provide an effective solution to the problem of high drug prices in the U.S."

In the United States, the Pharmaceutical Research and Manufacturers of America (PhRMA), the Partnership for Safe Medicines and the Council for Affordable Health Coverage sued HHS in November 2020, alleging that FDA's 2020 rulemaking failed to comply with Section 804 of the FDCA and that the program proposed in the 2020 final rule violates the First and Fifth Amendments to the United States Constitution. The lawsuit was dismissed in February 2023 on standing grounds because, at the time of the suit, no SIP had yet been authorized and there was thus no showing of concrete harm. Now that FDA has authorized the Florida SIP, the associations are expected to raise their claims again in federal court.

Drug companies are also reportedly trying to thwart the SIP through private contracting provisions, conditioning their sale of products into Canada on the agreement that those drugs will not then be shipped back into the United States under a SIP program.

Finally, political opponents of the SIP continue to extol the importance of a closed system in the United States as a mechanism to ensure drug safety and argue that opening the borders to reimported drugs puts American consumers at risk. Many who seek lower drug prices in the U.S. also question whether importing Canadian price controls for a subset of drugs will translate into any meaningful change.

Looking Ahead

The above obstacles justify skepticism of the potential success of the SIP program. Even if FDA's rulemaking withstands judicial challenge, the opposition from Health Canada and the manufacturers of the affected products will frustrate implementation. There is also widespread skepticism about proof of concept; many stakeholders doubt Floridians will see any significant savings once the cost of product testing and program management are factored in.

Ultimately the politics of reimportation are messy. The belief (or hope) that importation from Canada will lower drug prices in the United States drives these import programs forward and is the reason for the language in the MMA, FDA's 2020 rulemaking and the myriad SIP proposals pending with FDA today. Conventional wisdom is that FDA granted the Florida SIP to help defuse growing pressure, meaning the authorization was a symbolic act supporting a popular idea that may in fact translate into savings for a few very expensive brand name drugs, but authorization will likely be limited to a narrow scope of products given the burdens of the program and the control exercised by FDA through the Pre-Import Request.

Those who approved the Florida program may rightly regard the authorization as limited and measured, but now that a program has been approved, a blueprint is in place for future administrators who may wish to expand these programs.

A change in administration may necessitate a change in this outlook, however. In the years following the MMA, FDA steadfastly opposed importation of prescription drugs from Canada on safety grounds, arguing that opening the borders would increase the risk of adulterated or counterfeit product entering the U.S. drug supply. As political support for the idea persisted, the architecture for such a program slowly developed. During the Trump administration, FDA "rediscovered" section 804 and promulgated the final rule under which the Florida SIP was authorized. Those who approved the Florida program may rightly regard the authorization as limited and measured, but now that a program has been approved, a blueprint is in place for future administrators who may wish to expand these programs. Although there are many obstacles to wholesale effectuation of SIPs under the law, this genie may now be permanently out of the bottle.

FDA Finalizes Its Amended Quality System Regulation for Medical Devices

On February 2, 2024, the FDA issued a final rule amending its Quality System Regulation (QSR), which is codified at 21 CFR Part 820 and sets forth current good manufacturing practice (cGMP) standards for medical devices. The rule culminates FDA's efforts to bring U.S. standards more in line with the consensus international standard for medical device cGMP, ISO 13485, which is now incorporated by reference into Part 820. The rule

also adopts related definitions and vocabulary from Clause 3 of ISO 9000. The change is intended to reduce regulatory burdens on device companies operating internationally by allowing them to harmonize procedures across jurisdictions in ways that still safeguard the public health.

ISO 13485 is a medical device regulation established by the International Organization for Standards, an independent, nongovernmental organization that develops and publishes international standards with input from standards bodies around the world. Like the current (now modified) 21 CFR Part 820, ISO 13485 sets quality system standards for the entire life cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning.

The medical device industry has been expecting the FDA to adopt ISO 13485 in some capacity since early 2018, when the plans to harmonize the QSR with ISO 13485 first appeared in the agency's biannual unified agenda. FDA issued the rule proposing the changes in February 2022. (See Skadden's prior client alert on the proposed rule for more information.)

The effective date for the final rule is February 2, 2026, which will give the industry a full two years to come into compliance with the modified requirements.

Summary of the Proposed Rule

The rule incorporates the 2016 version of ISO 13485 into Part 820 by reference. To accommodate the change, and to reduce redundancy, most of the prior sections in Part 820 have been withdrawn and replaced with ISO 13485, except for a few definitions, clarifying concepts and additional requirements that the FDA has determined are necessary to preserve certain key elements of Part 820 and to ensure the final rule conforms to the FDCA. To solve for any delegation issues, only the 2016 version of ISO 13485 has become part of the new rule; any future revisions to the ISO standard will not alter the final rule and will only become part of the FDA's regulatory regime if the agency adopted the revised standard by additional amendment through the rulemaking process. The new rule is now called the Quality Management System Regulation (QMSR).

In terms of scope, the final rule applies only to finished devices, meaning that device components and raw materials are still exempt from the QMSR (even though FDA has long encouraged finished product manufacturers to manage the quality of these articles through supply and quality contracts). The rule also does not apply to device refurbishers, third-party servicers or articles containing or consisting of human cells or tissues that are intended for implantation, transplantation or infusion (HCT/Ps).

In the preamble to the final rule, the FDA emphasizes that the requirements in ISO 13485 are, when considered in totality, substantially similar to the requirements of the current Part 820. This similarity is the reason FDA feels comfortable replacing much of Part 820 with the ISO standard (the idea is that FDA can help harmonize international standards for the industry without sacrificing quality).

FDA modified some discrete aspects of the ISO language, however, to avoid inconsistencies with the FDA's broader statutory and regulatory framework. FDA also highlights some gaps in the ISO standard — relating to labeling and document controls, for example — that necessitate preserving discrete sections of Part 820. Accordingly, the rulemaking includes several carve-outs. Noteworthy differences include:

Definitions: The rulemaking incorporates several FDA-specific definitions to avoid creating inconsistencies with the FDCA and its implementing regulations.

- Most notably, new section 820.3 states that all statutory definitions in section 201 of the FDCA that apply to quality management systems supersede the correlating terms under ISO 13485.
- The codified language also adds specific superseding definitions for "**implantable medical device**," "**rework**," "**manufacturer**" and "**safety and performance**."
- In addition, the new rule preserves several current definitions that do not appear in ISO 13485 or ISO 9000, such as "**component**" and "**finished device**."

