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2021 Enforcement Review: FDA-Regulated Medical Products

Introduction

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While the continuing COVID-19 public health emergency remained an obstacle to many Food and Drug Administration ("FDA") inspections in 2021, the pandemic did not preclude criminal and civil enforcement actions related to core FDA regulatory violations, especially those matters that have been under investigation since before the pandemic. The Department of Justice ("DOJ") announced numerous indictments, civil and criminal settlements and criminal sentences involving those accused of violating the Federal Food, Drug, and Cosmetic Act ("FDCA") and other laws in connection with schemes involving FDA-regulated products. COVID-19 related fraud remained a top priority as did cases involving opioids and clinical trial fraud.

If any unifying theme can be attributed to government enforcement actions in 2021 against drug and medical device companies in the public health arena, lack of transparency may be the best candidate. DOJ is an eager partner in prosecuting those who appear to be trying to get in the way of FDA's work through fabrication, deceit or obstruction. DOJ's Consumer Protection Branch, which is involved in most judicial enforcement related to violations of FDA requirements, has shored up its ranks (the office now has more than two hundred employees, including attorneys, agents and support personnel[1]) enabling close cooperation with FDA and local U.S. Attorney's offices on enforcing the FDCA and related laws. We should all expect continuing scrutiny of FDA-regulated entities in the coming year, and life sciences companies should be laser-focused on transparency with their primary regulators and the public, as lack of such transparency is motivating not only FDCA-based cases, but a wide variety of fraud and conspiracy cases against industry actors.

This 2021 enforcement review covers key criminal and civil enforcement actions against life sciences companies, starting with those related to the ongoing COVID-19 pandemic. It turns next to actions involving the illicit distribution of opioids, which continue to be a DOJ priority, and then focuses on an emerging area of law enforcement interest: clinical trial fraud. The article then looks at other enforcement actions brought under the FDCA and related criminal statutes, as well as the civil False Claims Act, that are predicated upon a somewhat wider variety of alleged FDA regulatory violations. The article wraps up by looking forward to what FDA-regulated companies can expect on the enforcement horizon in 2022.

COVID-19-Focused Enforcement

DOJ continued to prosecute fraudulent and misleading practices related to COVID-19, though the number of prosecutions related to selling "quack" COVID cures appeared to be down from the prior year. In March 2021, DOJ charged a Thai citizen with introducing misbranded and unapproved new drugs into interstate commerce, as well as with mail fraud, wire fraud, smuggling, and false statements, arising out of his sale and distribution of unapproved chloroquine phosphate as a treatment for COVID-19 and malaria.[2] The defendant allegedly sold chloroquine phosphate via eBay and falsely claimed that it was the same drug "that the FDA has recently issued an emergency authorization to treat COVID-19."[3]

In May 2021, law enforcement officers arrested the owner of a holistic medicine company on charges of distributing unapproved new drugs, after the company had previously received FDA warning letters in March and April 2020.[4] In the warning letters, FDA had informed the defendant, who was selling online what she claimed to be a treatment for COVID-19, that she was selling adulterated, misbranded and unapproved new drugs.[5] In responding to the warning letters, the defendant falsely claimed she would be closing the product line and her website. Notwithstanding her representations, undercover agents were still able to purchase the products from a password-protected website that the defendant created in the old website's place.[6]

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DOJ also pursued enforcement action against fraudulent COVID-19 vaccines. DOJ filed a criminal wire fraud and false statements case in July 2021 against a licensed naturopathic doctor who allegedly was offering homeoprophylaxis immunizations and fabricating COVID-19 vaccine cards that stated that the holders, who had received the naturopath's product, had in fact received Moderna's COVID-19 vaccine.[7] The defendant also administered homeoprophylaxis immunizations and claimed that they satisfied California school vaccine requirements and falsified, fabricated, and altered records that were submitted to California schools.[8] Separately, DOJ seized a number of domain names that purported to be biotechnology companies offering unapproved vaccines and treatments for COVID-19.[9]

In February 2021, a pharmacist in Wisconsin pled guilty to attempting to tamper with vaccines, by removing them from the cold storage required for them to retain their safety and efficacy, and then returning them to the refrigerator where they would be used on patients the following day.[10] The pharmacist was sentenced in June 2021 to three years in prison.[11] This case did not allege fraud explicitly. However, had the attempted tampering not been discovered, it could have resulted in consumers unknowingly receiving a vaccine that lacked the expected safety and efficacy due to its improper storage.

In addition to action by DOJ, the Federal Trade Commission ("FTC") has been very active this year and in 2020, sending hundreds of cease and desist letters ordering companies to stop making baseless claims that their products and supposed therapies can treat or prevent COVID-19.[12] FDA and FTC have also issued numerous joint warning letters to companies allegedly selling unapproved products that may violate federal law by making deceptive or scientifically unsupported claims about their ability to treat or cure COVID-19.[13]

Opioids

While DOJ continues to prioritize opioid cases, we did not see any new criminal prosecutions against large pharmaceutical manufacturers or distributors this year that paralleled the Purdue Pharma and Indivior criminal resolutions described in our 2020 year-end enforcement review. However, the government is still battling opioid distributors and their executives, and states and other localities continue to pursue and settle actions for their share of payments from opioid-manufacturers and distributors in civil lawsuits related to allegations that these companies fueled the opioid crisis.[14] Two significant cases involving Controlled Substances Act ("CSA") charges that continued to be active in 2021 are the criminal prosecution of former Rochester Drug Cooperative CEO Laurence Doud III that is being tried in the Southern District of New York as this review goes to print, and the Department of Justice's civil monetary penalties action against Walmart.[15]

