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2020 Enforcement Review: FDA-Regulated Medical Products and Food Safety

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The dynamic nature of the COVID-19 pandemic demanded an all-hands-on-deck approach to enforcement in 2020 by the U.S. Food and Drug Administration ("FDA"), the Department of Justice ("DOJ"), and other regulatory and law enforcement agencies. Protecting the public from those who sought to exploit opportunities to make a quick buck by marketing quack COVID-19 cures, unproven COVID-19 prevention products and substandard personal protective equipment quickly emerged as top government enforcement priorities.

While the bulk of the year's most significant criminal and civil enforcement actions were pandemic-related, 2020 also saw noteworthy developments in more traditional areas of FDA enforcement. A global resolution of criminal and civil allegations against Purdue Pharma, which included allegations related to facilitating the dispensing of opioids without a legitimate medical purpose and inappropriate opioid marketing, incorporated the highest penalty ever assessed against a pharmaceutical manufacturer. In addition, four former executives of life sciences companies were sentenced in connection with misdemeanor misbranding offenses related to allegedly inappropriate marketing: two cases involving misleading statements made about an opioid use disorder drug and two cases involving the marketing of an FDA-cleared sinus spacer device for an unapproved drug delivery use. On the food safety front, FDA also resolved precedent-setting cases that included record criminal fines and penalties, including a deferred prosecution agreement with Chipotle tied to allegations of foodborne illness outbreaks.

This review revisits the year's key FDA and DOJ enforcement actions related to FDA-regulated products, and offers insights into likely enforcement priorities for 2021.

I. COVID-19 Enforcement

A. COVID-19-Related Enforcement Under the FDCA and Other Fraud Statutes

In response to the rampant marketing of unapproved medical products as safe and effective for the treatment, cure, or prevention of COVID-19, FDA assembled a cross-center COVID-19 Fraud Task Force to share and analyze consumer complaints and reports about such products.[1] In March 2020, FDA launched "Operation Quack Hack," which has led to the identification of thousands of products making potentially violative claims related to COVID-19, ranging from teas and botanical oils to colloidal silver and chlorine dioxide products. In 2020, FDA issued nearly 150 warning letters for unapproved, adulterated, or misbranded products intended for COVID-19 uses.[2] The majority of warning letters targeted products marketed with drug claims, while 13 warning letters were directed at medical devices, including COVID-19 antigen test kits for at-home use.[3] FDA also issued public safety alerts and recommended recalls of products it viewed as unsafe, including for hand sanitizers manufactured with toxic wood alcohol.[4]

DOJ has similarly prioritized the investigation and prosecution of fraudulent or otherwise misleading practices related to COVID-19.[5] In 2020, DOJ filed more than ten civil injunction actions under either the Federal Food, Drug, and Cosmetic Act ("FDCA") or the Anti-Fraud Injunction Act,[6] and more than ten criminal actions relating to alleged violations of the FDCA or wire and mail fraud statutes involving the fraudulent marketing of products intended for uses related to COVID-19.[7] These included actions against sellers of filtering face piece respirators with unsupported filtration claims, as well as actions against those marketing dietary supplements, cellular therapies, and homeopathic remedies with unapproved and unsupported drug claims related to COVID-19 treatment or prevention. In January 2021, DOJ filed misdemeanor misbranding charges against a purported "biotech expert" who had been offering an unapproved and untested COVID-19 "vaccine" for injection as early as March 2020.[8] DOJ also targeted frauds in which fictional

products were marketed but not actually distributed. In March 2020, DOJ successfully blocked a website from taking payment for non-existent COVID-19 vaccine kits as part of a scheme to steal credit card information.[9] The following month, DOJ brought criminal charges against a man for attempting to defraud the Department of Veterans Affairs out of $750 million for orders of face masks and other PPE that he did not have and could not supply.[10]

The U.S. Department of Homeland Security also stepped in to counter the threat of counterfeit COVID-19 products and drugs. In late 2020, the department's Immigration and Customs Enforcement Homeland Security Investigations unit launched Operation Stolen Promise 2.0 to end the production, sale, and distribution of counterfeit or unauthorized COVID-19 vaccines and treatments.[11] The initiative builds on previous efforts to detect and deter COVID-19 fraud and specifically aims to end fraudulent schemes, remove illegal websites and online marketplaces, and seize fake COVID-19 vaccines and treatments.[12]

Now that the first COVID-19 vaccines have received emergency use authorization from FDA, we are likely to see an uptick in enforcement activity in 2021 focused on the marketing and distribution of counterfeit or unapproved vaccines.