Design and Development: One point of focus in the proposed rule was whether Clause 7.3 of ISO 13485 (Design and Development) applied to class I devices and, if so, whether FDA intended to expand the reach of the QSR accordingly. In the final rule, FDA clarifies that most class I devices will remain exempt from the design control provisions in the new QMSR. Moving forward, design controls will apply to class II and III devices, as well as class I devices that are automated with computer software or specifically listed in the rulemaking, including certain medical gloves, catheters and restraints. The new rule's preamble also includes considerable discussion about whether each stage of design development requires an independent review. The final rule does not include such a requirement, but FDA suggests that, under Clause 7.3 of ISO 13485, independent review can be an important part of the design process.

Traceability Requirements: Potential differences between the scope of ISO 13485 and FDA's current requirements generated much discussion of traceability requirements in the proposed rule. New Section 820.10(d) requires compliance with the applicable unique device identification (UDI) provisions under 21 CFR Part 830, the applicable traceability requirements under 21 CFR Part 821, and the traceability requirements under Clause 7.5.9.2 in ISO 13485 for devices that support or sustain life, regardless of whether those devices are implantable. FDA explains in the new rule's preamble that "[t]he traceability requirements and the manner in which they are applied in the QMSR, the FDCA, and its implementing regulations are substantially similar to those found in the [current] QS regulation."

Labeling and Packaging: The final rule retains labeling and packaging requirements from the current Part 820 on the grounds that these requirements are not otherwise covered by ISO 13485. FDA cites the fact that many device recalls in the United States are related to labeling and packaging as a reason to preserve these specific controls. New Section 820.45 requires the examination of labeling and packaging prior to release or storage, and the section requires manufacturers to establish procedures to prevent mix-ups, including inspection of labeling and packaging before use.

Records: FDA's proposed rule contained a lengthy discussion of record-keeping requirements, including the need for specific controls related to signatures, service reports and complaints. New Section 820.35 specifically requires device manufacturers to maintain records relating to complaints and servicing activities. FDA dropped the language in the proposed rule that would have required signatures (and dates) from each individual who approved or reapproved a record. The change is not intended to relax FDA's current Data Integrity or Good Document Practices, but to help ensure consistency and continuity with the QS regulation. FDA notes that ISO 13483 already requires signatures and dates to "approve" certain controlled documents. Importantly, the preamble to the final rule also clarifies that the signature requirements in the QMSR can be met with electronic signatures that otherwise comply with 21 CFR Part 11.

The FDA rule also includes conforming edits to 21 CFR Part 4, which governs cGMP for combination products. FDA characterizes these edits as strictly technical and asserts they will not impact the current regulation of combination products that contain device constituent parts.

Implications for the Industry

This rule marks an important step toward global harmonization of medical device regulation, which FDA states is its primary reason for adopting ISO 13485. The agency explains that harmonization of regulatory compliance efforts not only benefits manufacturers from a cost-savings perspective, but also helps patients by reducing the barriers to access that arise from a fractured regulatory environment.

One of the most notable differences between the old and new regimes is that ISO 13485 places a greater emphasis on risk-management activities than does the current QSR. Specifically, the current Part 820 primarily addresses risk management in the design validation requirements in Section 830.30(g), whereas risk management is broadly integrated throughout ISO 13485. Many global medical device companies have elaborated their risk-management processes over the last decade in response to ISO, but for those who operate solely under the aegis of Part 820, the integration of ISO 13485 will necessitate a fresh look at these issues. FDA clearly expects that industry will incorporate risk management into the life cycle of medical devices, especially those to which design controls apply.

Application of the updated design control requirements may also take some adjustment moving forward. Long-standing FDA terms such as "device master record" (DMR), "design history file" (DHF) and "device history record" (DHR) do not appear in ISO 13485 and are not separately defined in FDA's final rule. FDA explains there is no need to retain these terms because companies must now document the same information in a Medical Device File (MDF) under Clauses 7 and 4.2 of ISO 13485. We note that although the design documents historically covered in DHRs and DHFs can be subsumed into MDFs under the new rule, the vocabulary associated with these activities may need to evolve, as will the corresponding Quality SOPs used to comply with the current QSR. Design Control has long been a specialized aspect of cGMP, unique to medical devices, and efforts to realign these historic systems with the Design provisions in ISO 13485 will require specific attention, even assuming the approaches are conceptually similar.

We also expect that, under the new rule, FDA will focus on management controls, including how medical device companies integrate the updated rule into their quality control systems as well as a focus on management's overall commitment to quality throughout the life cycle of a device. The economic analysis in the proposed rule and presumed adoption of ISO 13485 should not require an overhaul of a quality control system, as QMSR and QSR requirements largely align, but we anticipate an emphasis on management's oversight of risk moving forward. The FDA preamble discusses the meaning of "top management" in order to use the term used in ISO 13485, but FDA makes clear it will continue to hold all levels of management, including executive management, responsible for compliance with the QMSR.

Finally, the new rule will likely impact FDA's approach to establishment inspections. In the preamble, FDA commits to replacing its current approach — the Quality System Inspection Technique (QSIT) — with a new methodology that is more consistent with the updated regulations. The rulemaking offers little detail on how the approach will evolve, but indicates that FDA will provide additional guidance and clarity in the future.

Key Highlights of the Proposed Reorganization

- A deputy commissioner for human foods will be responsible for oversight of all human food products.
- The associate commissioner for regulatory affairs will now be the associate commissioner for inspections and investigations, reporting directly to the FDA commissioner.
- ORA will become the Office of Inspections and Investigations (OII), and many ORA personnel will be redeployed to work with the product-specific compliance programs already in existence.
- The Office of the Chief Scientist (OCS) will oversee cosmetics (except compliance) and color certifications, and will now oversee a number of labs within its Office of Analytical and Regulatory Laboratories and the Office of Specialty Laboratories and Enforcement Support.

FDA says its inspections will not result in the issuance of certificates of conformance to ISO 13485 and advises that manufacturers with a certificate of conformance will not be exempt from agency inspections. We do not expect the new rule to impact FDA's continued participation in, and use of, international inspection programs such as the Medical Device Single Audit Program (MDSAP).

The FDA website offers more information on the administration's final rule.

