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2019 FDA Enforcement Review: Drugs, Biologics, Devices, and Dietary Supplements

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The ongoing public health crises of opioid addiction and youth vaping[1] undoubtedly captured significant attention and enforcement resources in 2019, a phenomenon that is unlikely to change as we head into 2020. However, despite the time and energy devoted to these issues, FDA and its partners at the Department of Justice ("DOJ") nonetheless took significant regulatory and judicial action in 2019 that brought attention to alleged compliance gaps across the medical and health product industries, focusing on entities potentially making higher risk products, such as sterile injectables and stem cell therapies, and on foreign and domestic facilities that may have received less oversight in the past (e.g., API and OTC drug manufacturers). The agencies also took action in 2019 against entities allegedly distributing unapproved or non-conforming products, marketing products without sufficiently highlighting important risks or disclosing material information about product indications and limitations of use, failing to comply with regulatory reporting requirements, and refusing to cooperate with FDA inspections.

DOJ continued to use the False Claims Act ("FCA") to take enforcement action in connection with conduct by FDA-regulated companies that some might argue fell squarely within FDA's regulatory orbit. However, the number of FCA-only settlements focused on core FDA regulatory issues continues to diminish as DOJ's civil and criminal fraud units focus more of their attention on anti-kickback theories and more traditional health care fraud.

This year-end review recaps notable enforcement actions involving FDA-regulated entities in 2019 and comments on trends likely to continue in 2020.

Opioids

Across the federal government, addressing the nation's opioid addiction crisis was the number one public health concern in 2019, and is likely to remain so in 2020. FDA worked closely with partner agencies, including DOJ, Drug Enforcement Agency ("DEA"), and Customs and Border Protection ("CBP"), to prosecute opioid-related fraud and abuse; crack down on the marketing of unapproved and misbranded opioids, and unapproved products intended for the treatment of opioid addiction or for withdrawal; and stem the flow of unapproved products and illicit substances (not approved for use in any legally marketed drug) across the border.[2]

The SUPPORT Act

Over the past year, FDA has worked to implement the SUPPORT Act, which expanded the agency's regulatory authority with respect to opioids, including by making it easier for FDA to detain illegal imports of FDA-regulated products, to debar those convicted of a felony for illegal importation and to issue mandatory recall orders for controlled substances.[3] As part of those efforts, FDA and CBP devoted additional resources to enhance screening of packages entering the United States through international mail facilities. Since the law's enactment in October 2018, FDA has identified more than 9,000 products at such facilities as illicit drugs that pose significant public health risks and has issued multiple notices of debarment for a felony conviction involving the illegal importation of drugs.[4] Outside of the enforcement context, the agency also has taken steps under the SUPPORT Act to clarify FDA post-market authorities, provide guidance on the agency's risk-benefit framework for review of opioid analgesic drugs, and identify barriers to abuse-deterrent formulations under Medicare.[5]

Administrative Actions

FDA sent multiple opioid-related warning letters in 2019, at times in tandem with other federal agencies.[6] In September, FDA and the DEA jointly issued first-of-their-kind letters to four online networks warning about the sale of unapproved opioids and other Controlled Substances Act ("CSA") violations.[7] Since 2017, FDA has sent warning letters to more than 20 networks operating over 450 websites and has brought more than 450 domain names to the attention of search engine operators.[8] FDA sent warning letters regarding the sale of unapproved drugs marketed for the treatment of opioid withdrawal symptoms.[9] In addition, three repackers that distributed active pharmaceutical ingredients, including opioids, received warning letters for significant current good manufacturing practice ("cGMP") violations.[10] In February, FDA made headlines for sending a warning letter to a major drug distributor for violations of the Drug Supply Chain Security Act ("DSCSA") related to verification requirements, including with respect to opioids.[11] The action marked the first warning letter issued by the agency under the DSCSA.[12] In connection with the marketing of approved opioids, FDA's Office of Prescription Drug Promotion ("OPDP") warned a manufacturer in December about a print advertisement promoting a drug intended to prevent relapse to opioid dependence following detoxification, concluding the advertisement was false or misleading because it omitted warnings about the drug's most serious risks, including the potential for fatal opioid overdose. [13]

Judicial Actions

Most opioid-related criminal enforcement actions in 2019 involved violations of the CSA or the federal Anti-Kickback Statute rather than violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Nevertheless, approximately 40% of the 2019 press releases issued by FDA's Office of Criminal Investigations ("OCI") described opioid-related cases.[14] Thus, despite the limited use of FDA's criminal authorities in the opioid context, the agency's criminal agents nevertheless appear to be spending significant time investigating and assisting with opioid-related actions, which is unlikely to change in the coming year.