Rochester Drug Cooperative Former CEO: Laurence Doud III

In 2019, the U.S. Attorney's Office for the Southern District of New York announced that it had indicted the Rochester Drug Cooperative ("RDC"), a major distributor of opioids, as well as two executives of the company for unlawfully distributing controlled substances.[16] That announcement noted that the distributor had agreed to enter into a consent decree and pay a $20 million penalty and that the criminal charges filed against it (including conspiracy to distribute controlled substances, conspiracy to defraud the United States and willfully failing to file suspicious order reports) would be deferred assuming the company's compliance with the agreement it had reached.[17] The former Chief Compliance Officer pled guilty at the same time and to the same charges, pursuant to a cooperation agreement with the government.[18]

The former RDC CEO, however, is fighting the charges and is currently in the midst of trial after the district court rejected his arguments that the government had overreached by charging what were essentially regulatory offenses as federal criminal drug offenses. He had also argued that he could not be charged legally for a conspiracy to commit drug trafficking offenses when he had no knowledge that his business decisions could lead to such a charge.[19] In denying Doud's motion to dismiss, the court explained that the existence of a specific regulatory or statutory provision prohibiting certain behavior does not preclude prosecution for federal criminal drug offenses.[20] Some in the press have

suggested that the narcotics conspiracy charge, which the U.S. Attorney's Office touted as a "first of its kind prosecution," will be difficult for the government to establish beyond a reasonable doubt. More specifically, it may be difficult to establish that, based on the information the defendant received, he had to know the opioids RDC was distributing were being distributed illegally.[21] Whether a jury is convinced that an executive in the defendant's position had the requisite intent for the crimes charged will likely have a significant impact on how similar cases are charged in the future.

Walmart Civil Money Penalties Action

The civil case against Walmart, filed in late 2020 in the District of Delaware, alleges that the pharmacy giant unlawfully dispensed controlled substances from pharmacies it operated nationwide, resulting in thousands of CSA violations, and seeks civil money penalties as well as injunctive relief.[22] The complaint alleged the company had filled prescriptions for controlled substances that were not issued for a legitimate medical purpose, and that the company had received thousands of suspicious orders that it failed to report.[23] Civil money penalties in the billions of dollars may ultimately be assessed if the government prevails. However, in November 2021, the district court stayed the case[24] until the Supreme Court decides two consolidated cases[25] involving charges brought against physicians with respect to prescribing outside the "usual course of medical practice" in violation of the CSA and applicable DEA regulations.[26] These cases, slated for oral argument in March 2022, raise the question of the state of mind required for a jury to convict a prescriber under these provisions, whether or not a "good faith" defense is available that would negate the required *mens rea*, and what the contours of such a defense should be.

In addition to the continued litigation of these high profile cases in 2021, numerous criminal cases against individuals were filed charging CSA violations that alleged trafficking, tampering or inappropriate prescribing.[27] In addition, DOJ has continued to use its civil injunction authority under the CSA (21 U.S.C. § 843(f)) to enjoin providers from prescribing opioids and other controlled substances.[28]

Clinical Trial Fraud

FDA and DOJ have focused increasing resources on prosecuting clinical trial fraud in the last two years[29] and 2021 saw a continuation of those efforts. DOJ Deputy Attorney General Arun Rao made it very clear that prosecuting such cases will continue to be a priority for the agency in a speech he gave in December 2021 at the Food and Drug Law Institute's annual Enforcement, Compliance and Litigation conference, promising to bring further actions in the coming months.[30]

Since August 2020, DOJ has charged four defendants each from two Miami-based CROs for their alleged involvement in falsifying documents for clinical trials they purported to be conducting on behalf of sponsors. The defendants in these cases include CRO owners, CEOs, clinical investigators, study coordinators, project managers, and receptionists.[31] Defendants in both cases allegedly entered false information in case history files to make it appear that subjects were enrolled in studies, when in fact they were not.[32] In January 2021, a licensed physician who served as the primary investigator of one of the CROs pled guilty to one count of conspiring to falsify clinical trial data and was sentenced in March to 63 months in prison.[33] A study coordinator at the same CRO pled guilty to conspiring to commit wire fraud and was sentenced to 30 months in prison.[34] Defendants at the second CRO, including a study sub-investigator, an assistant study coordinator, and an individual who served as a project manager and coordinator, each admitted to agreeing to falsify medical records and pled guilty to conspiracy to commit mail and wire fraud in 2021.[35] All three defendants were sentenced to 30 months in prison and ordered to pay over $2 million in restitution.[36] Other defendants' cases are still being litigated.

DOJ also indicted eight employees of an Ohio- and Tennessee-based CRO in July 2020 with conspiracy to commit mail and wire fraud, mail fraud, wire fraud, aggravated identity theft, and conspiracy to defraud the FDA and a number of pharmaceutical companies on whose behalf the CRO was conducting "research."[37] A licensed medical doctor who served

as the organization's principal investigator and who oversaw most clinical trials, was also charged with failure to maintain adequate records in violation of the FDCA, 21 U.S.C. § 331(e).[38] The indictment alleges that he and others fabricated and falsified medical records, informed consent forms, and other documentation for fictitious study subjects.[39] A jury trial is set to begin on August 1, 2022.

