Parallel Enforcement: SEC Authorities and How They Can Impact FDA's Civil and Criminal Enforcement

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I. INTRODUCTION

Life sciences companies frequently must determine what information to communicate to investors about key developments in clinical trials or the U.S. Food and Drug Administration's (FDA) regulatory review process. Although the details of a company's interactions with FDA during its approval process are not public, the valuation of a life science company often depends on its ability to bring a drug or device to market, making information about the likelihood of the FDA approval critical to investors. The decision of whether to disclose this information is further complicated in instances where a company has incomplete information. For example, a publicly traded pharmaceutical company may only have partial results from a pivotal clinical trial. When deciding what (if anything) to say in such circumstances, the company's disclosures will be scrutinized for accuracy and completeness by a separate regulatory agency—the U.S. Securities and Exchange Commission (SEC or the Commission). Should SEC conclude that the company's disclosures were inaccurate or misleading, the consequences of enforcement may be severe, including prohibiting individuals from serving as a director or officer at a publicly traded company, substantial financial sanctions, and, in extreme cases, referral to the U.S. Department of Justice (DOJ) for criminal prosecution.

This Article analyzes the interplay between the SEC and the FDA regulatory regimes concerning life science companies. Part II provides an overview of the FDA enforcement powers. Part III summarizes the SEC regulatory framework and the SEC enforcement actions that may specifically target the FDA-regulated companies. Part IV analyzes the circumstances in which these agencies act in conjunction with each other to enforce their various statutes and regulations and provides several examples of companies that have experienced such parallel enforcement.

II. THE FOOD AND DRUG ADMINISTRATION

FDA's mission is to protect the public health by regulating a broad range of products that millions of consumers use daily.[1] While Congress has placed the responsibility

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[1] FDA regulates $2.1 trillion worth of products a year, including drugs, biological products, medical devices, animal drugs and feed, tobacco, and many food products. FDA regulation accounts for nearly 75% of the U.S. food supply, over 20,000 approved prescription drug products, 6,700 medical device products, and over 671 licensed biologics products. These products represent over one-fifth of the United States' total

for complying with the laws enforced by FDA primarily on regulated industry,[2] the Federal Food, Drug, and Cosmetic Act (FDCA) contains broad enforcement mechanisms.

Congress enacted the FDCA in 1938 under its constitutional authority to regulate interstate commerce. Consistent with its constitutional hook, the FDCA includes numerous "prohibited acts" designed to protect the public health by preventing unapproved, adulterated, or misbranded articles from entering interstate commerce.[3] Violations of these prohibited acts can result in FDA referring cases to DOJ for injunctions, criminal penalties, and seizure of the violative products. While FDA routinely refers cases for these types of federal court actions, it also benefits from regulatory and administrative tools that it generally uses before it reverts to civil or criminal remedies.

The graphic below provides a framework for FDA's "enforcement toolbox," loosely defined to include regulatory tools, administrative tools, civil enforcement, and criminal enforcement.

	Regulatory Tools	Administrative Tools	Civil Enforcement	Criminal Enforcement
Description	Tools to Encourage Voluntary compliance	Administrative Proceedings	United States District Court Proceeding	United States District Court Proceeding
Examples	• Premarket applications (e.g., NDA, PMA, 510(k)) • IND or IDE • Clinical hold letters • Inspections/483 notifications • Untitled letters • "It Has Come to Our Attention" Letters • Warning letters • Recalls (voluntary)	• Administrative detentions • Recalls (mandatory) • Import alerts • Civil money penalties • Debarment	• Seizures • Injunctions • Civil Contempt	• Criminal Investigations • Grand Jury • Prosecution

Fig. 1: FDA Enforcement Tools

A. Regulatory Tools

Perhaps the broadest of the four categories, regulatory tools encompass a range of actions developed or enumerated by FDA to encourage voluntary compliance with the FDCA. While these tools cannot directly result in civil or criminal penalties, attempts to circumvent or failure to comply may result in FDA taking further action through administrative, civil, or criminal proceedings.

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gross domestic product (GDP). *See* U.S. FOOD & DRUG ADMIN., FDA AT A GLANCE (Apr. 2023), https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance.

[2] *See* United States v. Dotterweich, 320 U.S. 277 (1943). While this Article focuses on the Federal Food, Drug, and Cosmetic Act (FDCA), note that FDA also enforces certain provisions of the Public Health Service Act, including those concerning biological products. Because biological products are also regulated as drugs under the FDCA, they will be covered in the general discussion about drugs and medical products generally.

[3] 21 U.S.C. § 331.

FDA's regulatory tools span the full product lifecycle, from development and approval through post-approval/product commercialization. During drug or device development, FDA may issue a clinical hold of an investigation (when a hold is issued, the company must cease administering the investigational product to subjects[4]), issue warning letters[5] to investigators or clinical sites, or disqualify investigators from conducting clinical investigations.[6] These tools help to safeguard study participants as well as ensure the integrity of the data used to support new drugs or devices.

Another key regulatory tool is FDA's premarket review process, which requires sponsors to submit applications to FDA before certain products can be lawfully distributed in interstate commerce (e.g., New Drug Applications (NDAs) for small-molecule drugs, Biologics License Applications (BLAs) for biological/large molecule products, Premarket Approvals (PMAs) for high-risk devices, Requests for De Novo Designation for novel low- or moderate-risk devices, and 510(k) notifications for other low- or moderate-risk devices).

Inspections are yet another powerful regulatory tool available to FDA throughout the product lifecycle.[7] FDA may conduct an inspection for multiple reasons, such as pre-approval of a manufacturing facility listed in an NDA or BLA, routine inspections for establishments manufacturing and distributing FDA-regulated products, and for-cause inspections to follow-up on suspected or alleged noncompliance.[8] During these inspections, an FDA investigator visits a company's offices or facilities to observe the operations and may issue an FDA Form 483 (483) that lists the investigator's observations, which are generally reviewed, along with any response to the 483, by the appropriate FDA center to determine whether further regulatory or enforcement action is warranted.[9]

FDA has also relied on other tools, such as record requests, to obtain information about FDA-regulated entities and products.[10] Additionally, as announced in a 2021 guidance, in lieu of in-person inspections, FDA created a new, inspection-like "remote interactive evaluations" tool, which are livestream or prerecorded videos through which FDA investigators could virtually inspect data and/or facilities.[11]

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4 21 C.F.R. § 312.42; *IND Application Procedures: Clinical Hold*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-procedures-clinical-hold (last updated Oct. 9, 2015).

5 *See* discussion of Warning Letters, *infra*.

6 21 C.F.R. § 312.70; 21 C.F.R. § 312.70.

7 21 U.S.C. § 374.

8 *See Inspection Basics*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics (last updated Mar. 15, 2023).

9 21 U.S.C. § 374(b).

10 21 U.S.C. § 374(a)(1). *See also* U.S. FOOD & DRUG ADMIN., MANUFACTURING, SUPPLY CHAIN, AND DRUG AND BIOLOGICAL PRODUCT INSPECTIONS DURING COVID-19 PUBLIC HEALTH EMERGENCY QUESTIONS AND ANSWERS—GUIDANCE FOR INDUSTRY (May 17, 2021), www.fda.gov/media/141312/download.

11 U.S. FOOD & DRUG ADMIN., REMOTE INTERACTIVE EVALUATIONS OF DRUG MANUFACTURING AND BIORESEARCH MONITORING FACILITIES DURING THE COVID-19 PUBLIC HEALTH EMERGENCY—GUIDANCE FOR INDUSTRY (Apr. 2021), https://www.fda.gov/media/147582/download. This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) in accordance with Section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. § 247d(a)(2)). *See* Guidance Documents Related to Coronavirus Disease 2019 (COVID-19), 88 Fed. Reg. 15,417 (Mar. 13, 2023), https://www.federalre

Issuing Warning Letters is another common way that FDA puts regulated industry on notice and seeks to compel compliance.[12] In FY 2022, FDA issued over 16,000 Warning Letters, though only roughly 184 of those were for human medical products (10 for biologics; 24 for devices; and 150 for drugs).[13] A Warning Letter notifies a sponsor of FDCA violations and explains that if the entity fails to correct these violations, FDA may seek an injunction, seizure, or prosecution. Warning Letters serve as a deterrent for regulated industry due the potential consequences that flow from receiving one. Because Warning Letters generally are publicly available,[14] they bring reputational damage and can make the recipient a target for costly lawsuits and class actions brought by private litigants, including in the securities context.

Recalls are another important regulatory tool.

