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## Fraud or Confusion: A Pill for Chronic Securities Litigation in the Life Sciences Sector

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# FRAUD OR CONFUSION: A PILL FOR CHRONIC SECURITIES LITIGATION IN THE LIFE SCIENCES SECTOR

**Abstract:** Publicly traded life science companies must navigate two overlapping regulatory agencies with distinct disclosure policies. The Food & Drug Administration (FDA) has a policy of under-disclosure to incentivize drug development while the Securities and Exchange Commission (SEC) encourages over-disclosure to avoid securities fraud. The FDA's far-reaching and complex regulations, coupled with its acquiescence to confidentiality, obfuscates a life science company's obligations under SEC regulation; as a result, life science companies are an attractive target for securities litigation. This Note explores the interplay between FDA and SEC regulations to pinpoint the source of the disproportionately high rate of securities litigation. It identifies two possible causes, one calling for drastic reforms and the other requiring a modest solution in comparison. It subsequently recommends the FDA release broad guidance on good disclosure practices in an attempt to reduce litigation for life science companies before more radical reforms are required.

## INTRODUCTION

Publicly traded life science companies primarily operate in two regulatory domains, complying with both the FDA and the SEC.<sup>1</sup> The FDA seeks to promote public health by ensuring the safety and efficacy of marketed drugs, while the SEC protects investors against securities fraud.<sup>2</sup> Balancing these distinct interests has created unique regulatory stressors that place life science companies in an increasingly vulnerable position.<sup>3</sup> The crux of this risk is a life science company's decision on what information, if any, it will disclose to investors.<sup>4</sup>

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<sup>1</sup> See Joseph G. Milner, *Sunlight and Other Disinfectants: Disclosure Obligations Under the Federal Securities and Regulatory Regimes*, 72 FOOD & DRUG L.J. 141, 143 (2017) (describing the regulatory purpose of the Food & Drug Administration (FDA) and the Securities and Exchange Commission (SEC) and how they interact with life science companies).

<sup>2</sup> See *id.* (pointing to the distinct regulatory purposes of the SEC and FDA).

<sup>3</sup> See Katherine Cohen et al., *Predictable Materiality: A Need for Common Criteria Governing the Disclosure of Clinical Trial Results by Publicly-Traded Pharmaceutical Companies*, 29 J. CONTEMP. HEALTH L. & POL'Y 201, 202 (2013) (investigating the difficulties that life science companies face when assessing materiality for SEC disclosures); Stuart R. Cohn & Erin M. Swick, *The Sitting Ducks of Securities Class Action Litigation: Bio-Pharmas and the Need for Improved Evaluation of Scientific Data*, 35 DEL. J. CORP. L. 911, 914 (2010) (analyzing the confusion surrounding materiality for life science companies); Milner, *supra* note 1, at 143 (assessing the competing disclosure issues in the life science sector generated by the separate regulatory purposes).

<sup>4</sup> See Milner, *supra* note 1, at 143–45 (highlighting the importance of disclosure decisions that generate legal liability for life science companies).

The FDA puts new drugs through a rigorous approval process to ensure their safety and efficacy.<sup>5</sup> The information generated from this process mostly remains confidential due to statutory constrictions on FDA disclosure and deep-rooted incentives for life science companies to protect their competitive advantage.<sup>6</sup> Simultaneously, the SEC encourages life science companies to over-disclose information related to the FDA approval process to avoid misleading investors and subsequent securities litigation.<sup>7</sup>

Obfuscating the issue is the SEC's disclosure trigger—materiality—that asks companies to assess the significance of a given fact from the perspective of a reasonable investor.<sup>8</sup> Because the FDA must determine that a drug is safe and effective before it is sold to consumers, the FDA effectively dictates the marketability of a life science company's product.<sup>9</sup> As the FDA regulates the marketability of a drug, so too does it heavily influence the materiality of information produced.<sup>10</sup> Life science companies are therefore subjected to disclosure requirements from one regulatory agency that are triggered by the decisions of another.<sup>11</sup> Where the FDA promulgates intricate regulations spanning decades, but offers no guidance on disclosure practices, life science companies must constantly predict what information is significant enough to the FDA that it may be material, and require disclosure, under SEC regulation.<sup>12</sup>

The confidentiality incentives and complex disclosure triggers created by the regulatory bodies have sparked a hotbed for litigation in the life science sector.<sup>13</sup> In 2017 alone, eighty-eight securities lawsuits were filed against life sci-

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<sup>5</sup> See Cohn & Swick, *supra* note 3, at 916–23 (providing a full description of FDA pre- and post-market approval regulation).

<sup>6</sup> See Milner, *supra* note 1, at 144–45 (describing this information as competitive trade secrets protected under federal law).

<sup>7</sup> See Cohn & Swick, *supra* note 3, at 924, 926–29 (highlighting the extensive disclosure requirements and pressures placed on life science companies by securities regulation and investors).

<sup>8</sup> See Milner, *supra* note 1, at 149 (explaining the materiality standard promulgated by the SEC that often prompts disclosure requirements).

<sup>9</sup> See *id.* at 153 (pointing to the FDA's authority to prohibit the marketing of a drug unless it has received approval).

<sup>10</sup> See Cohn & Swick, *supra* note 3, at 925 (describing how the marketability of a drug, as influenced by the FDA, is significant to investors and therefore affects materiality).

<sup>11</sup> See *id.* (explaining how the FDA's effect on marketability generates information that is material to a reasonable investor).

<sup>12</sup> See Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 26 (2016) (estimating the average length of time for FDA approval of a sample of drugs to be eleven years and considering post-approval regulation that can span years).

<sup>13</sup> See DAVID H. KISTENBROKER ET AL., DECHERT LLP, DECHERT SURVEY: DEVELOPMENTS IN SECURITIES FRAUD CLASS ACTIONS AGAINST U.S. LIFE SCIENCES COMPANIES, at 6 (2018), <https://www.dechert.com/knowledge/publication/2018/2/dechert-survey—developments-in-securities-fraud-class-actions-a.html> [<https://perma.cc/EV2A-Y3SW>] (finding a disproportionately high number of securities class action suits against life science companies); see also Cohn & Swick, *supra* note 3, at

ence companies, representing twenty-one percent of all securities suits filed.<sup>14</sup> This number has been increasing, as life science companies faced 225% more securities suits in 2017 than 2012.<sup>15</sup>

Part I of this Note provides the regulatory framework in which life science companies operate.<sup>16</sup> Part II discusses the confusions surrounding the legal standard of materiality which acts as a trigger for disclosure requirements under the SEC.<sup>17</sup> Finally, Part III argues that there are two possible causes of the securities litigation problem: intentional fraud or reckless fraud as a result of confusion surrounding the SEC's materiality standard in the context of FDA regulation.<sup>18</sup> It calls for comprehensive guidance from the FDA that clarifies best disclosure practices such that life science companies can accurately predict the materiality of events.<sup>19</sup>

## I. REGULATORY REALITY FOR LIFE SCIENCE COMPANIES

This Part explores the various regulatory requirements placed on publicly traded life science companies and the subsequent safeguards for confidentiality.<sup>20</sup> Section A outlines the FDA's drug approval process, post-approval regulation, and the incentives that attract life science companies.<sup>21</sup> Section B explains the FDA's statutory requirements to keep drug sponsor information confidential.<sup>22</sup> Finally, Section C provides an overview of regulations promulgated by the SEC that is relevant to life science companies.<sup>23</sup>

### A. FDA Regulation of Drug Products

An understanding of the extensive and costly FDA approval process is required to appreciate the disclosure tensions placed on life science companies.<sup>24</sup> Life science companies are subject to immense pre- and post-market regulations that span almost two decades.<sup>25</sup> The huge cost of complying with these regula-

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915 (discussing the interaction between FDA and SEC regulations that generate heightened risk for life science companies).

<sup>14</sup> See KISTENBROKER ET AL., *supra* note 13, at 5 (pointing out the disproportionately high number of securities suits for life science companies compared to their market share).

<sup>15</sup> See *id.* (compiling lawsuit data from 2012 to 2017).

<sup>16</sup> See *infra* notes 20–147 and accompanying text.

<sup>17</sup> See *infra* notes 148–220 and accompanying text.

<sup>18</sup> See *infra* notes 221–272 and accompanying text.

<sup>19</sup> See *infra* notes 257–272 and accompanying text.

<sup>20</sup> See *infra* notes 21–147 and accompanying text.

<sup>21</sup> See *infra* notes 24–77 and accompanying text.

<sup>22</sup> See *infra* notes 78–99 and accompanying text.

<sup>23</sup> See *infra* notes 100–147 and accompanying text.

<sup>24</sup> See Cohn & Swick, *supra* note 3, at 924 (explaining how the ongoing FDA-Sponsor communications and clinical trial data create the regulatory clash).

<sup>25</sup> See DiMasi et al., *supra* note 12, at 31 (calculating the full cost of drug development and post-approval monitoring to be \$2.9 billion).

tions naturally generates trade secrets that offer a competitive advantage.<sup>26</sup> Accordingly, the large research and development costs incentivize sponsors to keep any and all competitive advantages confidential.<sup>27</sup>

### 1. Pre-Market Regulation

The FDA derives its statutory authority to regulate drug products from the Federal Food, Drug and Cosmetic Act of 1938 (FDCA).<sup>28</sup> To promote public health, the FDA requires companies prove the safety and efficacy of any drug before it is marketed to consumers.<sup>29</sup> Highly regulated clinical investigations must be conducted by the appropriate personnel to prove a new product's safety and efficacy for human use.<sup>30</sup>

Research and development (R&D) of a new product to prove its safety and efficacy goes through three distinct steps: (1) pre-clinical testing, (2) clinical trials, and (3) post-clinical steps.<sup>31</sup> Prior to FDA involvement, companies initiate drug discovery programs to find chemical compounds with promising treatment potential.<sup>32</sup> They then test those compounds on animal subjects in pre-clinical studies to confirm the initial findings of drug effectiveness.<sup>33</sup> Although the FDA does not directly regulate pre-clinical investigations, companies design them with FDA standards in mind to raise the odds of subsequent approval for clinical trials.<sup>34</sup>

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<sup>26</sup> Milner, *supra* note 1, at 144. "Trade secret" is a term of art that grants special protected status barring disclosure by federal agencies or actors. See 18 U.S.C. § 1905 (2018) (prohibiting the release of information that qualifies as a trade secret).

<sup>27</sup> See Milner, *supra* note 1, at 144–45 (likening this information to business strategies that allow a company to maximize profit after making investments).

<sup>28</sup> See Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 U.S.C. §§ 301–399 (2018) (providing the FDA regulatory authority to ensure the safety and efficacy of food, drugs, and cosmetics); Allison Stoddart, Note, *Missing After Mensing: A Remedy for Generic Drug Consumers*, 53 B.C. L. REV. 1967, 1971–73 (explaining that the lengthy and expensive drug approval process heavily incentivizes drug companies to protect their investment through all means possible).

<sup>29</sup> See Cohn & Swick, *supra* note 3, at 917 (showing Congress at the time was concerned with fraudulent marketing of ineffective drugs that may be detrimental to a person's health).

<sup>30</sup> See *id.* (pointing to the extensive and intricate clinical trials necessary to prove a drug's safety and efficacy).

<sup>31</sup> See *id.* (using the clinical trials as the reference point, indicating their significance in the approval process).

<sup>32</sup> See *id.* (discussing research programs initiated by life science companies to identify marketable drugs).

<sup>33</sup> See PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 669–70 (4th ed. 2014) (indicating the significance of animal trials before any testing is conducted in human subjects).

<sup>34</sup> See *id.* (showing how life science companies structure their decisions around FDA authority even when they do not regulate that activity). Pre-clinical studies should yield preliminary information on the drug's efficacy, manufacturing constructs, and toxicity in animals. See *id.* at 670–71 (projecting success with important clinical trial goals).

A drug may then proceed to clinical trials in the absence of FDA objection.<sup>35</sup> Clinical trials were traditionally broken down into distinct groups called Phase I, II, and III, but recent FDA guidance has blurred these distinctions.<sup>36</sup> Companies are encouraged to conduct an exploratory investigational new drug (IND) study, or Phase Zero Trial, to screen out compounds likely to fail in clinical trials.<sup>37</sup> Phase I then explores the side effects on humans at various doses so an effective Phase II study can be designed.<sup>38</sup> Subsequent Phase II studies seek to produce preliminary data on the efficacy of a drug and identify any prominent short-term side effects.<sup>39</sup>

Phase III studies are the crux of the FDA approval process and provide the backbone for a drug's claim of safety and efficacy.<sup>40</sup> These studies administer the drug at its intended doses to the population it seeks to treat.<sup>41</sup> Companies conducting Phase III studies, with FDA consultation, establish key endpoints they hope the drug will achieve during the trials.<sup>42</sup> Such endpoints provide a

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<sup>35</sup> See Cohn & Swick, *supra* note 3, at 917 (explaining how the FDA must take affirmative action to stop a company from proceeding with clinical trials).

<sup>36</sup> See 21 C.F.R. § 312.21 (2019) (creating three phases of clinical investigations); see also HUTT ET AL., *supra* note 33, at 678 (pointing to the recent addition of Phase Zero clinical trials which has obfuscated traditional approval stage demarcations). The traditional three-phase structure for FDA approval has recently seen the addition of both Phase Zero and Phase IV trials, which may be required. See HUTT ET AL., *supra* note 33, at 678 (describing when the extra phases may be needed).

<sup>37</sup> See CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, INVESTIGATORS, AND REVIEWERS: EXPLORATORY IND STUDIES, at 1 (2006), <https://www.fda.gov/files/Guidance-to-Industry-and-Reviewers—Exploratory-IND-Studies-%28PDF%29.pdf> [<https://perma.cc/P944-GPVS>] (naming Phase Zero trials “exploratory IND [(investigational new discovery) studies” according to official FDA guidance). These initial studies do little to prove a drug's safety and efficacy because they are not typically conducted with humans. See *id.* at 3 (alluding to the FDA's preference for a smaller number of successful IND applications instead of a larger number of unfiltered applications).