B. Securities Fraud Enforcement Against Diagnostic Test Manufacturers

In June 2020, DOJ filed a criminal complaint against the president of a medical technology company charging one count of securities fraud and one count of conspiracy to commit health care fraud.[13] The complaint alleged that the executive made false claims about the company's ability to provide accurate, fast, reliable and cheap COVID-19 testing with its finger-prick blood allergy test technology, despite notice from FDA that the test did not perform at an acceptable level.[14] The complaint also alleged that the executive instructed patient recruiters and medical clinics to bundle the company's COVID-19 test with an expensive allergy test regardless of medical necessity, causing the filing of over $69 million in false and fraudulent claims for allergy and COVID-19 testing.[15]

In December 2020, a federal grand jury indicted the CEO of a medical device company for his participation in an alleged scheme to defraud investors regarding a purported COVID-19 finger-stick test.[16] The executive allegedly made numerous false and misleading statements to investors, including falsely claiming that the company had developed a 15-second test to detect COVID-19, when, in fact, the test had never been properly validated. The executive also allegedly told investors that FDA would soon approve a request for an emergency use authorization for the test, despite knowing that FDA would not authorize the test without reviewing results from required clinical testing that the company had not performed.[17]

C. Next Phase of COVID-19 Enforcement

Moving forward, the government is likely to continue to target for enforcement companies and individuals making unsupported and misleading claims about unapproved or unauthorized medical products intended to diagnose, treat, cure or prevent COVID-19, or engaging in other forms of fraud related to COVID-19. At a recent enforcement conference, Deputy Assistant Attorney General Daniel Feith, who oversees DOJ's Consumer Protection Branch, sent a clear message that fraud related to COVID-19 would not be tolerated.[18] DOJ will also likely continue to implement a staged approach to removing fraudulent and unlawful products from the market by quickly bringing civil injunctions under the FDCA and the Anti-Fraud Injunction Act followed by criminal charges against companies and their owners.[19] Deputy Assistant Attorney General Feith referred to this as a "one-two punch" used "to act quickly to protect public health and to punish fraud."[20]

Beyond the low-hanging fruit of blatant COVID-19-related fraud, future enforcement may also target noncompliance with FDA emergency use authorizations ("EUAs") or enforcement discretion policies by new industry entrants with immature compliance programs or veteran entities that fail to ensure appropriate compliance controls. In addition, the government has spent billions of dollars through various federal programs, grants and contracts to, among other things,

spur the production and acquisition of critical drugs and devices needed to fight the pandemic and fund the development of COVID-19-related therapeutics and vaccine candidates. Entities that have received significant federal funding may also find themselves under the microscope, especially if problems are identified in connection with the products they have been funded to produce. The House of Representatives Select Subcommittee on the Coronavirus Crisis has already initiated investigations into federal contractors that may have failed to fulfill their obligations under federal contracts.[21] The government is likely to use the False Claims Act ("FCA") as a tool to recover federal dollars paid for misleadingly labeled or otherwise defective or non-compliant medical products.

Whether and how the government will pursue enforcement against COVID-19 laboratory developed tests ("LDTs") that may not meet their claims remains to be seen. Agency authority to require premarket review for LDTs emerged during the pandemic as an area of dispute between the Department of Health and Human Services ("HHS") and FDA in 2020, leading to the marketing of many LDTs without agency review and to FDA's de-prioritization of tests voluntarily submitted for review.[22] According to trade press reports, HHS subsequently directed FDA to review EUA requests voluntarily submitted for COVID-19 LDTs, though FDA said little publicly in response to that directive.[23] Since those reports, HHS has awarded a contract to regulatory consultancy NDA Partners to conduct technical and regulatory reviews of COVID-19 LDT EUA requests and provide to HHS written assessments to assist with authorization decisions.[24] Neither FDA nor new HHS leadership has yet commented on how this contract will factor into the review process for EUAs that have been submitted for LDTs. The competing perspectives on FDA's regulatory authority over LDTs, and its obligation to review EUA requests voluntarily submitted, could make it very difficult for the government to take action against laboratories that market unreviewed and unauthorized tests. However, should such tests fail to meet their labeling claims, the government could nevertheless pursue FDCA misbranding theories or other fraud theories. Makers of COVID-19 tests paid for with federal or state funds, whether such tests are developed by laboratories or commercial manufacturers, are likely to be a target for enforcement if the tests fail to perform as marketed.

