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2022 Enforcement Review for FDA-Regulated Products: Back to Basics

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Introduction

As the COVID-19 public health emergency has slowly receded from the headlines, the U.S. Food and Drug Administration ("FDA") and its enforcement partner, the Department of Justice ("DOJ"), have spent much of the past year focused on traditional areas of enforcement, including manufacturing practices, product safety, data integrity, and the removal of unapproved products from the market. Although we expect enforcement action in connection with COVID-19-related fraud to continue, FDA appears highly motivated to clear its inspection backlog and ramp up enforcement for manufacturing and data integrity-related deficiencies. Industry stakeholders would be well advised to ensure their compliance infrastructures are appropriately focused on core FDA issues like product quality and ensuring appropriate product approval prior to marketing.

This 2022 enforcement review highlights key trends and developments relating to enforcement that may be of interest to FDA-regulated companies when considering risks in 2023, including:

- A renewed focus on food safety
- A continuing emphasis on drug quality and current good manufacturing practices ("cGMPs")
- The invocation of rarely used medical device authorities
- The viability of FDA's authority over certain stem cell products
- A new FDA focus on product fulfillment platforms
- Continued scrutiny of clinical trial fraud
- More aggressive enforcement against noncompliant tobacco products
- New DOJ expectations for post-resolution compliance in actions involving alleged violations of the Federal Food, Drug, and Cosmetic Act ("FDCA").

Renewed Focus on Food Safety

2022 Infant Formula Crisis

For the first time in recent memory, FDA-related headlines focused not on supply shortages caused by the COVID-19 pandemic, but on shortages of infant formula prompted by the February 2022 recall and manufacturing shutdown of a facility operated by a major infant formula supplier. The recall and shutdown stemmed from complaints to FDA of *Cronobacter* illness potentially being associated with the formula and environmental samples taken during an inspection of the relevant formula manufacturing facility that suggested the potential presence of *Cronobacter*.[1] The inspection did not identify evidence of *Cronobacter* in released product lots, but the company recalled any released product and halted manufacturing operations nonetheless.

Shortages were exacerbated by the dearth of domestic suppliers and FDA's restrictions on importing foreign-made formula that had not been subject to the appropriate premarket notifications to FDA.[2] By the beginning of June, when the plant at issue resumed manufacturing operations,[3] out-of-stock rates for formula had climbed to over 70% nationwide, with certain states experiencing rates higher than 90%.[4] To help ease the shortage, in May 2022, FDA announced a guideline to ease importation of nutritionally adequate and safe foreign-made formula.[5]

Ultimately, the path forward for the resumption of formula production was paved with a May 2022 civil consent decree that provided conditions for the resumption of manufacturing. As part of the decree, the formula manufacturer agreed to retain outside expert assistance to help develop plans designed to control the risks of bacterial contamination at the plant.[6] The expert was also retained to periodically evaluate compliance with FDA requirements and the consent decree. While the consent decree was finalized in record time by modern standards, this fact did not save the company from further scrutiny. The company confirmed media reports in January 2023 that the DOJ was investigating and that the company was fully cooperating.[7]

With the immediate crisis under control, Congress seized the opportunity to enact legislation to shore up supply chain resiliency and require congressional notification at the first sign of a future infant formula shortage. Regulatory changes were included in the Food and Drug Omnibus Reform Act of 2022 ("FDORA") enacted in December 2022, as described in a prior Ropes & Gray alert. With significant scrutiny on the infant formula industry—including a Federal Trade Commission inquiry into, among other things, the factors that led to concentration and supply chain fragility in the infant formula market[8]—there may be opportunities for new players to enter this sector. However, new market entrants should be fully versed in FDA's complex regulatory and compliance requirements. In November 2022, FDA stopped accepting new requests for enforcement discretion for imported infant formula. Companies that had been operating under enforcement discretion are expected to bring their products into full regulatory compliance if they want to continue distributing formula.[9]