A recalling company may act on its own initiative or FDA may inform the company that a distributed product violates the law and recommend the company recall the product. FDA has the authority to require recalls of certain products in particular circumstances, such as controlled substances, biological products, human cells, tissues and cellular and tissue-based products, medical devices, and foods.[15]

FDA relies on the voluntary recall process or other enforcement tools explained below to ensure violative products are removed from the marketplace.

B. Administrative Enforcement Tools

The FDCA also grants FDA the ability to take direct action against individuals or entities that perform specified prohibited acts. FDA may impose civil monetary penalties (CMPs) for specified violations of the FDCA.[16] These include penalties for, among others: violations concerning prescription drug marketing practices,[17] medical devices,[18] and dissemination of false or misleading direct-to-consumer advertisements for approved drugs or biological products.[19] FDA may assess these penalties against both individuals and corporations. To determine the penalty for many violations, the agency must consider the nature and circumstances surrounding the violation, the person's ability to pay, the effect on the person's ability to continue to do business, and any history of similar acts.[20] CMPs are adjudicated by administrative law judges

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gister.gov/documents/2023/03/13/2023-05094/guidance-documents-related-to-coronavirus-disease-2019-covid-19.

[12] FDA may also send "untitled" letters to a target company. In these letters, FDA cites violations that do not meet the threshold of regulatory significance for a warning letter. U.S. FOOD & DRUG ADMIN., *Advisory Actions*, *in* REGULATORY PROCEDURES MANUAL (11th ed., 2022), https://www.fda.gov/media/71878/download.

[13] *Compliance Actions: Warning Letters by Fiscal Year*, U.S. Food & Drug Admin., https://datadashboard.fda.gov/ora/cd/complianceactions.htm (last accessed May 17, 2023).

[14] *Id.*

[15] Press Release, U.S. Food & Drug Admin., FDA Urges Companies to be 'Recall Ready' to Protect Public Health as Part of Final Guidance for Voluntary Recalls (Mar. 3, 2022), https://www.fda.gov/news-events/press-announcements/fda-urges-companies-be-recall-ready-protect-public-health-part-final-guidance-voluntary-recalls.

[16] 21 U.S.C. § 333.

[17] 21 U.S.C. § 333(b).

[18] 21 U.S.C. § 333(f)(1).

[19] 21 U.S.C. § 333(g).

[20] *See* 21 U.S.C. §§ 335b(b)(2), 333(f)(5)(B).

(ALJs) through formal proceedings, and judicial review of the civil penalty proceedings is available in the federal courts.[21] In part because of other available enforcement tools, FDA does not often use its CMP authority (except for tobacco products), although it has brought CMP actions against non-tobacco products. For example, in 2005, FDA filed a CMP complaint against TMJ Implants, Inc. for failing to submit medical device reports. The ALJ's ruling was affirmed in a Final Decision by a Departmental Appeals Board and ultimately upheld by the Tenth Circuit.[22]

Another administrative remedy available to the agency is the ability to "debar" or prohibit corporations or individuals from participating in certain FDA-regulated activities based on their related conduct.[23] FDA has five years from the date of the triggering conviction or conduct related to importation to initiate debarment proceedings.[24]

FDA may begin debarment proceedings on its own initiative or in response to a petition. An individual subject to permissive debarment may be debarred for a period of not more than five years while an individual subject to mandatory debarment is permanently debarred.[25] Debarment will be terminated if the conviction that served as the basis for the debarment is reversed. Debarment may also be reduced to one year if FDA finds that the individual has taken steps to mitigate the impact of the offense on the public, including the recall or discontinuation of suspected drugs, and has demonstrated substantial assistance in its investigations or prosecutions.[26] The names of debarred individuals are published in the *Federal Register* and maintained on a list made publicly available by FDA.[27]

FDA's final administrative tools relate to its ability to take direct action against violative marketed products. For instance, FDA may issue an import alert about a product that is in violation of FDA's laws and regulations.[28] An import alert permits border officials to automatically, and indefinitely, detain without physical examination products that violate laws or regulations.[29] FDA can also administratively detain violative products that are found in the United States, generally as a precursor to a seizure action.[30] Although FDA has had the authority to administratively detain drugs since 2012 and devices since the device amendments to the FDCA were enacted in 1976,[31] FDA has used this authority only once for drugs in 2018 and very infrequently for devices.[32]

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[21] 21 C.F.R. §§ 17.47, 17.51.

[22] TMJ Implants, Inc. v. U.S. Dep't of Health & Hum. Servs., 584 F.3d 1290 (10th Cir. 2009).

[23] 21 U.S.C. § 335a.

[24] 21 U.S.C. § 335a(l)(2).

[25] 21 U.S.C. § 335a(c)(2).

[26] 21 U.S.C. § 335a(c)(3).

[27] U.S. FOOD & DRUG ADMIN., SMG 7712, FDA STAFF MANUAL GUIDES—DEBARMENT PROCEEDINGS (Feb. 28, 2020), https://www.fda.gov/media/80036/download.

[28] *Import Alerts*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/actions-enforcement/import-alerts (last updated Jan. 30, 2023).

[29] *Id.*

[30] 21 U.S.C. § 334.

[31] 21 C.F.R. § 800.55.

[32] Press Release, U.S. food & Drug Admin., FDA Seizes Food and Medical Products Held Under Insanitary Conditions at an Arkansas Grocery Warehouse (Nov. 9, 2018), https://www.fda.gov/news-

C. Civil Enforcement Actions

Under the FDCA, the government can seek injunctive relief against entities that engage in any prohibited act, such as distributing an unapproved, adulterated, or misbranded medical product in interstate commerce.[33] While the precise legal tests vary somewhat by jurisdiction, to obtain an injunction under the FDCA, FDA must show that: 1) there has been a violation of the FDCA, and 2) there is a reasonable likelihood that the violations will recur.[34] While not a requirement under the legal test, in practice, FDA generally only refers injunction cases to DOJ based on a company's history of repeated violations. This is in part based on caselaw stating that past conduct is evidence of the likelihood of continued violations.[35]

Most injunction cases resolve via a Consent Decree of Permanent Injunction, which is a settlement agreement between the government and the defendants outlining the terms the government believes will bring the defendants' future operations into compliance. These settlement agreements generally contain a series of standard provisions that have been used for more than two decades. Such provisions include a cessation of activity while the defendants bring their operations into compliance; retention of an outside expert to assist with remediation; regular audits by the outside expert for the duration of the Consent Decree; continuous compliance for a set period of time, generally sixty months; and to notify "associated persons" about the Consent Decree. Many Consent Decrees also contain a provision whereby FDA can shut down the facility for noncompliance, and/or assess liquidated damages for violations of the Consent Decree.[36] Though entry of a Consent Decree is typical, injunction cases sometimes are litigated through summary judgment and even trial. Given the favorable legal standard enjoyed by the government, the fact that such injunction matters are bench trials (tried before a judge rather than a jury), and the public health mission emphasized in these actions, FDA has a strong track record of prevailing in such cases.[37]

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events/press-announcements/fda-seizes-food-and-medical-products-held-under-insanitary-conditions-arkansas-grocery-warehouse (Nov. 9, 2018).

[33] *See* 21 U.S.C. §§ 331(a), 331(d), 332, 351, 352, 355.

[34] *See* United States v. Chung's Prods. LP, 941 F. Supp. 2d 770 (S.D. Tex. 2013); United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp. 2d 30 (E.D.N.Y. 2001); United States v. Lane Labs-USA, Inc., 324 F. Supp. 2d 547 (D.N.J. 2004).

[35] United States v. W.T. Grant Co., 345 U.S. 629, 633 (1953); SEC v. Opulentica, LLC, 479 F. Supp. 2d. 319 (S.D.N.Y. 2007); *Chung's Prods. LP*, 941 F. Supp. at 794.