This year, DOJ announced a record-breaking $1.4 billion settlement in connection with the alleged misleading marketing of an opioid addiction treatment drug.[15] The settlement, which resolved civil and criminal allegations, marks the largest recovery by the United States in an opioid case to date. As part of the settlement, the defendant agreed to forfeit $647 million and not manufacture, market, or sell Schedule I, II, or III controlled substances for three years as part of a non-prosecution agreement; pay a total of $700 million to the federal government and states to resolve civil FCA claims; and pay $50 million to the Federal Trade Commission ("FTC") to resolve claims that it engaged in unfair methods of competition.[16] Three months prior to the settlement, DOJ indicted the company's subsidiary in connection with related allegations. That case is slated for trial this year.[17]

In April, federal prosecutors also made history by bringing the first-ever felony criminal charges for illegal distribution of controlled substances against a pharmaceutical distributor and its executives.[18] DOJ charged one of the nation's largest pharmaceutical distributors with unlawfully distributing opioids, conspiring to defraud the DEA, and knowingly failing to file suspicious order reports required by the CSA. Under the terms of the deferred prosecution agreement, the distributor agreed to pay a $20 million penalty, improve its CSA compliance program, and submit to supervision by an independent monitor.[19]

DOJ also has continued to make use of its CSA civil injunction authority to stop health care providers from prescribing and dispensing opioids unlawfully. In 2018, the agency obtained a "first-of-its-kind" restraining order to enjoin two physicians from writing prescriptions.[20] In 2019, DOJ went further and obtained restraining orders to block two Tennessee pharmacies, their majority owner, and three pharmacists from continuing to fill controlled substances prescriptions.[21] A deputy assistant attorney general has stated that more of these actions can be expected this year.[22]

Product Quality and Manufacturing

Consistent with its enforcement activities in past years, and its mandate to ensure product quality and safety, FDA focused significant attention in 2019 on potential gaps in manufacturing practices and quality systems observed through its domestic and foreign inspection program.

Administrative Actions

Of the nearly 200 drug-related warning letters issued in calendar year 2019[23] (up from 176 letters in 2018), approximately 60% cited cGMP violations or insanitary conditions.[24] FDA issued 14 warning letters to compounders and outsourcing facilities,[25] 13 of which involved cGMP violations or citations for insanitary conditions. The number of warning letters to compounding facilities dropped from 24 in calendar year 2018[26] to 11 in calendar year 2019, and is significantly down from 2016, when nearly 50% of drug cGMP warning letters went to compounders.[27] While the number of warning letters issued to device manufacturers in 2019 was up by one from the prior year, a smaller though still significant percentage of those letters involved violations of quality system regulations (QSR) (16 of 27 in 2019 as compared to 20 of 26 in 2018). Approximately half of the warning letters issued to dietary supplement manufacturers cited cGMP violations.[28]

During a hearing in October 2019, FDA and other officials sounded an alarm regarding the nation's dependence on foreign manufacturers of active pharmaceutical ingredients ("APIs") and finished drug products and the quality and security risks such dependence could create.[29] In addition, numerous media outlets—as well as a book released in 2019 by journalist Katherine Eban titled "Bottle of Lies"—directed their attention to significant quality lapses and data integrity concerns among foreign generic drug manufacturers.[30] Despite such concern about the quality of drugs manufactured abroad, for the first time in at least five years, the number of letters to domestic drug manufacturers in fiscal year 2019 was higher than the number issued to foreign manufacturers, even when excluding letters to drug compounders.[31] According to CDER's Office of Manufacturing Quality, an increase in FY 2019 warning letters was largely driven by firms making OTC drugs, cited for, among other issues, the inadequate testing of raw materials and components and the failure to conduct finished product testing.[32] Nevertheless, in Fiscal Year 2019, more than one-third of drug-related warning letters were sent to foreign firms, with firms in India and China receiving the most letters.[33] Common issues identified by such letters include impurities in APIs;[34] microbial contamination of non-sterile products from water system deficiencies;[35] and inadequate aseptic processing.[36] In 2019, FDA also added at least 45 facilities to Import Alert 66-40, which prevents the import of drugs from the firms listed due to non-compliance with cGMP regulations.[37]