Contaminated Breakfast Cereal

In another food matter related to deficient manufacturing practices, the former Director of Quality Assurance for a food processor linked to a 2018 outbreak of salmonella poisoning in cereal, Kerry, Inc. ("Kerry"), pleaded guilty to three misdemeanor counts of causing the introduction of adulterated food into interstate commerce. The charges rested on the theory that insanitary conditions at the plant rendered the food made there adulterated.[10] The defendant, Ravi Kumar Chermala, oversaw the sanitation programs at various manufacturing plants for Kerry, whose customer, Kellogg's, distributes the popular Honey Smacks cereal. Chermala admitted that between June 2016 and June 2018, he directed subordinates to avoid reporting certain information to Kellogg's about conditions at a facility and to alter the plant's pathogen monitoring program, limiting the facility's ability to accurately detect insanitary conditions. More than 130 cases of salmonella poisoning were ultimately linked to the facility, and in June 2018, Kellogg's voluntarily recalled all Honey Smacks manufactured at the plant for the prior year. Chermala's role in hiding information about manufacturing issues and adjusting plant processes to avoid detection no doubt made him an attractive prosecution target for DOJ. Kerry remediated manufacturing issues identified in an FDA inspection following the outbreak that led to a warning letter,[11] and the warning letter was closed out in 2019.[12]

Alleged Insanitary Conditions at Retail Storage Warehouse

An early 2022 inspection of a Dollar Tree warehouse in Arkansas cited particularly dramatic allegations concerning insanitary conditions at the warehouse. The FDA's 483 issued to the storage facility for human and animal foods as well as over-the-counter ("OTC") drugs and devices noted that dead birds and rodents were found in various areas; a breakroom had been closed off due to the "putrid odor" of decaying rodents; numerous products displayed rodent gnaw marks; and investigators had observed rodent excreta pellets and fluorescing stains. Despite the company's responses to FDA explaining that the facility would be closed, FDA still issued a warning letter to Dollar Tree in November 2022.[13]

Continued Emphasis on Drug Quality and cGMPs

In a case arising out of an FDA investigation into a *Burkholderia cepacia* ("*B. cepacia*") outbreak that sickened numerous children, the former owner and CEO of a company that manufactured an OTC laxative product landed a sentence of 37 months in prison for allegedly covering up contamination issues at his company's Florida manufacturing

facility. Pharmatech was first inspected by FDA in July 2016 in the aftermath of an initial *B. Cepacia* outbreak, and a sample taken from the company's water supply also tested positive for the bacteria. After promising to remediate, upon re-inspection in March 2017, Figeroa allegedly told inspectors that the water supply had met "acceptance criteria" and specifically excluded Diocto Liquid, made with water from the facility's water supply, from the FDA-requested list of products recently distributed by the company. Four months later, multiple *B. cepacia* infections occurred at children's hospitals on both coasts among patients who had been given the firm's Diocto Liquid.[14] Ultimately, 63 cases of *B. Cepacia*, some extremely serious, were conclusively tied to Pharmatech's Diocto Liquid, and 45 additional cases are also thought to be tied to the drug.[15]

Figueroa ultimately pleaded guilty to charges of conspiring to defraud FDA, falsifying records in an FDA investigation, obstructing proceedings before FDA, and distributing adulterated drugs. Some of these charges were directly tied to Figueroa's attempt to cover up its production and distribution of Diocto Liquid upon re-inspection.

In another case involving drug manufacturing issues, Morton Grove, an Illinois manufacturer of both prescription and OTC drugs, was enjoined from making or selling adulterated drugs after numerous FDA inspections repeatedly identified manufacturing problems. FDA inspected the company's facility five times between 2011 and 2021 and issued a warning letter in 2017 that highlighted facility deficiencies. Despite significant notice from FDA, the company purportedly failed to institute adequate procedures to prevent cross-contamination of equipment, reject drug lots using a contaminated ingredient, and fully investigate the root cause of such contamination. DOJ sought an injunction on FDA's behalf,[16] and the company agreed to resolve the suit via consent decree, which notes the company's plan to discontinue all operations and "undertake an orderly closure of the business."[17]