Your Cheese is Being Moved — FDA's Biggest-Ever Reorganization Is Likely Headed Your Way in 2024

What began as a request from Commissioner Robert Califf for an external review of the tobacco and human foods program in July 2022 following an outcry over several issues (including FDA's response to an infant formula shortage) blossomed into a proposed multidisciplinary agency reorganization that extends far beyond FDA's regulation of liquid tobacco products and human foods.

As detailed below, FDA has proposed a massive reorganization that is expected to impact approximately 8,000 employees across the agency, including most product centers and the Office of Regulatory Affairs (ORA). The Center for Biologics Evaluation and Research (CBER), The Center for Devices and Radiological Health (CDRH), The Center for Drug Evaluation and Research (CDER), The Center for Food Safety and Applied Nutrition (CFSAN), The Center for Veterinary Medicine (CVM) and ORA will be impacted, with only the Center for Tobacco Products (CTP) and the Oncology Center of Excellence (OCE) remaining unchanged. FDA submitted the reorganization proposal to HHS in December 2023 and hopes to receive approval to implement the changes in 2024.

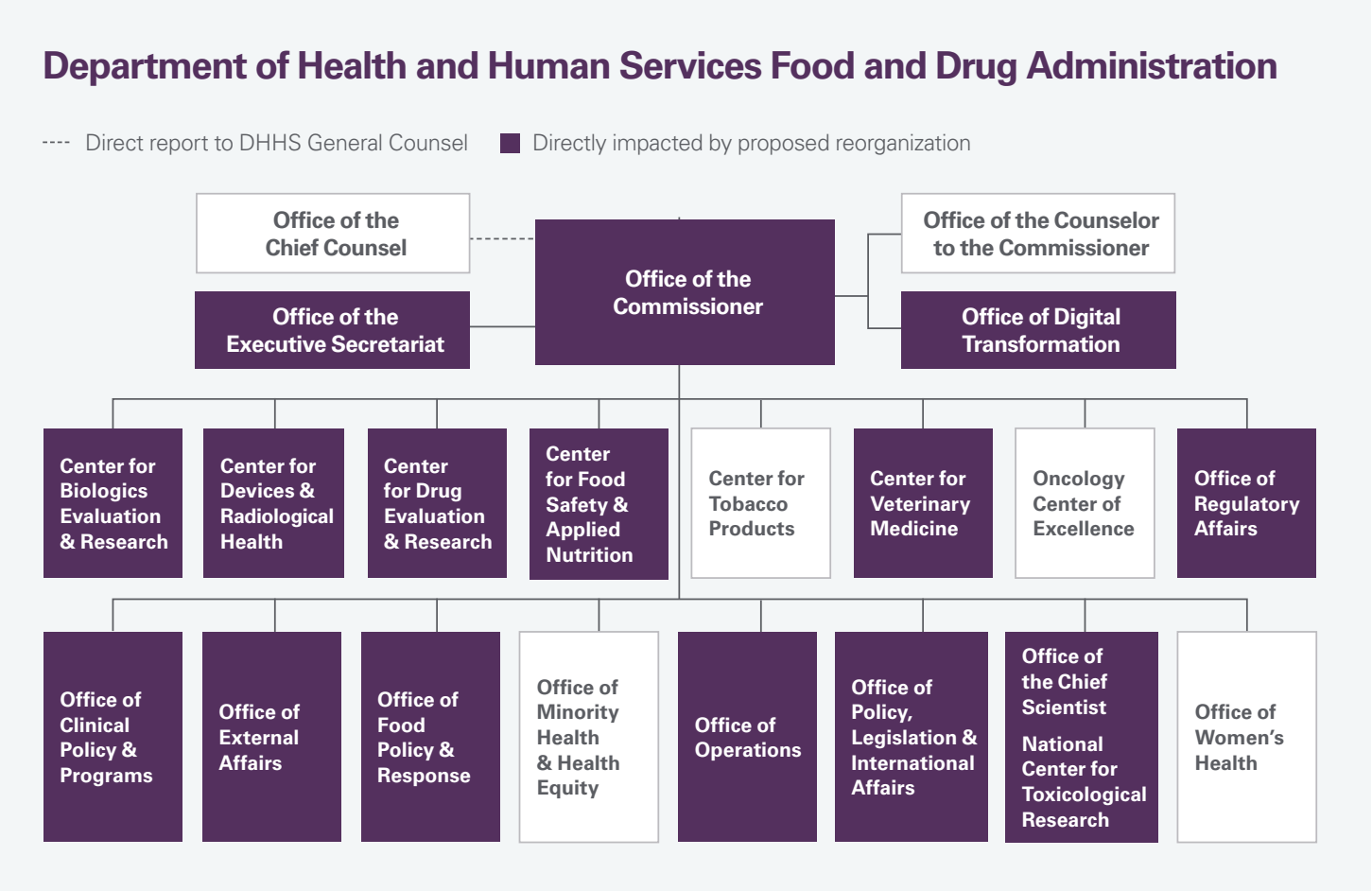
How an External Review Spawned FDA's Largest-Ever Reorganization

In July 2022, Commissioner Califf announced that he had ordered an external review of FDA's offices on food safety and tobacco regulation, stating, "The agency has confronted a series of challenges that have tested our regulatory frameworks and stressed the agency's operations, prompting me to take a closer look at how we do business." FDA engaged the Reagan-Udall Foundation (RUF), an independent group that advises FDA, to conduct a review and to provide recommendations. In December 2022, RUF issued its report and recommendations in "Operational Evaluation of the FDA Human Foods Program" (the RUF Report).

The RUF Report recommended, among other things, that FDA create a culture that enhances collaboration and decision-making by establishing an organizational model with clear leadership and clear roles and responsibilities — which could be accomplished for foods by creating a unified human foods program to replace the current system trifurcated between CFSAN, ORA and the Office of the Commissioner. Additionally, the RUF Report recommended providing additional resources to the agency through appropriations and/or user fees, which could be used to improve FDA's ability to recruit and retain needed scientific experts and to modernize the agency's IT systems.

Following receipt of the RUF Report, FDA announced it would develop a proposal for a unified Human Foods Program (HFP) and a new ORA model. On December 13, 2023, FDA provided an update on its efforts, including additional details about the proposed structure, status of activities and timeline for next steps.