Homeopathic drugs emerged as an interesting area of focus for FDA in 2019. In October, the agency released updated draft guidance and withdrew its decades-old compliance policy guide regarding enforcement for homeopathic drugs.[38] The agency, however, had already stepped up enforcement against manufacturers of homeopathic drugs earlier in 2019. In April, FDA announced that it had issued warning letters to four homeopathic manufacturers that had committed significant cGMP violations.[39] A few weeks later, the agency posted five more warning letters to entities that failed to ensure the sterility of their homeopathic products.[40]

Judicial Actions

Multiple high-profile civil and criminal actions involved compounding and outsourcing facilities in 2019. Most notably, a federal court jury in Indianapolis found the former CEO and owner of the compounding company Pharmakon Pharmaceuticals guilty of conspiring to defraud FDA and obstruct FDA inspections, of distributing super-potent or sub-potent drugs, and of adulterating drugs while they were held for sale. Certain of the drugs distributed were super-potent opioids ultimately administered to hospitalized infants.[41] The indictment alleged that, at the direction of the former CEO, Pharmakon routinely distributed drugs it manufactured before receiving test results verifying their potency. It further

alleged that, upon learning that test results showed distributed drugs to be out of specification for potency, Pharmakon neither informed the customer or FDA, nor recalled the already distributed drugs. Pharmakon's former CEO was sentenced to 33 months in prison.[42] The director of compliance also was sentenced to five months in prison after pleading guilty.[43]

The federal government also obtained multiple civil injunctions against compounders and outsourcing facilities. In May, a federal court entered a consent decree of permanent injunction enjoining PharMedium Services, a large outsourcing facility, from manufacturing or distributing drugs until adequate remedial measures are implemented.[44] The company had allegedly failed to comply with 503B outsourcing facility requirements and had prepared, packed, or held drugs under insanitary conditions.[45] Similar permanent injunctions were entered against three other outsourcing and compounding facilities as well.[46]

DOJ also sought permanent injunctions against dietary supplement companies as a result of manufacturing and quality issues. For example, in September, a federal court in Tennessee enjoined two companies from distributing misbranded and adulterated dietary supplements, a misbranded and adulterated device, and unapproved new drugs.[47] FDA had alleged numerous cGMP violations related to the companies' production of dietary supplements.[48]

Dietary supplement companies likely can expect more enforcement attention from DOJ in 2020. At an enforcement conference in December, a DOJ official noted that the Consumer Protection Branch added six new attorneys to focus on investigating and litigating against dietary supplement companies.[49]

Unapproved Products or Intended Uses

In 2019, the distribution and marketing of unapproved products remained an FDA enforcement priority. Notable areas of enforcement focus included dietary supplements, cannabidiol ("CBD") products, and stem cell products, all of which likely will continue to face scrutiny in 2020.

Administrative Actions

FDA's OPDP issued untitled letters to two companies engaged in pre-approval promotion of investigational products; one of the company's websites claimed that the unapproved drug "cured a rare form of brain cancer."[50] Two warning letters issued by OPDP cited companies for broadening the approved indications for use by failing to disclose material information about the drug's approved indication.[51] FDA's increased scrutiny of homeopathic drugs also resulted in warning letters about unapproved products in addition to cGMP violations. For example, in March, the agency issued a warning letter to Nutra Pharma Corp., accusing the company of marketing unapproved products labeled as homeopathic and with claims that they could treat addiction and other serious conditions.[52]

Of 27 device-related warning letters in calendar year 2019, nine letters involved the distribution of unapproved products and two letters cited companies for marketing cleared devices for unapproved and uncleared uses.[53] In addition, FDA issued 14 warning or untitled letters related to biological products, nearly all of which (12 of 14) addressed human cells, tissues, and cellular and tissue-based products ("HCT/Ps").[54] Half of the 12 letters involving HCT/Ps went to companies FDA alleged were marketing unapproved products, including stem cell therapies and products derived from human umbilical cord and blood. The other half alleged significant deviations from the HCT/Ps regulations observed during FDA inspections.[55]