[36] *See, e.g.*, United States v. Medtronic Inc., No. 15-cv-2168, (D. Minn. Apr. 29, 2015), ECF No. 8; United States v. Atrium Med. Corp., No. 15-cv-41, (D.N.H. Feb. 3, 2015), ECF No. 5; United States v. Invacare Corp., No. 12-cv-3086 (N.D. Ohio Dec. 21, 2013), ECF No. 4; United States v. Accurate Set, Inc., No. 11-cv-7585 (D.N.J. Feb. 7, 2012), ECF No. 7; United States v. Terumo Cardiovascular Sys. Corp., No. 11–11179 (E.D. Mich. Mar. 29, 2011), ECF No. 2; United States v. Sybaritic, Inc., No. 09-cv-3672 (D. Minn. Jan. 5, 2010), ECF No. 4; United States v. Undetermined Quantities of Boxes of Signature Edition Gold, No. 06-cv-1706 (S.D. Cal. Feb. 18, 2009), ECF No. 23-2, 16A; United States v. Medtronic Inc., No. 08-cv-649 (W.D. Wash. May 9, 2008), ECF No. 3; United States v. Lane Labs-USA, Inc., 324 F. Supp. 2d 582, 584–87 (D.N.J. 2004); United States v. Syntrax Innovations, Inc., 149 F. Supp. 2d 880, 885 (E.D. Mo. 2001); United States v. Universal Mgmt. Servs., Inc., 999 F. Supp. 974, 983, 985 (N.D. Ohio 1997); United States v. Richlyn Lab'ys, Inc., 822 F. Supp. 268, 274 (E.D. Pa. 1993).

[37] *See* 21 U.S.C. § 332; *e.g.*, United States v. Endotec, Inc., 563 F.3d 1187 (11th Cir. 2009); United States v. U.S. Stem Cell Clinic, LLC, 998 F.3d 1302 (11th Cir. 2021). *But see* United States. v. Cal. Stem Cell Treatment Ctr., Inc., No. EDCV-18-1005 (JGB), 2022 WL 3756509 (C.D. Cal. Aug. 30, 2022).

Though they are largely successful, there has been a downward trend in bringing these actions since 2016, a watermark year where there were nineteen injunctions secured by FDA. In 2022, the agency obtained only five injunctions, an 80% drop.[38] Although the precise reasons for this decrease are not entirely clear, one possibility is the lack of fresh evidence to support injunctions given the reduced numbers of inspections during the COVID-19 pandemic. For example, FDA would not have the factual bases to seek injunctions rooted in current Good Manufacturing Practice (cGMP) violations as these cases historically have been based on on-site observations by FDA investigators—which were severely curtailed during the height of the COVID-19 pandemic given the travel restrictions.

Another historically popular civil enforcement tool is the seizure action. These in rem actions are brought against the violative products on the market, and are typically filed by the U.S. Attorney's Office located closest to the products to be seized.[39] This enforcement tool is used when the removal of adulterated or misbranded products from interstate commerce is necessary to reduce consumer accessibility to those goods in order to protect the public health. FDA will initiate such actions where, for example, a company does not effectively recall a violative product or when a product has been detained by a state government or administratively detained by FDA.[40] For example, in 2015, U.S. Marshals seized over $16 million of unapproved prescription drug products from a pharmaceutical company located in Miami, Florida.[41]

D. Criminal Enforcement

The FDCA also provides criminal remedies for violations of the FDCA's prohibited acts. These cases are generally investigated by agents from FDA's Office of Criminal Investigations (OCI), who work closely with lawyers within FDA's Chief Counsel's Office and DOJ to obtain and gather evidence, including by executing warrants, and to testify in support of indictments at trial. Importantly, although Congress granted FDA broad authorities to conduct inspections, FDA's OCI works independently to collect evidence in support of its criminal cases.[42] While FDA OCI may receive

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[38] *Compliance Actions: Injunctions and Seizures by Fiscal Year*, U.S. FOOD & DRUG ADMIN., https://datadashboard.fda.gov/ora/cd/complianceactions.htm (last accessed May 17, 2022).

[39] *See* U.S. DEP'T OF JUST., JUSTICE MANUAL § 4-8.220 (2018), https://www.justice.gov/jm/jm-4-8000-consumer-protection ("FDA routinely recommends seizure actions under the FDCA (authorized by 21 U.S.C. § 334) by direct referral to USAOs.").

[40] Seizures are permitted "when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer." 21 U.S.C. § 334(a)(1). FDA's seizure authority gives "speedy protection" from products that could harm the public unless stopped before they reach the consumer. Ewing v. Mytinger & Casselberry, 339 U.S. 594, 601 (1950).

[41] Press Release, U.S. Food & Drug Admin., U.S. Marshals Seize Unapproved Drugs from Florida Distributor (Apr. 16, 2015), https://wayback.archive-it.org/7993/20170111235556/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm443109.htm.

[42] This distinction is apparent on the face of the FDCA. For example, evidence that FDA obtains from common carriers through the FDCA "shall not be used in a criminal prosecution of the person from whom obtained . . . ." 21 U.S.C. § 373(a).

information or tips from the "regulatory" side of FDA, the agency must be careful not to use its civil and regulatory processes to gather evidence for criminal cases.[43]

Under the FDCA, an entity or individual can be punished with criminal fines and imprisonment of up to one year for misdemeanor violations. However, if such violations are committed with the intent to defraud or mislead their customers or the federal government, or if there are subsequent FDCA misdemeanor violations, then the violations are punished as felonies, carrying criminal fines and jail time of up to three years imprisonment. Criminal forfeiture is also available as a remedy in certain cases investigated by OCI. OCI works closely with both the U.S. Attorney's Offices and DOJ's CPB to bring criminal FDCA cases.

For example, in 2018, Olympus and one of its former senior executives, Hisao Yabe, pleaded guilty to distributing misbranded medical devices (duodenoscopes, which are used in 500,000 procedures per year in the United States) in interstate commerce in violation of the FDCA. DOJ alleged in its complaint that Olympus failed to file timely reports to FDA, known as medical device reports (MDRs). To resolve the criminal case, Olympus agreed to pay $80 million in fines and $5 million in criminal forfeiture. In the press release announcing the resolution, the then-Assistant Attorney General Jody Hunt explained that "when a device manufacturer becomes aware of risks that could lead to illness, injury, or death, there is a statutory obligation to report that information to the FDA in a timely manner. By failing to do so, Olympus and Mr. Yabe put patients' health at risk."

As part of the resolution, Olympus was also required to take a number of steps aimed at achieving compliance with the FDCA and its implementing regulations, including retaining an independent expert, periodic review by the expert of Olympus's operations for three years, and a review and audit of the device classification and market pathway for certain endoscope devices manufactured by Olympus. Olympus was also obligated to inform certain health care providers about its plea, and to provide information to those health care providers regarding Olympus's failure to file the required MDRs. The Olympus case represents a good example of how criminal penalties can incorporate some elements of relief typically sought in civil enforcement cases, such as compliance monitoring by outside experts.

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Part II of this Article will provide an overview of SEC enforcement of life sciences companies. Although SEC may receive leads concerning potential securities violations by life sciences from numerous other sources, FDA and SEC also have a formal policy concerning inter-agency cooperation. Under this policy, FDA may inform SEC of potential securities violations by FDA-regulated companies and share nonpublic information with SEC. This inter-agency cooperation permits SEC to more efficiently determine whether an FDA-regulated company's disclosures were false and misleading or whether it failed to disclose something that it should have. The remainder of this Article will provide key takeaways on how SEC enforcement can affect FDA's enforcement. It will explain why life sciences companies must remain

[43] *E.g.*, Benjamin Greenberg & Susan Torres, *Parallel Proceedings in Health Care Fraud*, 66 DOJ J. FED. L. & PRAC. 15, 20–21 (2018) (explaining the so-called "stalking horse" doctrine whereby the government cannot bring a civil action solely to obtain evidence for its criminal prosecution).

vigilant to ensure compliance with the laws and regulations of other agencies, specifically the SEC. It will also cover the ways FDA remains committed to protecting companies' confidential information, and what protections apply when submitting documents to SEC.

III. THE SECURITIES AND EXCHANGE COMMISSION

SEC is an independent federal regulatory agency responsible for protecting investors and maintaining the integrity of the U.S. capital markets. Established in 1934 in the wake of the stock market crash of 1929 that led to the Great Depression,[44] SEC oversees securities exchanges, securities brokers and dealers, investment advisers, and mutual funds in an effort to promote the accurate disclosure of important market information and to prevent fraud on the markets and investors. Through its Enforcement Division, SEC brings numerous civil enforcement actions against entities and individuals alleging violations of securities laws every year. It is involved in virtually every major securities violation investigated in the United States, often working either directly or in conjunction with DOJ. Common examples of offenses prosecuted by SEC include fraudulent disclosures, insider trading, and selective disclosures.