FDA announced that its proposed changes would impact commodities beyond human food, including medical products and cosmetics, by creating an enterprisewide structure designed to improve collaboration between ORA investigators and subject-matter experts throughout the entire agency. FDA explained that the reorganization proposal includes additional improvements to modernize and strengthen the agency parts to work more cohesively and collaboratively together to accomplish FDA's public health mission. As the below FDA graphic indicates, the proposed reorganization will directly impact much of the agency.



Re-Imagining FDA's Oversight of Human Foods

Core to FDA's proposed reorganization is a fundamental rethinking of the way the agency regulates human food products. One recommendation from the RUF Report highlighted a need to centralize oversight and decision-making in this space. Currently, responsibility is shared by CFSAN, the Office of Food Policy and Response (OFPR) and certain parts of ORA. Under the new proposal, a deputy commissioner for human foods would oversee and have full authority over the entire HFP. The deputy commissioner will report directly to the commissioner and will manage public health risk through three areas of focus: nutrition, microbiological food safety and chemical safety.

The Nucleus: Life Sciences Enforcement and Regulatory Updates

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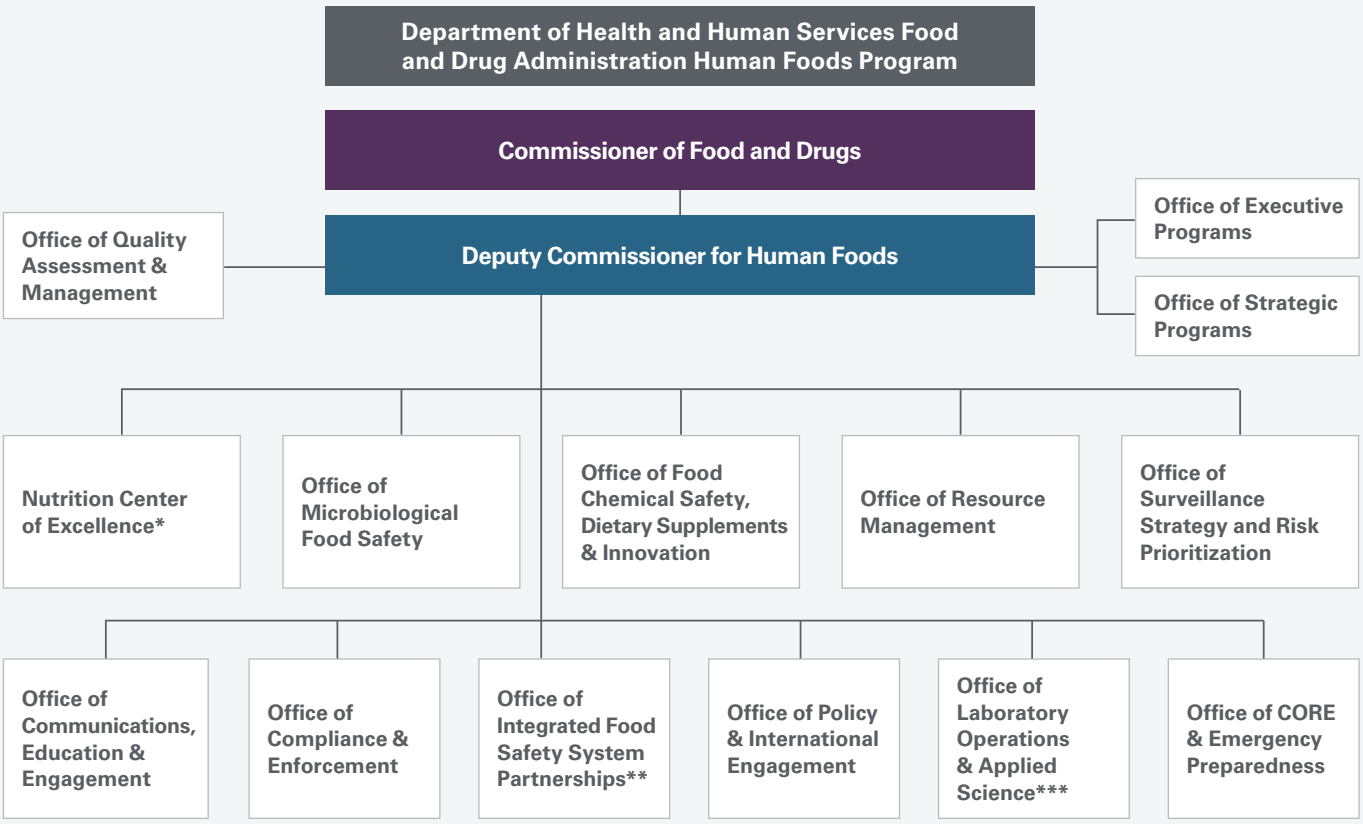
As illustrated in FDA's proposed organization chart below, the Nutrition Center of Excellence, which includes the Office of Critical Foods, will work to reduce diet-related chronic diseases, improve health equity and ensure the safety and nutritional adequacy of infant formula. The Office of Microbiological Food Safety will work to advance prevention strategies and reduce the burden of pathogen-related foodborne illness. Finally, The Office of Food Chemical Safety, Dietary Supplements, and Innovation will work to modernize and strengthen oversight of food chemical safety, advance dietary supplement safety and enable the HFP to support and regulate innovation in food ingredients.

Proposed Human Foods Program Organization Chart



* Includes Office of Critical Foods

** OFSSP will work in close coordination with the Center for Veterinary Medicine.

*** OLOAS will work in close coordination with the Office of the Chief Scientist and Center for Veterinary Medicine.

Note: The proposed changes reflected here are not approved and will not be implemented until all required reorganization steps have been met.