II. Opioids

Efforts to combat the opioid crisis remained a significant enforcement priority for FDA and DOJ in 2020.

A. FDA Administrative Actions

One of FDA's most important objectives in the area of opioid addiction is to reduce exposure for those already affected by opioid use disorder and to reduce the rate of new addiction.[25] In line with these goals, FDA launched a 120-day pilot program in June 2020 with the Department of Commerce's National Telecommunications and Information Administration to target unapproved opioids illegally sold online.[26] Under the pilot, FDA flagged for participating internet registries website operators that had received, but had not timely and adequately responded to, FDA warning letters. Flagging such operators allowed the registries to decide whether to voluntarily suspend or block certain domain names.[27] Relatedly, in September 2020, FDA issued warning letters to 17 website operators for distributing unapproved and misbranded opioids.[28]

B. Criminal Settlement with Purdue Pharma

In November 2020, after years of federal investigation into Purdue Pharma LP's marketing and distribution practices, the opioid drug manufacturer pleaded guilty to three felony charges: one count of a dual-object conspiracy to defraud the U.S. Drug Enforcement Administration and violate the FDCA under 18 U.S.C. § 371, and two counts of conspiracy to violate the Anti-Kickback Statute.[29] The company admitted that, over the course of at least ten years, it had conspired to defraud the U.S. by, among other things, facilitating the dispensing of opioid drugs without a legitimate medical purpose, thereby aiding and abetting violations of the FDCA.[30] The government's settlement sets a new record for penalties assessed against a pharmaceutical manufacturer, including a criminal fine of $3.544 billion and an additional $2 billion in criminal forfeiture.[31] Under the resolution's financial terms, as approved by a bankruptcy court in the Southern District

of New York, the company will emerge from bankruptcy as a public benefit company, and all profits will be directed to state and local opioid abatement programs.[32] In separate civil settlements, the company must also pay $2.8 billion, and its individual shareholders must pay $225 million to resolve civil liabilities under the FCA.[33] Notably, DOJ's announcement of the resolution of these investigations highlighted that the resolution did not include criminal releases for any individuals or civil releases for any of the company's executives or employees. It remains to be seen whether additional actions will be brought.

C. Criminal Prosecutions of Indivior and Its Executives

Large criminal and civil penalties in 2020 were also assessed against a drug manufacturer and its executives in connection with the allegedly fraudulent marketing of an opioid use disorder drug. In July 2020, Indivior Solutions pled guilty to a felony charge of making false statements relating to health care matters.[34] The company admitted to communicating misleading statements and false data to a state Medicaid program in an effort to expand coverage for a newer formulation of Suboxone.[35] In an alleged scheme to make Suboxone Film appear safer and less susceptible to diversion and abuse, a medical affairs manager allegedly emailed MassHealth manipulated data that made it appear as though Suboxone Film, a combination of buprenorphine and naloxone, had the lowest rates of unintended pediatric exposure in the state. The unaltered data showed that this was not true. In a resolution agreement, the company agreed to pay a total of $600 million to resolve its criminal and civil liability, and the agreement contained novel restrictions on the company's future promotional activities.[36] Among other things, the agreement required the company to disband its sales force, prohibited the use of data from health care provider surveys for sales and promotional purposes, and required the company's CEO to annually certify that the company complied with the FDCA and did not commit health care fraud (or otherwise list all non-compliance and remedial activities).[37]