Products marketed as dietary supplements also generated numerous warning letters. In April, for example, FDA issued 12 warning letters regarding products that contained the chemical compound DMHA.[56] FDA asserted in these letters that DMHA is either a "new dietary ingredient" for which the manufacturers had not submitted required notifications to the agency, or an "unsafe food additive," rendering the products legally adulterated.[57] Similarly, FDA issued 12 warning letters and five online advisory letters in February to companies that marketed products as dietary supplements that

qualified as unapproved new drugs or misbranded drugs because of labeling claims that the products could prevent, treat, or cure Alzheimer's and other diseases.[58]

Lastly, in November, FDA issued CBD-related warning letters to 15 companies, including for marketing unapproved new human and animal drugs that contained CBD, selling CBD products as dietary supplements, and adding CBD to human and animal food.[59]

Judicial Actions

In June, 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.[60] The Florida-based clinic had marketed these products as containing stem cells derived from adipose tissue that could treat a range of serious diseases. The clinic asserted that its activities involved removing and re-implanting patients' tissues back into their bodies during the "same surgical procedure," thereby falling under an exception in FDA regulations. The federal district court rejected the clinic's argument and deferred to FDA's interpretation of the regulation governing the applicability of this exemption under *Auer v. Robbins*.[61] The court found the stem cell products manufactured at the clinic to be drugs that were misbranded because they lacked adequate directions for use and adulterated because of the clinic's failure to comply with cGMP regulations.[62] The decision potentially provides DOJ and FDA with a precedent to rely upon in seeking to enforce its interpretation of the law against other entities that market stem cell products that FDA considers to be illegal drugs. However, the case is currently on appeal in the 11th Circuit.[63] Despite several significant injuries allegedly suffered by clinic patients due to treatment at the clinic (including three patients who became blind following injections at the clinic to treat macular degeneration), more than 95 clinic patients moved to intervene in the case to prevent the destruction of their banked stem cells. They argued that treatments at the clinic had been effective, and the judge halted any destruction pending appeal of the case.[64] This appeal will be a case to watch in 2020, especially in light of the Supreme Court's opinion in *Kisor v. Wilkie*, regarding *Auer* deference, handed down three weeks after the decision in the U.S. Stem Cell case.[65]

Unapproved products were also the subject of various criminal actions. For example, in December, a federal court in California sentenced Carolina Liquid Chemistries to pay $50,000 for developing and marketing an unapproved medical device.[66] The company had sold a system to test urine for drugs without FDA clearance or approval.[67]

In March, DOJ charged six individuals and two companies in connection with a scheme to distribute unapproved new drugs labeled as dietary supplements.[68] The defendants had sold hundreds of thousands of products marketed as dietary supplements that contained allegedly unapproved new drugs, controlled substances such as anabolic steroids, and other illegal ingredients.[69]

On the FCA front, DOJ obtained a $9.5 million settlement with Avalign Technologies and its subsidiary Instrumed International.[70] From 2007 to 2014, Instrumed allegedly sold medical devices that were not cleared by FDA, claiming that such products did not require clearance or approval because they were marketed prior to the Medical Device Amendments of 1976, despite internal emails seemingly suggesting that the company did not actually believe this to be correct.[71] In a related FCA settlement, CareFusion, a medical device distributor, agreed to pay $3.3 million to resolve allegations related to the company's distribution of Instrumed's unapproved and uncleared devices.[72]

In September, DOJ announced that a pharmaceutical manufacturer had agreed to pay more than $108 million to resolve criminal and civil allegations related to an alleged kickback scheme.[73] While the FCA allegations primarily involved a paid speaker's program, DOJ also claimed that the company had marketed its drug in long-term care facilities for uses that had not been approved by FDA.[74]

Reporting, Data Integrity, and Other Requirements

The government also took action in 2019 against companies engaged in conduct it viewed as deceptive or that allegedly impeded FDA's regulatory mandate. Frequently cited allegations included failure to report required information, data manipulation, or impeding FDA investigations or implementation of agency programs.