<sup>38</sup> See 21 C.F.R. § 312.21(a) (describing the results and structure of Phase I clinical trials that allow Phase II trials to begin). Phase I studies should examine the metabolic and pharmacologic actions of the drug in the human body and any associated side effects. *Id.* Twenty to eighty subjects participate in Phase I trials. *Id.*

<sup>39</sup> See *id.* § 312.21(b) (explaining that Phase II trials are more stringently controlled to produce stronger data of safety and efficacy). Results from Phase II trials may produce a dose/response curve and data on benefits to the general population derived from a few hundred subjects. *Id.*

<sup>40</sup> See HUTT ET AL., *supra* note 33, at 681–82 (highlighting the importance of Phase III results in the FDA's ultimate benefit-risk analysis).

<sup>41</sup> See *id.* (providing efficacy data that will support a bid for FDA approval). The larger population sample and longer duration provide more data on a drug's risks and effectiveness, allowing the FDA to adequately weigh the risks and benefits of market approval. *Id.*

<sup>42</sup> See ONCOLOGY CTR. OF EXCELLENCE ET AL., U.S. FOOD & DRUG ADMIN., CLINICAL TRIAL ENDPOINTS FOR THE APPROVAL OF CANCER DRUGS AND BIOLOGICS: GUIDANCE FOR INDUSTRY, at 1–3 (2018), <https://www.fda.gov/media/71195/download> [<https://perma.cc/P5LE-3HLM>] (providing the regulatory authority for relying on endpoints to deduce the efficacy of a drug treating cancer). Clinical endpoints are physiological indicators, such as blood pressure, that are generally accepted in the medical field as having a relationship with primary outcomes such as survivability. See *id.* at 2 (“[T]he FDA may grant approval based on an effect on a surrogate endpoint that is *reasonably likely* to predict clinical benefit.”).

glimpse into the marketability of a drug if it were to succeed in Phase III trials and receive full FDA approval for the desired indications.<sup>43</sup> Data from a successful Phase III trial should justify an assumption of safety and efficacy for a drug's use in the general population.<sup>44</sup>

Following successful clinical trials, a drug moves into the post-clinical stage in which the sponsor files a new drug application (NDA) for market approval.<sup>45</sup> The NDA should provide everything there is to know about the drug thus far, including the events of the new drug approval process, the safety and efficacy data, manufacturing information, and proposed labeling.<sup>46</sup> A team comprising various disciplines then determines if the drug meets FDA standards of safety, efficacy, and quality needed for market approval.<sup>47</sup> The review team generates an opinion to either approve or deny the application that a senior FDA official takes into consideration when making the ultimate determination of approval.<sup>48</sup>

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<sup>43</sup> See *id.* at 3–4 (allowing the inference that a drug may be approved for marketing to specific endpoint populations, which can be measured to estimate profitability).

<sup>44</sup> See HUTT ET AL., *supra* note 33, at 681–82 (comprising an essential component of the marketing application that allows the FDA to conduct a risk-benefit analysis). This information is also used to create adequate labeling pursuant to FDA requirements. See 21 C.F.R. § 312.21(c) (highlighting the uses of Phase III data in FDA regulation).

<sup>45</sup> Cohn & Swick, *supra* note 3, at 918.

<sup>46</sup> See *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> [<https://perma.cc/37NW-4622>] (providing a template for new drug applications (NDAs) and what information should be included). An NDA is the sole vehicle through which a company may commercialize a drug product. See *id.* (stating that every new drug since 1938 has submitted an NDA before market approval). Applicants should include all preceding animal and human clinical trials so the FDA can effectively review the drug's safety and efficacy. See *id.* (accomplishing this by using NDAs "to tell the drug's whole story"). The FDA also reviews proposed labeling and manufacturing controls that must be approved before commercialization. *Id.*

<sup>47</sup> See *Review Team Responsibilities*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm161531.htm> [<https://perma.cc/CND6-8Q5T>] (describing the composition and function of the review team). Each review team consists of a project manager, medical officer, pharmacology/toxicology specialist, statistician, clinical pharmacology/biopharmaceutics expert, and some combination of chemists, biologists, and microbiologists. See *id.* (explaining in detail the responsibilities of each review team member).

<sup>48</sup> See *Step 4: FDA Drug Review*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405570.htm> [<https://perma.cc/U99N-AAZK>] (highlighting that the review team's expert recommendation is not dispositive, leaving room for counterintuitive results). The review team has six to ten months to review an NDA as well as to inspect on-site manufacturing practices. See *id.* (describing how each member independently reviews the portion of the application within their area of expertise and then compiles their review with others to create a general recommendation).

## 2. Post-Market Regulation

Even after a drug is approved for marketing, the FDA must continue to ensure its safety and efficacy for the general population.<sup>49</sup> Drug manufacturers are therefore subject to post-approval safety monitoring and reporting requirements.<sup>50</sup> For example, a drug sponsor must report specified adverse drug events within fifteen days and submit quarterly reports of any other adverse events for three years following NDA approval.<sup>51</sup>

The FDA may also condition NDA approval on a sponsor's agreement to conduct post-approval testing, called Phase IV clinical trials.<sup>52</sup> For drugs that have already received marketing approval, the FDA may require a company to conduct Phase IV studies if new information about a drug's safety is discovered.<sup>53</sup> Further, companies must include progress reports for Phase IV studies in each of their annual NDA reports and provide specific reasons for any delay in post-approval trials.<sup>54</sup>

If an approved drug appears to pose a safety threat or proves to be ineffective, the FDA may require a recall.<sup>55</sup> The FDA provides for two avenues of recall: a voluntary recall or a recall requested by the FDA.<sup>56</sup> Typically sponsors voluntarily recall a drug when new information poses serious questions about the drug's safety.<sup>57</sup> Companies thus must remain vigilant in their post-approval

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<sup>49</sup> See HUTT ET AL., *supra* note 33, at 834–59 (outlining the FDA's extensive post-approval regulation that ensures ongoing safety and efficacy of a drug).

<sup>50</sup> See *id.* (describing the broad post-approval regulations needed to ensure ongoing safety and efficacy).

<sup>51</sup> See 21 C.F.R. § 314.80(c) (requiring sponsors to report any "serious adverse drug experience" that happens when any one of the drug responses enumerated in § 314.80(a) occurs). A company need only submit annual reports of other adverse events more than three years after NDA approval. *Id.* § 314.80(c)(2)(i).

<sup>52</sup> See 21 U.S.C. § 355(o)(3)(A) (allowing the secretary to demand post-approval clinical trials as a condition for commercialization). Post-approval studies are typically focused on monitoring a drug's safety as it is used in the general population. See *id.* § 355(o)(3)(B) (pointing to risk assessment as the primary purpose for post-approval studies).

<sup>53</sup> See *id.* § 355(o)(3)(C) (making the presence of new safety information a necessity for demanding Phase IV studies from already approved drugs). "New safety information" is defined as any information suggesting that the drug poses a serious risk or that the sponsor's risk evaluation and mitigation strategies are ineffective. See *id.* § 355-1(b)(3) (allowing a wide range of sources for the new information).

<sup>54</sup> See 21 C.F.R. § 314.81(b)(2)(vii) (enumerating status reports on post-approval studies as a requirement for annual NDA reports). The regulation asks that progress reports uniquely describe the post-marketing study, provide a study schedule for significant milestones, and list the current status of any post-marketing studies. See *id.* (providing specific guidelines for submissions requiring that the reasons for any delay provide a direct explanation for each change in the post-marketing study schedule).

<sup>55</sup> See *id.* § 7.40 (providing that recall is appropriate where a product threatens public health and well-being).

<sup>56</sup> See *id.* § 7.40(b) (establishing the methods by which the FDA recalls products).

<sup>57</sup> See *id.* ("A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations . . ."); see also *FDA 101: Product Recalls*, U.S. FOOD & DRUG ADMIN., <http://>



monitoring requirements and be willing to submit unfavorable reports to the FDA if such information is found.<sup>58</sup> During recalls, the FDA supervises the company's recall plan to make sure it is sufficiently implemented and effectively notifies the public about the product's dangers.<sup>59</sup>

### 3. Incentives and the Cost of Doing Business

The extensive pre- and post-approval regulations create a large financial burden on a company.<sup>60</sup> Achieving market approval takes an average of eleven years and creates \$2.6 billion in R&D costs.<sup>61</sup> With additional post-approval costs, the total average bill reaches a staggering \$2.9 billion per new drug.<sup>62</sup>

Intellectual property laws that grant patents lasting twenty years from the time of filing are the primary mechanism for protecting a life science company's investment in developing a new drug.<sup>63</sup> A patented drug still cannot generate revenue from sales of the drug until the FDA approves it for marketing.<sup>64</sup> To combat this issue, the U.S. Patent and Trademark Office (USPTO) offers Patent Term Extensions (PTE) for inventions that required extensive regulatory review

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[www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm) [<https://perma.cc/VCD4-WVBG>] (detailing the normal recall process). New information about a drug's safety can be discovered in a myriad of ways including sponsor divulgence, FDA inspection, health reports, or discussions with the Centers for Disease Control and Prevention. *See FDA 101: Product Recalls, supra* (providing potential sources of new safety information). If new safety information changes the FDA's cost-benefit analysis of a drug such that it poses a serious hazard, it will alert the public. *See id.* (disseminating this information through press conferences, public press releases, and updates to the FDA's website).

<sup>58</sup> *See FDA 101: Product Recalls, supra* note 57 (indicating the extensive post-approval requirements levied on life science companies).

<sup>59</sup> *See FDA's Role in Drug Recalls*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DrugSafety/DrugRecalls/ucm612550.htm> [<https://perma.cc/U7S2-4VTW>] (stating the FDA's commitment to enforce drug recalls and its role in the process). The FDA classifies recalls in three groups based on the threat posed. *Id.* Additionally, the FDA updates recalls through weekly enforcement reports. *See id.* (allowing investors to see the status of various drug recalls). If a recall strategy is deemed ineffective, the FDA will impose further requirements to ensure public safety. *Id.*

<sup>60</sup> *See DiMasi et al., supra* note 12, at 31 (analyzing a random sample of 106 new drugs researched by ten international pharmaceutical companies).

<sup>61</sup> *See id.* (considering the costs of both failed new drugs and those granted market approval). The investigators estimated the direct research cost per new drug as well as the added costs of having money tied up in a research project for over a decade. *See id.* at 24 (measuring capitalized investment costs with a model that balances the cost of equity and debt to pharmaceutical companies). The \$2.6 billion represents the combined cost for direct investment and lost opportunity due to private research. *See id.* at 24, 31 (accounting for vacillations in market health and increased inflation).

<sup>62</sup> *See id.* at 26, 31 (incorporating costs associated with required postmarketing research, reporting, and monitoring requirements).

<sup>63</sup> *See* 35 U.S.C. § 154(a) (2018) (providing twenty-year patents starting from the date filed with the U.S. Patent and Trademark Office). The holder of a patent on a drug has the right to exclude others from manufacturing, marketing, using, and selling that drug in the United States for the term of the patent. *Id.*

<sup>64</sup> *See* 21 C.F.R. § 314.1 (requiring FDA approval before a drug can be marketed in the United States).

before marketing.<sup>65</sup> Nonetheless, the maximum PTE is a meager five years, a far cry from a decade or more lost in regulatory limbo.<sup>66</sup> The length of the FDA's approval process therefore directly reduces a company's ability to capitalize on its investment, creating temporal pressures to achieve approval as fast as possible.<sup>67</sup>

To supplement drug patents, the FDA offers various incentives to encourage investments in innovative new drugs.<sup>68</sup> Certain drugs are granted exclusive marketing rights that statutorily preclude the FDA from approving other similar drugs.<sup>69</sup> For instance, the FDA provides seven years of market exclusivity to Orphan Drugs that target conditions afflicting fewer than 200,000 people in the United States.<sup>70</sup> The FDA also grants five-year market exclusivity to new chemicals and three-year exclusivity when an NDA submits a new clinical investigation deemed essential to its approval.<sup>71</sup> FDA-granted market exclusivity begins

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<sup>65</sup> See 35 U.S.C. § 156 (allowing Patent Term Extensions (PTE) if (1) the patent has not expired; (2) the patent has not been extended before; (3) a timely application has been filed; (4) the invention was subjected to a "regulatory review period;" and (5) the marketing approval is novel, except for technology primarily using recombinant DNA methods). For new drugs, the "regulatory review period" is calculated as the sum of the time taken for new drug trials and application approval to be achieved. See *id.* § 156(g)(1)(B) (providing a formula for calculating the regulatory review period); *Small Business Assistance: Frequently Asked Questions on Patent Term Restoration Program*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program> [<https://perma.cc/V45P-RCCE>] (explaining that the regulatory review period is broken into two periods, the testing phase and approval phase). Further minimizing the benefits of a PTE, active ingredients in a drug constitute a "product" under the statute which may limit a patent holder's ability to extend a patent that uses an already extended active ingredient patent. See Scott Whittaker & Anthony Walker, *Pharmaceutical Patent Term Extension: An Overview*, ALACRITA, <https://www.alacrita.com/whitepapers/pharmaceutical-patent-term-extension-an-overview> [<https://perma.cc/GX7H-RX8Y>] (acknowledging that PTEs are limited to the patented active ingredient); *Small Business Assistance: Frequently Asked Questions on Patent Term Restoration Program*, *supra* (clarifying what constitutes an active ingredient).

<sup>66</sup> 35 U.S.C. § 156(g)(6)(A).

<sup>67</sup> See *id.* § 154(a)(2) (providing twenty-year patents); see also Cohn & Swick, *supra* note 3, at 924 (describing market pressure on FDA companies to reach approval).

<sup>68</sup> See Milner, *supra* note 1, at 185 (pointing to the FDA's promise of confidentiality and grant of exclusive marketing for certain drugs).

<sup>69</sup> See CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE, FDA/CDER SBIA CHRONICLES: PATENTS AND EXCLUSIVITY, at 2 (2015), <https://www.fda.gov/downloads/drugs/developmentapproval-process/smallbusinessassistance/ucm447307.pdf> [<https://perma.cc/84VZ-G52U>] (describing the exclusivity granted to various drug applications). The FDCA, as amended, creates exclusivity in four different scenarios because the FDA is statutorily barred from approving competing drugs. See *id.* (distilling the statutory requirements for each situation).

<sup>70</sup> See *id.* (describing Orphan Drug status as "[g]ranted to drugs designated and approved to treat diseases or conditions affecting fewer than 200,000 in the U.S. (or more than 200,000 and no hope of recovering costs)").