Invocation of Rarely Used Medical Device Authorities

Marshalling statutory authorities rarely, if ever, used by FDA, the agency issued both a "notification order" under section 518(a) and a proposal to order a plan for the repair, replacement, or refund of medical devices under section 518(b) of the FDCA to Philips Respironics in connection with a recall of certain breathing assistance devices. The impacted devices were recalled due to the breakdown, over time, of sound abatement foam within the devices. As the foam broke down, debris and chemicals were released into the devices' air pathway, potentially leading to lung damage and respiratory impairment. FDA issued a 518(a) order in March 2022 requiring further notification by the company to affected customers. Such an order is available when a device presents an unreasonable risk of substantial harm and notification is necessary to eliminate that risk. FDA determined that the order was warranted because of "Philips' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons (including consignees, distributors, retailers, and devices users) who should be notified, and the health risks presented by the Recalled Products."[18] The notification order to Philips marked the first 518(a) notification issued by FDA since 1995. Then, on May 2, 2022, FDA issued Philips a notice of opportunity for a hearing regarding why the agency should not require Philips to submit a plan for the repair, replacement, or refund of the purchase price of recalled products.[19] The issuance of this notice marked the first time FDA has ever invoked its section 518(b) authority. Philips declined the hearing in favor of a written response. In July 2022, the company announced it was in discussions with DOJ regarding a consent decree.[20]

FDA's scrutiny is unsurprising in light of a perceived lackluster effort to effectuate a recall of a potentially high-risk product and following inspections that identified an apparent slowness to act on the issue. We will be paying close attention to how this case develops in the coming year and whether FDA chooses to exercise its section 518 authorities again in another context, or whether it was the specific facts and circumstances of the Philips matter that drove FDA to invoke these authorities.

Uncertain Future for FDA Jurisdiction: Adipose-Derived Stem Cell Products

As described in a prior Ropes & Gray client alert, the possibility of a circuit split currently looms that could undermine FDA's authority to regulate certain stem cell treatments. In late 2022, the government appealed a Central District of California injunction denial in the case of a California clinic that was marketing and administering adipose-derived stem cell products. The agency had previously won an injunction in the Southern District of Florida, affirmed by the 11th Circuit, against a stem cell clinic that unsuccessfully argued its similar stem cell products constituted human cell, tissue, and tissue-based products ("HCT/Ps") that were exempt from FDA regulation. Though working with nearly identical facts for a different clinic, the court on the opposite coast determined in August 2022 that the same HCT/P exemption at issue in the Florida case did in fact apply. Regardless of what happens in the 9th Circuit, the case may ultimately make its way to the Supreme Court, where deference to an agency's interpretation of its own ambiguous regulations is far from assured.

FDA Focus on Product Fulfillment Platforms: Amazon.com and Walmart

In a signal that FDA may be ushering in a new era of regulatory exposure for third-party distribution platforms, FDA issued two warning letters to online retail giant Amazon.com. The first, issued in August 2022, was part of a spate of warning letters to distributors of skin tag and mole removal products. Though Amazon does not itself produce products for skin tag or mole removal, the online retailer nonetheless received a warning letter for its role in introducing and delivering such products into interstate commerce. The warning letter resulted from the activities Amazon undertakes through its "Fulfillment by Amazon" service in which sellers store products in Amazon's fulfillment centers with Amazon picking, packing, shipping, and providing customer service for the sale of these products.[21] The agency's decision to issue a warning letter followed previously issued consumer warnings regarding the dangers of mole and skin tag removal remedies marketed for OTC use, when no drugs for these uses had ever been approved by FDA.[22]

FDA sent another warning letter to Amazon in October 2022 focused on the company's distribution, also through "Fulfillment by Amazon," of products labeled as dietary supplements that contained an unlabeled drug ingredient, diclofenac, that allegedly rendered the products misbranded drugs.[23] Walmart also received a warning letter for its distribution of the same products through a third-party fulfillment mechanism similar to Amazon's.[24]

In the retail context, FDA's enforcement efforts have historically targeted individual physical or virtual storefronts (or their suppliers) peddling violative wares. The warning letters to Amazon and Walmart may signal that FDA is setting its sights further up the distribution chain to the operators of platforms through which today's virtual storefronts routinely operate. FDA action against platforms like these may enable significantly more efficiency in enforcement if such action leads the platforms to start self-policing the products for which they provide "fulfillment" services.