Administrative Actions

Multiple warning letters cited companies for failing to report required information. For example, a November warning letter asserted that a drug company had failed to submit required NDA Field Alert Reports regarding out-of-specification stability testing results for distributed drug products.[75] Similarly, FDA sent a warning letter to a wheelchair manufacturer, regarding, among other issues, the company's failure to report information related to death or serious injury potentially caused by its products.[76]

In December 2018, FDA published a final guidance document on data integrity and compliance with cGMP for drugs.[77] Since then, a significant number of drug warning letters have included discussion of data integrity issues and cited the agency's guidance. Examples include letters to a Chinese over-the-counter manufacturer, an American generic manufacturer, and an American contract testing laboratory.[78] FDA also sent a warning letter to a Chinese contract testing laboratory that refused to allow the agency to conduct an inspection of its facility.[79]

In addition, in August 2019, FDA took the unusual step of releasing a statement revealing that a gene therapy company had discovered manipulation of testing data while the company's biologics license application ("BLA") was under review, but had not notified the agency until after FDA had approved the application.[80] Although FDA stood by its approval decision, the agency threatened to take further action, if appropriate, using the full range of its enforcement authorities.[81]

Judicial Actions

In July, DOJ announced that device manufacturer ACell Inc. had pleaded guilty and entered into a $15 million settlement to resolve criminal and civil charges related to the company's alleged violation of FDCA reporting requirements, among other issues.[82] DOJ alleged that ACell had removed its MicroMatrix powder wound dressing product from the market due to endotoxin contamination, but did not report the recall to FDA, explain the reasons for the recall to health care providers and consumers, or alert doctors who had used products from the contaminated lots. ACell also settled FCA allegations regarding the misrepresentation of clinical data by sales representatives, the provision of incorrect coding recommendations to providers, and the payment of improper inducements to prescribers.[83]

Another notable case involved misdemeanor criminal charges brought against two employees of an Ohio company that purportedly sold "tinctures, salves and herbal formulas," for refusing an FDA inspection, and distributing drugs and devices that were adulterated because they were manufactured in a facility that refused inspection.[84] The individuals were sentenced to six months of probation and a small fine. The company was fined approximately $165,000.[85] This case was noteworthy in that the FDCA inspection refusal and related adulteration provisions charged in the case are rarely enforced criminally.

Another unusual FDA-related FCA matter that bears mention involved a pharmaceutical company that allegedly engaged in a deceptive scheme to deprive FDA of Prescription Drug User Fee Act ("PDUFA") user fees.[86] Under PDUFA, companies filing a new drug application ("NDA") generally must pay a user fee; however, the law waives such fees when a small business applicant submits its first NDA. The defendant here had previously obtained a waiver. To avoid having to pay fees for two later NDAs, the company was alleged to have covertly arranged for two different small businesses that had never submitted NDAs to submit defendant's applications. Unaware of the relationship between the

companies applying and the defendant, FDA granted the fee waivers. As part of a settlement, the company agreed to pay $4 million in civil penalties.[87]

In 2020, companies should expect heightened scrutiny of potential data integrity and reporting violations and perceived fraud on the agency. A DOJ official stated recently that data manipulation and fraud, especially in the context of clinical research, will be an increased area of focus for enforcement.[88]

FCA Update

In 2019, DOJ and relators continued to rely on the FCA as a powerful enforcement tool for policing the health care and life sciences industries. The total recovery in civil FCA cases in Fiscal Year 2019 eclipsed $3 billion, a roughly 5% increase from 2018.[89] Consistent with previous years, the majority of dollars recovered came from health care and life sciences defendants, which paid more than $2.60 billion, a slight increase from the $2.53 billion they paid in Fiscal Year 2018.[90]

In our enforcement recap last year,[91] we noted a pair of actions by DOJ in late 2018 that suggested DOJ might more frequently invoke a provision of the FCA that permits the federal government to seek dismissal of FCA qui tam cases, including those in which DOJ does not intervene.[92] DOJ's follow-up actions in 2019 confirmed that it would seek dismissal of cases when doing so would, in DOJ's view, serve the government's interests. For example, in November 2018, DOJ submitted an amicus brief urging the U.S. Supreme Court to deny certiorari in an FCA case involving alleged cGMP violations by a drug manufacturer; the government stated that it planned to seek dismissal in the district court to avoid burdensome discovery and testimony from FDA that "would distract from the agency's public-health responsibilities."[93] After the Supreme Court declined to hear the appeal, DOJ successfully moved to have the lower court dismiss the action.[94] Moreover, DOJ obtained dismissal of nine of ten similar qui tam cases brought by professional relators under the FCA regarding certain patient assistance and support services provided by pharmaceutical manufacturers.[95]