In light of DOJ's attention to fraud in clinical research and FDA's obvious concern about how such fraud impacts product submissions and approvals, we are likely to see the agencies cooperate closely on similar cases in the future. The agency routinely issues warning letters to investigators when violations of good clinical practices are found. FDA also has the authority (1) to disqualify and prevent drug and device investigators from receiving investigational products under FDA regulations (21 CFR § 312.70 and 21 C.F.R. § 812.119), and (2) to debar individuals under the FDCA (21 U.S.C. § 335a) from assisting with FDA drug submissions, including research, when such individuals have been convicted of a felony for conduct related to the development or approval of a drug product. However, DOJ has the additional flexibility to initiate criminal proceedings against a variety of actors involved in research fraud using a number of different charging theories, including those of conspiracy, fraud and false statements. In addition, DOJ can take enforcement action under the False Claims Act when fraudulent conduct relates to federally funded research.

To date, DOJ has focused on CROs conducting trials on behalf of pharmaceutical companies where the pharmaceutical company sponsors, along with FDA, have been the victims of the frauds at issue. However, trial sponsors should delegate their clinical trial responsibilities very carefully, and closely monitor and audit CROs working on their trials. Now that these cases have put a spotlight on the industry, expectations will increase for trial sponsors to scrupulously vet their CROs. The consequences of not doing so include the exclusion of data from FDA submissions, the potential disqualification or debarment of investigators, and potentially criminal and civil liability if the government can show the sponsors looked the other way or worked in concert with offending CROs.

Other FDCA Criminal Enforcement

While clinical trial fraud has emerged as a major priority for the government, DOJ has continued to pursue other more traditional cases relying on FDA regulatory violations, especially when such violations involve misleading or obstructing FDA.

In February 2021, DOJ announced a criminal settlement with Fresenius Kabi Oncology Limited ("FKOL") involving allegations that the company had purposely concealed and destroyed records showing deficiencies in current Good Manufacturing Practices ("cGMPs") from a plant prior to an FDA inspection of that facility.[40] FKOL owns and operates a plant in Kalyani, India that manufactures active pharmaceutical ingredients ("APIs") intended for use in oncology products.[41] After FDA notified the company in January 2013 that it would inspect the Kalyani plant, management at the plant allegedly instructed employees to delete records from computers and to remove certain physical records and computers from the facility in order to hide evidence of regulatory violations.[42] The records allegedly showed that APIs were unofficially tested and blended to conceal impurities.[43] In particular, employees would test API batches to identify those that had unacceptable impurity levels and then blend those out-of-specification API batches with acceptable batches to keep batches within specification for impurities. The criminal information alleged that the employees documented only the results of batches with acceptable impurity levels to conceal the fact that they had blended the API batches.[44] FKOL pled guilty to refusing to permit access to records in violation of the FDCA (21 U.S.C. §§ 331(e) and 374(a)), entered a plea agreement, and was sentenced to a criminal fine of $30 million and criminal forfeiture of $20 million.[45]

A deferred prosecution agreement entered into by Avanos Medical Inc. also highlights the government's prioritization of cases where alleged lack of transparency is a key concern. In resolving allegations against it, Avanos admitted that it sold surgical gowns that it labeled as meeting the highest level for protection against virus and fluid penetration that FDA has adopted when in fact the gowns did not meet that standard.[46] In announcing the settlement, the government also

referenced an allegation that a company employee had obstructed an FDA for-cause inspection by making false entries into documents requested by FDA. The criminal information filed with the agreement charged the company with misbranding its gowns with the intent to defraud or mislead. Under the agreement, to avoid prosecution for this charge, the company must take on certain compliance obligations and pay more than $22 million, which includes a victim compensation payment of $8.9 million, a criminal monetary penalty of $12.6 million, and a disgorgement payment of $689,000.[47]

In 2021, DOJ also signaled it is likely to be paying close attention to manufacturing problems associated with COVID-19-related products, especially those that involve significant government contracts. In May 2021, Eli Lilly disclosed that it had received a DOJ subpoena related to the New Jersey manufacturing plant where it makes its COVID-19 treatment, balmanivimab.[48] Press reports noted that a month earlier employees had accused the company, in an internal complaint, of altering FDA-required documents in order to hide quality problems.[49] Emergent BioSolutions, the contract manufacturer for the drug substance used in J&J's COVID-19 vaccine, also disclosed that it had received "preliminary inquiries and subpoenas to produce documents" from DOJ, SEC and other government investigators.[50] These inquiries appear to have been prompted by FDA's discovery that ingredients from AstraZeneca's COVID-19 vaccine, also being produced in the Emergent facility, had contaminated a batch of J&J's vaccines and halted operations at the plant.[51]

FDCA Civil Injunctions

While criminal prosecutions grab the most headlines, eight civil FDCA injunctions resolved either through litigation or agreement of the parties in 2021, including one case that could have threatened FDA's ability to regulate clinics that administer unapproved stem cell treatments made in part from patients' own fat tissue.