Indivior's former CEO and former medical director separately pleaded guilty to FDCA-based charges tied to the same conduct. In October 2020, the former CEO was sentenced to six months of imprisonment and assessed a $600,000 criminal fine and forfeiture for conviction on one misdemeanor count of introducing misbranded drugs into interstate commerce.[38] In December 2020, the former medical director was sentenced to six months of home detention and 100 hours of community service for his conviction on the same charge.[39]

In total, monetary penalties assessed against Indivior and its former executives combined with a 2019 settlement of $1.4 billion with Indivior's former parent company resulted in more than $2 billion of government recovery.[40]

III. Medical Product Promotion

Misleading promotional practices are likely to remain a target for FDA and DOJ in 2021, especially considering the cross-government focus on fraud related to COVID-19.

A. Warning and Untitled Letters

FDA's Office of Prescription Drug Promotion ("OPDP") issued four warning letters in 2020 related to the allegedly inappropriate promotion of approved drugs.[41] One warning letter cited a company for off-label promotion of its asthma drug for the unapproved use of treating symptoms associated with COVID-19.[42] The letter also cited the company for failing to include any risk information about the product when touting its benefits for treating COVID-19 symptoms, which in FDA's view rendered the promotional materials false and misleading.[43] Another letter objected to a Google-sponsored link that, in FDA's view, constituted false and misleading promotion both because it lacked risk information and cherry-picked favorable efficacy data.[44] The two other 2020 warning letters, as well as two untitled letters issued by OPDP, also cited companies for promotional materials that were false or misleading due to inadequate risk presentation.[45]

The agency also continued to scrutinize homeopathic drugs, issuing 21 homeopathic drug-related warning letters in 2020, up from 14 such warning letters issued in 2019.[46] In June 2020, for example, FDA issued warning letters to four companies selling unapproved injectable drug products labeled as homeopathic, many of which contained potentially toxic ingredients.[47]

B. Convictions of Former Device Company Executives Upheld

In September 2020, a Massachusetts federal judge denied post-trial motions for acquittal or a new trial filed by two former executives of a medical device manufacturer.[48] The former CEO and former Vice President of Sales had been convicted in 2016 on multiple misdemeanor counts of introducing misbranded and adulterated medical devices into interstate commerce, based on their involvement in the promotion of the company's 510(k)-cleared sinus spacer device for the unapproved and uncleared use of delivering steroids to the sinuses.[49] While expressing some discomfort about the strict liability nature of the misdemeanors charged, and suggesting that Congress may not have intended to criminalize the conduct at issue, the court nevertheless rejected arguments that the convictions violated the First Amendment because they were based on evidence of truthful and non-misleading speech. The court also rejected arguments that the strict liability misdemeanor convictions violated the defendants' due process rights.[50]

On January 13, 2021, the court sentenced William Facteau, the former CEO, to a $1 million fine and Patrick Fabian, the former Vice President of Sales, to a $500,000 fine, but neither executive received jail time. The ultimate impact of the court's decision to uphold these convictions on the landscape for manufacturer communications remains to be seen. Defendants are likely to appeal, and it is unclear whether the First Circuit, or potentially the Supreme Court, will agree with the district court's analysis. However, DOJ has other tools in its tool box to use against companies and individuals who market their products for unapproved uses, to the extent such marketing is misleading and can be charged as fraud. Such tools include the increasing use of criminal and civil fraud injunctions in the life sciences context, as we have seen for COVID-19-related products and opioids. They also include continued use of the civil False Claims Act,[51] and, potentially, use of criminal Klein conspiracy charges,[52] to the extent the government can prove that two or more people conspired to market products for uses that require and lack FDA approval and that doing so constituted an agreement to defraud the government (FDA) by evading the regulatory approval process and thereby interfering with its lawful government functions.