Ongoing Scrutiny of Clinical Trial Fraud

In addition to protecting the public from defective, unapproved, or otherwise unsuitable products, FDA and DOJ have focused on ensuring that product approval and manufacturing quality is based on data that have the requisite hallmarks of integrity. Following on cases described in last year's enforcement update, in September 2022, a Florida jury convicted a Miami woman involved in a clinical trial studying the effectiveness of asthma drugs with making a false statement to a government investigator and conspiring to commit wire fraud.[25] At a separate clinical research site, two other Florida women pleaded guilty in July to agreeing to defraud clients paying for clinical trial work by, in part, fabricating data for fictitious trial participants.[26]

Clint Narver, assistant director of the DOJ Consumer Protection Branch ("CPB"), recently underscored the importance that clinical trial investigators and site managers remain vigilant in ensuring compliance, even following receipt of a clean FDA inspection report. Narver highlighted that a passing inspection may "really just [be] one more step in the

fraud scheme," and subpoenas or other investigational tools could still be deployed if the government has reason to believe a fraud is being perpetuated.[27]

More Aggressive Enforcement Against Unauthorized Tobacco Products

For the first time since FDA received authority to regulate tobacco products under the 2009 Family Smoking Prevention and Tobacco Control Act, the agency (with DOJ's assistance) initiated injunction proceedings to enforce the FDCA's premarket review requirements for new tobacco products.[28] In the crosshairs were six e-cigarette manufacturers that not only failed to submit premarket applications for their products, but that had previously been issued FDA warning letters in 2021[29] and yet continued to manufacture, sell, and distribute their products. The injunctions would require the companies and named individuals to stop engaging in such activities and also require the defendants obtain marketing authorization from FDA before marketing such products. As of the time of this article, four cases have been resolved via consent decree,[30] and two are on pace to go to trial.[31]

FDA also continued to issue warning letters to makers of unauthorized tobacco products, especially those products featuring youth-appealing packaging.[32] FDA issued warning letters to manufacturers of unauthorized tobacco products that were shaped to mimic toys or food (e.g., popsicles, glowsticks, beepers, Game Boys) or had images of popular characters printed on them (e.g., Rick and Morty, the Simpsons, Minions).[33] FDA noted in an announcement regarding the relevant warning letters, "It's a hard sell to suggest that adults using e-cigarettes with the goal of quitting smoking need a cartoon character emblazoned across the front of the product in order to do so successfully."[34]

Enhanced DOJ Expectations for FDCA Case Resolutions

For firms that have reached the end of a government investigation into allegations of criminal violations of the FDCA or related criminal provisions, the scrutiny may be far from over. DOJ has made clear that it plans on taking an active role to ensure that firms maintain a "culture of compliance" on a going-forward basis. Lisa Monaco, Deputy Attorney General, unveiled new policies aimed at incentivizing responsible corporate citizenship in September 2022, summarized in this Ropes & Gray alert.[35] Those policies address the Department's continuing focus on individuals when investigating misconduct, consideration of a company's complete compliance history when evaluating resolution options, enhancing incentives for voluntary self-disclosure including potential declination, and additional requirements for compliance monitors. Deputy Assistant Attorney General Arun Rao, who oversees DOJ's CPB, emphasized the new Department policies in a December 2022 speech and suggested that the CPB would soon issue its own voluntary self-disclosure policy, like all DOJ sections, consistent with the "core principles" outlined by Monaco.[36]

The CBP, which has oversight responsibility for cases involving the FDCA under the Justice Manual,[37] also recently established a Corporate Compliance and Policy Unit ("CCP") tasked with helping to craft and enforce corporate resolutions and ensure defendants follow the compliance and reporting provisions in their resolutions.[38] In addition to the continued involvement of DOJ's CPB in assessing compliance, firms resolving a False Claims Act matter, either as part of a resolution of liability in connection violations of the FDCA or as a separate matter, may also be required to sign a Corporate Integrity Agreement ("CIA") overseen by the Office of the Inspector General for the Department of Health and Human Services. At times, these agreements have also involved oversight over compliance with FDA requirements.[39]

At a December 2022 conference, attorneys from FDA, DOJ, and private practice debated whether DOJ might be usurping FDA's traditional role in evaluating FDA regulatory violations and monitoring compliance and whether that might be a particularly significant problem in cases involving manufacturing practice violations. Panelists expressed concern that DOJ might criminalize additional violations occurring in the aftermath of a criminal resolution, despite a firm's best efforts to remediate manufacturing issues. An attorney from CPB's new CCP Unit suggested that this was not DOJ's goal and that DOJ would be more focused on the response to the incident and what changes were or could be made to ensure the same mistake does not recur.[40]