SEC's regulatory and enforcement authority derives from a series of statutes, including, among others, the Securities Act of 1933 (Securities Act) and the Securities Exchange Act of 1934 (Exchange Act).[45] The Exchange Act requires that public companies—those with securities offered to the public on an exchange, such as the New York Stock Exchange or NASDAQ—engage in mandatory public disclosures and it allows both private parties and the agency to seek remedies against companies who knowingly make misstatements or omissions in their public disclosures.[46] The Securities Act governs the registration and public sale of securities on public exchanges and imposes potential civil liability for misstatements or omissions in the offer or sale of securities (e.g., in a registration statement or prospectus related to a public securities offering).[47] Based on this statutory authority, the resulting regulatory system SEC oversees is made up of two interrelated components: mandatory disclosure and anti-fraud regulations. The remainder of this part will summarize a few of the primary enforcement mechanisms SEC utilizes as part of its administration of federal securities laws.

A. SEC's Investigative Powers and Process

SEC holds substantial, expansive investigatory and enforcement power, consistent with its broad congressional authority to investigate as the agency "deems necessary to determine whether any person has violated, is violating, or is about to violate" federal securities laws.[48] SEC is not required to substantively articulate the reason,

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[44] 15 U.S.C. §§ 78a–nn.

[45] 15 U.S.C. § 78d.

[46] 15 U.S.C. §§ 78l–m, o(d); Ernst & Ernst v. Hochfelder, 425 U.S. 185, 195 (1976) (discussing how the 1934 Act was intended to protect investors against manipulation of stock prices through regulation and the imposition of regular reporting requirements).

[47] 15 U.S.C. § 77a *et seq*.

[48] 15 U.S.C.A. § 78u (a)(1); *see also* Cochran v. SEC, 20 F.4th 194, 228 (5th Cir. 2021) (Oldham, J., concurring) (noting SEC's may "administer oaths and affirmations, subpoena witnesses, compel their

purpose, or scope of their investigations in the first instance, and subjects of investigation have few effective methods for challenging an SEC investigation.[49]

SEC has explained it "obtains evidence of possible violations of securities laws" from multiple sources that can trigger investigations, including (among other things) "market surveillance activities, investor tips and complaints, other Divisions and Offices of the SEC, the self-regulatory organizations and other securities industry sources, and media reports."[50] SEC has also established multiple task forces and subgroups to monitor specific categories of potential violations[51] and maintains a "whistleblower" program that encourages current and former employees to provide tips on potential securities violations in exchange for financial renumeration.[52] SEC's Enforcement Division, with a home office in Washington, DC and eleven regional offices around the country, initiates and pursues these investigations.[53]

SEC may seek documents and information through "voluntary" requests or subpoenas.[54] These investigations are non-public in the sense that SEC is generally bound to keep confidential the existence of the investigation, as well as any information provided to the agency in response to investigatory requests.[55] However, SEC's form notice makes clear that SEC may "make[] its files available to other

attendance, take evidence, and require the production of any books, papers, correspondence, memoranda, contracts, agreements, or other records" deemed "relevant or material to the inquiry" as part of their investigatory authority (quoting 15 U.S.C. § 78u(b)).

[49] SEC v. Arthur Young & Co., 584 F.2d 1018, 1030 (D.C. Cir. 1978) (describing SEC's broad investigative authority, and explaining that agencies such as SEC can commence investigations based merely on "suspicion that the law is being violated, or even just because it wants assurance that it is not" (quoting United States v. Morton Salt Co., 338 U.S. 632, 642–43 (1950)).

[50] *How Investigations Work*, U.S. SEC. & EXCHANGE COMM'N (last modified Jan. 27, 2017), https://www.sec.gov/enforcement/how-investigations-work.

[51] *See, e.g.*, *Enforcement Task Force Focused on Climate and ESG Issues*, U.S. SEC. & EXCHANGE COMM'N (last modified Apr. 11, 2023), https://www.sec.gov/securities-topics/enforcement-task-force-focused-climate-esg-issues; *Financial Reporting and Audit (FRAud) Group*, U.S. SEC. & EXCHANGE COMM'N (last modified Feb. 10, 2020), https://www.sec.gov/securities-topics/financial-reporting-and-audit-task-force.

[52] U.S. SEC. & EXCHANGE COMM'N, SEC WHISTLEBLOWER OFFICE ANNOUNCES RESULTS FOR FY 2022 1 (Nov. 15, 2022), https://www.sec.gov/files/2022_ow_ar.pdf (noting that "the Commission received over 12,300 whistleblower tips," which was the "largest number of whistleblower tips received in a fiscal year," and that agency "awarded approximately $229 million" in total financial awards).

[53] *See Division of Enforcement*, U.S. SEC. & EXCHANGE COMM'N, https://www.sec.gov/page/enforcement-section-landing (last modified Apr. 14, 2015).

[54] *See* U.S. SEC. & EXCHANGE COMM'N, ENFORCEMENT MANUAL § 3.2.3 (Nov. 28, 2017), https://www.sec.gov/divisions/enforce/enforcementmanual.pdf. In practice, if one declines to comply with these "voluntary" requests, SEC can quickly send a subpoena in most circumstances and the staff will note the witness's prior declination. Also, pursuant to Sections 17(a) and (b) of the Exchange Act and Section 204 of the Investment Advisers Act of 1940, regulated entities must generally provide the requested information even without a subpoena.

[55] *See Investor Bulletin: SEC Investigations*, U.S. SEC. & EXCHANGE COMM'N (Oct. 22, 2014), https://www.sec.gov/oiea/investor-alerts-bulletins/ib_investigations ("SEC investigations are generally conducted on a confidential basis to maximize their effectiveness and protect the privacy of those involved. Because SEC investigations are generally nonpublic, Enforcement will not confirm or deny the existence of an investigation unless the SEC brings charges against a person or entity involved.").

governmental agencies, particularly United States Attorneys and state prosecutors."[56] Further, if SEC initiates an enforcement action, information provided during the course of the investigation may become public during the relevant litigation proceedings in the absence of applicable protective order provisions. SEC's records are also subject to release through the Freedom of Information Act (FOIA), though in practice most documents submitted to SEC are exempt from release in response to a FOIA request because, among other grounds, they would constitute either "[r]ecords or information compiled for law enforcement purposes, the release of which . . . could reasonably be expected to interfere with law enforcement proceedings,"[57] or constitute "[t]rade secrets or . . . confidential commercial or financial information."[58] Companies may seek protection from FOIA disclosure by following the steps set forth in 17 C.F.R. § 200.83, which outlines the procedure by which persons submitting information to SEC can request confidential FOIA treatment.

SEC also has the authority to seek court orders compelling compliance with investigatory subpoenas in the face of non-compliance.[59] The relative utility of forcing SEC to compel compliance with an investigatory subpoena, however, is minimal. The standard for forcing compliance is fairly low: agencies like SEC are permitted to initiate investigations on the mere "suspicion that the law is being violated, or even just because it wants assurance that it is not."[60] Accordingly, SEC need only demonstrate the requested information may be "relevant or material to the inquiry" to fall within the scope of the agency's investigatory powers.[61] As a result—in addition to the fact that inviting SEC to compel compliance would reveal the existence of an otherwise confidential investigation, as noted above—individuals and entities looking for relief from an overbroad subpoena are usually best served by first seeking to work with SEC staff to narrow its scope.

B. Common Claims Brought by SEC

This Section will summarize some of the more common claims asserted in SEC enforcement actions against life sciences companies and executives.

1. Section 10(b) of the Exchange Act and Rule 10b-5

The securities laws are the primary means for ensuring that a company's public disclosures—whether made in required, periodic filings with SEC, press releases, or

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[56] *See* U.S. SEC. & EXCHANGE COMM'N, SEC Form 1662, Supplemental Information for Persons Requested to Supply Information Voluntarily or Directed to Supply Information Pursuant to a Commission Subpoena, https://www.sec.gov/files/sec1662.pdf (last modified Sept. 2021).

[57] 5 U.S.C. § 552 (b)(7).

[58] *Id.* § 552 (b)(4); 21 C.F.R. § 20.64. Notably, the U.S. Supreme Court recently held that commercial information qualifies as "confidential," and is thus entitled to FOIA exemption, so long it is "customarily and actually treated as private by its owner and provided to the government under and assurance of privacy." Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2358 (2019). Under this decision, a submitter no longer need also show that the disclosure of the information would likely inflict on it "substantial competitive harm." *See id.*

[59] *See* 15 U.S.C. §§ 77v(b), 78u(c).

[60] SEC v. Arthur Young & Co., 584 F.2d 1018, 1024, 1030 (D.C. Cir. 1978) ("[I]t has long been clear that 'it is sufficient if the [SEC's] inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant.'").