<sup>71</sup> See *id.* (outlining the statutory requirements for marketing exclusivity). New chemicals are defined as drugs that contain a chemical moiety not yet granted approval by the FDA. *Id.*

at the time of approval, thereby failing to provide further protection unless a drug's patent life is nearly over.<sup>72</sup>

At the core of an applicant's willingness to invest in FDA regulated R&D is the FDA's promise of confidentiality.<sup>73</sup> Due to its interpretation of federal statutes restricting disclosures from federal agencies, the FDA has generally held sponsor information as confidential and refused to release it to the public.<sup>74</sup> Because the FDA expects constant communication with a company regarding its application and clinical trial progress, it is privy to vast amounts of sensitive information.<sup>75</sup> These communications often contain valuable information produced during the application process such as safety and efficacy data, intellectual property, manufacturing practices, and more.<sup>76</sup> Without the confidentiality requirement, information produced from multi-billion dollar investments could be disclosed to the public and subsequently utilized by competitors.<sup>77</sup>

### B. Confidentiality of FDA Correspondence and Data

Two statutes, the Trade Secrets Act and FDCA § 301(j), work in conjunction to create the FDA's requirement of confidentiality.<sup>78</sup> Together, these laws restrict the FDA's ability to disclose any sponsor information received through

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<sup>72</sup> See *id.* (explaining the time frames for market exclusivity for a variety of drugs).

<sup>73</sup> See Milner, *supra* note 1, at 144 (pointing to the FDA's promise of confidentiality as an assurance to life science companies). Companies investing billions into research and development (R&D) are comforted by the fact that new discoveries will remain private between them and the FDA. *Id.*

<sup>74</sup> See *id.* at 158–59 (“This interpretation reflects FDA’s belief that sponsor-provided clinical data is confidential information.”). The FDA has also previously defined trade secret as any information that provides a competitive advantage. See 39 Fed. Reg. 44,602, 44,613, 44,631 (Dec. 24, 1974) (determining that a trade secret, for the purposes of the Freedom of Information Act (FOIA), is any information that provides a competitive advantage). This interpretation, according to the FDA, was consistent with Section 757 of the *Restatement of Torts*, as well as the Supreme Court’s interpretation. See *id.* at 44,612 (citing Supreme Court dicta that the Restatement definition used by the FDA is “widely relied-upon” (quoting *Kewanee Oil Co. v. Bloron Corp.*, 416 U.S. 470, 474 (1974))).

<sup>75</sup> See CTR. FOR DRUG EVALUATION & RESEARCH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., BEST PRACTICES FOR COMMUNICATIONS BETWEEN IND SPONSORS AND FDA DURING DRUG DEVELOPMENT: GUIDANCE FOR INDUSTRY AND REVIEW STAFF, at 3 (2017), <https://www.fda.gov/files/drugs/published/Best-Practices-for-Communication-Between-IND-Sponsors-and-FDA-During-Drug-Development.pdf> [<https://perma.cc/4X4D-H72R>] (outlining the general principle of communication between the FDA and drug sponsor). The FDA should communicate about any scientific, medical, and procedural issues that emerge during the review process. See *id.* at 5 (accepting communications over various mediums). Simultaneously sponsors are expected to seek advice from the FDA where they are confused or unsure about their drug development. See *id.* (explaining the general responsibilities of both the FDA and drug sponsors during drug development).

<sup>76</sup> See *id.* at 5 (indicating that correspondence may contain clinical data, clinical trial design, financial information, operational choices, and more).

<sup>77</sup> See Milner, *supra* note 1, at 185 (showing how disclosure could lead to huge economic losses overseas).

<sup>78</sup> See 18 U.S.C. § 1905 (restricting federal agencies from releasing trade secrets); 21 U.S.C. § 331(j) (prohibiting the FDA from releasing any information protected as a trade secret under the Trade Secrets Act).

the drug application process.<sup>79</sup> The FDA is permitted to release certain confidential information in specific conditions pursuant to two other federal laws.<sup>80</sup> Nonetheless, these exceptions ultimately maintain the prohibition on FDA disclosure of a drug sponsor's trade secrets.<sup>81</sup>

### 1. Statutory Requirements of FDA Confidentiality

The FDA has interpreted the Trade Secrets Act and § 301(j) of the FDCA to explicitly prohibit the release of certain information produced during the drug application process.<sup>82</sup> The language of the Trade Secrets Act prohibits a federal agency from disclosing a company's trade secrets, processes, operations, or confidential statistical data unless authorized by law.<sup>83</sup> This does not create an absolute bar, however, as agencies may disclose trade secrets permitted by a separate statute.<sup>84</sup> The FDA's statutory authority, the FDCA, also explicitly restricts the release of trade secrets under § 301(j).<sup>85</sup> According to § 301(j), the agency may not reveal any trade secrets entitled to protection which the FDA acquired in the course of its regulation.<sup>86</sup>

Neither statute offers a definition of trade secret, but the FDA has implemented a broad interpretation of the term.<sup>87</sup> Historically, during the drug approval process, the FDA has refused to release any information that offers the company a competitive advantage.<sup>88</sup> Clinical trial results clearly offer a competitive advantage, and the FDA has accordingly refused to disclose safety and efficacy data.<sup>89</sup> The FDA similarly protects correspondence with drug sponsors during

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<sup>79</sup> See Milner, *supra* note 1, at 157 (describing how the FDA has interpreted 21 U.S.C. § 301(j) to bar the release of sponsor information).

<sup>80</sup> See *id.* (referencing FOIA and the Federal Advisory Committee Act (FACA)).

<sup>81</sup> See *id.* at 161 (pointing to exceptions in FOIA and FACA for information protected as trade secrets).

<sup>82</sup> See Public Information, 37 Fed. Reg. 9128, 9129 (proposed May 5, 1972) (to be codified in scattered pts. of 21 C.F.R.) (explaining the statutory FDA requirements of confidentiality and the FDA's interpretations of such statutes); see also Milner, *supra* note 1, at 157 (discussing the FDA's interpretation of its statutory authority to release drug sponsor information).

<sup>83</sup> See 18 U.S.C. § 1905 (applying to information received by federal agencies during their regulatory operations).

<sup>84</sup> See *id.* (prohibiting disclosures "to any extent not authorized by law"); see also Milner, *supra* note 1, at 158 (authorizing disclosure where another statute permits).

<sup>85</sup> See 21 U.S.C. § 331(j) (restricting the disclosure of "trade secrets" obtained through an extensive but enumerated number of regulatory provisions).

<sup>86</sup> See *id.* (applying to any trade secrets protected under the Trade Secrets Act); see also Public Information, 37 Fed. Reg. at 9129 (describing the FDA commissioner's interpretation of "trade secrets" as it relates to § 301(j)).

<sup>87</sup> See Milner, *supra* note 1, at 158 (exploring the FDA's refusal to release and sponsor submitted information because it may contain trade secrets).

<sup>88</sup> See 39 Fed. Reg. at 44,613, 44,631 (stating the FDA's refusal to disclose trade secrets that offer a current or future competitive advantage, as determined by the agency).

<sup>89</sup> See Milner, *supra* note 1, at 159 (pointing to the longstanding FDA practice of confidentiality regarding safety and efficacy data).

the approval process, which highlights the FDA's understanding that extensive sponsor communications often contain commercial secrets that offer a competitive advantage.<sup>90</sup>

## 2. Statutory Exceptions Allowing Disclosure

Though the FDA offers broad confidentiality to sponsors, two federal exceptions allow disclosure under narrow circumstances.<sup>91</sup> The Freedom of Information Act (FOIA) allows the public to request certain information from federal agencies such as internal policies, manuals, and records.<sup>92</sup> FOIA has allowed the public to obtain abandoned NDAs and protocols for post-market approval clinical studies.<sup>93</sup> Not all information must be released, however, and FOIA creates an exemption for trade secrets and confidential commercial information.<sup>94</sup> The FDA has functionally interpreted FOIA as exempting any information that creates a competitive advantage or is ordinarily kept confidential in the industry.<sup>95</sup>

The Federal Advisory Committee Act (FACA) requires advisory committee meeting materials be made public.<sup>96</sup> In compliance with FACA, the FDA generally posts background material for advisory meetings at least two days before the meeting and all meeting minutes within thirty days after.<sup>97</sup> The FDA has stated it will redact any FOIA-exempt information from meeting materials disclosed in accordance with FACA.<sup>98</sup> With this interpretation, FACA and FOIA do not di-

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<sup>90</sup> See *id.* (alluding to the FDA's preference against disclosure of confidential sponsor information because it would discourage cooperation and disclosure with the FDA).

<sup>91</sup> See *id.* at 160 (pointing to FOIA and FACA).

<sup>92</sup> See 5 U.S.C. § 552(a)(2) (2018) (outlining the types of files that federal agencies must make public).

<sup>93</sup> See Peter Lurie & Allison Zieve, *Sometimes the Silence Can Be Like the Thunder: Access to Pharmaceutical Data at the FDA*, LAW & CONTEMP. PROBS., Summer 2006, at 85, 94–96 (describing when public requests for information have been successful in requesting information from the FDA).

<sup>94</sup> See 5 U.S.C. § 552(b)(4) (exempting any “trade secrets and commercial or financial information obtained from a person and privileged or confidential”).

<sup>95</sup> See 39 Fed. Reg. at 44,631 (stating the FDA's position that it will not disclose information that provides a competitive advantage to a sponsor).

<sup>96</sup> See 5 U.S.C. app. II § 10(b) (2018) (requiring transcripts or material from advisory committee meetings to be posted publicly in one location).

<sup>97</sup> See *Common Questions and Answers About FDA Advisory Committee Meetings*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm> [<https://perma.cc/EDQ9-7YAT>] (detailing the FDA's compliance policies for FACA). The FDA uses advisory committees to provide third-party assessments of new drug applications that culminate in an independent recommendation for approval or disapproval of said application. See *Human Drug Advisory Committees*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/default.htm> [<https://perma.cc/VKR8-K7ZR>] (providing a brief description of an advisory committee's role). The advisory committee's recommendation is nonbinding, although the FDA usually follows it. *Id.*

<sup>98</sup> See U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY ADVISORY COMMITTEE MEETINGS—PREPARATION AND PUBLIC AVAILABILITY OF INFORMATION GIVEN TO ADVISORY COMMITTEE MEMBERS, at 10–11 (2008), <https://www.fda.gov/media/75436/download> [<https://perma.cc/LP36->

minish the FDA mandate to keep trade secrets and other confidential information private.<sup>99</sup>

### C. SEC Disclosure Requirements

Publicly traded life science companies face a peculiar challenge under SEC regulations that may require disclosure of confidential FDA trade secrets.<sup>100</sup> The volatility of the life science sector creates a heightened pressure to release information on a company's FDA approval progress.<sup>101</sup> In doing so, life science companies must be wary of both periodic disclosure requirements and investor communication rules.<sup>102</sup> Sponsors must identify what information is material to investors and be sure not to make misleading statements of either fact or opinion regarding that material information.<sup>103</sup> New amendments offer a safe harbor for forward-looking statements, but they do not always protect FDA-related disclosures.<sup>104</sup>

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7YD7] (providing examples of information typically protected under FOIA including manufacturing processes, clinical data, and non-labeled product information).

<sup>99</sup> See Milner, *supra* note 1, at 161 (explaining how the FDA refuses to disclose trade secrets under FOIA and FACA).

<sup>100</sup> See Cohen et al., *supra* note 3, at 231 (providing an example where securities regulation may require disclosure where the FDA does not); see also Andrew J. Ceresney et al., *INSIGHT: The SEC/FDA Nexus: Best Practices for Publicly Traded Life Science Companies*, BLOOMBERG L. (Nov. 19, 2018), <https://news.bloomberglaw.com/securities-law/insight-the-sec-fda-nexus-best-practices-for-publicly-traded-life-sciences-companies> [<https://perma.cc/A9RJ-KU87>] (“[D]isclosure may be required . . . where a company has incomplete information. A life sciences company may, for example, be uncertain about the status of the FDA’s regulatory review, have partial results from a pivotal clinical trial, or have reports of serious adverse events in the absence of confirmatory evidence.”). As Cohen describes, where pharmaceutical companies conduct extensive research on the economic viability of a drug, the SEC may require disclosure if the information is material to investors while the FDA remains indifferent. See Cohen et al., *supra* note 3, at 231.

<sup>101</sup> See Cohn & Swick, *supra* note 3, at 923–24 (describing the pressure levied on life science companies by hungry investors); see also Richard E. Baltz, *Biotech Cos. Face Pressure to Disclose*, LAW360 (May 9, 2016), <https://www.law360.com/articles/793630/biotech-cos-face-pressure-to-disclose> [<https://perma.cc/2P9L-89T9>]. Baltz writes:

Investors demand information about clinical trials and regulatory developments . . . . [T]he clinical stage company is valued by the market based on the perceived future potential of its product candidates. In this environment, investors do not perceive “no news” as “good news,” and silence can be reflected in a volatile stock price.

Baltz, *supra*.

<sup>102</sup> See Cohn & Swick, *supra* note 3, at 926–29 (exploring the various disclosure requirements placed on life science companies by the SEC).

<sup>103</sup> See *id.* at 929 (pointing to the difficulty in assessing materiality when the FDA and SEC do not maintain uniform standards); see also Ceresney et al., *supra* note 100 (“[A] company’s financial well-being is dependent on one developmental product, in which case even relatively routine regulatory developments may be deemed ‘material’ and require disclosure.”).

<sup>104</sup> See Milner, *supra* note 1, at 152–53 (explaining that the safe harbors of the Private Securities Litigation Reform Act of 1995 (PSLRA) do not apply to hard clinical trial data, SEC enforcement actions, or statements surrounding an Initial Public Offering (IPO)).