In June 2021, the Eleventh Circuit ruled in favor of FDA in an important FDCA injunction case against U.S. Stem Cell Clinic, LLC that had been in litigation since 2018.[52] This case involved FDA's ability to regulate an experimental procedure involving the removal of fat tissue from a patient, use of a processing technique to isolate the stem cells in that tissue sample to create a substance referred to as "stromal vascular fraction" ("SVF"), and implantation of the SVF into the patient from whom the fat tissue was originally removed. The court rejected Defendant's argument that the procedure was subject to the "same surgical procedure" exception to FDA regulation of human cells, tissues, and cellular and tissue-based products" ("HCT/Ps") outlined in 21 C.F.R. 1271.15(b) and agreed with FDA that the SVF was an FDA-regulated drug. Since the exception applies where an establishment "removes HCT/Ps from an individual and implants *such* HCT/Ps into the same individual during the same surgical procedure" (emphasis added), the 11th Circuit examined whether the fat tissue (classified as an "HCT/P") removed from the patient was the same as the tissue HCT/P implanted back into the patient. The court agreed with FDA that it was not.[53] A similar injunction case based on interpreting the very same regulation, *U.S. v. California Stem Cell Treatment Center*, was tried beginning in May 2021 in the Central District of California.[54] A verdict has not yet issued.

Another litigated injunction case initiated in 2019 and resolved in 2021 involved a dietary supplement manufacturer with a long history of alleged cGMP violations called Confidence USA. [55] The manufacturer argued that a permanent injunction was inappropriate in part because FDA's evidence of cGMP violations was stale, as the most recent inspection had taken place more than two years prior to judicial review. Since that time, the manufacturer claimed that it had hired a GMP consultant and implemented significant remedial measures. GMP audits by the consultant had supposedly verified that the manufacturer was generally in compliance with cGMPs. Notwithstanding these arguments, the court still ordered a permanent injunction because of the likelihood of recurrence of noncompliant behavior, even assuming the defendants had remediated the problems previously identified.[56]

DOJ also entered into a consent decree with Premier Pharmacy Labs, a Florida-based drug outsourcing facility, to settle allegations that Premier introduced adulterated and unapproved new drugs into interstate commerce.[57] These allegations stem from a series of inspections beginning in 2014 that found that Premier's facilities were insanitary.[58] The

government also took issue with Premier's failure to comply with cGMPs, which apply to outsourcing facilities like Premier.[59] In particular, DOJ alleged that Premier did not conduct adequate investigations into discrepancies that could impact the quality and safety of sterile drug products, did not ensure that the firm's quality control unit properly approved batches for release and qualified suppliers, and did not conduct sterility testing, endotoxin testing, and visual checks for particles before products were released, among other alleged violations.[60]

Another injunction case resolved by consent decree involved a Nevada-based bottled water manufacturer whose water was associated with significant injuries.[61] The allegations in the injunction complaint related to noncompliance with hazard analysis and risk-based preventative control requirements, noncompliance with bottled water cGMP regulations, and labeling violations.[62] The consent decree requires the company to shut down until it can come into compliance with FDA requirements.[63]

Of the remaining consent decrees entered into in 2021, two specifically related to the distribution of unapproved new drugs to treat COVID-19,[64] one enjoined further distribution of unapproved and misbranded animal drugs,[65] and one enjoined the distribution of purported dietary supplements that were allegedly adulterated, misbranded and constituted unapproved new drugs.[66]

When FDA is able to return to pre-pandemic inspection levels, we are likely to see more civil injunctions as well as regulatory enforcement actions arising out of deficiencies identified in those inspections.[67]

Civil False Claims Act Cases

Another fertile area for DOJ enforcement against life sciences companies that is often predicated on FDA regulatory violations is the Civil False Claims Act ("FCA"). Sometimes FCA actions are brought alongside criminal charges, but often they are resolved without a companion criminal charge. Two important FDA-related FCA cases were resolved in 2021 on a civil-only basis.

Alere Inc.

In July 2021, Alere Inc. and Alere San Diego Inc. agreed to pay $38.75 million to resolve allegations that they violated the FCA by knowingly selling blood coagulation monitors that had a defect that led to inaccurate and unreliable results when some patients used the monitors.[68] The defects allegedly led to more than a dozen deaths and hundreds of injuries, such as intra-cerebral hemorrhaging and cardiovascular events.[69] The government alleged the companies knew about and concealed the defects, and continued for years to bill Medicare for use of the devices.[70] The settlement also resolved allegations that, despite knowing of the defects since 2008, the companies did not take appropriate corrective action until 2016, when FDA requested that the firm initiate a Class I recall to remove the devices from the market.[71]

St. Jude Medical Inc.

Also in July 2021, St. Jude Medical Inc. agreed to pay $27 million to settle FCA allegations.[72] The government alleged that St. Jude knowingly sold defective implantable heart devices to health care facilities, that the devices were implanted in patients covered by federal health care programs, and that St. Jude ultimately billed federal health care programs for the defective devices.[73] Lithium batteries in the devices allegedly caused lithium clusters to form, which are often harmless but can prematurely drain the batteries of power.[74] St. Jude submitted a premarket approval application supplement to FDA in 2013 seeking approval of an improvement to the batteries in the implantable devices that would prevent clusters from forming.[75] The government alleged that in that submission to FDA, St. Jude knowingly made false and misleading representations that there had not been any serious injury, permanent harm, or deaths associated with the lithium clusters.[76]

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Looking Forward to 2022

In the coming year, we can expect scrutiny of drug and medical device companies and their executives to remain high.