[61] *See, e.g.*, *id.* at 1023–25 (D.C. Cir. 1978) (citing 15 U.S.C. § 78u(b)); SEC v. Wheeling-Pittsburgh Steel Corp., 648 F.2d 118, 128 (3d Cir. 1981) (en banc).

other public statements—are accurate and not misleading, through the imposition of civil liability for fraudulent misstatements and/or omissions. Among the most well-known (and most regularly enforced) federal securities laws is Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder, which serve as primary weapons in SEC's civil enforcement arsenal.[62] Under Section 10(b) (and its related regulation, Rule 10b-5), companies may be liable for material misstatements and omissions in any public disclosures. Rule 10b-5 makes it unlawful for any person to engage in fraudulent behavior concerning the purchase or sale of securities.[63] Importantly, to establish securities fraud under Section 10(b) and Rule 10b-5 (as compared to other federal securities laws), SEC or a private litigant must demonstrate that the defendant entity or individual made the material misleading statement or omission with the intent to deceive—that is, with "scienter."

A representative example is SEC's May 31, 2022 enforcement action against New York-based SCWorx Corp. (SCWorx) and its former Chief Executive Officer, alleging violations of Section 10(b) and Rule 10b-5 for making false and misleading statements about SCWorx's plans to distribute COVID-19 rapid test kits.[64] Specifically, SEC claimed that defendants had seized upon the COVID-19 outbreak by falsely stating that SCWorx had a "committed purchase order" from an unnamed buyer to purchase 2 million COVID-19 rapid test kits, and that the purchase order included a "provision for additional weekly orders of 2 million units for 23 weeks, valued at $35M[illion] per week."[65] This announcement caused SCWorx's stock price to increase 425% from the prior trading day. According to SEC, however, at the time defendants issued the press release, SCWorx knew that FDA had recently notified it that its manufacturing partner was not authorized to distribute COVID-19 test kits in the United States.[66]

i. Materiality

In assessing claims under Section 10(b) of the Exchange Act, as well as those under Sections 17(a) of the Securities Act and Regulation FD (discussed *infra*), a key consideration is whether the fact in question is "material." The Supreme Court has explained that a fact is material where there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."[67] Of course, the determination of whether a fact is "material" is a nuanced one, heavily dependent on the specific facts and circumstances, what information the company previously disclosed on the relevant issue, and requiring a judgment as to how the near-mythical "reasonable investor" would view the new information.[68] At any given

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[62] 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5 (making it unlawful for any person to engage in conduct which would operate as a fraud or deceit upon any person in connection with the purchase or sale of a security).

[63] 17 C.F.R. § 240.10b-5.

[64] Compl., SEC v. Schessell, 22-cv-03287 (D.N.J. 2022), ECF No. 1.

[65] *Id.* at 13.

[66] *Id.* at 12.

[67] Basic, Inc. v. Levinson, 485 U.S. 224, 231–32 (1988) (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)).

[68] *See, e.g.*, Paul Munter, *Assessing Materiality: Focusing on the Reasonable Investor When Evaluating Errors*, U.S. SEC. & EXCHANGE COMM'N (Mar. 9, 2022), https://www.sec.gov/news/statement/munter-statement-assessing-materiality-030922 (assessing materiality of disclosures related to financial

time, this determination "will also depend upon a balancing of both the . . . probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity."[69] As a practical matter, if the information is likely to have a significant impact on the stock price when disclosed, it will be hard not to consider it "material."[70]

One example of FDA feedback that would likely constitute "material information" is a clinical hold. In *SEC v. Ferrone*,[71] SEC brought an enforcement action based on violations of the Securities Act and the Exchange Act against the founder of a pharmaceutical company seeking FDA approval of a drug to treat multiple sclerosis and AIDS. FDA issued a "full clinical hold" that completely "barred any use of [the investigational drug] on humans, including through so-called compassionate use waivers."[72] Not only did the company not disclose the clinical hold, but the founder also made further public statements falsely claiming FDA had allowed the company to continue clinical trials through the use of compassionate use waivers and suggesting further clinical trials were forthcoming.[73] The District Court for the Northern District of Illinois granted SEC's motion for summary judgment, explaining that in light of the clinical hold, the founder's statements were false.[74] SEC has made similar determinations of materiality as to, for example, FDA guidance regarding the need for further clinical trials.[75]

The receipt of interim FDA feedback, by contrast, raises a more complicated question. Courts generally recognize that pharmaceutical companies need not disclose an FDA action or communication if it "does not constitute a final determination."[76] But in practice, this general principle is not so black and white. For example, courts differ as to whether a Form 483—a "form of interim feedback" following manufacturing site inspections, which may list "significant conditions . . . indicat[ing] a drug is being prepared in ways that do not comply with FDA regulations"—is *per se* material.[77]

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statements, and acknowledging that the "materiality analysis is not a mechanical exercise, nor should it be based solely on a quantitative analysis" and requires "consideration [of] all relevant facts and circumstances").

69 *Basic, Inc.*, 485 U.S. at 238 (quoting SEC v. Texas Gulf Sulphur Co., 401 F.2d 833, 849 (2d Cir. 1968)).

70 Of course, in practice, company executives often want to say a fact is not material primarily because they are concerned about the negative impact that fact's disclosure would have on the stock price.

71 SEC v. Ferrone, 2014 WL 5152367 (N.D. Ill. Oct. 10, 2014).

72 *Id.* at *1–2.

73 *Id.* at *2.

74 *Id.* at *6–7.

75 *See* Final Judgment as to Defendant AVEO Pharms., Inc., SEC v. AVEO Pharms., Inc., No. 16-cv-10607 (D. Mass. Mar. 29, 2016), ECF No. 4-1 (alleging failure to disclose need for further clinical trials was material).

76 *See, e.g.*, Hoey v. Insmed Inc., 2018 WL 902266, at *14 (D.N.J. Feb. 15, 2018) ("[T]he law with respect to this issue is clear: a biopharmaceutical corporation need not share a regulatory agency's response or criticism to a trial and its results if it does not constitute a final determination." (collecting cases)); Vallabhaneni v. Endocyte, Inc., 2016 WL 51260, at *11–12 (S.D. Ind. Jan. 4, 2016) ("[N]umerous courts have concluded that a defendant pharmaceutical company does not have a duty to reveal interim FDA criticism regarding study design or methodology.").

77 Shaeffer v. Nabriva Therapeutics, 2020 WL 7701463, at *2 (S.D.N.Y. Apr. 28, 2020).

Although there is no "standalone duty to disclose [the] existence" of a Form 483,[78] which constitutes interim FDA feedback, courts have come to differing conclusions regarding whether a Form 483 constitutes material information and requires disclosure based on the specific circumstances at issue.[79] As the Eighth Circuit has explained, the materiality of a Form 483 is dependent "on a number of factors, including the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA."[80]

It bears noting that a company is not required to disclose all information that an investor might be interested in.[81] Nor is it necessarily required to disclose such information even if it is material.[82] Absent a specific disclosure requirement (e.g., an SEC form line-item), a duty to disclose "material" information arises only if disclosure is necessary "to make statements made, in the light of the circumstances under which they were made, not misleading."[83]

2. Insider Trading

Insider trading is prohibited pursuant to Section 10(b) of the Exchange Act and Rule 10b-5.[84] There are two primary theories. First, there is the "classical" theory, which involves a "corporate insider [who] trades in the securities of his corporation on the basis of material, nonpublic information."[85] The "corporate insider" must have a fiduciary duty to the relevant company, such that trading the company's securities (to the detriment of otherwise uninformed stockholders) could constitute a violation of

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[78] *Id.* at *9.

[79] *Compare* Yanek v. Staar Surgical Co., 388 F. Supp. 2d 1110, 1129–30 (C.D. Cal. 2005) (holding that Form 483 was *per se* material because it contained "facts bearing on possible delays in FDA approval"), *with* City of Pontiac Gen. Emps' Ret. Sys. v. Stryker Corp., 865 F. Supp. 2d 811, 825 (W.D. Mich. 2012) ("Defendants were under no duty to disclose the Mahwah Form 483 because it did not constitute a final agency determination. At that point, any information in the Form 483 was 'soft' information as to the existence of regulatory violations at the Mahwah facility.").

[80] Pub. Pension Fund Grp. v. KV Pharm. Co., 679 F.3d 972, 982–83 (8th Cir. 2012).

[81] *See In re* Keryx Biopharmaceuticals, Inc., Sec. Litig., 2014 WL 585658, at *11 (S.D.N.Y. Feb. 14, 2014); *In re* Keryx Biopharmaceuticals, Inc., Sec. Litig., 2014 WL 585658, at *7, *11 (S.D.N.Y. Feb. 14, 2014) (explaining there is "no rule requiring [a] 'deep dive' disclosure" of all information regarding clinical trials and noting "disclosure is not required simply because an investor might find the information relevant or of interest"); *In re* Time Warner Inc. Sec. Litig., 9 F.3d 259, 267 (2d Cir. 1993) ("[A] corporation is not required to disclose a fact merely because a reasonable investor would very much like to know that fact.").