## 1. The Demand to Satiat Investors During FDA Approval Process

Investing in the life science sector is extremely risky due to the high failure rate for new drug applications and high R&D expenses.<sup>105</sup> Life science companies simultaneously offer a high return on investment if they strike gold with the next breakthrough drug.<sup>106</sup> Trying to stay ahead of the volatile market, investors apply constant pressure for updates on a company's drug approval status.<sup>107</sup> Companies may disclose this information in periodic reports required by the SEC or volunteer it on an ad hoc basis.<sup>108</sup>

Deciding what information to disclose, and how to frame disclosure for investors, offers an incredible challenge.<sup>109</sup> While pursuing FDA approval, there are countless setbacks, milestones, ambiguous clinical results, and seemingly insignificant communications that could affect the ultimate marketability of the drug.<sup>110</sup>

## 2. Periodic Disclosure Requirements

The Securities Act of 1933 and the Securities Exchange Act of 1934 establish periodic reporting requirements for companies that sell shares on the open market.<sup>111</sup> Companies entering the securities market through an initial public

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<sup>105</sup> See DiMasi et al., *supra* note 12, at 20, 31 (estimating full R&D costs at \$2.9 billion and elucidating the countless drugs that fail to achieve FDA approval).

<sup>106</sup> See Milner, *supra* note 1, at 145–46 (describing the high reward market in which life science companies operate); see also Celgene Corp., Annual Report 40 (Form 10-K) (Dec. 31, 2018) (reporting \$9.69 billion in net sales for Celgene's FDA approved drug Revlimid).

<sup>107</sup> See Milner, *supra* note 1, at 145–46 (discussing the pressure that the volatile life science investment market places on life science companies). The market is accordingly quick to react to any adverse news about a company's prospects for drug approval. See Ceresney et al., *supra* note 100 (explaining how a company's disclosure of efficacy data caused its stock price to fall sixty percent in one day); Alex Keown, *Akcea Therapeutics Stunned by FDA Rejection of FCS Treatment Waylivra, Shares Plunge*, BIOSPACE (Aug. 28, 2018), <https://www.biospace.com/article/akcea-therapeutics-stunned-by-fda-rejection-of-fcs-treatment-waylivra-shares-plunge/> [<https://perma.cc/9J8W-7ZET>] (reporting how the FDA's denial of a drug application caused a company's stock to fall by twenty-eight percent).

<sup>108</sup> See Cohn & Swick, *supra* note 3, at 926 (describing the methods by which companies may disclose information to investors).

<sup>109</sup> See *id.* at 924 (pointing to the disclosure pressures placed on FDA-regulated companies throughout the drug approval process).

<sup>110</sup> See *id.* (alluding to the stringent FDA regulations that create complex hurdles during the approval process); Ceresney et al., *supra* note 100 (pointing to nuanced scenarios where investors pressure a life science company to issue a statement, but the company is not fully equipped to accurately describe their regulatory status).

<sup>111</sup> See 15 U.S.C. § 77a–77aa (2018) (requiring companies planning to offer securities on a public exchange to file a registration that discloses material information); *id.* § 78a–78pp (granting the Securities and Exchange Commission (SEC) its authority to regulate public markets); see also Elisabeth Keller & Gregory A. Gehlmann, *A Historical Introduction to the Securities Act of 1933 and the Securities Exchange Act of 1934*, 49 OHIO ST. L.J. 329, 329–31 (1988) (exploring the history of securities regulation in the United States).

offering (IPO) must register with the SEC through a Form S-1.<sup>112</sup> This filing describes in narrative form the nature of the registrant's business, risks the business will face, and the business' financial condition.<sup>113</sup> After a company is registered on the exchange, it must submit templated periodic reports to update investors.<sup>114</sup> Companies must submit annual reports through Form 10-K, quarterly reports through Form 10-Q, and reports of other current events through Form 8-K.<sup>115</sup>

All of the forms must comply with Regulation S-K that establishes what information should be submitted.<sup>116</sup> Item 303 of Regulation S-K requires companies to submit management's discussion and analysis (MD&A) of their fiscal standing and operating results.<sup>117</sup> In their MD&As, companies explain any changes to their financial and operational condition.<sup>118</sup> Companies also provide projections for financial and operational targets and risks associated with those projections.<sup>119</sup> This requirement is particularly important for life science companies whose financial and operational condition is so closely tied to FDA approval.<sup>120</sup> These forward-looking projections are typically protected under the safe harbor amendments.<sup>121</sup>

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<sup>112</sup> See 17 C.F.R. § 239.11 (2019) (establishing the requirements for registration to the securities exchange).

<sup>113</sup> See *Form S-1*, at 4–5 (2019), U.S. SEC. & EXCHANGE COMM'N, <https://www.sec.gov/files/forms-1.pdf> [<https://perma.cc/5WXD-P72K>] (providing a template for IPO submissions to the SEC).

<sup>114</sup> See 15 U.S.C. § 78m(a)(2) (allowing the SEC to promulgate requirements of periodic reporting).

<sup>115</sup> See 17 C.F.R. § 240.13a-11; *id.* § 249.308a; *id.* § 249.310. Companies use Form 8-K when a material event, based on the facts and circumstances, occurs in-between periodic reports. See Div. of Corp. Fin., *Current Report on Form 8-K: Frequently Asked Questions*, U.S. SEC. & EXCHANGE COMM'N (Nov. 23, 2004), <https://www.sec.gov/divisions/corpfin/form8kfaq.htm> [<https://perma.cc/W2VE-4Y98>] (describing the ad hoc analysis needed to determine materiality).

<sup>116</sup> See 17 C.F.R. § 229.10 (necessitating management's discussion and analyses for virtually all SEC filings required by the Exchange Act).

<sup>117</sup> See *id.* § 229.303 (enumerating information to be submitted and further requiring issuers of stock to include any information they believe is relevant to understanding the company's financials and operations).

<sup>118</sup> See *id.* § 229.303(a) (including any changes that materially affected the amount of income, favorable or unfavorable impact on sales, and more). These requirements will naturally lead to life science companies including updates on FDA approval in their periodic filings because FDA approval has such a large economic impact on the company. See Cohn & Swick, *supra* note 3, at 917 (explaining how companies must receive FDA approval before marketing their drugs).

<sup>119</sup> See 17 C.F.R. § 229.303(a) (requiring the inclusion of risk to better inform investors).

<sup>120</sup> See Cohn & Swick, *supra* note 3, at 924, 927 (discussing how financial operations of life science companies are dictated by the FDA approval process).

<sup>121</sup> See Milner, *supra* note 1, at 148 (pointing out that projections, by their nature, are forward-looking statements). The PSLRA creates safe harbors that protect companies against liability for forward looking statements. See 15 U.S.C. § 78u-5(c) (protecting both oral and written statements).



### 3. Rule 10b-5, the Law of Not Misleading

The SEC disclosure requirements are enforced through Section 10(b) of the Securities Exchange Act of 1934.<sup>122</sup> Section 10(b) makes it unlawful to deceive investors in connection with purchases or sales of stocks traded on the exchange.<sup>123</sup> Under the authority of Section 10(b), the SEC promulgated Rule 10b-5 to combat companies that would defraud investors.<sup>124</sup> Pursuant to Rule 10b-5, companies may not release any untrue statement of material fact or fail to release a material fact necessary to make other statements not misleading.<sup>125</sup>

The U.S. Supreme Court has created a right of action for investors implied from the text and purpose of Section 10(b).<sup>126</sup> To succeed with this cause of action, plaintiffs must prove: (1) misrepresentation or omission of a material fact; (2) scienter; (3) connection to the buying or selling of a security; (4) reliance on the material misstatement or omission; (5) economic loss; and (6) causation between the reliance and economic loss.<sup>127</sup>

Proving scienter under the Private Securities Litigation Reform Act of 1995 (PSLRA) places a heavy burden on plaintiffs, as they must plead with particularity the facts giving rise to both the fraudulent statements and requisite state of mind for each statement made.<sup>128</sup> Unanimous circuit decisions lessen this burden, however, by allowing a recklessness standard where plaintiffs need only show that an inference of scienter is at least as compelling as the inference of nonfraudulent intent.<sup>129</sup>

Although courts have found that Rule 10b-5 prohibits the omission of a material fact, that is only true when the company has a duty to disclose that information.<sup>130</sup> A company only has a statutory duty to disclose information required

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<sup>122</sup> 15 U.S.C. § 78j; see Cohen et al., *supra* note 3, at 217 (describing Rule 10b as the primary enforcement tool because a private right of action has been imported).

<sup>123</sup> See 15 U.S.C. § 78j (counteracting companies that defraud investors).

<sup>124</sup> *Id.*; see Cohn & Swick, *supra* note 3, at 148 (recognizing Rule 10b-5 as the source for private enforcement actions against securities fraud).

<sup>125</sup> See 17 C.F.R. § 240.10b-5(b) (omitting a definition of materiality).

<sup>126</sup> See *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 318 (2007).

<sup>127</sup> See *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005) (laying out the six required elements for a Rule 10b-5 cause of action).

<sup>128</sup> See 15 U.S.C. § 78u-4(b)(2) (heightening the scienter pleading requirements for private securities claims).

<sup>129</sup> See *Tellabs, Inc.*, 551 U.S. at 314 (requiring only that evidence weighing for recklessness be equal to or greater than evidence weighing against it). See generally Kurtis A. Kemper, Annotation, *What Constitutes Recklessness Sufficient to Show Necessary Element of Scienter in Civil Action for Damages Under 10(b) of Securities Exchange Act of 1934 (15 USCS § 78j(b)) and Rule 10b-5 of the Securities and Exchange Commission?*, 49 A.L.R. FED. 392 (1980) (reviewing the decisions that allowed 10b-5 complaints in all circuits to proceed by showing recklessness).

<sup>130</sup> See *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44–45 (2011) (clarifying that Rule 10b-5 only creates an affirmative duty to disclose material facts where it is necessary to ensure that another material fact is not misleading). This leaves companies in control of what information they

in the periodic reports.<sup>131</sup> Accordingly, a company may choose not to disclose a material fact unless it is needed to make a periodic report or other statement not misleading.<sup>132</sup>

#### 4. Liability for Misleading or Untrue Statements of Opinion

In 2015, in *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, the Supreme Court considered the viability of a securities action claiming a company misled investors with false opinions.<sup>133</sup> At issue was Omnicare's registration statement filed publicly with the SEC regarding its IPO.<sup>134</sup> In the filing, Omnicare issued two statements establishing its belief that it was in full compliance with both state and federal law.<sup>135</sup> After Omnicare asserted these statements, the federal government brought enforcement actions against Omnicare for a scheme of accepting drug manufacturer rebates in violation of anti-kickback laws.<sup>136</sup> Investors subsequently filed a securities action accusing Omnicare of misleading its investors by providing opinions that the company could not have believed were true.<sup>137</sup>

In its opinion, the Court pointed to the language of the Securities Act of 1933 that only creates a right of action for untrue statements of fact.<sup>138</sup> Nonetheless, statements of opinion constitute actionable statements of fact in three dis-

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disseminate to their investors. *See id.* (qualifying that this holds true only in the absence of some other duty to disclose the information).

<sup>131</sup> *See* Cohn & Swick, *supra* note 3, at 147 (explaining that the Securities Act of 1933 and Securities Exchange Act of 1934 only create a duty to disclose information required in periodic reports); *see also* 17 C.F.R. § 240.13a-11 (outlining the Form 8-K requirements); *id.* § 249.308a (establishing Form 10-Q requirements); *id.* § 249.310 (creating Form 10-K requirements).

<sup>132</sup> *See* Basic Inc. v. Levinson, 485 U.S. 224, 239 n.17 (1988) ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5.").

<sup>133</sup> *See* 575 U.S. 175, 175 (2015) (analyzing whether a cause of action exists for misleading material opinions). Plaintiffs sued under Section 11 of the Securities Act of 1933, which contains the same enforcement language as Rule 10b-5. *See id.* at 176 (precluding companies from making untrue statements of material fact or omitting statements of material fact necessary to make other statements not misleading).

<sup>134</sup> *See id.* at 178 (pointing to investors as the target audience for such a filing).

<sup>135</sup> *See id.* at 180-82 (noting the use of "we believe" to indicate a statement of opinion as opposed to a statement of fact). These statements were accompanied by cautionary language warning of increased federal enforcement actions for similarly situated companies and that their interpretation of compliance is subject to alternative opinions. *See id.* at 180-81 (attempting to fall within the PSLRA safe harbor provision bespeaks caution doctrine).

<sup>136</sup> *See id.* at 183 (making it clear that Omnicare's opinions were incorrect).

<sup>137</sup> *See id.* at 186 (highlighting internal communications that showed Omnicare officers did not have reasonable grounds to believe that their actions complied with anti-kickback laws). The Sixth Circuit Court of Appeals reversed the district decision to grant Omnicare's motion to dismiss, finding an opinion that turns out to be untrue can constitute a false statement of fact. *See id.* at 182.

<sup>138</sup> *See id.* at 182-84 (stating that "facts" and "opinions" are different by definition and Congress acted purposefully when using the word fact).

tinct avenues outlined by the Court.<sup>139</sup> First, material misrepresentations of opinion create liability if the opinion is false and the issuer knows such to be false.<sup>140</sup> Second, liability may exist where a statement of opinion is embedded with underlying statements of fact that are materially false or misleading.<sup>141</sup> Lastly, the Court held that omission of a material fact necessary to make a statement of opinion not misleading to a reasonable investor may give rise to liability.<sup>142</sup>

## 5. PSLRA Safe Harbor Provisions for Forward-Looking Statements

Recognizing the liability created by projection requirements in Regulation S-K and fraud protections in Rule 10b-5, Congress created safe-harbor provisions in the PSLRA for three scenarios: (1) forward-looking statements coupled with specifically tailored cautionary language; (2) immaterial forward-looking statements; and (3) forward-looking statements made without actual knowledge of falsity or its misleading nature.<sup>143</sup> At first glance, the PSLRA safe harbor appears to provide substantial protection for life science companies, but it is severely limited in a few key ways.<sup>144</sup> Most important for life science companies, hard data falls outside the definition of a “forward-looking statement” that the safe harbor protects; therefore, the clinical data underlying projections may be the subject of litigation.<sup>145</sup> The safe harbor provisions also only apply to private litigation, leaving forward-looking statements open to an SEC enforcement ac-

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<sup>139</sup> See *id.* at 183–87 (outlining three theories of liability for materially misleading statements of opinion).

<sup>140</sup> See *id.* at 183–84 (alluding to the falsity of expressed opinion not actually held in fact).

<sup>141</sup> See *id.* at 185–86 (contemplating scenarios where an issuer of opinion explains or supports their stance with facts).