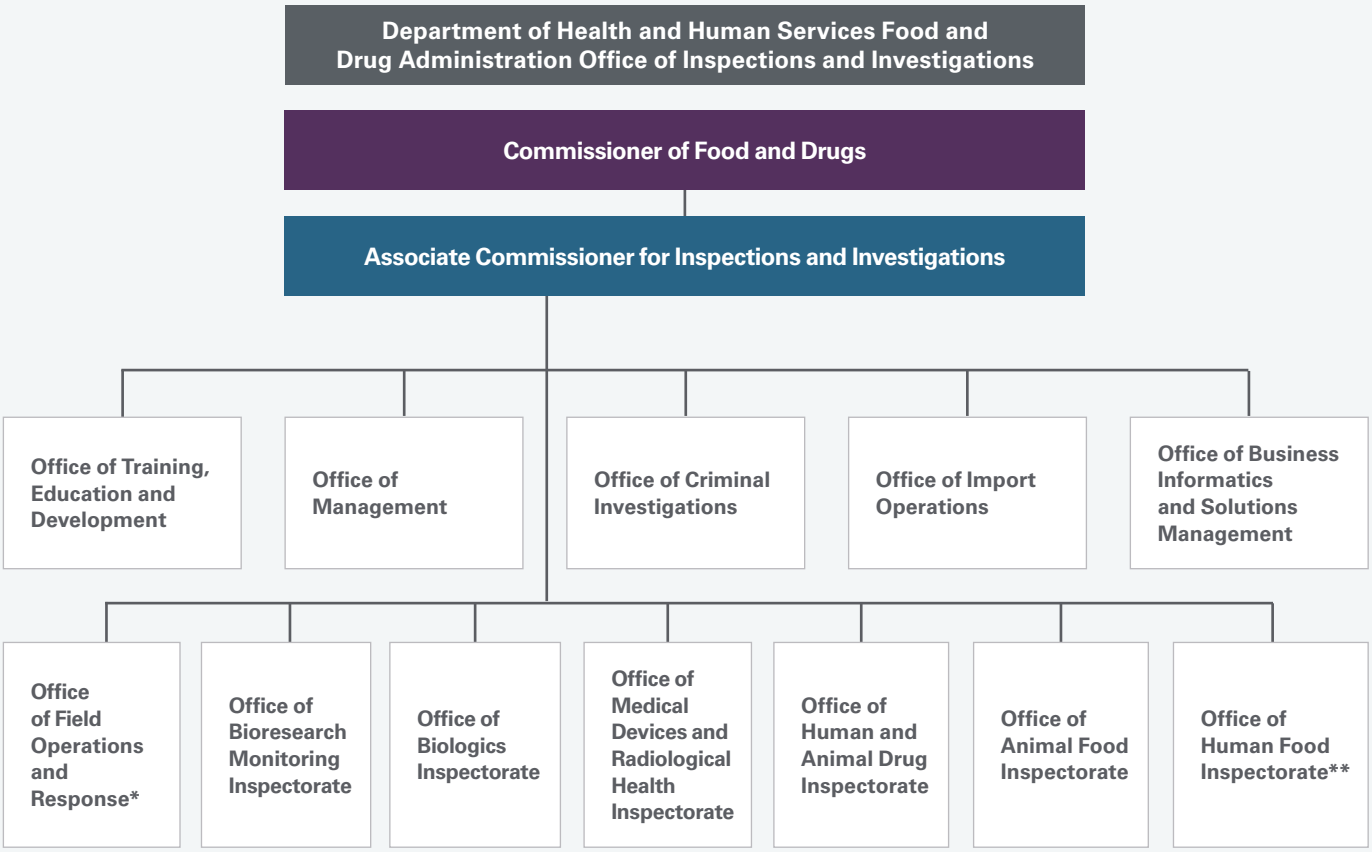
(Updated Dec. 6, 2023)

From ORA to OII

The linchpin that makes this proposed reorganization particularly impactful are the proposed changes to ORA, which will become OII. Under the new system, the associate commissioner for inspections and investigations will lead OII, which will focus on three enforcement areas: inspections, investigations and imports.

Much of the inspectorate will be redeployed to support FDA's product centers, continuing a trend away from geographic based inspectional assignments toward assignments based on subject-matter expertise. With this change, OII will be (i) overseeing commodity inspection functions and aligning inspection resources with center and program priorities, and (ii) executing specialized operations across FDA's portfolio via the Office of Criminal Investigations, the Office of Field Operations and Response and the Office of Import Operations, all of which will remain in OII.

Proposed Office of Inspections and Investigations (OII) Organization Chart



* Includes Division of Tobacco Inspectorate

** Includes specialized teams for products such as infant formula

(Updated Dec. 6, 2023)

FDA has offered little clarity on how the proposed reorganization of ORA will impact current procedures to evaluate and escalate inspection results and Forms 483. For domestic inspections, we expect OII will continue to issue Forms 483 and evaluate inspection results in the first instance. Consistent with recent trends, we expect the ORA divisions and the new Food Safety Program to be more involved in decisions relating to warning letters, civil money penalties and other regulatory action. As more ORA full-time equivalents (FTEs) become embedded in the ORA centers, the historical lines between ORA and the FDA's central compliance offices have blurred, and the latter have assumed more control over enforcement decisions. We expect that trend to continue under this reorganization, just as it has over the past decade in FDA's foreign inspections.

FDA's Office of the Chief Scientist Picks Up New Responsibilities

We note that the Office of the Chief Scientist appears to be receiving more responsibility under the proposed reorganization. For example, OCS will now have primary responsibility for regulating cosmetics (other than compliance, which will remain with OII) and color certification functions, which were once the province of CFSAN. In addition, OCS will maintain an Office of Analytical and Regulatory Laboratories and an Office of Specialty Laboratories and Enforcement Support, which will also house the medical product, tobacco product and specialty labs that were once the province of ORA. Under the proposed structure, OCS will also create a new Office of Occupational Safety and Health, as well as a new Office of Regulatory and Emerging Science.

Summary

Whether the significant changes being proposed will transform FDA's efficiency and effectiveness as a regulator, or whether they simply amount to a rearranging of deck chairs, remains to be seen. The agency has previously undertaken efforts to tweak or refine CFSAN. The creation of a separate OFPR, which was established in the Office of the Commissioner nearly twenty years ago to help enhance food regulation, is now recognized as part of the problem. In our view, the proposal to centralize authority in a single executive is promising, as the relationship between the director of CFSAN and the deputy commissioner for OFPR in the Office of the Commissioner was never fully understood or optimized. But how the reorganization will impact day-to-day activities in critical spaces such as the Office of Food Additive Safety is not yet clear. FDA communicated significant information regarding the proposed reorganization in an effort to bring the public along in the shift. Nevertheless, change can be difficult, both for those at FDA who will be impacted, and for the industry that FDA regulates. Understanding who to call and how things work may take additional time in the short run, but if the changes result in a better resourced and more effective regulator, these inconveniences will be a small opportunity cost.