With the significant sums of money the government has earmarked for COVID-related vaccines and therapeutics, the government will no doubt be looking to make sure the beneficiaries of research and development funding and significant government contracts are living up to their compliance commitments. Robust compliance programs, regular audits of contract-related commitments, transparency with regulators and comprehensive investigations and remediation, when necessary, will provide the best defenses against government enforcement should criminal subpoenas or civil investigative demands issue to those entities that have signed significant government contracts for pandemic-related products,

DOJ is still very focused on entities and individuals responsible for fueling the opioid crisis, and will no doubt continue to pursue providers who are inappropriately prescribing opioids or pharmacists who are inappropriately dispensing them. Whether such cases are pursued criminally or civilly may be impacted by cases currently being litigated.

Further, as discussed above, we fully expect DOJ and FDA to continue to work closely together to investigate and prosecute clinical trial fraud. To date, much of the enforcement in this area has focused on CROs engaged in clear, bright-line fraud, such as studies where all or most subjects and records are fabricated by investigators or others working with them. We may see DOJ begin to focus on the selection of CROs by pharmaceutical and device manufacturers and what role they may have played in failing to prevent fraud.

The DOJ under Attorney General Merrick Garland has also made policy changes likely to make a meaningful impact in the context of enforcement actions against life sciences companies and their leaders in the coming year and beyond.

In a speech to the white collar bar in October 2021, summarized in a prior Ropes & Gray alert, Deputy Attorney General Lisa Monaco made it very clear that accountability for criminal conduct begins with individuals. She also announced the restoration of prior DOJ guidance making any cooperation credit contingent on the provision to DOJ of all non-privileged information about individuals involved in or responsible for alleged misconduct.[77] Monaco emphasized that prosecution of responsible individuals consistent with the Principles of Federal Prosecution will be the first priority for the Department, even if such cases may, at times, be difficult to win.[78] In addition, Monaco put corporations on notice that when considering the appropriate resolution of a corporate enforcement matter, the Department will review the entirety of a company's "criminal, civil, and regulatory record."[79]

Attorney General Garland has also reversed the policies of former Attorney General Jeff Sessions and former Associate Attorney General Rachel Brand that strictly limited the use of sub-regulatory agency guidance in enforcement actions.[80] While enforcement based solely on agency guidance alone is never appropriate, life sciences companies may see more liberal use of agency guidance as evidence in enforcement actions.

Life sciences companies, like all corporations, can expect to face an aggressive enforcement climate for the foreseeable future. A serious, demonstrated commitment to compliance, evidenced by robust and well-resourced compliance programs and supported by leaders who can serve as role models for ethical and compliant behavior, will be critical to navigating the government inquiries that are sure to come. Serious and thoughtful advocacy will also be more important than ever, especially to place prior regulatory enforcement and remediation efforts into appropriate perspective.

If you have any questions regarding enforcement related to FDA-regulated products in 2021 or what to expect from regulators and prosecutors in 2022, please contact any member of our Life Sciences Regulatory and Compliance practice or your usual Ropes & Gray advisor.