[82] *In re* Keryx Biopharmaceuticals, Inc., Sec. Litig., 2014 WL 585658, at *7.

[83] Kleinman v. Elan Corp., 706 F.3d 145, 153 (2d Cir. 2013) ("Disclosure is required . . . only when necessary 'to make statements made, in the light of the circumstances under which they were made, not misleading.'"); *see, e.g.*, Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011) ("[I]t bears emphasis that § 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information.").

[84] SEC v. Talbot, 530 F.3d 1085, 1091 (9th Cir. 2008) (imposing liability for insider trading and explaining history of insider trading violations under Section 10(b) and Rule 10b-5); *see also* United States v. O'Hagan, 521 U.S. 642, 652 (1997) (endorsing for first time "misappropriation" theory of insider trading under Section 10(b) and Rule 10b-5).

[85] *Talbot*, 530 F.3d at 1090.

their fiduciary duties.[86] An insider who does not trade may also be liable for insider trading if they "tip" a non-insider who trades.[87]

The second theory of insider trading is the "misappropriation" theory. First endorsed by the Supreme Court in *United States v. O'Hagan*, the "misappropriation" theory extends the scope of potential violations from insiders to outsiders where there is "breach of a duty owed to the source of the information."[88] For example, an outsider who enters into a confidentiality agreement with a company would not have an insider's fiduciary duty to the company, but they would have a duty to keep company information confidential, and they may therefore be liable under the misappropriation theory if they traded on that information. Again, individuals need not trade in the subject securities themselves to be liable for insider trading under the misappropriation theory—they may still be subject to Section 10(b)'s grasp where material, non-public information is "tipped" to others who ultimately trade on that information.[89]

As an example of an insider trading case arising with respect to FDA communications, on December 1, 2021, SEC initiated an enforcement action against Usama Malik, the former Chief Financial Officer of Immunomedics, Inc. ("Immunomedics"), and his former girlfriend for insider trader.[90] On April 6, 2020, Immunomedics announced that a clinical trial to evaluate one of the company's drugs "had been halted because existing data already showed the drug was effective," thus prompting the company's stock price to rise 99%.[91] SEC alleged that Mr. Malik had learned from his colleagues on April 2, 2020, that FDA had concurred with the company's recommendation that the clinical study should be halted because of its successful results. Despite his duty to the company to keep this news confidential, Mr. Malik disclosed the nonpublic information to his former girlfriend and several relatives. Within hours of these conversations, each of the tippees began purchasing Immunomedics shares and held their shares through the April 6, 2020 announcement, generating substantial gains.

While SEC has consistently pursued insider trading for decades, recent comments from SEC Chair Gary Gensler suggest that SEC will adopt a renewed enforcement focus to combat insider trading.[92] Their recent policy decisions confirm that goal, as

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[86] Chiarella v. United States, 445 U.S. 222, 228–29 (1980) (explaining that "one who fails to disclose material information prior to the consummation of a transaction commits fraud only when he is under a duty to do so").

[87] Salman v. United States, 580 U.S. 39, 49–50 (2016) (insider trading conviction upheld where insider "tipper benefit[ed] personally" based on "gift of trading information" provided to tipper's brother and ultimately disseminated further to investment banker).

[88] *O'Hagan*, 521 U.S. at 652–53 ("The classical theory targets a corporate insider's breach of duty to shareholders with whom the insider transacts; the misappropriation theory outlaws trading on the basis of nonpublic information by a corporate 'outsider' in breach of a duty owed not to a trading party, but to the source of the information.").

[89] *Salman*, 580 U.S. at 43–44.

[90] *See,* Press Release, U.S. Sec. & Exchange Comm'n, SEC Charges Pharma CFO and Former Partner with Insider Trading (Dec. 2, 2021), https://www.sec.gov/news/press-release/2021-249.

[91] *See* Compl., SEC v. Mailk et al., No. 21-cv-20300, at ¶ 1 (D.N.J. Dec. 2, 2021).

[92] *SEC Chair Comments on Insider Trading*, YAHOO! FIN. (Mar. 8, 2022), https://ca.finance.yahoo.com/video/sec-chair-comments-insider-trading-110000042.html (SEC Chair Gary Gensler, discussing insider trading, noting his belief that there are "too many gaps in this area" and promising "vigorous enforcement" of insider trading laws, expressing concern that "senior management might be trading stock when they're in receipt of material nonpublic information.").

SEC has proposed new, more stringent regulations for corporate executives seeking to sell shares.

3. Section 17(a) of the Securities Act

Though less known than the more commonly applied provisions of Section 10(b) of the Exchange Act and associated Rule 10b-5, SEC's use of enforcement actions under anti-fraud provisions of the Securities Act has increased in recent years.[93] At first glance, Section 10(b) of the Exchange Act and Sections 17(a) of the Securities Act appear to cover the similar unlawful activity. The provisions prohibit the making of a material misstatement or omission of a material fact concerning the purchase or sale (Section 10(b)) or the offer or sale (Section 17(a)) of any security. However, there is a key difference: unlike its counterparts under the Exchange Act, a civil violation of Sections 17(a)(2)-(3) does not require that SEC demonstrate scienter—that is, the *intent* to defraud; instead, a showing of negligence is sufficient.[94] It can often prove difficult to show that a false statement was made with illegal intent, so by bringing a claim under these provisions, SEC eliminates a key hurdle and reduces its evidentiary burden.

4. Selective Disclosures and Regulation FD

In 2000, in response to concerns regarding the disclosure of material, nonpublic information to select investors, analysts, or other individuals, SEC adopted Regulation FD (Fair Disclosure).[95] At the time, former SEC Chair Arthur Levitt expressed his consternation about issuers of securities "selectively disclos[ing] information to certain influential analysts, in order to curry favor with them and reap a tangible benefit, such as a positive press spin," while also acknowledging that such "selective disclosures" may increase the probability of insider trading.[96] Regulation FD prohibits public companies from intentionally making disclosures to a select group without also disclosing the relevant information to the larger public.[97]

SEC's 2019 enforcement action against TherapeuticsMD, Inc. provides an illustrative example of Regulation FD's prohibition against selective disclosures.[98] In that case, SEC alleged that an executive of the defendant company disclosed information regarding an FDA meeting regarding its lead drug candidate, a hormone therapy, to multiple analysts, causing the stock price to jump significantly.[99] Despite

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[93] Nick Oberheiden, *The Growing Risk of Securities Fraud Litigation Under Section 17(a)*, NAT'L L. REV. (Nov. 4, 2021), https://www.natlawreview.com/article/growing-risk-securities-fraud-litigation-under-section-17a; Aaron v. SEC, 446 U.S. 680, 701–02 (1980).

[94] SEC v. Hughes Cap. Corp., 124 F.3d 449, 453–54 (3d Cir. 1997).

[95] Selective Disclosure and Insider Trading, 65 Fed. Reg. 51716 (Aug. 24, 2000) (to be codified at 17 C.F.R. pts. 240, 243, 249).

[96] *Selective Disclosure, Regulation FD*, U.S. SEC. & EXCHANGE COMM'N, https://www.sec.gov/answers/seldisc.htm (last updated May 13, 2003).

[97] SEC v. AT&T, Inc, 2022 WL 4110466, at *1 (S.D.N.Y. Sept. 8, 2022); 17 C.F.R. § 243.100(a) ("Whenever an issuer, or any person acting on its behalf, discloses any material nonpublic information regarding that issuer or its securities to any person described in paragraph (b)(1) of this section, the issuer shall make public disclosure of that information . . . (1) Simultaneously, in the case of an intentional disclosure; and (2) Promptly, in the case of an non-intentional disclosure.").

[98] In the Matter of Therapeuticsmd, Inc. Respondent., Release No. 86708 (Aug. 20, 2019), https://www.sec.gov/litigation/admin/2019/34-86708.pdf.

[99] *Id.*

the New York Stock Exchange (NYSE) inquiring about the possibility of disclosure of material information, the company did not publicly disclose that the meeting occurred until several days later and even then, did not provide material information regarding the details of that meeting (despite having provided that information to select investors).[100] The company ultimately settled the claims for $200,000.