<sup>142</sup> See *id.* at 189–90 (conceding that issuers need not release all facts cutting against statements of opinion because reasonable investors are aware that uncertainty exists in such opinions).

<sup>143</sup> See 15 U.S.C. § 78u-5(c) (providing safe harbors for oral and written forward-looking statements); *id.* § 78u-5(c)(1)(A)(i) (explaining sufficient cautionary language as “meaningful . . . [in] identifying important factors that could cause actual results to differ materially from those in the forward-looking statement”); *id.* § 78u-5(c)(1)(A)(ii) (memorializing the obvious conclusion that a Rule 10b-5 action fails if statements made are immaterial). “Boilerplate warnings” do not qualify for the safe harbor according to the PSLRA House Conference Report. H.R. REP. NO. 104-369, at 43 (1995) (Conf. Rep.). The protections offered by the PSLRA surpass the judge-made “bespeaks caution doctrine” that makes statements not misleading as a matter of law if reasonable minds could agree in their interpretations of the statements. See *Levi v. Atossa Genetics, Inc.*, 868 F.3d 784, 798 (9th Cir. 2017) (analyzing the doctrine in the context of a Rule 10b-5 action against a life science company).

<sup>144</sup> See Milner, *supra* note 1, at 152 (describing the limitations of the safe harbor provisions).

<sup>145</sup> See 15 U.S.C. § 78u-5(i)(1) (defining forward-looking statements to include projections, plans and objectives, statements of future performance, and assumptions); see also Milner, *supra* note 1, at 152 (pointing out that clinical data does not change and is factual, thus not qualifying as forward-looking).

tion.<sup>146</sup> Lastly, the safe harbor does not apply to statements made regarding an IPO.<sup>147</sup>

## II. MATERIALITY AND DISCLOSURE THROUGH AN FDA LENS

Actions brought pursuant to securities regulation often hinge on the materiality of a statement or omission, yet neither the SEC nor the FDA provide any definition for what constitutes “materiality.”<sup>148</sup> The FDA’s regulation of marketing for life science companies creates a unique and difficult issue when determining materiality.<sup>149</sup>

Section A of this Part analyzes the standard of materiality that life science companies must use to make disclosure decisions.<sup>150</sup> Section B discusses how federal courts have applied the Supreme Court’s materiality standard to life science companies.<sup>151</sup> Lastly, Section C synthesizes rationales from federal case law to isolate the sources of increased securities litigation in the life science sector.<sup>152</sup>

### A. Supreme Court Standard for Materiality

Two decisions from the U.S. Supreme Court establish the framework through which life science companies must determine the materiality of a certain fact.<sup>153</sup> In the first, the Court outlined the appropriate standard to determine materiality; in the second, the Court applied that test to the life sciences context.<sup>154</sup> Subsequently, lower federal courts have been left to assess materiality in Rule 10b-5 actions on their own.<sup>155</sup>

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<sup>146</sup> See William O. Fisher, *Key Disclosure Issues for Life Sciences Companies: FDA Product Approval, Clinical Test Results, and Government Inspections*, 8 MICH. TELECOMM. TECH. L. REV. 115, 126 (2001–2002) (explaining the narrowing application of the safe harbor provisions).

<sup>147</sup> See 15 U.S.C. 78u-5(b)(2)(D) (excluding application to statements made in connection to an initial public offering expressly).

<sup>148</sup> See, e.g., *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 27 (2011) (denying defendant’s motion to dismiss because plaintiffs successfully pled fraud as to a material fact); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015) (dismissing plaintiff’s Rule 10b-5 action for lack of materiality); see also Milner, *supra* note 1, at 149 (pointing to case law as the only source for interpreting the meaning of material within Rule 10b-5).

<sup>149</sup> See Cohen et al., *supra* note 3, at 202 (discussing the complex disclosure criteria promulgated by the FDA that obfuscates the SEC’s materiality standard for disclosure).

<sup>150</sup> See *infra* notes 153–178 and accompanying text.

<sup>151</sup> See *infra* notes 179–207 and accompanying text.

<sup>152</sup> See *infra* notes 208–220 and accompanying text.

<sup>153</sup> See Milner, *supra* note 1, at 149–50 (pointing to the decisions in *Matrixx Initiatives, Inc.* and *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) as providing the only materiality criteria from the Supreme Court).

<sup>154</sup> See *Matrixx Initiatives, Inc.*, 563 U.S. at 30–31 (applying the materiality analysis to a life science company); *Basic Inc.*, 485 U.S. at 232 (establishing the materiality inquiry).

<sup>155</sup> See *Matrixx Initiatives, Inc.*, 563 U.S. at 30–31 (standing as the last Supreme Court decision to address the materiality standard).

## 1. Setting the Foundation for Materiality

In 1988, in *Basic Inc. v. Levinson*, the U.S. Supreme Court solidified the now controlling test for materiality.<sup>156</sup> The facts establish that for two years a company engaged in negotiations to be purchased, during which time they released three public statements denying any such negotiations.<sup>157</sup> In 1978, the company agreed to sell all common stock at forty-six dollars per share.<sup>158</sup> Former shareholders brought a Rule 10b-5 action against the company for failure to disclose the ongoing merger negotiations on which plaintiffs relied when choosing to sell their shares.<sup>159</sup>

According to the Court, a material misstatement or omission is made when, from the perspective of a reasonable investor, the statements are substantially likely to shift the total mix of public investment information.<sup>160</sup> This analysis calls for an ad hoc inquiry considering the specific facts and context of each case.<sup>161</sup> Further, the Court expressed concern with creating too low a standard for materiality for fear of over-disclosure such that reasonable investment decisions are actually hindered, not informed.<sup>162</sup>

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<sup>156</sup> See *Basic Inc.*, 485 U.S. at 231–32 (stating the materiality test adopted by the Court). The test had been previously espoused in Supreme Court precedent, but disagreements between lower courts persisted. See *id.* (resolving a circuit split on when merger negotiations become material under securities law).

<sup>157</sup> See *id.* at 227–30 (providing the factual setting of the dispute).

<sup>158</sup> See *id.* at 227–28 (requesting the Stock Exchange halt trading of their shares immediately). This date marked the end of the class period, as shares could no longer be traded. *Id.*

<sup>159</sup> See *id.* at 228 (alleging financial loss because plaintiffs would have kept their shares to sell at the marked-up merger price). In allowing the class certification, the U.S. Sixth Circuit Court of Appeals adopted the fraud-on-the-market theory that assumes that plaintiffs relied on the company's material misrepresentation in deciding to buy or sell shares. See *id.* at 229–30 (specifying that this creates a rebuttable presumption for plaintiffs).

<sup>160</sup> See *id.* at 231–32 (emphasizing that materiality is determined from a reasonable investor's point of view). Specifically, the Court asked whether 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 available." *Id.* (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)).

<sup>161</sup> See *id.* at 238–40 (indicating materiality is unique for every company based on the circumstances). In the context of merger negotiations, for example, the Court stated that the "indicia of interest" in a transaction shows the probability that it may take place, which in turn has an effect on materiality. See *id.* (pointing to factors such as board actions and negotiations to evidence the indicia of interest). Accordingly, the Court dismissed the company's request to create a bright-line rule for the materiality of merger discussions. See *id.* at 233 (pointing again to the significance of a reasonable investor's perspective that a bright-line rule fails to consider). Such a bright-line rule would take for granted the intelligence of investors, who have the statutory right to material information—no matter how complex—that could alter their decision to invest. See *id.* (chastising the Third Circuit's bright-line rule for assuming investors are "nitwits").

<sup>162</sup> See *id.* at 234 (providing rationale for adoption of the totality standard applied to the materiality inquiry). Over-disclosure of corporate information could flood investors with so much information that it is near impossible to decipher. See *id.* (indicating the Court's preference to balance interpretative statements from corporations against the risk of misleading investors).

## 2. Materiality in a Life Sciences Context

In 2011, in *Matrixx Initiatives, Inc. v. Siracusano*, the U.S. Supreme Court applied its analysis from *Basic Inc.* to the life sciences context.<sup>163</sup> In the case, a company received reports that its FDA-approved drug Zicam, a nasal spray administered to alleviate cold symptoms, could be causing anosmia.<sup>164</sup> Despite consistent reports indicating a causal link between Zicam and anosmia over a five-year period, the company released highly optimistic projections for the fiscal year and failed to disclose being a party to multiple products liability suits regarding the drug's safety.<sup>165</sup> Following a report revealing an FDA investigation into Zicam, the company issued a press release pointing to the drug's successful clinical trials that showed no causal link between Zicam and anosmia.<sup>166</sup> As more reports elucidated Zicam's danger, stock prices fell and plaintiffs filed suit for the company's misleading statements.<sup>167</sup>

The company argued that it did not have a duty to report the adverse events of anosmia because they were statistically insignificant.<sup>168</sup> Accordingly, Zicam's clinical trials returned no proof of a causal link between the drug and adverse

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<sup>163</sup> See *Matrixx Initiatives, Inc.*, 563 U.S. at 30–31 (applying the ad hoc materiality test from *Basic Inc.* to omission of a material fact by a drug company); see also *Basic Inc.*, 485 U.S. at 232 (establishing the test). The Court granted certiorari to clarify whether statistical significance, which is often dispositive in the scientific world, is dispositive of materiality under SEC regulation. *Matrixx Initiatives, Inc.*, 563 U.S. at 30–31; see Cohn & Swick, *supra* note 3, at 933 (discussing the disconnect between scientific and investor standards of materiality that could be resolved by the Supreme Court in *Matrixx Initiatives, Inc.*).

<sup>164</sup> See *Matrixx Initiatives, Inc.*, 563 U.S. at 31 (defining anosmia as the loss of smell).

<sup>165</sup> See *id.* at 33–34 (releasing a Form 10-Q for November 2003 with no mention of the two filed lawsuits alleging Zicam had caused plaintiffs' anosmia). *Matrixx's* Form 10-Q was coupled with general cautionary language that products liability claims, whether successful or not, could have a material effect on the company's growth by affecting its public reputation. See *id.* (quoting *Matrixx's* SEC submission).

<sup>166</sup> See *id.* (stating further that clinical trials revealed no instances of anosmia whatsoever). *Matrixx's* press release points to the statistical insignificance of any adverse findings in their clinical trials. See *id.* at 34–35 (“The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.” (quoting Press Release, *Matrixx Initiatives, Inc.*, *Matrixx Initiatives Reaffirms Safety of Intranasal Zicam® Cold Remedy* (Feb. 2, 2004), <https://www.sec.gov/Archives/edgar/data/1006195/000095015304000327/p68781exv99w1.htm> [<https://perma.cc/A4HR-2YKL>])).

<sup>167</sup> See *id.* at 34–35 (relying on the Rule 10b-5 right of action). The plaintiff class for the combined action consisted of nine plaintiffs who had all lost their sense of smell and previously filed four individual lawsuits. *Id.* at 33.

<sup>168</sup> See *id.* at 30 (suggesting that reasonable investors would not rely on statistically insignificant data because it holds no scientific weight). The dissociation between statistical significance and materiality for dually regulated life science companies was thoroughly discussed preceding the decision in *Matrixx Initiatives, Inc.* See Cohn & Swick, *supra* note 3, at 930–33 (exploring the confusion created by the separation between scientific standards of significance and SEC standards of materiality). Traditionally, life science companies operate in a world where statistical significance is the gold standard for determining the relevance of information. See *id.* (noting that courts have refused to adopt statistical significance as a standard for materiality).

events, so they could not be material.<sup>169</sup> The Court declined to apply the bright-line rule, and instead pointed to the methods by which the FDA and medical professionals evaluate causation.<sup>170</sup> Significantly, because the FDA assesses causation in a number of ways, reasonable investors are entitled to do the same.<sup>171</sup> Because the overwhelming evidence from prescribing physicians, peer-reviewed research, and the adverse reports taken together could have altered a reasonable investor's view of the total mix of available information, the Court denied the company's motion to dismiss.<sup>172</sup>

### 3. Synthesizing the Standard for FDA-Regulated Companies

Taken together, *Basic Inc.* and *Matrixx Initiatives, Inc.* provide the tools for life science companies to determine what information is material and thus requires disclosure under SEC regulation.<sup>173</sup> Making this assessment requires sponsors to consider how a reasonable investor views the total mix of information, so they are able to make informed investment decisions.<sup>174</sup> The analysis is complicated, however, because FDA regulation for approval, labeling, and advertising controls a company's marketability.<sup>175</sup> Essentially a life science company must predict how the FDA will assess a specific fact to determine that fact's materiality to a reasonable investor.<sup>176</sup> As the Court in *Matrixx Initiatives*,

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<sup>169</sup> See *Matrixx Initiatives, Inc.*, 563 U.S. at 40–42 (calling for a clear-cut rule that statistical insignificance automatically makes information immaterial).

<sup>170</sup> See *id.* at 41–42 (stating that medical professionals and the FDA do not limit their evidence to statistical significance). The FDA, for instance, may require labeling changes if any reasonable evidence presents a question of safety, even without proof of causation. See *id.* (alluding to the reasonable investor's interest in FDA standards of assessment).

<sup>171</sup> See *id.* at 43 (“Given that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well.”). The FDA can rely on post-approval evidence that only indicates causation. See 21 C.F.R. § 201.80(e) (2019) (“The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.”).

<sup>172</sup> See *Matrixx Initiatives, Inc.*, 563 U.S. at 45–46 (pointing to the plethora of evidence that suggested a causal link outside the statistically insignificant adverse events). Significantly, because the FDA may have used insignificant data to demand a recall, such insignificant data can alter the total mix of information available. See *id.* at 41–42 (indicating the investor's deference to the FDA's stance).

<sup>173</sup> See *id.* at 40–42 (applying the test to the life sciences context); *Basic Inc.*, 485 U.S. at 228–30 (establishing the materiality test); see also Cohen et al., *supra* note 3, at 232 (writing about the remaining challenge of determining materiality for disclosure purposes).

<sup>174</sup> See *Basic Inc.*, 485 U.S. at 228–31 (describing the purpose of the 1934 Act to prohibit the fraudulent manipulation of stock prices without the investors' knowledge).

<sup>175</sup> See Cohn & Swick, *supra* note 3, at 914 (discussing the FDA's effect on materiality through their control on the marketability of a product).