[1] DOJ, "Consumer Protection Branch," https://www.justice.gov/civil/consumer-protection-branch.
[2] DOJ, "Thai National Charged With Fraudulently Selling Unapproved Chloroquine Phosphate As A Treatment For Covid-10" (Mar. 31, 2021), *available at* https://www.justice.gov/usao-mdpa/pr/thai-national-charged-fraudulently-selling-unapproved-chloroquine-phosphate-treatment.
[3] Indictment, *United States. v. Chunhasomboon*, No. 3:21-cr-00093-RDM (M.D. Pa. Mar. 30, 2021).
[4] DOJ, "North Carolina Woman Arrested for Selling Unapproved Remedies for Covid-19" (May 11, 2021), *available at* https://www.justice.gov/usao-nh/pr/north-carolina-woman-arrested-selling-unapproved-remedies-covid-19.
[5] *Id.*
[6] *Id.*
[7] DOJ, "Napa Women Arrested For Fake Covid-19 Immunization And Vaccine Card Scheme" (July 14, 2021), *available at* https://www.justice.gov/usao-ndca/pr/napa-woman-arrested-fake-covid-19-immunization-and-vaccine-card-scheme.
[8] *Id.*
[9] DOJ, "Maryland U.S. Attorney's Office Seizes Fifth Domain Name Purporting to be the Website of a Biotech Company Producing a Treatment for COVID-19" (Mar. 9, 2021), *available at* https://www.justice.gov/usao-md/pr/maryland-us-attorneys-office-seizes-fifth-domain-name-purporting-be-website-biotech; DOJ, "Maryland U.S. Attorney's Office Seizes Three Domain Names Purporting to be Websites of Biotechnology Companies with Treatments for Covid-19" (Apr. 7, 2021), *available at* https://www.justice.gov/usao-md/pr/maryland-us-attorney-s-office-seizes-three-domain-names-purporting-be-websites; DOJ "Maryland U.S. Attorney's Office Seizes Domain Name Falsely Purporting to Provide COVID-19 Vaccines" (May 3, 2021), *available at* https://www.justice.gov/usao-md/pr/maryland-us-attorney-s-office-seizes-domain-name-falsely-purporting-provide-covid-19.
[10] DOJ, "Hospital Pharmacist Sentenced for Attempt to Spoil Hundreds of COVID Vaccine Doses" (June 8, 2021), *available at* https://www.justice.gov/usao-edwi/pr/hospital-pharmacist-sentenced-attempt-spoil-hundreds-covid-vaccine-doses.
[11] *Id.*
[12] FTC, "With Omicron Variant on the Rise, FTC Orders More Marketers to Stop Falsely Claiming Their Products Can Effectively Prevent or Treat COVID-19" (Jan. 18, 2022), *available at* https://www.ftc.gov/news-events/press-releases/2022/01/omicron-variant-rise-ftc-orders-more-marketers-stop-falsely.
[13] FTC, "FTC Coronavirus Warning Letters to Companies" *available at* https://www.ftc.gov/coronavirus/enforcement/warning-letters.
[14] *See, e.g.*, Ropes & Gray Life Sciences Litigation & Enforcement Blog, "Johnson & Johnson, McKesson Corp., Amerisource Bergen Corp, and Cardinal Health proceed with $26 billion Settlement with States to Resolve Opioid Claims" *available at* https://www.lifescienceslitigation.com/2021/09/johnson-johnson-mckesson-corp-amerisourcebergen-corp-and-cardinal-health-proceed-with-26-billion-settlement-with-states-to-resolve-to-resolve-opioid-claims/#more-2116; MDL 2084 Opiate Litigation, No. 1:17-MD-2804, *available at* https://www.ohnd.uscourts.gov/mdl-2804; MDL 2804, National Prescription Opiate Litigation groups thousands of lawsuits filed against many types of defendants for their alleged role in the opioid epidemic. Defendants include large opioid manufacturers and distributors as well as smaller pharmacies and individual physicians and prescribers.
[15] Sealed Indictment, *United States v. Doud*, No. 1:19-cr00285-GBD (S.D.N.Y. Apr. 22, 2019), *available at* https://www.justice.gov/usao-sdny/press-release/file/1156386/download; Complaint, *United States v. Walmart Inc.*, No. 1:99-mc-09999 (D. Del. Dec. 22, 2020), *available at* https://www.justice.gov/opa/press-release/file/1347906/download.
[16] DOJ, "Manhattan U.S. Attorney and DEA Announce Charges Against Rochester Drug Co-Operative and Two Executives For Unlawfully Distributing Controlled Substances" (Apr. 23, 2019), *available at* https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-and-dea-announce-charges-against-rochester-drug-co-operative-and.
[17] *Id.*
[18] *Id.*
[19] Memorandum Decision and Order, *United States v. Doud*, No. 1:19-cr-00285-GBD (S.D.N.Y.Jan. 5, 2022).
[20] *Id.*
[21] Jack Queen, Pharma Exec's Drug Trafficking Trial Tests Bold Legal Theory, Law360 (Jan. 14, 2022), https://www.law360.com/articles/1455825/pharma-exec-s-drug-trafficking-trial-tests-bold-legal-theory.
[22] DOJ, "Department of Justice Files Nationwide Lawsuit Against Walmart Inc. for Controlled Substances Act Violations," (Dec. 22, 2020), *available at* https://www.justice.gov/opa/pr/department-justice-files-nationwide-lawsuit-against-walmart-inc-controlled-substances-act.
[23] Complaint, *United States v. Walmart Inc.*, No. 1:99-mc-09999 (D. Del. Dec. 22, 2020), https://www.justice.gov/opa/press-release/file/1347906/download.