IV. INTRA-AGENCY COOPERATION, ATTENDANT CONSIDERATIONS, AND MINIMIZING THE RISK OF REGULATORY ENFORCEMENT

A. Formal Collaboration between FDA and SEC

In February 2004, FDA and SEC announced they would be initiating a formal collaboration through which the agencies would establish processes allowing FDA employees to inform SEC of any potentially false or misleading statements made by FDA-regulated companies.[101] Although the agencies did not enter into a Memorandum of Understanding (MOU) (as FDA sometimes does with other agencies), SEC and FDA agreed as part of this collaboration to designate individual "points of contact for the SEC" within each of FDA's "main organizational components" and indicated their "commitment to endeavor" toward continued sharing of non-public information between the agencies.[102] To that end, FDA agreed to "streamline" the way it shares nonpublic information with SEC,[103] though the collaboration did not alter FDA's disclosure regulations requiring that any disclosed records not be further disclosed by the receiving agency without FDA's express written permission.[104]

The formal collaboration was perhaps first publicly demonstrated in SEC's enforcement actions against Biopure, Inc., as the investigation arose from a tip from FDA.[105] There, SEC charged the Massachusetts biotech company and a company executive for making materially misleading statements to investors about the company's prospects for obtaining regulatory approval for its synthetic blood product, Hemopure.[106] In July of 2003, FDA had declined to approve Hemopure for use in orthopedic surgery and raised concerns about its safety. Despite this news, Biopure continued issuing public statements that characterized the company's communications

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[100] *Id.*

[101] Press Release, U.S. Sec. & Exchange Comm'n, SEC and FDA Take Steps to Enhance Inter-Agency Cooperation (Feb. 5, 2004), https://www.sec.gov/news/press/2004-13.htm. The agencies initiated this initiative following congressional inquiries into FDA's handling of an insider trading case involving drug company ImClone, in which stocks were traded prior to FDA's public rejection of the ImClone's NDA for its oncologic drug. *See* Marcy Gordon, *SEC, FDA to Improve Cooperation*, Associated Press (Feb. 4, 2004), https://apnews.com/article/e613158cde6a094e50281e61288d3a0f.

[102] *SEC and FDA Takes Steps to Enhance Inter-Agency Cooperation*, *supra* note 101.

[103] *See* Liora Sukhatme, *Deterring Fraud: Mandatory Disclosure and the FDA Drug Approval Process*, 82 N.Y.U. L. REV. 1210, 1234 (2007) (noting the "new procedures are intended to streamline and simplify the reporting of such concerns").

[104] *See, e.g.*, 21 C.F.R. § 20.85.

[105] *See* Bailey Somers, *FDA Tip Sparks SEC Biopure Investigation*, LAW360 (Oct. 10, 2005), https://www.law360.com/articles/4233/fda-tip-sparks-sec-biopure-investigation.

[106] Compl., SEC v. Biopure Corp., No. 05-cv-11853 (D. Mass. Sept. 14, 2005), https://www.sec.gov/litigation/complaints/comp19376.pdf.

with FDA as positive, which caused the company's stock price to increase. The Complaint alleged that defendants violated, among others, Section 10(b) and Rule 10b-5, as well as Section 17(a) of the Securities Act.[107]

B. Issues That Arise When SEC Investigates a Company in the Midst of FDA Approval Process

On occasion, SEC will conduct an investigation of a company while it remains engaged in the drug or device development process with FDA. Such circumstances can raise a host of concerns for a company, not the least of which is that SEC scrutiny may influence the sponsor's actions, and potentially even FDA, even if unintentionally, for example if there is a suggestion that the sponsor has provided fraudulent or misleading information. Indeed, the mere fact of SEC's investigation would suggest that they have at least a suspicion that the company may have misled investors about the nature of their interactions with FDA. However, there are limitations to SEC's ability to get documents and information from FDA, even during an investigation. FDA is prohibited from sharing with SEC or other federal departments and agencies trade secrets and certain confidential commercial and financial information, including documents and information submitted by a company during approval processes.[108] To obtain such information, SEC would first need a waiver from the company allowing FDA to provide it, where allowed.[109] Then, even when this information is released to SEC, the agency must enter into written agreement that the information not be further disclosed by other departments or agencies, except with written permission of FDA.[110]

C. Issues That Arise When SEC and FDA Investigate a Company Post-Approval

Post-approval investigations and enforcement are common for both regulators, using the various tools outlined in this Article. For example, on September 22, 2017, SEC filed fraud charges against a Massachusetts-based biopharmaceutical company Aegerion. SEC alleged that the company had exaggerated the number of new patients that had filled prescriptions for their sole drug, Juxtapid, which was approved by FDA to treat a rare and potentially life-threatening genetic condition that causes extremely high cholesterol.[111] Without admitting or denying the allegations, Aegerion agreed to pay a $4.1 million penalty to settle SEC charges that it misled investors on multiple occasions. Separately, DOJ charged Aegerion with criminal FDCA charges for distributing Juxtapid in interstate commerce because Aegerion failed to comply with the drug's Risk Evaluation and Mitigation Strategy (REMS). The "specific purpose" of the Juxtapid REMS was "to educate prescribers about the risks of liver toxicity"

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[107] *Id.*; *SEC Settles Civil Injunctive Action Against Biopure Corporation and Its General Counse*l, U.S. SEC. & EXCHANGE COMM'N (Sept. 12, 2006), http://www.sec.gov/litigation/litreleases/2006/lr19825.htm.

[108] 21 C.F.R. § 20.85.

[109] 21 C.F.R. §§ 20.47, 20.61.

[110] *Id.* As noted above, most documents submitted to SEC would be exempt from release in response to a FOIA request.

[111] *See Pharmaceutical Company Paying Penalty for Misleading Investors about Sales Metric*, U.S. SEC. & EXCHANGE COMM'N (Sept. 22, 2017), https://www.sec.gov/litigation/litreleases/2017/lr23942.htm.

associated with the drug and to restrict its access to only those patients with a clinical or laboratory diagnosis consistent with the rare disease for which it was approved. The DOJ resolution also included a deferred prosecution agreement "relating to criminal liability under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)," as well as a $28.8 million settlement "to resolve federal and state civil liability for causing false claims for Juxtapid to be submitted to government health care programs (Medicare, Medicaid, and TRICARE)." In total, Aegerion agreed to pay more than $39 million with respect to these matters, and also entered into a civil consent decree of permanent injunction under the FDCA and a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General, to "ensure that its promotional activities and any arrangements and interactions with third-party patient assistance programs complied with the law."[112]

There are many potential pitfalls for companies that are simultaneously investigated by multiple regulators, such as Aegerion, including that the investigations may not be in-sync. Among other things, a company may have to respond to multiple sets of government inquiries and will want to be consistent in its responses, including the scope of document productions and any statements made during proffer sessions, yet they may not know the scope of the questions from each regulator.

When in the cross-hairs of multiple administrative agencies, companies should ensure that the government is affording all defendants appropriate process. Companies have successfully asserted constitutional challenges, for example, under the Fourth Amendment where evidence has been obtained in a parallel civil case and then improperly used against a defendant in a criminal case.[113] These types of "stalking horse" arguments are likely to succeed only where there is evidence that the government's use of civil process was *solely* to obtain evidence for a criminal case, and not for another legitimate purpose.[114] Similarly, where the government officials involved in an action affirmatively or intentionally mislead the subject of an investigation, such that incriminating statements made during what a defendant believed was a wholly civil investigation, courts have concluded that such statements violated a defendant's Fifth Amendment rights and disallowed the use of such statements in criminal cases.[115] While courts are sensitive to defendants' rights and ensuring that the government follow appropriate procedures in these cases, courts routinely uphold the government's ability to seek parallel actions.[116]

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[112] Press Release, U.S. Sec. & Exchange Comm'n, Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations (Sept. 22, 2017), https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and.

[113] *See, e.g.*, SEC v. Olsen, 354 F.2nd 166, 170 (2nd Cir. 1965).

[114] *Id.*

[115] *E.g.*, United States v. Stringer, 408 F. Supp. 2d 1083 (D. Or. 2006); United States v. Robson, 477 F.2d 13, 18 (9th Cir. 1973). Note that such arguments may be difficult to make with respect to the SEC investigations given that with each request for information, SEC provides its Form 1662, which warns that any information provided may be shared with other law enforcement agencies and used against the provider in any criminal proceeding.

[116] *E.g.*, SEC v. Dresser Indus. Inc., 628 F.2d 1368, 1377 (D.C. Cir. 1980).