C. Notable False Claims Act Settlements

Several investigations into allegedly improper medical product promotion were resolved via FCA settlements in 2020, without any associated prosecution under the FDCA directly related to the promotional conduct. For example, in August 2020, the subsidiary of a large drug manufacturer agreed to pay $20.75 million and enter a corporate integrity agreement to settle FCA allegations that the company caused physicians to submit false claims to federal health care programs by knowingly promoting a drug administration process that was both less effective than and inconsistent with the FDA-approved labeling.[53] In November 2020, a medical device company agreed to pay $10 million to settle FCA allegations that a former subsidiary, while still owned by the company, caused false claims to be submitted to federal health care programs by improperly promoting a combination product for unapproved indications in the pediatric population.[54] The government's allegations in the case also extended to the private equity firm that owned the subsidiary for two-and-a-half years. The firm agreed to pay $1.5 million to resolve allegations that the subsidiary had continued its improper promotional activities after its acquisition.[55] Interestingly, the complaint against the private equity firm lacked any specific allegations regarding the firm's involvement in the allegedly fraudulent marketing scheme or its exertion of control over the subsidiary.[56]

D. *New Proposed Intended Use Rule*

In September 2020, FDA published a proposed rule to amend its intended use regulations.[57] This proposal represents the latest development in a five-year-long rulemaking process to clarify the agency's interpretation and application of these regulations to drugs and devices. The proposed rule would not provide significant new limits with respect to the types of evidence that the government can rely on to establish the intended use of a drug or device, though it does clarify that knowledge of off-label use of an approved or cleared medical product is not alone sufficient to establish the product's intended use. The proposed rule would leave unchanged the government's ability to look to the "circumstances surrounding the distribution of an article" to establish a product's intended use. Finally, the revised proposed rule would add, for the first time, that the government may look to the "design or composition" of an article to establish its intended use. This new language, which focuses on evidence of intended use that is unrelated to promotional claims, would reduce the burden of proof for the government in cases where products are shipped in unlabeled containers, or bear labeling that may not reflect what the government alleges to be their true intended use.

If the proposed rule is finalized in its current form, and survives any legal challenges that may be brought, the government will remain free to rely on a wide variety of evidence to establish intended use in enforcement actions involving the marketing of wholly unapproved products or approved products for unapproved uses. Regardless of whether the intended use rule is finalized as proposed, however, the outcome of potential appeals in the Facteau and Fabian cases discussed above could still threaten the government's ability to take criminal enforcement action based on evidence of off-label promotion if, for example, the court of appeals hearing those cases were to reject the prosecution's misbranding and adulteration theories.

IV. Medical Device Safety

In 2020, medical device safety remained on the government's radar, particularly with respect to the cleaning and reprocessing of reusable medical devices and ensuring that single-use devices are not used on multiple patients inappropriately.

A. Pentax Deferred Prosecution Agreement

In April 2020, DOJ reached an agreement with Pentax Medical Company in connection with the firm's shipment of misbranded endoscopes that lacked FDA-cleared cleaning instructions and its failure to file timely medical device reports.[58] The company entered into a three-year deferred prosecution agreement that enabled it to avoid criminal conviction by complying with certain reforms and enhanced compliance requirements, and the company agreed to pay a $40 million criminal fine and $3 million criminal forfeiture.[59] The settlement with Pentax followed a 2018 criminal resolution with another endoscope manufacturer related to its own failure to file timely medical device reports.[60]

B. Individual Prosecutions in Scheme Related to Reuse of Single-Use Device

Government investigations also led to convictions in May 2020 of a doctor and nurse practitioner related to, among other things, the adulteration of single-use rectal pressure sensors and anorectal manometry catheters through their re-use on multiple patients.[61] In October 2020, the doctor was sentenced to 57 months of incarceration and the nurse practitioner to three years of probation with 3,000 hours of community service. Together, the defendants, along with an office manager, agreed to pay more than $1.25 million in separate civil settlements.[62] Similarly, in December 2020, the director of clinical services of the rectal pressure sensor manufacturer pleaded guilty to a misdemeanor adulteration charge related to training health care providers to reuse single-use rectal pressure sensors on multiple patients.[63] The director faces up to one year in prison.

V. Drug Manufacturing and Quality

FDA and DOJ enforcement actions related to drug quality and compliance with current good manufacturing practices ("cGMP") were relatively sparse in 2020, likely due, in part, to decreased FDA inspectional activities. As the pandemic recedes and FDA is able fully to resume its inspectional program, we are likely to see an increase in regulatory and judicial enforcement related to manufacturing practices.