<sup>176</sup> See *id.* (highlighting life science companies' reliance on FDA regulation to release investor communications); see also *Matrixx Initiatives, Inc.*, 563 U.S. at 40–42 (likening materiality to how the FDA would determine a causal link between Zicam and anosmia because it would mean recall pursuant to FDA regulation).

*Inc.* conceded, however, the FDA does not rely on a clear-cut test to assesses a drug's safety and efficacy—the key requirements for marketability—but instead applies a myriad of tools, strategies, and factors.<sup>177</sup> In the highly complex and unpredictable life science market, failure to accurately predict the FDA's conclusion on ambiguous assessment factors can easily appear reckless in hindsight.<sup>178</sup>

### B. Identifying the Issue

The Supreme Court's rationale in *Matrixx Initiatives, Inc.* purportedly settles the legal assessment of materiality needed to make disclosure decisions, yet life science companies continue to defraud investors.<sup>179</sup> Since 2012, the number of securities suits brought against life science companies has risen dramatically.<sup>180</sup> To elucidate the core issues at the heart of increased securities regulation, an analysis of federal cases finding material misstatements since *Matrixx Initiatives, Inc.* is necessary.<sup>181</sup>

#### 1. Reliance to Materiality

In 2017, in *Levi v. Atossa Genetics, Inc.*, the U.S. Court of Appeals for the Ninth Circuit heard a case involving a company that created and sold detection devices to predict cancer development.<sup>182</sup> The FDA approved one of the compa-

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<sup>177</sup> See *Matrixx Initiatives, Inc.*, 563 U.S. at 41–42 (quoting amorphous FDA assessment standards such as “biologic plausibility,” “potential to mitigate the risk in the population,” and the “temporal relationship of product use and the [adverse] event” of FDA Guidance); CTR. FOR DRUG EVALUATION & RESEARCH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: GOOD PHARMACOVIGILANCE PRACTICES AND PHARMACOEPIDEMIOLOGIC ASSESSMENT, at 18 (2005), <https://www.fda.gov/files/drugs/published/Good-Pharmacovigilance-Practices-and-Pharmacoepidemiologic-Assessment-March-2005.pdf> [<https://perma.cc/K5ZW-3VP3>] (providing a non-exhaustive list of factors to be considered when assessing the severity of adverse events).

<sup>178</sup> See Cohn & Swick, *supra* note 3, at 936 (emphasizing how the vast amount of data plaintiffs sift through, when looked at with a retrospective lens, can easily yield misstatements of material facts that appear reckless).

<sup>179</sup> See Milner, *supra* note 1, at 151 (pointing to *Matrixx Initiatives, Inc.* as the last Supreme Court decision on materiality for a life science company); see also KISTENBROKER ET AL., *supra* note 13, at 4 (showing the increasing prevalence of life science securities litigation).

<sup>180</sup> See KISTENBROKER ET AL., *supra* note 13, at 4 (showing an increase by 225% from 2012 to 2017). Investors sought recourse for many alleged violations including misrepresentations about products during development, falling stock prices after failed clinical trials, optimism towards achieving FDA approval, and repurposing of FDA-approved products. See *id.* (exploring the types of securities claims brought against life science companies in 2017).

<sup>181</sup> See Milner, *supra* note 1, at 168–80 (analyzing various federal cases that have addressed the materiality standard).

<sup>182</sup> See *Levi v. Atossa Genetics, Inc.*, 868 F.3d 784, 790 (9th Cir. 2017) (providing the factual background). In general, medical device companies are subject to the same types of FDA and SEC regulation as pharmaceutical companies. See Cohn & Swick, *supra* note 3, at 913 (discussing disclosure regulations for both medical device and pharmaceutical companies as one in the same).



ny's devices, the Mammary Aspirate Specimen Cytology Test System (MASCT System), to collect samples from patients, but not as a diagnostic tool to indicate the presence of breast cancer.<sup>183</sup> The company first presented the MASCT System as an independent collection device, but subsequently joined its marketing with a diagnostic device, ForeCYTE, that had not received FDA approval.<sup>184</sup> Language in the company's initial public offering documents reflected a belief that the FDA was not regulating certain types of tests created by complex laboratories, such as ForeCYTE.<sup>185</sup> In public marketing statements following its IPO, the company referred to ForeCYTE as "FDA cleared" and the MASCT System as FDA approved following alterations to the device.<sup>186</sup> The FDA sent a warning letter to the company specifying violations and explicit ramifications.<sup>187</sup> In response to the warning letter, the company filed a Form 8-K specifically disclosing the FDA's requirement of new MASCT System approval, but otherwise providing only boiler plate descriptions of the letters.<sup>188</sup> The company then consistently manifested confidence in the sufficiency of its response to the FDA and ability to receive the necessary approvals.<sup>189</sup> Seven months after its warning letter, the FDA required the company to recall both the MASCT System and ForeCYTE.<sup>190</sup> The company did not disclose the recalls for almost three weeks, and when it informed investors, the company's share price dropped by over forty-six percent.<sup>191</sup>

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<sup>183</sup> See *Atossa Genetics, Inc.*, 868 F.3d at 790 (describing how the Mammary Aspirate Specimen Cytology Test System (MASCT System) received FDA approval through the 510(k) process). Under Section 510(k) of the FDCA, a medical device that is functionally the same as an already approved device can receive approval through a letter from the FDA. See *id.* (explaining how Atossa purchased the MASCT System in 2009 after it had already received 510(k) approval). The fact that Atossa purchased the System in 2009 raises questions of whether Atossa was fully familiar with the 510(k) process and specifics regarding the MASCT System's approval. See *id.* (considering Atossa's decision to use MASCT System for non-approved purposes).

<sup>184</sup> See *id.* (stating that Atossa would have needed FDA approval for both independent ForeCYTE marketing and combined marketing with MASCT System).

<sup>185</sup> See *id.* at 790–91 (including Atossa's recognition that FDA regulation of its products may change as the FDA exerts more authority in the field of laboratory-developed tests).

<sup>186</sup> See *id.* at 791 (pointing to the FDA's warning letter that Atossa had marketed the devices in such a manner).

<sup>187</sup> See *id.* (explaining how the FDA warned that the MASCT System required new 510(k) approval, that ForeCYTE required independent approval, and that Atossa's website contained false and misleading information about the devices).

<sup>188</sup> See *id.* at 791–92 (concealing the FDA's concerns with ForeCYTE). Companies submit a Form 8-K with the SEC when a material event occurs between quarterly and yearly reporting requirements. See Div. of Corp. Fin., *supra* note 115 (stating that companies must assess materiality based on their particular facts and circumstance).

<sup>189</sup> See *Atossa Genetics, Inc.*, 868 F.3d at 792 (pulling from Atossa's CEO's statements that indicated FDA clearance had been achieved through clinical trials and manufacturing practices). At this time the MASCT System and ForeCYTE were still unapproved yet continually marketed. *Id.*

<sup>190</sup> See *id.* (stating that the FDA recalled the products for marketing without approval).

<sup>191</sup> See *id.* at 792–93 (describing how Atossa's CEO participated in an investing webinar six days after the FDA recall where he failed to reveal that fact).

The U.S. Court of Appeals for the Ninth Circuit denied the company's motion to dismiss because plaintiffs sufficiently pled a Rule 10b-5 claim.<sup>192</sup> In analyzing materiality, the court contrasted the specificity of the FDA's correspondence to the generality of the company's disclosures to investors, ultimately finding it omitted material facts.<sup>193</sup> In particular it appears that statements made in the wake of serious FDA correspondence should match the scope and magnitude of the FDA's concerns.<sup>194</sup> Further, the court noted the close association between materiality and investor reliance, as the degree to which investors relied on the information, or lack thereof, in making investment decisions to their detriment may alter the materiality of a fact.<sup>195</sup> Accordingly, the investors' direct reliance on the company's false statements supported a finding of materiality, even after the FDA publicly disclosed information to the contrary.<sup>196</sup>

## 2. Materiality to Scierter

In 2016, in *In re ARIAD Pharmaceuticals, Inc. Securities Litigation*, the U.S. Court of Appeals for the First Circuit addressed a Rule 10b-5 action brought against a bio-pharmaceutical company and members of its executive team.<sup>197</sup> Starting in 2008, the company began R&D of ponatinib, a drug aimed at treating chronic myeloid leukemia.<sup>198</sup> Due to the risk posed by the disease, the company was able to apply for limited FDA approval of ponatinib before completion of Phase III clinical trials.<sup>199</sup> The FDA rejected the company's proposed label in October 2012, naming concerns of adverse cardiac events and dosage

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<sup>192</sup> See *id.* at 803 (enumerating the statements sufficiently pled to be misleading as to a material fact).

<sup>193</sup> See *id.* at 798 (describing how the FDA specified the issues with ForeCYTE's lack of clearance, but Atossa suspiciously left ForeCYTE out of its Form 8-K submission).

<sup>194</sup> See *id.* at 797 (highlighting the imbalance in the FDA's warning letter and Atossa's subsequent disclosures to investors). In the absence of similarly contrived language, a company's disclosures effectively tell investors that there is nothing more to worry about. See *id.* (describing how such omissions can be misleading as to a material fact).

<sup>195</sup> See *id.* at 795 ("If [the CEO's] alleged statements contained false information about a subject that reasonable investors would consider important, and Plaintiffs relied on those statements, then those statements are material."). The two elements' association may make a statement materially misleading even when contradictory evidence publicly exists in the investor's total mix of information. See *id.* (describing how investors directly and reasonably relied on the company's materially false statements even though the FDA warning letter was publicly available).

<sup>196</sup> See *id.* (qualifying that this type of materiality would change if plaintiffs had not directly relied on Atossa's statements). Reliance can be pled in two manners: direct reliance or fraud on the market. *Id.* Fraud on the market postulates investor reliance on the strength of a company's stock in the market. See *id.* (describing fraud on the market).

<sup>197</sup> See 842 F.3d 744, 748 (1st Cir. 2016) (naming ARIAD and its CEO, Chief Financial Officer, Chief Medical Officer, and Chief Scientific Officer as defendants to the securities action).

<sup>198</sup> See *id.* at 748–49 (providing factual underpinnings of the case).

<sup>199</sup> See *id.* at 749 (pointing to ARIAD's ongoing recruitment for Phase III clinical trials while applying for limited approval).

reductions, but a few months later the FDA granted ponatinib limited approval with the condition that a “black box” warning be placed on the label.<sup>200</sup> Following its limited approval the company expressed belief in ponatinib’s viability, even with the black box requirement indicating the FDA’s safety concerns.<sup>201</sup> In October 2013, the company disclosed that the FDA requested they halt all clinical trials and marketing of ponatinib, leading to a crash in share value and subsequent litigation that the company misled investors as to ponatinib’s likelihood of approval.<sup>202</sup>

The court addressed the scienter and materiality elements of the company’s statements in two different time frames: before and after ponatinib’s limited approval.<sup>203</sup> Plaintiffs failed to establish that the company had actual knowledge of ponatinib’s cardiac risk and necessary dosage reduction prior to their October 2012 meeting with the FDA, meaning the complaint could not, as a matter of law, create a strong inference of scienter as to statements made during that time.<sup>204</sup> One of the company’s statements following the October 2012 meeting, on the other hand, was found to mislead investors concerning a material fact.<sup>205</sup> During its analysis, the court noted that materiality shares a strong connection with scienter because the materiality of a fact lends weight to an inference that it

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<sup>200</sup> See *id.* (alluding to the significance of a “black box” warning). A black box warning is used to alert consumers to the serious or life-threatening risks posed by a drug. See U.S. FOOD & DRUG ADMIN., A GUIDE TO DRUG SAFETY TERMS AT FDA, at 2 (2012), <https://www.fda.gov/downloads/forconsumers/consumerupdates/ucm107976.pdf> [<https://perma.cc/FE9R-VSXS>] (indicating the severity of a black box warning label and likelihood that it would be considered material to a reasonable investor).

<sup>201</sup> See *In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d at 749 (providing no specific instances where ARIAD touted confidence in ponatinib).

<sup>202</sup> See *id.* (speaking of the FDA’s halt of ponatinib as sudden and unexpected). In the wake of the FDA’s halt on clinical trials, ARIAD stocks dropped to \$2.20 per share. *Id.* A halt in clinical trials and marketing essentially kills the company’s ability to profit from ponatinib, which naturally leads to a negative investor reaction. See *id.* (alluding to the causal link between the FDA’s halt in marketing and drop in share price).

<sup>203</sup> See *id.* at 751–54 (breaking the analysis into two large sections).

<sup>204</sup> See *id.* at 751 (calling plaintiff’s attempt “fraud in hindsight”). Plaintiffs sought to draw an inference of scienter by referencing ARIAD’s Phase II clinical trials with a 2012 report from the Center for Drug Evaluation and Research that indicated cardiac risks and dosage reduction. See *id.* (stating that plaintiffs cannot prove that ARIAD knew of the risks and thus finding no duty to disclose them).

<sup>205</sup> See *id.* at 752–53 (finding the CEO misled investors by naming pancreatitis, as opposed to cardiac events, as the most common adverse event). Because the CEO had actual knowledge that his statements were false from the FDA meeting, plaintiffs pled a strong inference of scienter and materiality. See *id.* (allowing the claim as to this statement to survive defendant’s motion to dismiss). In December 2012, a report quoted the company’s management team as expecting “a favorable label” for ponatinib while naming pancreatitis as the leading adverse effect of the drug. See *id.* (noting that the CEO affirmed “low rates of cardiovascular issues”). The court specifically points to the CEO’s pancreatitis statement, in the wake of contrary knowledge from the FDA meeting, as creating satisfactory evidence for both scienter and a material misrepresentation. See *id.* (citing the CEO’s comment when explaining the court’s rationale).

was intentionally concealed or misconstrued.<sup>206</sup> The court went on to find that statements regarding serious adverse events for the company's top drug would clearly be material to a reasonable investor, and subsequently that plaintiffs had successfully pled a strong inference of scienter.<sup>207</sup>

### C. Disclosure Confusion

*ARIAD* and *Atossa Genetics, Inc.* highlight the intricate task that life science companies face when determining what information must be disclosed now, because it could become material later.<sup>208</sup> As the decisions make clear, the Rule 10b-5 elements of scienter, materiality, and reliance are closely linked to one another.<sup>209</sup> Connectivity of these pleading elements creates a self-fulfilling loop whereby investor reaction can dictate both materiality and scienter.<sup>210</sup> In this paradigm, hindsight has the power to create liability where it may not have existed otherwise.<sup>211</sup> Furthermore, life science companies operate in a notoriously volatile market where some discover a Unicorn drug, but most fail.<sup>212</sup> Investors are typically aware of the sector's inherent risks and are abnormally willing to buy or sell shares at the slightest hint of changing fortunes with the FDA.<sup>213</sup>

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<sup>206</sup> See *id.* at 750 (pointing to the common-sense link that “the marginal materiality of an omitted fact ‘tends to undercut the argument that defendants acted with the requisite intent . . . in not disclosing’ it” (citing *Fire & Police Pension Ass’n of Colo. v. Abiomed, Inc.*, 778 F.3d 228, 242 (1st Cir. 2015))).