OIG Updates

What Life Sciences Companies Should Know About OIG's New General Compliance Program Guidance

On November 6, 2023, the Department of Health and Human Services Office of Inspector General (HHS-OIG) issued its long-awaited General Compliance Program Guidance (GCPG) for health care stakeholders. The GCPG represents the first significant overhaul of HHS-OIG's compliance guidance framework in two decades, and HHS-OIG promised that the release will be followed by industry-specific guidance starting in 2024 and continuing into future years. Given that the GCPG is intended to apply to all health care industry stakeholders, it is framed broadly, leaving life sciences companies to consider which aspects are most salient for them. Here are the elements we recommend focusing on:

1. **Formalizing expectations previously included in Corporate Integrity Agreements (CIAs).** In a number of areas, the GCPG establishes as baseline recommendations for all health care stakeholders expectations that previously were only required for companies operating under CIAs. Notable examples include an annual, formalized risk assessment process, annual policy and procedure review, and integration of incentives into a company's compliance program. In addition, the GCPG strongly advises that a company's compliance officer should report directly to the CEO and should not (i) lead or report to the entity's legal or financial function, (ii) provide the entity with legal or financial advice, or supervise anyone who does, or (iii) be responsible, directly or indirectly, for providing health care services, billing or coding. In other words, the compliance officer's primary responsibility should be overseeing and monitoring the implementation and operation of the compliance program and advising senior leadership, including the board, on compliance risks facing the company. As these restrictions can prove challenging in practice — particularly for smaller and younger companies, note that adherence to the GCPG's recommendations is voluntary.
2. **Increased activities and expectations of compliance committees.** The GCPG conveys an expectation that compliance committees will play a more active role in the development, implementation and evaluation of a compliance program than reflected in prior HHS-OIG guidance. Consistent with prior guidance, the GCPG states that the purpose of the compliance committee is to "aid and support" the compliance officer and recommends that the committee include "leaders of both operational and supporting departments … who have the authority and ability to speak for the department[s] they represent." In addition, however, aligning with language from recent CIAs, the GCPG sets forth granular expectations for committee engagement. For example, the GCPG advises that the duties of a compliance committee should include assessing, developing, and regularly *reviewing* policies and procedures as well as training needs and training effectiveness; *conducting* annual risk assessments; and *developing* the compliance work plan, among other things. The GCPG also recommends that the compliance officer periodically provide a report to the board on the compliance committee's performance, including how the entity implemented committee decisions and recommendations, and that compliance committee performance be included in members' performance evaluations. In light of these heightened expectations, companies will want to ensure compliance committee members are well-trained on what is expected of them and that compliance personnel consider how best to ensure active committee member participation.
3. **Integration of quality into compliance programs.** The GCPG includes a new recommendation that "[e]ntities should incorporate quality and patient safety oversight into their compliance programs." More specifically, HHS-OIG recommends that an entity's compliance committee "should include members responsible for

quality assurance" and "establish a program for performing quality audits and reviews" and that the compliance officer "should be responsible for implementing a compliance program that includes and addresses **quality** … risks" just as the officer does "for any other compliance risk integral to the entity's health care segment" (emphasis in original). The GCPG specifically focuses on "both quality in manufacturing and supplying drugs, devices, and other items and quality of care in the provision of items and services," even as it recognizes that quality is "often treated as wholly separate and distinct from compliance." Because this distinction is the case for most life sciences companies, integrating quality into life sciences compliance programs is likely to cause growing pains. At the same time, as the GCPG notes, quality issues increasingly have become the basis for False Claims Act liability in addition to traditional Food, Drug, and Cosmetic Act theories. Therefore, ensuring compliance visibility into quality — whether through formal oversight or simply reducing information siloes to foster more open communication — may allow companies to better gauge exposure in an area that has become a greater source of risk in recent years.

4. **Focus on ownership structures.** The GCPG flags HHS-OIG's concern that private investment in health care entities may have a potential "impact of ownership incentives (*e.g.*, return on investment) on the delivery of high quality, efficient health care." This aligns with a recent uptick in FCA resolutions implicating private equity owners of health care entities. As private investment is a mainstay of life sciences companies, particularly in their earlier stages, the GCPG highlights the need to ensure both that life sciences investors understand the unique laws applicable to the health care industry and that compliance programs consider how financial incentives created by ownership structures may impact decision-making and associated risk.

Ensuring compliance visibility into quality — whether through formal oversight or simply reducing information siloes to foster more open communication — may allow companies to better gauge exposure in an area that has become a greater source of risk.

These are just a few of the more remarkable items included in the substantial, lengthy GCPG. Life sciences counsel and compliance personnel can benefit from closely reviewing the guidance, insofar as it reflects increased governmental expectations for industry stakeholders — including that to be effective, a compliance program must continuously improve and adapt with the company. This is consistent with recent remarks from both HHS-OIG and DOJ officials emphasizing that strong and well-resourced compliance programs and empowered compliance officials are key to preventing misconduct and ensuring that it is swiftly addressed when it occurs.

OIG Approves Another Cost-Sharing Subsidy Arrangement for Clinical Trial Participants

On December 21, 2023, HHS-OIG added to a growing list of advisory opinions that have blessed the subsidization of cost-sharing obligations by manufacturers in the context of a clinical trial.[7] Under the proposed arrangement, the requestor, a medical device manufacturer, would pay cost-sharing obligations that federal health care program beneficiaries participating in the clinical trial otherwise would owe for trial-related items and services provided during the trial that are reimbursable by Federal health care programs, up to a maximum of $2,000 per trial participant.

In addition to the remuneration that the manufacturer would provide to Federal health care program beneficiaries in the form of cost-sharing subsidies, HHS-OIG noted that the proposed arrangement offered remuneration to the clinical investigators and sites

[7] Advisory Opinion 23-11 (Dec. 21, 2023).

in two forms: (i) the opportunity to bill Federal health care programs for items and services related to the study; and (ii) a guaranteed payment of beneficiary cost sharing (up to the $2,000 limit). However, HHS-OIG determined that the safeguards in place sufficiently lowered the risk of fraud and abuse.