The DOJ attorney also noted that CPB was working on creating a "template" agreement to ensure the standardization of compliance requirements.[41] She suggested that a future resolution agreement would contain these standardized requirements and thus would put industry on notice of what they could expect, especially alongside Non-Prosecution and Deferred Prosecution Agreements. What is abundantly clear is that resolving an FDCA case may mark just the beginning of extended communications with and oversight by DOJ, and it remains to be seen what role FDA will play in such discussions.

Looking Ahead

For 2023, we expect FDA and DOJ to continue to focus on regulated products that pose a safety risk, whether as a result of deficient manufacturing practices, lack of FDA review and approval, or because of data integrity concerns. Where FDA and DOJ find individuals and companies that "prioritize profits over patient safety" (a familiar refrain from press releases announcing enforcement action), prosecutors will no doubt seek to build an enforcement case. Whether cases involve breakfast cereal, infant formula, drugs, or devices, FDA and its law enforcement partners will be looking to penalize those who ignore or cover up regulatory violations to the detriment of consumers and patients. The contours of any corporate resolution will be shaped, as DOJ has noted, by a firm's compliance history, whether there has been voluntary self-disclosure and significant cooperation, and the strength of a firm's compliance program.

If you have any questions regarding enforcement related to FDA-regulated products or about what to expect from regulators and prosecutors in 2023, please contact any member of our Life Sciences Regulatory and Compliance practice or your usual Ropes & Gray advisor.

[1] FDA, "Timeline of Infant Formula Related Activities," https://www.fda.gov/media/158737/download.
[2] *See* 21 U.S.C. § 350a(c)–(d).
[3] Abbott, "Abbott Restarts Production of Specialty Formulas at its Michigan Plant" (June 4, 2022), https://www.abbott.com/corpnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall.html.

