# COGNITIVE DISSONANCE UNDERCUTS DETERRENCE IN THE C-SUITE: WHY OTHERWISE ETHICAL FDA-DEPENDENT MANAGERS KEEP FALLING DOWN THE RABBIT HOLE OF 10(B) CLASS ACTION LITIGATION

*Edwin Adlam Herod**

## I. INTRODUCTION

Inside or outside of the legal world, for most people, *Enron*,[1] *Madoff*,[2] and *Theranos*[3] all conjure up images of investor fraud, white collar crime, and executives-gone-bad. Those cases have involved headline-grabbing securities violations[4]—among a host of other legal,

* J.D. Candidate, 2022, Seton Hall University School of Law; B.A., Kenyon College. This Comment would not have been possible without the support and guidance of Professor Jacob Elberg—few others would appreciate spirited discussions on the contours between incrementalism and induction.

[1] *History: Famous Cases & Criminals: Enron*, FED. BUREAU OF INVESTIGATIONS, https://www.fbi.gov/history/famous-cases/enron (last visited Oct. 24, 2021).

[2] United States v. Bernard L. Madoff *and Related Cases*, U.S. ATT'YS OFF., S. DIST. OF N.Y., DEP'T OF JUSTICE (June 5, 2020), https://www.justice.gov/usao-sdny/programs/victim-witness-services/united-states-v-bernard-l-madoff-and-related-cases [hereinafter *Madoff*] (describing case status updates regarding Bernard Madoff).

[3] Ben Popken, *How $9 Billion Startup Theranos Blew Up and Laid off 41%*, NBC NEWS (Oct. 26, 2016, 12:45 PM), https://www.nbcnews.com/business/consumer/how-9-billion-blood-testing-startup-theranos-blew-n671751.

[4] The Securities and Exchange Commission (SEC) filed a range of charges against all three actors listed—their managers, subsidies, and sometimes brothers—but all included claims under the Securities and Exchange Act of 1934, 15 U.S.C. § 78j ("§ 10(b)"). Press Release, Sec. & Exch. Comm'n, *SEC Charges Kenneth L. Lay, Enron's Former Chairman and Chief Executive Officer, with Fraud and Insider Trading* (July 8, 2004), https://www.sec.gov/news/press/2004-94.htm (SEC announcing § 10(b) and Rule 10b-5 civil charges against the "former Chairman and Chief Executive Officer of Enron Corp"); Complaint, SEC v. Bernard L. Madoff, No. 08-CIV-10791 (S.D.N.Y. Dec. 11, 2008), https://www.sec.gov/litigation/complaints/2008/comp-madoff121108.pdf (SEC complaint filed against Bernard L. Madoff and Bernard L. Madoff Investment Securities LLC with violations including § 10(b) and Rule 10b-5); Press Release, Sec. & Exch. Comm'n, *SEC Charges Peter Madoff with Fraud and False Statements to Regulators* (June 29, 2012), https://www.sec.gov/news/press-release/2012-2012-126htm (charging Peter Madoff—Bernard Madoff's brother—with § 10(b) and Rule 10b-5 violations); Litigation Release No. 24069, Sec. & Exch. Comm'n, *Securities and Exchange Commission v. Elizabeth Holmes, et al.* (Mar. 19, 2018), https://www.sec.gov/litigation/litreleases/2018/lr24069.htm (SEC charging Elizabeth Holmes, Theranos Inc, and Ramesh Balwani with § 10(b) and Rule 10b-5 violations).

ethical, psychological, and moral concerns. Some have contemplated that these sensational scandals may stem from deeper psychological issues.[5] While these large-scale frauds capture the public's imagination due to the grand nature of the crimes,[6] their impact on the day-to-day securities litigation landscape is outsized by less dramatic cases.[7] But the public's fascination with these large-scale frauds—and what drives the actors behind them—may place too large of an onus on a smaller subset of the overall problem.