- HHS-OIG considered the proposed arrangement to be a "reasonable means" of promoting both enrollment generally and a socioeconomically diverse set of participants in particular. HHS-OIG noted that the Centers for Medicare and Medicaid (CMS) approved the study for Medicare coverage, signaling that the rationale for the study was well-supported and that the study aimed to address an important need.
- To address concerns about overutilization and inappropriate utilization, HHS-OIG observed, among other things, that:
  - Individuals must satisfy enrollment criteria.
  - Investigators and sites must comply with the study protocol and are subject to oversight and monitoring by an Institutional Review Board.
  - Enrollment was capped at 1,500 people.
  - CMS had determined that the study meets criteria to ensure appropriate patient protections and legitimate need.
- HHS-OIG distinguished the proposed arrangement from problematic seeding arrangements, whereby a manufacturer offers a subsidy to secure subsequent utilization billed to Federal health care programs. Specifically, the trialed device system was intended as a one-time treatment that was not anticipated to prompt future utilization by clinical trial participants of any products manufactured or "under development" by the manufacturer.

While this advisory opinion and the clinical trial subsidy advisory opinions that proceeded it stand in stark contrast to HHS-OIG's (and DOJ's) view of co-pay subsidies in the commercial context, the result is not surprising given both FDA's stated aim of increasing diversity in clinical trials and the fact that many of the safeguards cited by HHS-OIG are largely inherent in the design of clinical trials.

OIG Declines To Define the Scope of the Patient Engagement Safe Harbor for Life Sciences Companies

On October 20, 2023, HHS-OIG rejected a proposal by a cochlear implant manufacturer, the requestor, to offer a complimentary hearing aid to patients who received the manufacturer's cochlear implant, a device reimbursable by Federal health care programs.[8] Because the manufacturer also operates as a durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) supplier in certain circumstances, HHS-OIG analyzed the arrangement under both the federal Anti-Kickback Statute and the Beneficiary Inducements Civil Monetary Penalty Law (CMPL).

In analyzing the AKS implications of the proposed arrangement, HHS-OIG quickly dispensed of the relatively new safe harbor — the safe harbor covering arrangements for patient engagement and support to improve quality, health outcomes and efficiency (Patient Engagement Safe Harbor) — upon finding that the free hearing aid exceeded the safe harbor's monetary cap. While a footnote in the advisory opinion appears to

[8] Advisory Opinion 23-08 (Oct. 20, 2023).

acknowledge the potential "digital health technology"[9] associated with the arrangement, the advisory opinion does not provide further guidance on the permissible scope of items and services that may be appropriately offered by life sciences companies pursuant to the Patient Engagement Safe Harbor — guidance that is greatly needed given the limited protection that the safe harbor generally affords to life science companies.[10] What is clear, however, is that, notwithstanding the recognized therapeutic benefit of the free hearing aid, HHS-OIG remained resolute in its "longstanding and continuing" belief that the provision of free items or services to federal health care program beneficiaries raises "steering, unfair competition, improper utilization, and quality and cost concerns."[11] HHS-OIG focused on the steering risk, observing that the hearing aid was not required for the cochlear implant to work properly and that, in most cases, the requestor's cochlear implant is not a more clinically appropriate option than a similar cochlear implant manufactured by a competitor. In other words, HHS-OIG viewed the complimentary hearing aid essentially as a giveaway to generate business.

With respect to the CMPL, HHS-OIG concluded that the "Promoting Access to Care" exception was not met because the hearing aid was not required for the cochlear implant to work properly. HHS-OIG similarly concluded that the "Financial Need-Based" exception was not met because receipt of the hearing aid would be conditioned on the purchase of the requestor's reimbursable cochlear implant, and the Financial Need-Based exception applies only when the items or services being offered for free or less than fair market value are not tied to the provision of other reimbursable items or services. In short, Advisory Opinion 23-08 reflects HHS-OIG's continued skepticism about manufacturer-provided patient support and engagement products, notwithstanding the therapeutic benefit they may bring.

OIG Looks Beyond Fair Market Value and Federal Health Care Program Carve-Out To Reject Laboratory Payment Arrangement

On September 25, 2023, HHS-OIG analyzed a proposed arrangement whereby an anatomic pathology laboratory, the requestor, with the ability to conduct and bill for both components of anatomic pathology services — specimen prep and specimen analysis — sought instead to pay other laboratories to prep the specimens of commercial patients. However, the laboratories that stood to receive the payments from the requestor were in a position to refer **both** commercial and federal business to the anatomic pathology laboratory.[12]

At first, the advisory opinion does not appear to have significant relevance to the life sciences industry, apart from providing another example of the increased scrutiny directed at laboratories and the entities that have arrangements with them. However, the advisory opinion includes several important reminders for life sciences industry stakeholders:

[9] The Patient Engagement Safe Harbor defines "digital health technology" to mean "hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care; such term includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose." 42 C.F.R. § 1001.952.

[10] Device manufacturers may avail themselves of the Patient Engagement Safe Harbor only if "the patient engagement tool or support is digital health technology" and the other requirements of the safe harbor are met. 42 C.F.R. § 1001.952(hh)(1)(v). DMEPOS suppliers are excluded from the Patient Engagement Safe Harbor unless they primarily furnish services. *Id.* at 1001.952(hh)(1)(vi).

[11] Advisory Opinion 23-08 at 6.

[12] HHS-OIG Advisory Opinion 23-06 (Sept. 25, 2023).

- **A legitimate commercial need is essential.** The proposed arrangement was not commercially reasonable and was, in HHS-OIG's view, a thinly veiled attempt to provide a financial incentive to key referral sources (of commercial and federal health care business).
- **Fair market value alone does not shield an arrangement from federal Anti-Kickback Statute scrutiny.** Notwithstanding assurances by the requestor that it would pay the laboratories fair market value for the services they rendered, HHS-OIG nevertheless concluded that the proposed arrangement raised significant fraud and abuse risks because remuneration would be provided to key referral sources.
- **Carving out federal health care program business does not automatically shield an arrangement from AKS scrutiny.** Attempting to carve out Federal health care program business from an otherwise questionable arrangement does not protect a company from AKS exposure, particularly where regulators "cannot conclude that there would be **no nexus** between the remuneration paid as part of the Proposed Arrangement and potential referrals to the requestor for services reimbursable by Federal health care programs."[13]

[13] HHS-OIG Advisory Opinion 23-06 at 6.

Digital Health Updates

HHS Moves Quickly To Roll Out Health Care Sector Cybersecurity Strategy

HHS has begun implementing its Healthcare Sector Cybersecurity Strategy (the Strategy), building on the Biden Administration's National Cybersecurity Strategy announced in March 2023. While the Strategy initially focuses primarily on hospitals and other health care providers, the life sciences industry is clearly within the Strategy's scope, and stakeholders should assess their cybersecurity measures accordingly.