[4] Martine Paris, "One in Five US States is 90% Out of Baby Formula," *Bloomberg* (June 2, 2022), https://www.bloomberg.com/news/articles/2022-06-02/us-baby-formula-shortages-hit-74-despite-biden-action.
[5] FDA, "Guidance for Industry: Infant Formula Enforcement Discretion Policy" (May 2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-enforcement-discretion-policy.
[6] DOJ, "Justice Department Files Complaint and Proposed Consent Decree to Ensure Safety of Abbott Laboratories' Infant Formula" (May 16, 2022), https://www.justice.gov/opa/pr/justice-department-files-complaint-and-proposed-consent-decree-ensure-safety-abbott.
[7] Liz Essley Whyte, et al., "Abbott Under Federal Criminal Investigation Over Baby Formula," *Wall Street Journal* (Jan. 20, 2023), https://www.wsj.com/articles/abbott-under-criminal-investigation-over-baby-formula-11674255871.
[8] Federal Trade Commission, "Federal Trade Commission Launches Inquiry into Infant Formula Crisis" (May 24, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/05/federal-trade-commission-launches-inquiry-infant-formula-crisis.
[9] FDA, "Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies" (Jan. 9, 2023), https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies.
[10] DOJ, "Former Kerry Inc. Manager Pleads Guilty in Connection with Insanitary Plant Conditions Linked to 2018 Salmonella Poisoning Outbreak" (Oct. 21, 2022), https://www.justice.gov/opa/pr/former-kerry-inc-manager-pleads-guilty-connection-insanitary-plant-conditions-linked-2018.
[11] FDA, Warning Letter issued to Kerry Inc. (July 26, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kerry-inc-560168-07262018.
[12] FDA, Closeout Letter issued to Kerry Inc. (Aug. 20, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kerry-inc-577100-08202019.
[13] FDA, Warning Letter issued to Dollar Tree, Inc. (Nov. 8, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dollar-tree-inc-629509-11082022.
[14] DOJ, "South Florida Federal Judge Orders Prison Time for Former Pharmatech CEO" (Sept. 1, 2022), https://www.justice.gov/usao-sdfl/pr/south-florida-federal-judge-orders-prison-time-former-pharmatech-ceo.
[15] FDA, "FDA Updates on 2017 *Burkholderia cepacia* Contamination" (Oct. 27, 2017), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-2017-burkholderia-cepacia-contamination.
[16] DOJ, "District Court Enjoins Illinois Pharmaceutical Manufacturer from Making and Selling Adulterated Drugs" (Aug. 19, 2022), https://www.justice.gov/opa/pr/district-court-enjoins-illinois-pharmaceutical-manufacturer-making-and-selling-adulterated.
[17] Consent Decree of Permanent Injunction, *United States v. Morton Grove Pharmaceuticals, Inc., et al.*, No. 1:22-cv-04367 (N.D. Ill. Aug. 19, 2022), https://www.justice.gov/opa/press-release/file/1527456/download.
[18] FDA, 518(a) Notification Order re: Philips Respironics Recall of DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C-Series ASV; C-Series S/T and AVAPS; OmniLab Advanced+; SystemOne (Q-Series); DreamStation; DreamStation Go; Dorma 400; Dorma 50); REMstar SE Auto; E30 (Emergency Use Authorization); Trilogy 100; Trilogy 200; Garbin Plus, Aeris, LifeVent; ASeries BiPAP Hybrid A30 (not marketed in US); A-Series BiPAP V30 Auto; A-Series BiPAP A40; A-Series BiPAP A30 issued to Thomas J. Fallon at Philips Respironics Inc. (Mar. 10, 2022), https://www.fda.gov/media/156811/download.
[19] FDA, Proposal for FDA to Issue an Order for Device Repair, Replacement, and/or Refund: Notice of Opportunity for a Hearing issued to Thomas J. Fallon at Philips Respironics, Inc. (May 2, 2022), https://www.fda.gov/media/158129/download.
[20] Philips, "Philips' Second-Quarter Results 2022" (July 25, 2022), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-second-quarter-results-2022.html.
[21] In the warning letter, FDA stated that it purchased the products "Deisana Skin Tag Remover, Mole Remover and Repair Gel Set" and "Skincell Mole Skin Tag Corrector Serum" through Amazon.com from sellers using the "Fulfillment by Amazon" service. FDA, Warning Letter issued to Amazon.com, Inc. (Aug. 4, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/amazoncom-inc-629452-08042022.
[22] FDA, "Products Marketed for Removing Moles and Other Skin Lesions Can Cause Injuries, Scarring" (Aug. 10, 2022), https://www.fda.gov/consumers/consumer-updates/products-marketed-removing-moles-and-other-skin-lesions-can-cause-injuries-scarring.
[23] FDA, Warning Letter issued to Amazon.com, Inc. (Oct. 28, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/amazoncom-inc-631751-10282022.
[24] FDA, Warning Letter issued to Walmart Inc. (Oct. 28, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/walmart-inc-631755-10282022.
[25] FDA, "Florida Jury Convicts Miami Woman of Making False Statement in Connection with Pediatric Asthma Drug Study" (Sept. 19, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/florida-jury-convicts-miami-woman-making-false-statement-connection-pediatric-asthma-drug-study.