It bears watching whether courts continue to be receptive to such dismissal motions and what level of scrutiny they apply. There is currently a split between circuit courts of appeals. Whereas the District of Columbia Circuit has held that the government has an unfettered right to dismissal, the Ninth Circuit has adopted a stricter standard of review known as the Sequoia Orange standard.[96] Under this test, DOJ must identify a valid government purpose for dismissal and demonstrate a rational relationship between dismissal and accomplishment of that purpose.[97] After the Supreme Court declined to hear the cGMP case mentioned above, the lower court applied the Sequoia Orange standard and ultimately granted DOJ's motion to dismiss, albeit after months of supplemental briefings and hearings.[98] On the other hand, in the one of ten similar patient assistance qui tam cases where DOJ failed to obtain dismissal, the district court applied the Sequoia Orange test and held that dismissal was not rationally related to a valid governmental purpose.[99] If more courts conduct such a searching review and question the government's reasons, then DOJ may become less inclined to seek dismissals of non-intervened cases.

DOJ's new policy with respect to dismissals has invited congressional scrutiny. In a September 2019 letter, Senator Charles Grassley (R-Iowa) expressed concern about DOJ's increased efforts to seek dismissal of greater numbers of qui tam cases for reasons "unrelated to the merits of individual cases" and questioned DOJ's reliance on "vague and at times questionable concerns over prerogatives or limited government resources to handle the cases."[100] DOJ responded to Grassley's letter in December 2019, assuring the Senator that DOJ would move to dismiss only in "the limited instances" where DOJ had determined that "relator's continued pursuit of a *qui tam* case would undermine the goal of preventing fraud or other important governmental interests."[101] Assistant Attorney General Stephen Boyd also noted that, since January 2018, more than 1,170 qui tams had been filed and that DOJ had moved to dismiss only 45 of those cases, constituting only 4% of filed cases during that nearly two-year period.[102]

Conclusion

FDA's enforcement priorities in 2020 likely will build on the agency's work in 2019. Public health crises involving opioids and vaping will remain at the forefront, while DOJ should be expected to continue prosecuting manufacturers, distributors, pharmacies, and providers for controlled substances violations as well as conduct the government sees as implicating federal fraud and abuse laws, including the FCA. In addition, as concerns continue to increase regarding the Coronavirus outbreak, we may see enforcement action against entities that distribute unapproved drugs or devices and misleadingly promote them as safe and effective as cures for the virus or to prevent its transmission. Industry should not let its guard down with respect to continued compliance with FDA regulatory obligations, including good manufacturing practices to ensure product quality, data integrity obligations, robust tracking of adverse events, timely reporting of required information, and truthful, non-misleading promotion. Released in April, DOJ's updated guidance on evaluating corporate compliance programs serves as an instructive reminder that a robust compliance program not only can help prevent incidents that might lead to an enforcement action, but also provides an important defense if and when the government comes calling.[103]