A. Impact of COVID-19 on FDA Inspections

The COVID-19 pandemic dramatically impacted routine FDA site inspections, with FDA temporarily suspending non-critical foreign and domestic inspections in March 2020. FDA's online compliance dashboard, which provides a window into FDA inspectional activities, illustrates the precipitous drop in 2020 inspections.[64] According to the dashboard, the number of domestic inspections for drugs and biologics dropped from 231 in February 2020 to 146 in March, and down to five in April 2020.[65] A similar trend was observed for the number of foreign inspections for drugs and biologics, dropping from 97 in February 2020 to 38 in March, and down to only one in April 2020.[66]

In July 2020, FDA announced plans to resume prioritized domestic inspections using a COVID-19 Advisory Rating system to help identify when and where it is safest to conduct on-site inspections.[67] However, after FDA's announcement, and in light of spiking COVID-19 infection rates throughout the U.S., domestic inspection rates did not return to prior-year levels. Overall, according to FDA's dashboard, FDA conducted less than one-third the number of drug and biologic-related inspections in 2020 than it did in 2019.[68]

In light of the restrictions imposed by the pandemic, the agency has turned to implementing alternative tools to provide oversight. These tools include drug sampling, using information shared by foreign regulatory partners, requesting records and information, and conducting remote assessments for outsourcing facilities and FDA's Biotech Monitoring program.[69] This has shifted the evidentiary basis for certain regulatory actions. According to the Director of FDA's Center for Drug Evaluation and Research Office of Compliance, as compared with other years, a greater number of warning letters and import alerts in connection with drug adulteration in 2020 were based on drug sampling and information requests, rather than FDA inspections.[70]

B. FDA Warning Letters

Not surprisingly, the number of drug and biologic-related warning letters that cite cGMP violations issued by FDA in 2020 dropped significantly in parallel with the decrease in drug- and biologic-related inspections carried out during the year. Of the more than 250 drug- and biologic-related warning letters in 2020, approximately 65 cited cGMP violations, as compared to 123 such letters in 2019.[71] There was, however, an apparent increase in the number of warning letters issued to drug compounders relative to the prior year. FDA issued 26 warning letters in 2020 to drug compounders related to quality issues, up from 11 issued in 2019.[72] The overwhelming majority of these letters were issued to traditional compounding pharmacies regulated under section 503A of the FDCA rather than outsourcing facilities regulated under section 503B.[73]

C. Injunction Complaint Against Animal Drug Manufacturer

Although the government did not initiate any injunction actions related to the quality of human drugs in 2020, it did seek to enjoin further distribution of allegedly adulterated animal drugs. In October 2020, DOJ filed a civil complaint in a California district court seeking a permanent injunction against an animal drug contract manufacturer, its CEO, and its Vice President of Quality Control in connection with the manufacturer's failure to remediate repeat cGMP violations, including with respect to maintaining drug sterility.[74]

VI. Regenerative Medicine

In 2020, FDA continued to focus policymaking efforts on cell and gene therapies and human cells, tissues, and cellular and tissue-based products ("HCT/Ps"), although neither FDA nor DOJ initiated significant enforcement actions.

In July 2020, FDA issued a consumer alert on unapproved regenerative medicine products[75] and revised its regenerative medicine policy framework.[76] In light of the challenges and obstacles presented by the COVID-19 pandemic, FDA extended its enforcement discretion policy with respect to Investigational New Drug ("IND") and premarket approval requirements for certain HCT/Ps.[77] According to the revised policy, manufacturers and potential sponsors will have until May 31, 2021 to determine if they need to submit, and if so, prepare, an IND or marketing application for certain HCT/Ps.[78] In addition to extending enforcement discretion for another six months, FDA issued "It Has Come to Our Attention" ("IHCTOA") letters throughout 2020. In general, FDA uses these letters to remind firms of FDA's regenerative medicine compliance and enforcement policies and to encourage firms to comply with FDA's regenerative medicine framework voluntarily. According to the Deputy Director of FDA's Center for Biologics Evaluation and Research ("CBER") Office of Compliance and Biologics Quality, FDA issued more than 200 such IHCTOA letters in 2020.[79]