<sup>207</sup> See *id.* at 753 (“[W]e have little difficulty concluding that disclosure of the FDA’s concerns or the rate of serious cardiovascular events with respect to *ARIAD*’s leading product would have altered the total mix of information available to investors.”).

<sup>208</sup> See *Atossa Genetics, Inc.*, 868 F.3d at 803 (finding *Atossa*’s statements to be materially misleading after significant reliance by investors); *In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d at 748 (rejecting *ARIAD*’s motion to dismiss in light of its materially misleading statements); see also Cohn & Swick, *supra* note 3, at 936 (highlighting the difficult decisions life science companies must make when determining what information will be relevant in the future).

<sup>209</sup> See *Atossa Genetics, Inc.*, 868 F.3d at 795 (explicitly recognizing that reliance on a statement contributes to an appearance of materiality); *In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d at 748 (stating materiality’s connection to scienter).

<sup>210</sup> See *Atossa Genetics, Inc.*, 868 F.3d at 795 (explaining how investors’ market actions made in reliance on a statement by a company can determine the materiality inquiry). Materiality in turn can be used as evidence of scienter. See *In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d at 748 (showing how scienter can be inferred when an obviously material fact is omitted).

<sup>211</sup> See Cohn & Swick, *supra* note 3, at 936 (pointing to the risk posed by a review of clinical trial data conducted to determine liability when the review is done with knowledge of adverse outcomes).

<sup>212</sup> See *id.* at 913–14 (describing how the high-risk and high-reward investments in life science companies are a result of high failure rates yet high payouts). The term “unicorn,” used to describe private tech companies worth over one billion dollars, is a particularly well-suited designation for a successfully developed drug that offers a return on its multi-billion-dollar price tag. See Erin Griffith, *The Next Wave of ‘Unicorn’ Start-Ups*, N.Y. TIMES (Feb. 10, 2019), <https://www.nytimes.com/2019/02/10/technology/new-wave-unicorn-start-ups.html> [<https://perma.cc/8UAT-99AF>] (using the term “unicorn” to describe privately held tech companies worth over one billion dollars).

<sup>213</sup> See Milner, *supra* note 1, at 146 (explaining how life science companies must seek high-risk investors).

Investor hypersensitivity can thus determine the materiality of a life science company's prior disclosure decisions.<sup>214</sup>

Although predicting materiality is difficult for life science companies, the materiality of *ARIAD* and *Atossa Genetics, Inc.* misstatements and omissions are clear once the market reacts.<sup>215</sup> In both cases, investors were provided misleading material facts upon which they relied to form investment decisions.<sup>216</sup> Nonetheless, the companies' true states of mind remain unclear.<sup>217</sup> Requiring plaintiffs to only plead a strong inference of recklessness creates liability for life science companies that unintentionally misinterpret materiality in one of the most complex, highly regulated sectors.<sup>218</sup> FDA-regulated companies operate in a scientific space where reasonable minds may differ, and reckless scientific disagreements could equate to misstatements of material fact under SEC regulations.<sup>219</sup> Consequently the disproportionate number of securities suits has raised alarms in the legal field, leading a number of scholars to call for legislative and regulatory action.<sup>220</sup>

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<sup>214</sup> See Cohn & Swick, *supra* note 3, at 915 (pointing to practical examples of how hindsight may determine a finding of recklessness).

<sup>215</sup> See *Atossa Genetics, Inc.*, 868 F.3d at 803 (holding that the plaintiffs properly pled claims for misleading statements of material fact, with regard to Atossa's statement that ForeCYTE was FDA cleared, the CEO's statement that ForeCYTE had completed the "FDA clearance process," Atossa's Form 8-K filing that omitted material facts regarding the FDA's warning letter, and the CEO's statement that Atossa had satisfied risk related to FDA clearance); *In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d at 748 (ruling ARIAD made false statements of material fact by pointing to pancreatitis as the largest adverse side effect of ponatinib when it was in fact serious cardiac events).

<sup>216</sup> See *Atossa Genetics, Inc.*, 868 F.2d at 803 (describing how Atossa's statements were in clear contradiction with the truth); *In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d at 748 (pointing to ARIAD's clearly false statement about ponatinib's adverse effects).

<sup>217</sup> See *Atossa Genetics, Inc.*, 868 F.2d at 803 (declining to delineate whether the company knew, or should have known, that their statements were misleading); *In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d at 748 (finding only that scienter had properly been pled, not whether the violations were reckless or intentional).

<sup>218</sup> See Cohn & Swick, *supra* note 3, at 915 (describing how a recklessness standard weakens the heightened pleading requirements implemented by the PSLRA because reasonable scientific interpretation may differ).

<sup>219</sup> See *id.* at 913–14 (explaining how experts in the field of medicine often disagree on interpretations of clinical results and correspondence). Adding to the confusion, experts within the FDA may disagree or even change their stance on the viability of a drug. See *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 518 (S.D.N.Y. 2015) (detailing how the drug Lemtrada received a negative report from the FDA advisory committee and was subsequently rejected, only for the FDA to change its opinion and approve Lemtrada for certain populations).

<sup>220</sup> See Alena Allen, *Regulating Health & Wealth*, 35 CARDOZO L. REV. 309, 343–47 (2013) (requesting legislative action to reform the structure of the FDA); Cohen et al., *supra* note 3, at 232 (asking for interagency cooperation to pass new regulation); Milner, *supra* note 1, at 182–87 (calling for legislative reforms to FDA disclosure restrictions).

### III. A PILL FOR CHRONIC LITIGATION: PROPOSED SOLUTIONS

Legal scholars have recognized the existing disclosure problem and called for various solutions, but they have failed to isolate the propelling legal nuances around which any solution must be centered.<sup>221</sup> The FDA's dispositive effect on materiality allows it to inadvertently trigger disclosure requirements under the SEC's regulations, thereby generating the disproportionate securities litigation risk for life science companies.<sup>222</sup> Due to the interconnectivity of the Rule 10b-5 pleading elements, unpredictable FDA regulatory action directly influences investor reaction that then supports findings of materiality and scienter.<sup>223</sup> This risk is compounded, not caused, by the enormous economic incentives that tip the scales towards confidentiality when a company faces equivocal SEC disclosure decisions.<sup>224</sup>

At the core of this increased litigation is the fact that life science companies continue to make disclosure decisions that mislead investors as to material facts.<sup>225</sup> Nonetheless, it is not clear what the companies' true states of mind are when they decide to release, or not release, misleading statements.<sup>226</sup> An analysis of the regulatory paradigm and the subsequent litigation brought against life science companies yields two possible inferences for scienter: (1) life science companies are actively and knowingly defrauding their investors; or (2) the vast complexity and duration of the FDA approval process produces a high chance of

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<sup>221</sup> See Allen, *supra* note 220, at 343–47 (pointing to bloated FDA regulations that require sweeping reforms on disclosure and regulatory purpose); Cohen et al., *supra* note 3, at 232 (calling for inter-agency collaboration to unify disclosure of clinical trial results while protecting business interests); Milner, *supra* note 1, at 182–87 (identifying competing disclosure interests between the SEC and FDA as the key focus for reforms).

<sup>222</sup> See Cohn & Swick, *supra* note 3, at 925 (pointing to the FDA's heavy influence on investor reactions); see also *Levi v. Atossa Genetics, Inc.*, 868 F.3d 784, 803 (9th Cir. 2017) (explaining the effect of investor reliance on materiality).

<sup>223</sup> See *Atossa Genetics, Inc.*, 868 F.2d at 803 (confirming the interconnectivity of the reliance and materiality elements); *In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d 744, 748 (1st Cir. 2016) (highlighting the relatedness of materiality and scienter).

<sup>224</sup> See Cohn & Swick, *supra* note 3, at 913–14 (highlighting the volatile life sciences market as a deterrent to disclosure); Milner, *supra* note 1, at 185 (discussing why life science companies have battled ferociously against mandatory disclosure of clinical trial data and correspondence).

<sup>225</sup> See *KISTENBROKER ET AL.*, *supra* note 13, at 11–16 (analyzing the increasing number of securities actions brought against life science companies in 2017).

<sup>226</sup> See *Atossa Genetics, Inc.*, 868 F.2d at 803 (generating only an inference of scienter); *In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d at 748 (finding plaintiffs sufficiently pled a strong inference of scienter).

unintentional, yet reckless misrepresentation of material facts.<sup>227</sup> These different conclusions, either fraud or confusion, each call for distinct solutions.<sup>228</sup>

Section A of this Part explains why proposals to restructure the FDA and completely remove the potential of fraud are too far reaching and impractical.<sup>229</sup> Section B offers a more realistic solution centered on a call for FDA guidance to clarify the scope of effective disclosure practices and coalesce relevant information to a single location.<sup>230</sup>

### A. Fraud

The more radical conclusion, that intentional fraud is rampant in the life science industry, calls for more sweeping solutions.<sup>231</sup> Legal scholars have identified legislative reform to the FDA as the ideal remedy for the high rates of fraud.<sup>232</sup> Such reforms have suggested a complete restructuring of the FDA's role in drug development and broad alterations to the FDA's ability to disclose sponsor information.<sup>233</sup> Such restructuring of the FDA would be accompanied by significant hurdles, confusion, and consequences.<sup>234</sup> A few ambitious proposals have been suggested, but they are not plausible under the current regulatory structure.<sup>235</sup>

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<sup>227</sup> See *Atossa Genetics, Inc.*, 868 F.2d at 803 (finding scienter had been proven because Atossa either knowingly or recklessly misled investors as to a material fact); *In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d at 748 (allowing the case to commence because ARIAD either acted knowingly or recklessly in misleading investors with a misleading material fact).

<sup>228</sup> See Cohen et al., *supra* note 3, at 232 (calling for a unified standard of materiality where confusion exists between FDA and SEC standards); Milner, *supra* note 1, at 182–87 (requesting Congress to unify disclosure standards and combat securities fraud by amending the Federal Food, Drug and Cosmetic Act of 1938).

<sup>229</sup> See *infra* notes 231–256 and accompanying text.

<sup>230</sup> See *infra* notes 257–272 and accompanying text.

<sup>231</sup> See Liora Sukhatme, Note, *Deterring Fraud: Mandatory Disclosure and the FDA Drug Approval Process*, 82 N.Y.U. L. REV. 1210, 1210 (2007) (suggesting life science companies are afforded too much discretion and are unable to make disclosure decisions that comply with SEC regulation on their own).

<sup>232</sup> See *id.* (calling for disclosure unification); see also Allen, *supra* note 220, at 343–47 (finding a need for widespread reform to the agency's statutory authority); Milner, *supra* note 1, at 182–87 (concluding that the best solution requires reform of the FDCA).

<sup>233</sup> See Allen, *supra* note 220, at 343–47 (insisting on far reaching reforms to the FDA that would completely change their regulatory role); Milner, *supra* note 1, at 182–87 (calling for disclosure reform that would remove company control).

<sup>234</sup> See Milner, *supra* note 1, at 185–87 (discussing the longstanding obstacles to disclosure reform).

<sup>235</sup> See Allen, *supra* note 220, at 343–47 (suggesting the FDA cease pre-market regulation and shift to a public disclosure role by disclosing safety and efficacy data); Milner, *supra* note 1, at 182–87 (suggesting reform to the FDCA that allows the FDA to disclose certain trade secrets and all clinical trial data).

## 1. Proposal 1: Rethinking the FDA's Role in Drug Development

One law professor proposed a vast reshuffling of the FDA's regulatory role.<sup>236</sup> This proposal suggests that the FDA halt pre-market regulation of clinical trials and instead focus on reviewing clinical trial results and monitoring post-approval adverse events.<sup>237</sup> Under this scheme the FDA would make public and accessible all clinical trial data, thus incentivizing companies to make statements in line with the clinical data and in compliance with SEC regulation.<sup>238</sup> Institutional Review Boards and full disclosure of clinical protocols and results would keep sponsors in check ethically in the absence of FDA oversight.<sup>239</sup>

This proposal's broad sweeping changes are unrealistic and still fail to effectively address the core disclosure issue in the life science sector.<sup>240</sup> This model does not remove the complexity and unpredictability of FDA decision making, and it may actually further obscure the process by removing FDA pre-approval regulation.<sup>241</sup> Investors will continue to press life science companies to speak on the likelihood of FDA approval, but companies will no longer be equipped with the extensive FDA correspondence explaining the agency's regulatory concerns.<sup>242</sup> Prior to FDA approval the clinical data will not be accessible, leaving

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<sup>236</sup> See Allen, *supra* note 220, at 343 (calling for a shift from merit-based FDA regulation to that of disclosure regulation). Alena Allen, an associate professor at the University of Memphis School of Law, focuses on healthcare policy and pharmaceutical regulation. *Alena Allen*, U. MEM., <https://www.memphis.edu/law/faculty-staff/alena-allen.php> [<https://perma.cc/KLR9-XA5F>].

<sup>237</sup> See Allen, *supra* note 220, at 343 (modeling the agency's structure prior to 1962, where the FDA could simply reject a drug application within sixty days if it were incomplete for failure to justify an assumption of safety and efficacy). If the FDA did not deny a drug application, it would be approved automatically, and the sponsor could begin marketing the drug. *See id.* (allowing companies to use the label submitted with the application and market the drug for purposes in the application). Further, all approved drugs would have five years to complete Phase IV clinical trials upon which continued marketing would be predicated. *Id.* at 344.