[24] Order, *United States v. Walmart Inc.*, No. 1:20-cv-01744-CFC (D. Del. Nov. 19, 2021).
[25] *Ruan v. United States*, No. 20-1410 (cert. granted Nov. 5, 2021); *Kahn v. United States*, No. 21-5261 (cert. granted Nov. 5, 2021).
[26] *See* 21 U.S.C. § 841(a)(1); 21 C.F.R. § 1306.04(a).
[27] *See, e.g.*, DOJ, "Two Men Charged in Multi-million Dollar Darknet Drug Distribution Conspiracy" (Feb. 12, 2021), *available at* https://www.justice.gov/opa/pr/two-men-charged-multi-million-dollar-darknet-drug-distribution-conspiracy; DOJ, "Justice Department Files Suit to Stop Utah Physician from Issuing Opioid and Other Prescriptions in Violation of the Controlled Substances Act" (Aug. 17, 2021), *available at* https://www.justice.gov/opa/pr/justice-department-files-suit-stop-utah-physician-issuing-opioid-and-other-prescriptions; DOJ, "Federal Court Enjoins Maryland Physician Assistant from Prescribing Opioids and Other Controlled Substances" (Nov. 19, 2021), *available at* https://www.justice.gov/opa/pr/federal-court-enjoins-maryland-physician-assistant-prescribing-opioids-and-other-controlled; DOJ, "Tennessee Nurse Practitioner Arrested for Unlawfully Distributing Prescription Opioids" (Dec. 16, 2021), *available at* https://www.justice.gov/opa/pr/tennessee-nurse-practitioner-arrested-unlawfully-distributing-prescription-opioids.
[28] *See, e.g.,* Complaint, *United States v. Bacaner*, No. 8:21-cv-00391 (M.D. Fla. Feb. 19, 2021), https://www.justice.gov/opa/press-release/file/1369226/download; Complaint, *United States v. Allen*, No. 1:21-cv-02905-DLB (D. Md. Nov. 12, 2021), https://www.justice.gov/opa/press-release/file/1449711/download.
[29] DOJ, "Eight charged in scheme to defraud FDA and falsify records used in clinical research trials" (July 31, 2020), *available at* https://www.justice.gov/usao-ndoh/pr/eight-charged-scheme-defraud-fda-and-falsify-records-used-clinical-research-trials.
[30] DOJ, "Deputy Assistant Attorney General Arun G. Rao Delivers Remarks at the Food & Drug Law Institute's (FDLI) 2021 Enforcement, Litigation and Compliance Conference" (Dec. 9, 2021), *available at* https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-arun-g-rao-delivers-remarks-food-drug-law-institute-s.
[31] Information, *United States. v. Villaman-Bencosme*, No. 1:20-cr-20190-BB (S.D. Fla. Aug. 31, 2020); Indictment, *United States. v. Valdes*, No. 1:21-cr-20106-RNS (S.D. Fla. Feb. 23, 2021), *available at* https://www.justice.gov/opa/press-release/file/1374741/download.
[32] *Id.*
[33] DOJ, "Florida Medical Doctor Pleads Guilty to Conspiring to Falsify Clinical Trial Data" (Jan. 8, 2021), *available at* https://www.justice.gov/opa/pr/florida-medical-doctor-pleads-guilty-conspiring-falsify-clinical-trial-data; DOJ, "Medical Doctor and Study Coordinator Sentenced to Prison in Scheme to Falsify Clinical Trial Data" (Mar. 22, 2021), *available at* https://www.justice.gov/opa/pr/medical-doctor-and-study-coordinator-sentenced-prison-scheme-falsify-clinical-trial-data.
[34] DOJ, "Medical Doctor and Study Coordinator Sentenced to Prison in Scheme to Falsify Clinical Trial Data" (Mar. 22, 2021.
[35] DOJ, "Clinical Researchers Plead Guilty in Connection with Scheme to Falsify Drug Trial Data" (June 8, 2021), *available at* https://www.justice.gov/opa/pr/clinical-researchers-plead-guilty-connection-scheme-falsify-drug-trial-data; DOJ, "Study Coordinator Pleads Guilty in Scheme to Falsify Clinical Drug Trial Data" (Oct. 26, 2021), *available at* https://www.justice.gov/opa/pr/study-coordinator-pleads-guilty-scheme-falsify-clinical-drug-trial-data.
[36] DOJ, "Clinical Researchers Sentenced in Connection with Scheme to Falsify Drug Trial Data" (Aug. 11, 2021), *available at* https://www.justice.gov/opa/pr/clinical-researchers-sentenced-connection-scheme-falsify-drug-trial-data-0; DOJ, "Florida Study Coordinator Sentenced in Scheme to Falsify Clinical Drug Trial Data" (Jan. 20, 2022), *available at* https://www.justice.gov/opa/pr/florida-study-coordinator-sentenced-scheme-falsify-clinical-drug-trial-data.
[37] Indictment, *United States v. Demming*, No. 1:20-cr-00395-SL (N. D. Ohio July 23, 2020).
[38] *Id.*
[39] *Id.*
[40] Information, *United States v. Fresenius Kabi Oncology Limited*, No. 2:21-cr-00020JAD-BNW (D. Nev. Mar. 23, 2021); Plea Agreement, *United States v. Fresenius Kabi Oncology Limited*, No. 2:21-cr-00020-JAD-BNW (D. Nev. Mar, 23, 2021); DOJ, "Indian Cancer Drug Manufacturer Agrees to Plead Guilty and Pay $50 Million for Concealing and Destroying Records in Advance of FDA Inspection" (Feb. 9, 2021), *available at* https://www.justice.gov/opa/pr/indian-cancer-drug-manufacturer-agrees-plead-guilty-and-pay-50-million-concealing-and; DOJ, "Indian Cancer Drug Manufacturer to Pay $50 Million for Concealing and Destroying Records in Advance of FDA Inspection" (Mar. 23, 2021), *available at* https://www.justice.gov/opa/pr/indian-cancer-drug-manufacturer-pay-50-million-concealing-and-destroying-records-advance-fda .
[41] Information, *United States v. Fresenius Kabi Oncology Limited*; Plea Agreement, *United States v. Fresenius Kabi Oncology Limited*.
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*