CBER also continued to send untitled letters and warning letters to firms marketing unapproved or unlicensed HCT/Ps that CBER views as subject to regulation as drugs, devices, or biological products. CBER issued 15 such untitled letters in 2020, compared to only three in the prior year, and seven such warning letters.[80] Four of the untitled letters and five of the warning letters specifically cited the inappropriate marketing of the unapproved or unlicensed HCT/Ps for the treatment or prevention of COVID-19.[81]

While no new judicial actions related to regenerative medicine were filed in 2020, significant developments are likely forthcoming in 2021 in two previously filed injunction actions against stem cell clinics. In June 2019, DOJ obtained an injunction against U.S. Stem Cell Clinic, which prevented the firm from manufacturing or distributing drug products purportedly consisting of stromal vascular fraction ("SVF") and ordered the destruction of banked stem cells at the clinic.[82] This case is on appeal in the Eleventh Circuit Court of Appeals where oral argument recently occurred on January 13, 2021. A similar injunction case against California Stem Cell Treatment Center is expected to go to trial in a California federal court this year.

VII. Food Safety

In 2020, DOJ obtained record fines and penalties in food safety cases and also sought the first FDCA injunction tied to violations of FDA's Produce Safety Rule, which became effective in 2016.

A. Chipotle Mexican Grill

In April 2020, Chipotle resolved criminal charges in connection with its alleged adulteration of food in violation of the FDCA, leading to the largest-ever fine in a food safety case.[83] From 2015 to 2018, the restaurant chain faced at least five foodborne illness outbreaks that allegedly sickened more than 1,100 people.[84] The restaurant chain entered into a three-year deferred prosecution agreement under which it agreed to pay a $25 million criminal fine and DOJ agreed not to file criminal charges if the company complies with an enhanced food safety program.[85]

B. Blue Bell Creameries

In September 2020, a federal court sentenced Blue Bell Creameries, L.P. to pay $17.25 million in criminal penalties for distributing adulterated ice cream products linked to a 2015 listeria outbreak.[86] The ice cream manufacturer pleaded guilty to two misdemeanor counts of introducing adulterated foods into interstate commerce in violation of the FDCA and entered a plea agreement, agreeing to pay a $9.35 million criminal fine and a $7.9 million forfeiture.[87] The company

also agreed to pay an additional $2.1 million to resolve civil FCA allegations involving sales to federal facilities, including the military.[88] In October 2020, a federal grand jury charged the company's former president with seven counts of wire fraud and conspiracy to commit wire fraud in connection with alleged efforts to conceal the company's sales of contaminated ice cream products.[89]

C. First Injunction Under Produce Safety Rule

In September 2020, DOJ and FDA successfully obtained the first consent decree of permanent injunction tied to violations of the Produce Safety Rule.[90] The government brought the action against a processor of sprouts and soy products after multiple FDA inspections and a warning letter identified significant noncompliance, including the presence of rodents, various insanitary conditions, failing to use equipment that can be adequately cleaned, and failing to sanitize food contact surfaces.[91]

VIII. Conclusion

Despite challenges created by the COVID-19 pandemic, DOJ and FDA continued to target violations of law involving FDA-regulated products in 2020 and specifically prioritized COVID-19-related fraud. Such fraud is likely to remain a key focus of enforcement in 2021 as the struggle continues to bring the pandemic under control. In addition, the government is expected to continue to fulfill its responsibility to investigate and take action against those distributing violative FDA-regulated products that pose a significant safety risk, whether related to opioids, medical devices, food safety or otherwise. We can also expect to see renewed focus on medical product manufacturing and quality issues when FDA inspections finally return to their pre-pandemic volume.

If you have any questions regarding enforcement related to FDA-regulated products in 2020 or what to expect from regulators and prosecutors in 2021, please contact any member of our FDA-regulatory practice or your usual Ropes & Gray advisor.

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[1] Testimony before the Senate Subcommittee on Manufacturing, Trade, and Consumer Protection by Catherine Hermsen, Assistant Commissioner, Office of Criminal Investigations, Office of Regulatory Affairs, "Protecting Americans from COVID-19 Scams (written testimony only)" (July 21, 2020), *available at* https://www.fda.gov/news-events/congressional-testimony/protecting-americans-covid-19-scams-written-testimony-only-07212020.