D. Minimizing Parallel Enforcement Risk: Protecting Against Hindsight Bias

One of the thorniest issues for companies defending against parallel enforcement is the government's after-the-fact review of materials that may appear incriminating when viewed months or years after they were made. For example, clinical hold letters and other FDA regulatory tools aimed at protecting patients and encouraging voluntary compliance can become evidence in future SEC actions, with SEC having the benefit of retrospective review to compare the timing of a company's regulatory steps with FDA to trading decisions.[117]

Similarly, the forward-looking nature of investor statements can cause problems with FDA post-approval. If a sponsor seeks approval for a drug for a specific indication, but projects in forward-looking investor statements a market share premised upon a larger patient population, government regulators could point to the forward-looking statements as evidence of an intent to misbrand the medical product by marketing it for off-label use. Such was the case in Aegerion, for example, in which the government used Aegerion's assertions to "Wall Street and other investors" about its product's potential market to support a misbranding claim.[118] The government may use these investor statements to demonstrate either a different intended use or an intent to defraud or mislead the government in seeking only a narrowed indication when the sponsor planned for broader sales and marketing upon the initial approval. Of course, these cases tend to raise bedrock principles of FDA law: can the government rely on these investor statements as labeling? And even if not "labeling," are such statements indicative of intended use?

Under the FDCA, "[t]he term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[119] Courts have interpreted "accompanying" broadly, and held that labeling "supplements or explains" a product and includes "advertising or descriptive matter" where "no physical attachment one to the other is necessary."[120] Under this broad interpretation, FDA has taken a position in past enforcement actions that a company's statements to investors regarding a product should constitute labeling.[121] Although the examples where FDA has relied on investor statements as labeling are not common, there is precedent, such as Aegerion, for the government to continue to bring enforcement actions, including criminal cases, premised upon investor statements that can result in misbranding charges under the FDCA, among other potential criminal charges.

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[117] *See, e.g.*, Consent Order, *In re* Sidney A. Spector, MD, PhD (No. 22-0910), https://www.sec.gov/litigation/admin/2022/33-11078.pdf (imposing penalty on consultant who sold company's shares after learning of impending clinical hold but before it was announced).

[118] *See, e.g.*, United States v. Aegerion Pharms., Inc., No. 17-cr-10288 (D. Mass. 2017), ECF No. 1 (Information); FDA Warning Letter to Aegerion Pharmaceuticals, Inc. (Nov. 8, 2013) (FDA cited the company CEO's statements during an interview on CNBC's television show, "Fast Money," as evidence that the company's drug product Juxtapid was intended for new uses for which it lacked approval).

[119] 21 U.S.C. § 321(m).

[120] Kordel v. United States, 335 U.S. 345, 348–50 (1948).

[121] *See* FDA Warning Letter to Imprimis Pharmaceuticals (Dec. 21, 2017) (where FDA cited investor materials (e.g., investor presentation) as labeling that misbranded the company's drugs), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/imprimis-pharmaceuticals-540678-12212017.

Moreover, investor statements are also relevant as evidence of "intended use." On August 2, 2021, FDA amended the intended use regulations applicable to both drugs and devices,[122] explaining that FDA is not limited to promotional claims to determine intent, but can instead rely on any relevant source.[123]

Approvability issues present another tricky area for FDA-regulated sponsors. While certain regulatory issues may impact FDA's ability to file an application and thus must be remedied before filing (or in a resubmission), others will only be addressed and decided upon by FDA during application review. Companies not only need to disclose its FDA filing status with investors, but also ensure that they are not viewed as trying to paint an overly rosy picture of their data or otherwise attempt to bias any steps in FDA's decision-making process. Viewing the facts from SEC's standpoint, overly optimistic projections of drug or device regulatory approval prospects or mischaracterizations of correspondence to FDA may trigger an SEC investigation.[124]

Given the interplay between FDA and SEC regulatory frameworks, as well as the enhanced cooperation between the agencies, life sciences companies should ensure they have a process to vet and review public communications to ensure their accuracy. For pre-approval communications, companies should assess whether anyone with full knowledge of clinical developments, the FDA communications, prior statements, and all relevant public information would consider the statements misleading in any respect.[125] Key considerations include whether disclosing the partial results of a clinical trial could be misleading, particularly knowing that the final results could be different. Similarly, when publicly describing the FDA interactions, companies must carefully consider at what point such communications become material, particularly when FDA's communication comes in two parts: partial information communicated initially, with the promise for a more complete response weeks or months later. Even for communications describing formal agency meetings, companies need to consider whether disclosing outcomes, for example, of Type A meetings,[126] could be misleading, particularly when the issues raised therein will be fully addressed by FDA upon review of an application.

A company's risk of FDA enforcement action significantly increases post-approval as that is when the FDCA prohibited acts, generally premised upon movement of a

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[122] 21 C.F.R. §§ 201, 801.

[123] Regulations Regarding ''Intended Uses," 86 Fed. Reg. 41383 (Aug. 2, 2021). *See* United States v. Article . . . Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969) (collecting cases); *see also* United States v. Travia, 180 F. Supp. 2d 115, 119 (D.D.C. 2001) (rejecting the argument that nitrous oxide cannot be a drug, even if balloons in which nitrous oxide was sold contained no labeling or advertising).

[124] *See, e.g.*, SEC v. Ferrone, No. 11-cv-05223 (N.D. Ill. 2011) (bringing claims against Immunosyn for allegedly misleading statements regarding prospects of commercial approval and communications with FDA); SEC v. Imaging3, Inc., No. 13-cv-4616 (N.D. Cal. 2013) (bringing claims against medical device company that made allegedly misleading statements regarding FDA's view of product and did not disclose FDA's concerns regarding quality of product's imaging).

[125] *See, e.g.*, Complaint at 5, SEC v. Selden, No. 05-cv-11805 (D. Mass. Sept. 1, 2005); In the Matter of A.P. Montgomery & Co., Inc. Richard S. Friedman, Release No. 10909 (July 9, 1974); Final Judgment as to Defendant AVEO Pharmaceuticals, Inc., SEC v. Aveo Pharmaceuticals, Inc., No. 16-cv-10607 (D. Mass. Mar. 29, 2016); SEC v. Holmes, No. 16-cv-01602 (N.D. Cal. Mar. 14, 2018).

[126] "A Type A meeting is a meeting needed to help an otherwise stalled product development program proceed." U.S. FOOD & DRUG ADMIN., FORMAL MEETINGS BETWEEN THE FDA AND SPONSORS OR APPLICANTS—GUIDANCE FOR INDUSTRY 2 (May 2009), https://www.fda.gov/media/72253/download.

violated FDA-regulated product in interstate commerce, come in to play. Post-approval, companies should continue to present truthful and non-misleading information and should ensure they adhere to the scope of their approved application and required labeling. This may include disclosures about more nuanced FDA regulatory issues, such as carefully explaining areas where FDA has expressed an intention to exercise enforcement discretion, and in promotional materials where companies compare their FDA-approved product to that of a competitor.[127]

Ideally, a company would involve in-house and outside counsel in its review process, and many companies do just that, for example, through a Promotional Review Committee (PRC) or Medical, Legal, Regulatory (MLR) committee that reviews advertising and labeling for compliance with the FDCA, its implementing regulations, and applicable FDA guidance. If any FDA or SEC investigation were to occur, such steps would help show the efforts the company took to get to the right result and make it more difficult to draw the conclusion that the company knowingly or negligently engaged in a misrepresentation or acted with an intent to defraud or mislead. More generally, companies should also take steps to ensure that they have a robust compliance program and that all employees are trained regularly on compliance policies and procedures.

V. CONCLUSION

Parallel enforcement is not a new phenomenon for the government, and it appears to be gaining favor among regulators. Ultimately, companies that find themselves in such situations should take care to understand the statutory mandates and key issues that will be important to each set of regulators, as well as the potential exposure presented by the allegations under the various statutes. For example, both SEC and DOJ are likely to be interested in evidence to show the necessary intent for various potential charges. However, OCI is likely to also be focused on public health risks of the alleged conduct, whether the responsible corporate officers had the ability to prevent or correct the violations, and the number of shipments that crossed state lines to support the interstate commerce elements required for most FDCA charges. Additionally, FDCA criminal investigations are likely to include other federal crimes, such as health care fraud, smuggling, and mail and wire fraud, among others. Being able to anticipate the steps and timing of parallel investigations is crucial for companies and their C-suites that are navigating responses to government enforcement actions.

[127] *See, e.g.*, U.S. FOOD & DRUG ADMIN., Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers—Guidance for Industry 8 (June 2018), https://www.fda.gov/media/102575/download.