[1] While vaping is an important FDA priority, a discussion of enforcement under FDA's tobacco-related authorities is beyond the scope of this article, which focuses on FDA-regulated medical products.
[2] See Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse, FDA.gov (last updated Dec. 20, 2019), https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse.
[3] See SUPPORT Act, H.R. 6, 115th Cong. (2018) (enacted Oct. 24, 2018).
[4] FDA Statement from Norman E. Sharpless, Statement on Agency's First Year Accomplishments Implementing SUPPORT Act Authorities to Address the Opioids Crisis, FDA.gov (Oct. 24, 2019), https://www.fda.gov/news-events/press-announcements/statement-agencys-first-year-accomplishments-implementing-support-act-authorities-address-opioids.
[5] *Id*.
[6] *See, e.g.*, FDA News Release, FDA Takes New Enforcement Actions as Part of the Agency's Ongoing Effort to Combat the Illegal Online Sales of Opioids, FDA.gov (Apr. 2, 2019), https://www.fda.gov/news-events/press-announcements/fda-takes-new-enforcement-actions-part-agencys-ongoing-effort-combat-illegal-online-sales-opioids.
[7] FDA News Release, FDA and DEA Warn Website Operators Illegally Selling Opioids, FDA.gov (Sept. 30, 2019), https://www.fda.gov/news-events/press-announcements/fda-and-dea-warn-website-operators-illegally-selling-opioids.
[8] Speech by Stacy Cline Amin, FDA Chief Counsel's Remarks to the 2019 FDLI Policy Conference, FDA.gov (May 2, 2019), https://www.fda.gov/news-events/speeches-fda-officials/fda-chief-counsels-remarks-2019-fdli-policy-conference-05022019.
[9] *See, e.g.*, FDA In Brief: FDA Issues Warning Letter for Products Illegally Marketed for the Treatment of Health Conditions, Including Opioid Withdrawal Symptoms, FDA.gov (Nov. 26, 2019), https://www.fda.gov/news-events/fda-newsroom/fda-brief-fda-issues-warning-letter-products-illegally-marketed-treatment-health-conditions.
[10] FDA News Release, FDA Warns Repackers Distributing Pharmaceutical Ingredients, Including Opioids, for Putting Consumers at Risk with Significant Violations of Manufacturing Quality Standards, FDA.gov (July 2, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-repackers-distributing-pharmaceutical-ingredients-including-opioids-putting-consumers-risk.
[11] FDA Statement from Scott Gottlieb, Statement from FDA Commissioner Scott Gottlieb, M.D., on Ongoing Efforts to Stop the Spread of Illicit Opioids, Further Secure the U.S. Drug Supply Chain and Forcefully Confront Opioid Epidemic, FDA.gov (Feb. 12, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-ongoing-efforts-stop-spread-illicit-opioids-further; Warning Letter, McKesson Corporation Headquarters, FDA.gov (Feb. 7, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mckesson-corporation-headquarters-2719-565854-02072019.
[12] *Id*.
[13] FDA News Release, FDA Issues Warning Letter for Not Including the Most Serious Risks in Advertisement for Medication-Assisted Treatment Drug, FDA.gov (Dec. 11, 2019), https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letter-not-including-most-serious-risks-advertisement-medication-assisted.
[14] See Press Releases, FDA.gov (last updated Jan. 21, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/press-releases.
[15] DOJ Press Release, Justice Department Obtains $1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History, justice.gov (July 11, 2019), https://www.justice.gov/opa/pr/justice-department-obtains-14-billion-reckitt-benckiser-group-largest-recovery-case.
[16] *Id*.
[17] *Id*.; DOJ Press Release, Indivior Inc. Indicted for Fraudulently Marketing Prescription Opioid, justice.gov (Apr. 9, 2019), https://www.justice.gov/opa/pr/indivior-inc-indicted-fraudulently-marketing-prescription-opioid.
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[19] *Id*.
[20] DOJ Press Release, Justice Department Takes First-of-its-Kind-Legal Action to Reduce Opioid Over-Prescription, justice.gov (Aug. 22, 2018), https://www.justice.gov/opa/pr/justice-department-takes-first-its-kind-legal-action-reduce-opioid-over-prescription.
[21] DOJ Press Release, Justice Department Files First of its Kind Action to Stop Tennessee Pharmacies' Unlawful Dispensing of Opioids, justice.gov (Feb. 8, 2019), https://www.justice.gov/opa/pr/justice-department-files-first-its-kind-action-stop-tennessee-pharmacies-unlawful-dispensing.

[22] DOJ, Deputy Assistant Attorney General David Morrell Delivers Remarks at the Food and Drug Law Institute Annual Enforcement, Litigation, and Compliance Conference, justice.gov (Dec. 11, 2019), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-david-morrell-delivers-remarks-food-and-drug-law.
[23] FDA's fiscal year runs from October 1 through September 30. Except where indicated otherwise, the statistics in this article are based on a Ropes & Gray analysis of calendar year 2019 warning letters, as published at Warning Letters, FDA.gov (updated Jan. 22, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.
[24] According to a Ropes & Gray analysis of calendar year 2019 FDA warning letters, as published at Warning Letters, FDA.gov (updated Jan. 22, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters. Statistics from 2018 are from Greg Levine et al., 2018 FDA Enforcement Review: Drugs, Biologics, and Devices, Law360 (Jan. 28, 2019), https://www.law360.com/articles/1122467/2018-fda-enforcement-review-drugs-biologics-and-devices.
[25] Of the 14 letters to compounding and outsourcing entities, 11 cited firms for failing to meet the requirements to qualify as a Section 503A traditional compounder and three went to outsourcing facilities that failed to comply with the requirements of Section 503B (according to a Ropes & Gray analysis of 2019 FDA warning letters, as published at Warning Letters, FDA.gov (updated Jan. 22, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters).
[26] *See* CDER Office of Compliance Calendar Year 2018 Annual Report, p. 14, *available at* https://www.fda.gov/media/128429/download.
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