[46] DOJ, "Avanos Medical Inc. to Pay $22 Million to Resolve Criminal Charge Related to the Fraudulent Misbranding of Its MicroCool Surgical Gowns" (July 8, 2021), *available at* https://www.justice.gov/opa/pr/avanos-medical-inc-pay-22-million-resolve-criminal-charge-related-fraudulent-misbranding-its.
[47] *Id.*
[48] Dan Levine & Marisa Taylor, Lilly hit by staff accusations, FDA scrutiny at COVID drug factories, Reuters (May 5, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/exclusive-lilly-hit-by-staff-accusations-fda-scrutiny-covid-drug-factories-2021-05-05/.
[49] *Id.*
[50] Emergent BioSolutions Inc., Quarterly Report (Form 10-Q) (July 30, 2021), *available at* https://www.sec.gov/Archives/edgar/data/0001367644/000136764421000115/ebs-20210630.htm.
[51] US authorities probing Emergent BioSolutions over COVID-19 vaccine issues – filing, Reuters (July 30, 2021), https://www.reuters.com/article/emergent-bio-probes-idCNL1N2P61K8.
[52] *United States v. U.S. Stem Cell Clinic, LLC*, 2021 998 F.3d 1305 (11th Cir. 2021).
[53] *Id. See also United States v. U.S. Stem Cell Clinic, LLC*, 403 F. Supp. 3d 1279, 1288 (S.D. Fla. 2019) (highlighting both parties' arguments regarding the meaning of "such HCT/Ps" within § 1271.15(b)).
[54] *United States v. California Stem Cell Treatment Center*, No. 5:18cv1005 (C.D. Cal).
[55] DOJ, "Federal Court Orders New York Company and its Operators to Stop Distributing Adulterated Dietary Supplements" (Mar.4, 2021), *available at* https://www.justice.gov/opa/pr/federal-court-orders-new-york-company-and-its-operators-stop-distributing-adulterated-dietary.
[56] Memorandum and Order, *United States v. Confidence USA, Inc.*, No. 2:19-cv-03073-ERK-SIL (E.D.N.Y. Mar. 3, 2021).
[57] Consent Decree of Permanent Injunction, *United States v. Premier Pharmacy Labs, Inc.*, No. 8:21-cv-02151-MSS-JSS (M.D. Fla. Sept. 17, 2021); DOJ, "Federal Court Enters Permanent Injunction Against Florida Compounding Pharmacy and its Owner to Prevent Distribution of Adulterated Drugs" (Sept. 17, 2021), *available at* https://www.justice.gov/usao-mdfl/pr/federal-court-enters-permanent-injunction-against-florida-compounding-pharmacy-and-its.
[58] *Id.*
[59] *Id*.
[60] *Id.*
[61] Complaint for Permanent Injunction, *United States v. Affinitylifestyles.com*, No. 21-cv-959 (D. Nev. May 19, 2021); DOJ, "Nevada Bottled Water Companies and Owners Ordered to Stop Distributing Adulterated and Misbranded Water Products" (June 1, 2021), *available at* https://www.justice.gov/opa/pr/nevada-bottled-water-companies-and-owners-ordered-stop-distributing-adulterated-and.
[62] *Id.*
[63] DOJ, "Nevada Bottled Water Companies and Owners Ordered to Stop Distributing Adulterated and Misbranded Water Products" (June 1, 20210), *available at* https://www.justice.gov/opa/pr/nevada-bottled-water-companies-and-owners-ordered-stop-distributing-adulterated-and.
[64] DOJ, "Court Orders Georgia Defendants to Stop Selling Vitamin D Products as Treatments for Covid-19 and Other Diseases" (Jan. 8, 2021), *available at* https://www.justice.gov/opa/pr/court-orders-georgia-defendants-stop-selling-vitamin-d-products-treatments-covid-19-and-other; DOJ, "District Court Orders New Jersey Defendants to Stop Distributing Unapproved 'Nano Silver' Products Touted as COVID Treatment" (Dec. 28, 2021), *available at* https://www.justice.gov/opa/pr/district-court-orders-new-jersey-defendants-stop-distributing-unapproved-nano-silver-products.
[65] DOJ, "Court Enjoins California Company from Manufacturing and Distributing Adulterated Sterile Animal Drugs" (Nov. 22, 2021), *available at* https://www.justice.gov/opa/pr/court-enjoins-california-company-manufacturing-and-distributing-adulterated-sterile-animal.
[66] DOJ, "District Court Orders Utah Company to Stop Distribution of Unapproved New Drugs and Adulterated Products" (Oct. 20, 2021), *available at* https://www.justice.gov/opa/pr/district-court-orders-utah-company-stop-distribution-unapproved-new-drugs-and-adulterated.
[67] Based on an analysis of pre-pandemic enforcement data, DOJ typically pursues 10-15 FDCA injunction cases per year. *See* Beth Weinman, Josh Oyster & Jessica Band, Deconstructing the Consent Decree: A Primer and Recent Trends for FDA Injunctions, FDLI, *available at* https://www.fdli.org/2020/11/deconstructing-the-consent-decree-a-primer-and-recent-trends-for-fdca-injunctions/.
[68] DOJ, "Medical Device Companies Alere Inc. and Alere San Diego Inc. Agree to Pay $38..75 Million to Settle False Claims Act Allegations" (July 8, 2021), *available at* https://www.justice.gov/opa/pr/medical-device-companies-alere-inc-and-alere-san-diego-inc-agree-pay-3875-million-settle.
[69] *Id.*
[70] *Id.*
[71] *Id.*

[72] Settlement Agreement, *United States v. St. Jude Medical, Inc.* (D. Md.), *available at* https://www.justice.gov/opa/press-release/file/1410456/download; DOJ, "St. Jude Agrees to Pay $27 Million for Allegedly Selling Defective Heart Devices" (July 8, 2021), *available at* https://www.justice.gov/opa/pr/st-jude-agrees-pay-27-million-allegedly-selling-defective-heart-devices.
[73] *Id.*
[74] *Id.*
[75] Settlement Agreement, *United States v. St. Jude Medical, Inc.*
[76] *Id.*
[77] DOJ, "Deputy Attorney General Lisa O. Monaco Gives Keynote Address at ABA's 36th National Institute on White Collar Crime" (Oct. 28, 2021), https://www.justice.gov/opa/speech/deputy-attorney-general-lisa-o-monaco-gives-keynote-address-abas-36th-national-institute.
[78] *Id.*
[79] *Id.*
[80] *See* Memorandum from the Attorney General, *Issuance and Use of Guidance Documents by the Department of Justice* (July 1, 2021), *available at* https://www.justice.gov/opa/page/file/1408606/download.

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