[2] According to a Ropes & Gray analysis of calendar year 2020 FDA warning letters.

[3] According to a Ropes & Gray analysis of calendar year 2020 FDA warning letters.

[4] FDA, "FDA updates on hand sanitizer consumers should not use" (updated Jan. 11, 2021), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use.

[5] DOJ, "Principal Deputy Assistant Attorney General Ethan P. Davis delivers remarks on the False Claims Act at the U.S. Chamber of Commerce's Institute for Legal Reform" (June 26, 2020), *available at* https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

[6] *See* 18 U.S.C. § 1345.

[7] For a summary of cases through August 2020, *see* Ropes & Gray's analysis in "*Keeping Track of the Quacks: Drug and Device Enforcement in the COVID-19 Era*."

[8] DOJ, "Purported Biotech Executive Charged With Introducing Misbranded Drug Into Interstate Commerce for Distribution of 'COVID-19 Vaccine'" (Jan. 21, 2021), *available at* https://www.justice.gov/usao-wdwa/pr/purported-biotech-executive-charged-introducing-misbranded-drug-interstate-commerce.

[9] DOJ, "Justice Department Files Its First Enforcement Action Against COVID-19 Fraud" (March 22, 2020), *available at* https://www.justice.gov/opa/pr/justice-department-files-its-first-enforcement-action-against-covid-19-fraud.

[10] DOJ, "Georgia Man Arrested for Attempting to Defraud the Department of Veterans Affairs in a Multimillion-Dollar COVID-19 Scam" (April 10, 2020), *available at* https://www.justice.gov/opa/pr/georgia-man-arrested-attempting-defraud-department-veterans-affairs-multimillion-dollar-covid.

[11] U.S. Department of Homeland Security, "ICE pivots to combat COVID-19 vaccine fraud with launch of Operation Stolen Promise 2.0" (Nov. 30, 2020), https://www.ice.gov/news/releases/ice-pivots-combat-covid-19-vaccine-fraud-launch-operation-stolen-promise-20.
[12] *Id.*
[13] DOJ, "Medical Technology Company President Charged in Scheme to Defraud Investors and Health Care Benefit Programs in Connection with COVID-19 Testing" (June 9, 2020), *available at* https://www.justice.gov/opa/pr/medical-technology-company-president-charged-scheme-defraud-investors-and-health-care-benefit.
[14] DOJ, Criminal Complaint, *United States v. Mark Schena*, 5:20-mj-70721-MAG (June 8, 2020), *available at* https://www.justice.gov/opa/press-release/file/1283931/download.
[15] *Id.*
[16] DOJ, "CEO of Medical Device Company Charged in COVID-19 Related Securities Fraud Scheme" (Dec. 18, 2020), *available at* https://www.justice.gov/opa/pr/ceo-medical-device-company-charged-covid-19-related-securities-fraud-scheme.
[17] *Id.*
[18] DOJ, "Deputy Assistant Attorney General Daniel Feith Delivers Remarks at the FDLI Enforcement, Litigation, and Compliance Conference" (Dec. 15, 2020), *available at* https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-daniel-feith-delivers-remarks-fdli-enforcement. (In connection with "DOJ's fight against COVID-related misconduct," he remarked, "We have used—and will continue to use—every civil and criminal tool available to punish and deter those trying to cheat and harm the public during this time.")
[19] *Id.*
[20] *Id.*
[21] *See* Letter from House of Representatives Select Subcommittee on the Coronavirus Crisis to Alex M. Azar II (July 14, 2020), *available at* https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-07-14.Select%20Cmte.%20to%20Azar-HHS%20Esper-DOD%20Wolf-DHS%20Wilkie-%20VA%20re%20Administration%20PPE%20Contractor%20%281%29.pdf.
[22] For more detail on COVID-19 LDT developments, see Ropes & Gray alerts, "*HHS Prohibits FDA from Requiring Premarket Review of LDTs, Including During the COVID-19 Emergency*," and "*FDA Announces It Will No Longer Review EUA Requests for COVID-19 Laboratory Developed Tests*."
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