HHS launched this initiative on December 7, 2023, by releasing a concept paper outlining the Strategy. Emphasizing the health care sector's vulnerability to cybersecurity risks and their commensurate threat to patient care and safety, the paper cites HHS Office of Civil Rights (HHS-OCR) statistics showing enormous increases in data breaches between 2018 and 2022. In the paper, HHS outlined four actions it intends to take in order to enhance cyber resiliency in the health care industry:

- Establishing voluntary Healthcare and Public Health Sector Cybersecurity Performance Goals (HPH CPGs) for the industry, including both "essential" goals outlining minimal foundational practices and "enhanced" goals encouraging more advanced practices.
- Providing resources for the industry to incentivize adoption of the HPH CPGs.
- Implementing an HHS-wide strategy to support greater enforcement and accountability, including proposing new Medicare and Medicaid cybersecurity requirements for hospitals and updating the Health Insurance Portability and Accountability Act (HIPAA) to include new cybersecurity obligations.
- Expanding HHS's ability to serve as a "one-stop shop" for health care sector participants to navigate federal cybersecurity resources.

Just seven weeks later, on January 24, 2024, HHS published the HPH CPGs, with the stated goal of helping health care organizations, especially health care delivery organizations, prioritize implementing cybersecurity practices. As previewed in the December 2023 concept paper, the HPH CPGs include both essential and enhanced goals. Notably, the HPH CPGs are presented as complementing other HHS cybersecurity initiatives that are particularly relevant to the life sciences sector:

- FDA's establishment of cybersecurity requirements for medical devices.
- HHS-OCR's ongoing enforcement of HIPAA's privacy, security and breach notification rules.

Commensurate with this initiative, HHS launched the new "HPH Cybersecurity Gateway" website, intended as a resource hub to help the health care sector put the HPH CPGs into practice. This site features FDA, HHS-OCR, CMS and several other health care-related government agencies and programs as resources for this initiative.

HHS also considers enforcement action to be part of the Strategy. On February 6, 2024, HHS-OCR announced a HIPAA Security Rule enforcement settlement with a hospital system for $4.75 million, based on a large data theft by a former employee that went undetected for years. While the large settlement amount and severe nature of the breach were significant in themselves, the case is especially noteworthy in this context because HHS-OCR characterized it as "the latest step by HHS" in its cybersecurity initiative, on the heels of the December 2023 concept paper "Healthcare Sector Cybersecurity" and the January 2024 HPH CPGs.

The fact that HHS-OCR tied this settlement to HHS's broader cybersecurity program less than two months after the program's launch signals the agency's determination to move quickly and apply multi-office leverage to its cybersecurity initiatives. Given that HHS already has identified FDA, along with other agencies with jurisdiction over the life sciences space, as participants in the effort, life sciences stakeholders should prepare to find their cybersecurity efforts under even greater regulatory scrutiny.

FTC Defeats Motion To Dismiss in Lawsuit Against Data Broker for Selling Sensitive Health Information

In August 2022, the Federal Trade Commission (FTC) filed a case seeking to enjoin data broker Kochava, Inc. (Kochava) against alleged violations of Section 5 of the FTC Act stemming from Kochava's collection, aggregation and commercialization of vast quantities of consumers' personal data, including sensitive health and medical information.

On February 3, 2024, the U.S. District Court for the District of Idaho denied Kochava's motion to dismiss the suit.

The FTC alleges that Kochava collects, aggregates and sells detailed, identifiable personal data from hundreds of millions of mobile device users without their awareness or permission. This data allegedly includes highly personal, sensitive information such as name, gender, age, ethnicity, income, marital status, political affiliation, time-stamped geolocation data and mobile app usage. By compiling and linking different data points, Kochava's product offerings allegedly enable its customers to obtain strikingly specific information about individual people, including highly revealing health information. For example, the FTC alleges that Kochava's products can be used to identify specific users who downloaded apps for monitoring serious health concerns such as cancer, addiction or sexually transmitted diseases, and to track their app usage or their movements around health clinics or other facilities that a patient might visit for treatment of those conditions. In the words of the District Court, "data revealing a device user's daily use of an app specifically designed to track and manage cancer treatments leaves little to the imagination."

Another example, cited by both the FTC and the District Court, is that Kochava's products allegedly could identify pregnant individuals and their movements around abortion clinics, with Kochava's data allegedly providing precise information to "within less than 10 meters" of a particular location and reflecting "movements as recent as the prior day."

The District Court found that the FTC's claims about the harms consumers may suffer from Kochava's business practices are "legally and factually plausible." Specifically, the court permitted the FTC to proceed on both theories of liability that it is pursuing under Section 5:

i. **Increased risk of secondary harms.** The FTC claims that Kochava's data practices expose consumers to harms including "stigma, discrimination, physical violence, [and] emotional distress." Two factors allegedly exacerbate this risk: (a) Kochava's lack of controls around which parties may access its data products and how such parties may use them, and (b) the company's data-linking practices, which make identifying specific consumers "easy."

While the ultimate outcome of this lawsuit has not yet been decided, the case is consistent with the FTC's recent vigorous enforcement activity against companies that endanger individuals' privacy, including their sensitive health information.

ii. **Invasion of privacy.** Emphasizing Supreme Court and Ninth Circuit decisions recognizing the "unique threat that modern technology can pose to privacy rights," the District Court found that Kochava's alleged privacy invasions are "substantial both in quantity and quality" and plausibly represent a substantial injury to consumers under Section 5.

While the ultimate outcome of this lawsuit has not yet been decided, the case is consistent with the FTC's recent vigorous enforcement activity against companies that endanger individuals' privacy, including their sensitive health information. Notably, unlike several other recent FTC cases, this one does not involve alleged violations of the FTC's Health Breach Notification Rule; here the FTC is proceeding against Kochava solely based on FTC Act Section 5 allegations. This demonstrates that the FTC is casting a wide net for alleged violations of consumers' health privacy and is not confining its enforcement activities to traditional health care or life sciences companies. Accordingly, the case represents yet another warning to all companies that handle health and other sensitive personal information to treat such data with caution.

The Nucleus: Life Sciences Enforcement and Regulatory Updates

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