<sup>238</sup> *See id.* at 345 (indicating the belief that life science companies are actively choosing to violate SEC regulation because of heavy handed incentives to keep clinical trial data confidential).

<sup>239</sup> *See id.* at 344 (relying on consumer backlash and professional ethics to keep companies in check).

<sup>240</sup> See Milner, *supra* note 1, at 182 (highlighting the challenge posed by convincing Congress and the public to take on such a vast change); see also Cohn & Swick, *supra* note 3, at 932 (identifying interpretation of the materiality standard as a significant contributor to the increase in securities litigation).

<sup>241</sup> See Allen, *supra* note 220, at 343 (maintaining the FDA's review structure where it addresses the safety and efficacy of a drug but removing pre-review communication where the FDA indicates its preference on trial design and outcomes).

<sup>242</sup> See CTR. FOR DRUG EVALUATION & RESEARCH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, *supra* note 75, at 3 (highlighting the importance of constant communication between drug sponsors and the FDA to achieve successful drug approval). Drug sponsors would still model their clinical trial designs in a manner most likely to gain FDA approval, but they will be left to interpret the proper design and outcomes that the FDA would prefer. *See HUTT ET AL.*, *supra* note 33, at 669 (describing how companies already design non-regulated studies with FDA approval in mind and seek input from the FDA). If the FDA maintains its decision-making strategies but offers no guidance on how they will be implemented, the risk of recklessly misleading investors will increase. *See Matrixx*



the door open for companies to mislead investors by recklessly misinterpreting how the FDA will view their application.<sup>243</sup> The professor's proposal may effectively address public health concerns, but it fails to remedy the securities risks posed.<sup>244</sup>

## 2. Proposal 2: FDCA Confidentiality Reforms

A less sweeping proposal to reform FDCA's disclosure restrictions has been offered by another legal scholar.<sup>245</sup> This proposal calls on Congress to reform § 301(j) of the FDCA to allow the FDA to disclose sponsor trade secrets, thus circumventing the restrictions created by the Trade Secrets Act.<sup>246</sup> Theoretically this would allow investors to check safety and efficacy data and determine the marketing viability of a drug for themselves.<sup>247</sup> This in turn would push companies to make statements directly in line with their data and correspondence, thereby deterring fraudulent statements or omissions.<sup>248</sup>

Reform allowing the FDA to disclose corporate trade secrets, however, would face significant pushback.<sup>249</sup> Congress has a long legislative history of protecting the confidentiality of trade secrets, and it shows no signs of changing.<sup>250</sup> More importantly, drug sponsors would lose a primary incentive for investing billions into developing new drugs that ultimately improve public health.<sup>251</sup> Although stricter intellectual property laws could be enacted, compa-

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Initiatives, Inc. v. Siracusano, 563 U.S. 27, 30–31 (2011) (finding an assessment of materiality may mirror the FDA's assessment strategies and citing guidance that explains such factors).

<sup>243</sup> See Allen, *supra* note 220, at 345 (contemplating an FDA structure that allows the FDA to initially see sponsor information with the submission of an NDA and subsequently make the information public).

<sup>244</sup> See *id.* (calling for uniform disclosure of clinical trials and the elimination of FDA correspondence, but failing to recognize that SEC regulations may still require life science companies to disclose predictions of FDA interaction).

<sup>245</sup> See Milner, *supra* note 1, at 182–83 (calling for reform to the FDA that would allow them to disclose sponsor information at their discretion).

<sup>246</sup> See *id.* at 183 (exempting FDA disclosure of trade secrets under the Trade Secrets Act because they would be authorized by law).

<sup>247</sup> See *id.* at 184 (discussing how such disclosure would adequately inform investors so that an issuer of stock could not mislead them).

<sup>248</sup> See *id.* (describing how statements from the company would not shift the total mix of information available because investors already have all the information).

<sup>249</sup> See *id.* at 185–87 (describing the critiques of broad disclosure reform).

<sup>250</sup> See *id.* at 185 (exploring Congress's unwillingness to adopt disclosure reform for protected trade secrets). This is likely due to the strong incentives voiced by the pharmaceutical industry. *Id.* Indeed, Congress has taken bipartisan action to strengthen trade secret protections with the Defend Trade Secrets Act (DTSA) that restricts the misuse of trade secrets and offers a remedy in court for violations. See *id.* at 166–67 (mentioning that DTSA does not affect statutory restrictions on disclosure for the FDA).

<sup>251</sup> See *id.* at 186 (proposing statutory carve-outs that would allow the FDA to release trade secrets even if they offer a competitive advantage).

nies would be left with no recourse against infringing competitors in foreign markets.<sup>252</sup>

Even in the face of the practical consequences of its drastic reforms, the proposal falls short of creating a life science sector void of fraud related to clinical data and FDA correspondence as it claims.<sup>253</sup> Under the theory of direct reliance, untrue or misleading material disclosures may generate liability even when the truth is made public by the FDA.<sup>254</sup> But the proposal's primary deficiency lies with its dependence on deterrence that presupposes intentional fraud on the part of life science companies.<sup>255</sup> Deterrence will have little effect, if any, on companies that intend to disclose the appropriate facts but fail because they cannot effectively predict all aspects of FDA action.<sup>256</sup>

### *B. Recommendation: Comprehensive Materiality Guidance from the FDA*

The conclusion that regulatory confusion and complexity lie at the heart of the abnormally high instances of investor fraud in the life science sector allows a more conservative solution.<sup>257</sup> A remedy focused on regulatory clarity, as opposed to reform, would allow the FDA to retain its current structure while theoretically reducing securities litigation.<sup>258</sup> This realistic, conservative remedy

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<sup>252</sup> See *id.* at 185 (suggesting that broad counteractions against IP theft overseas would be necessary to balance the consequences to pharmaceutical companies in the United States). Foreign drug manufacturers would be able to develop competitive drugs at a fraction of the price by utilizing publicly available clinical data. *Id.* Such reform could also be subject to a Takings Clause claim under the Fifth Amendment if intellectual property rights are denied without just compensation. See *Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals: Hearing Before the Subcomm. on Health of the Comm. on Energy and Commerce, 107th Cong. 115–18 (2001)* (statement of Richard F. Kingham) (arguing that just compensation must be provided for the release of proprietary trade secrets).

<sup>253</sup> See Milner, *supra* note 1, at 184 (concluding that as a result of its proposal, “[d]rug sponsors no longer could make misleading statements to investors with regard to clinical trial results . . . or with regard to FDA communications”); see also *Atossa Genetics, Inc.*, 868 F.3d at 795 (allowing an investor suit to proceed on the theory of direct reliance).

<sup>254</sup> See *Atossa Genetics, Inc.*, 868 F.3d at 798–99 (explaining that direct reliance by investors renders moot the public disclosure of contradictory information by the FDA). Investors are typically not expected to look beyond the information presented. *Id.*

<sup>255</sup> See Milner, *supra* note 1, at 184 (assuming the threat of FDA authority to release clinical trial data and FDA correspondence would effectively eliminate securities fraud in the life science sector).

<sup>256</sup> See *id.* (concluding that public disclosure would preclude sponsor “temptation not to announce or to put a positive spin on trial results or FDA decisions”). The author fails to address how a deterrence factor would have any effect on reckless conduct. See *id.* (taking for granted that the misstatements are purposeful).

<sup>257</sup> See Cohen et al., *supra* note 3, at 232 (analyzing the confusing disclosure regulations and calling for a unified standard that simultaneously protects investors and company interests).

<sup>258</sup> See *id.* (suggesting a combined materiality standard between the FDA and SEC would help to combat high litigation rates in the field).

must be implemented before broad sweeping reforms that threaten medical innovation are considered.<sup>259</sup>

The FDA must create comprehensive guidance that establishes and provides examples of best disclosure practices during the drug approval process.<sup>260</sup> Such guidance would help companies determine how the FDA will respond to a fact, which subsequently affects the materiality of that fact.<sup>261</sup> Ideally it would provide strategies whereby companies could effectively match the scope of their disclosure to the severity of FDA criticism and skepticism.<sup>262</sup> With the complexity and breadth of FDA regulation, it could also functionally consolidate and organize the FDA's thought process on what information is relevant to disclosure.<sup>263</sup> Corporate attorneys could be equipped with internal procedures that allow them to cross-reference other guidance particularly applicable to disclosure decisions for their clients.<sup>264</sup>

This solution serves two primary purposes: (1) it reduces instances of reckless misrepresentations or omissions of a material fact; and (2) allows companies to retain the choice of disclosure under SEC regulation.<sup>265</sup> Companies would not be bound to release any particular information, but only be better equipped to assess materiality through an FDA lens.<sup>266</sup> The incentives driving the life science industry would remain intact and no threat would be posed to the viability of

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<sup>259</sup> See PHRMA, 2018 PROFILE BIOPHARMACEUTICAL RESEARCH INDUSTRY, at 2 (2018), [http://phrma-docs.phrma.org/industryprofile/2018/pdfs/2018\\_IndustryProfile\\_Brochure.pdf](http://phrma-docs.phrma.org/industryprofile/2018/pdfs/2018_IndustryProfile_Brochure.pdf) [<https://perma.cc/J988-958F>] (pointing to the ninety billion dollars invested into drug research and development in 2016). If the life science industry believes that investments in an already risky market could have another layer of protection removed, they may reduce investment in exploratory products. *See id.* (stating the pharmaceutical industry's support for an open market to encourage innovation).

<sup>260</sup> *See* Cohen et al., *supra* note 3, at 232 (demanding regulatory clarity in the face of confusing disclosure standards).

<sup>261</sup> *See* Cohn & Swick, *supra* note 3, at 924 (confirming the FDA's effect on market reaction and therefore materiality).

<sup>262</sup> *See Atossa Genetics, Inc.*, 868 F.3d at 798–99 (pointing to the disparate scope of statements made by a company compared to the FDA's warning letter when allowing a Rule 10b-5 action to proceed).

<sup>263</sup> *See Search for FDA Guidance Documents*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm> [<https://perma.cc/KQH9-CH28>] (listing 2,702 different guidance documents). The FDA's vast reach and expansive publications can make it difficult to find which documents are relevant to a company's field. *See id.*

<sup>264</sup> *See id.* (displaying internal procedures for industry implementation). The FDA could take this opportunity to create a road map for documents that are relevant to the SEC's materiality standard. *Id.*

<sup>265</sup> *See* Cohn & Swick, *supra* note 3, at 914 (explaining that the lack of clarity surrounding materiality can easily lead to a finding of recklessness). Like securities law, companies would not have an affirmative duty to release all material facts. *See Matrixx Initiatives, Inc.*, 563 U.S. at 44–45 (explaining that companies retain the choice of disclosure under Rule 10b-5 unless such fact is necessary to make another material fact not misleading).

<sup>266</sup> *See Matrixx Initiatives, Inc.*, 563 U.S. at 41–44 (highlighting the importance of the FDA's assessment of a drug to materiality from a reasonable investor's point of view).

medical ingenuity.<sup>267</sup> Furthermore, the FDA has the capacity to generate effective guidance in this area because it already has experience assessing materiality through collaboration with the SEC and regulations on drug advertising.<sup>268</sup>

This proposal could face significant First Amendment challenges if life science companies believe the FDA is attempting to regulate investor communications.<sup>269</sup> The FDA would not be regulating speech, however, but only equipping companies with the necessary tools to fully comply with the SEC disclosure laws already in place.<sup>270</sup> Life science companies would still make the decision on what information to disclose, but will have a more clear picture of materiality as a result of the FDA guidance.<sup>271</sup> Further, private litigants and SEC enforcement actions, not the FDA, would ensure the effect of the guidance.<sup>272</sup>

### CONCLUSION

The complex and extensive FDA regulations that unpredictably influence the SEC disclosure trigger of materiality place life science companies at a heightened risk for securities litigation. The FDA approval process is marred by unpredictable setbacks and changing circumstances, and the process is ultimately tasked with assessing whether approving a drug is good for public health. A drug's marketability is unilaterally dictated by the FDA, making it difficult for life science companies to discern which facts are material to investors and subsequently must be disclosed.

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<sup>267</sup> See Milner, *supra* note 1, at 185 (recognizing confidentiality of trade secrets as a driving incentive for pharmaceutical investment).

<sup>268</sup> See 21 U.S.C. § 321(n) (2018) (prohibiting omission of material facts in labeling and advertising). See generally *FDA and Other Federal Agencies*, in *FDA ENFORCEMENT MANUAL* § 170 (Arthur N. Levine ed., 2015) (explaining the coordination between the FDA and SEC). The FDA has established internal policies and procedures to report company actions that may violate SEC regulations of disclosure. See *id.* (alluding to the FDA's ability to conduct an internal materiality assessment).

<sup>269</sup> See U.S. CONST. amend. I (providing the right to free speech); Memorandum, U.S. Food & Drug Admin., Public Health Interest & First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, at 20–21 (Jan. 2017), <https://www.regulations.gov/document?D=FDA-2016-N-1149-0040> [<https://perma.cc/7FV8-KSCY>] (discussing challenges to FDA regulation of speech with regard to unapproved medical product uses). The FDA relies heavily on its statutory authority to prohibit “unapproved, adulterated, or misbranded” products to enforce marketing for unintended uses. See *id.* at 22 (“[T]he FDA Authorities regulate the introduction of unapproved, adulterated, or misbranded medical products into interstate commerce and the speech of firms may be relevant to establishing an element of a violation of those provisions.”).

<sup>270</sup> See Memorandum, U.S. Food & Drug Admin., *supra* note 269, at 22 (discussing how the FDA's direct attempts to regulate speech trigger First Amendment challenges but that its uses of speech as an enforcement mechanism do not).

<sup>271</sup> See *Matrixx Initiatives, Inc.*, 563 U.S. at 41–44 (signifying the importance of the FDA's analysis to a materiality inquiry).

<sup>272</sup> See *id.* (highlighting a scenario where FDA action only provides evidence of a violation but does not enforce it unilaterally).

To combat this issue, the FDA must clarify its decision-making rationale through guidance aimed at best disclosure practices. This would not compel life science companies to disclose specific information, but merely suggest certain disclosure practices related to FDA communications and clinical data. This is the only practical solution unless grand changes are made to the FDA's regulatory structure.

ERIC SCHMID