[26] FDA, "Two Florida Medical Study Coordinators Plead Guilty in Connection with Scheme to Falsify Clinical Trial Data" (July 20, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/two-florida-medical-study-coordinators-plead-guilty-connection-scheme-falsify-clinical-trial-data.
[27] Sue Sutter, "Clinical Data Integrity: Clean US FDA Inspection No Guarantee That DOJ Won't Investigate" (Nov. 7, 2022), Pink Sheet, https://pink.pharmaintelligence.informa.com/PS147279/Clinical-Data-Integrity-Clean-US-FDA-Inspection-No-Guarantee-That-DoJ-Wont-Investigate.
[28] FDA, "FDA, DOJ Seek Permanent Injunctions Against Six E-cigarette Manufacturers" (Oct. 18, 2022), https://www.fda.gov/news-events/press-announcements/fda-doj-seek-permanent-injunctions-against-six-e-cigarette-manufacturers.
[29] FDA, Warning Letter issued to Morin Enterprises Inc. d/b/a Ecig Crib (Mar. 26, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/morin-enterprises-inc-dba-ecig-crib-614011-03262021; FDA, Warning Letter issued to Super Vape'z (Apr. 5, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/super-vapez-614054-04052021; FDA, Warning Letter issued to Lucky's Convenience & Tobacco, LLC d/b/a Lucky's Vape & Smoke Shop (Apr. 16, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/luckys-convenience-tobacco-llc-dba-luckys-vape-smoke-shop-614158-04162021; FDA, Warning Letter issued to Soul Vapor (May 21, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/soul-vapor-614881-05212021; FDA, Warning Letter issued to The Vapor Craft LLC, d/b/a Vapor Craft (Aug. 26, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vapor-craft-llc-dba-vapor-craft-617222-08262021; FDA, Warning Letter issued to Seditious Vapours, LLC d/b/a Butt Out Labs (Aug. 27, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/seditious-vapours-llc-dba-butt-out-labs-617278-08272021.
[30] Consent Decree of Permanent Injunction, *United States v. Vapor Craft LLC, et al.*, No. 4:22cv160 (M.D. Ga. Dec. 7, 2022); Consent Decree of Permanent Injunction, *United States v. Seditious Vapours LLC, et al.*, No. 2:22cv1777 (D. Ariz. Dec. 9, 2022); Consent Decree of Permanent Injunction, *United States v. Morin Enterprises, Inc., et al.*, No. 0:22cv2592 (D. Minn. Jan. 24, 2023); Consent Decree of Permanent Injunction, *United States v. Lucky's Convenience & Tobacco, LLC, et al.*, No. 22-cv-01237 (D. Kan. Jan. 26, 2023).
[31] *See United States v. Soul Vapor, LLC, et al.*, No. 1:22cv458 (S.D.W. Va.) (complaint filed Oct. 18, 2022); *United States v. Super Vape'z LLC, et al.*, No. 3:22cv5789 (W.D. Wash.) (complaint filed Oct. 18, 2022).
[32] FDA, "FDA Warns Firms for Selling Illegal E-Cigarettes That Look Like Toys, Food, and Cartoon Characters" (Nov. 16, 2022), https://www.fda.gov/news-events/press-announcements/fda-warns-firms-selling-illegal-e-cigarettes-look-toys-food-and-cartoon-characters.
[33] FDA, "Unauthorized E-cigarettes That Appeal to Youth" (Nov. 16, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/unauthorized-e-cigarettes-appeal-youth.
[34] FDA, *supra* note 32.
[35] Lisa Monaco, Memorandum re: Further Revisions to Corporate Criminal Enforcement Policies Following Discussions with Corporate Crime Advisory Group (Sept. 15, 2022), DOJ Office of the Deputy Attorney General, https://www.justice.gov/opa/speech/file/1535301/download.
[36] DOJ, "Deputy Assistant Attorney General Arun G. Rao Delivers Keynote Address at the Food and Drug Law Institute Enforcement, Litigation and Compliance Conference: for the Drug, Device, Food and Tobacco Industries" (Dec. 7, 2022), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-arun-g-rao-delivers-keynote-address-food-and-drug-law.
[37] DOJ, "4-8.200 – Federal Food, Drug, and Cosmetic Act Litigation," Justice Manual, https://www.justice.gov/jm/jm-4-8000-consumer-protection.
[38] DOJ, "Recent Highlights: Consumer Protection Branch" (Apr. 2022), https://www.justice.gov/file/1490441/download.
[39] A December 2022 CIA between Advanced Bionics and the Department of Health and Human Services' Office of the Inspector General requires independent review of the company's activities and processes relating to the preparation or submission of premarket approval applications and relevant performance standards. DOJ, "Advanced Bionics LLC to Pay Over $12 Million for Alleged False Claims for Cochlear Implant Processors" (Dec. 20, 2022), https://www.justice.gov/opa/pr/advanced-bionics-llc-pay-over-12-million-alleged-false-claims-cochlear-implant-processors.
[40] Brenda Sandburg, "GMP Violations Won't Trigger Breach of DOJ Compliance Agreement, Government Attorneys Say" (Dec. 22, 2022), *Pink Sheet*, https://pink.pharmaintelligence.informa.com/PS147442/GMP-Violations-Wont-Trigger-Breach-Of-DOJ-Compliance-Agreement-Government-Attorneys-Say.
[41] *Id*.