Willful fraud, and the mindsets behind it, may grab significant public attention, but a more elusive psychological phenomenon may lurk behind a broad swath of securities actions: cognitive dissonance. Cognitive dissonance, a process by which an actor can subconsciously deceive herself about the quality and effect of her actions, differs significantly from willful fraud: the actor may not comprehend the scope or trajectory of her conduct.[8] Understanding cognitive dissonance may offer insight to increasing the law's effectiveness as a deterrent and providing counsel a better understanding of their clients' actions to advise prospectively and retrospectively. Some scholars have suggested that cognitive dissonance has played a supporting role in larger frauds—and is a mechanism that enables employees to go along with the willfully fraudulent acts of their employers.[9] This Comment will look beyond the framework of cognitive dissonance as a supporting function to examine the effect cognitive dissonance has when it takes a lead role in securities violations.

With an average of $6 billion in settlements per year[10] and estimates of psychopathy in the general population at under one

[5] Alan Deutschman, *Is Your Boss a Psychopath?*, FASTCOMPANY (July 1, 2005), https://www.fastcompany.com/53247/your-boss-psychopath (Dr. Hare suggests, indirectly, that the CFO of Enron, Andrew Fastow, exhibits psychopathic behavior); Diana B. Henriques, *Letters from a Sociopath*, FORBES (Mar. 21, 2012, 6:00 PM), https://www.forbes.com/forbes/2012/0409/feature-bernie-madoff-prison-rewrite-letters-from-sociopath.html#666235803167 (an article about the correspondence between the author and Bernie Madoff); Jonathan Stempel, *Ex-Theranos CEO Holmes Puts Mental State at Issue, to be Examined by U.S. Experts*, REUTERS (Sept. 10, 2020, 12:02 PM), https://www.reuters.com/article/us-theranos-holmes/ex-theranos-ceo-holmes-puts-mental-state-at-issue-to-be-examined-by-u-s-experts-idUSKBN2612Q3 (stating that Elizabeth Holmes, of Theranos Inc, "may offer evidence she suffered from a mental disease or defect").

[6] *See supra* notes 1–3.

[7] *See infra* notes 10–13 and accompanying text.

[8] *See* discussion *infra* Sections V.A–D.

[9] *See* Prentice, *infra* note 97, at 431.

[10] MUKESH BAJAJ ET AL., ECONOMIC CONSEQUENCES: THE REAL COSTS OF U.S. SECURITIES CLASS ACTION LITIGATION, U.S. CHAMBER INST. FOR LEGAL REFORM 3 (Feb. 2014) [hereinafter

percent,[11] pinning the totality—or even a majority—of securities violations on psychopathy and related mental illness seems farfetched. Yet, the scope of the problem is substantial. While we cannot know the total number of actual violations—and therefore the scope of total harm to investors and the public—there is evidence that some companies are not making the proper disclosures to the investing public: namely, the $6 billion in settlements per year.[12] The scale here prompts an important question: Is there truly an incredible correlation between management and psychopathy that grossly exceeds the population average,[13] or is there another, perhaps more reasoned explanation for the psychological and ethical mindsets that bring corporate managers to run afoul of securities law?

One sector that has borne the particular brunt of securities actions based on the failure to make proper disclosures is the life sciences sector: twenty-four percent of securities class action suits in 2019 were filed against life sciences companies.[14] Of particular note are the public life science corporations on the lower capitalization side of the market.[15] Due to complications with and significant dependencies on the Food and

*Consequences*], https://instituteforlegalreform.com/research/economic-consequences-the-real-costs-of-u-s-securities-class-action-litigation/.

[11] Kent A. Kiehl & Morris B. Hoffman, *The Criminal Psychopath: History, Neuroscience, Treatment, and Economics*, 51 JURIMETRICS 355, 356 n.1 (2011) (indicating one-percent of men in the general, institutionalized population and significantly lower estimates for the general female population).

[12] *Consequences*, *supra* note 10, at 2–3.

[13] Some argue that there is data out there to show a skew towards narcissism and psychopathy in the C-Suite, though this Comment will not go there, taking the tact that, however much those numbers may vary, they do not represent a majority of these instances of securities violations. *See* Karen Landay, *Psychopaths in the C-Suite?*, AM. PSYCHOLOGICAL ASS'N (Oct. 15, 2018), https://www.apa.org/pubs/highlights/spotlight/issue-123 (stating that "the results do not support the idea that corporate leaders tend to have substantially higher levels of psychopathic tendencies"). *But see* Jack McCullough, *The Psychopathic CEO*, FORBES (Dec. 9, 2019), https://www.forbes.com/sites/jackmccullough/2019/12/09/the-psychopathic-ceo (stating "[t]here is a real chance that at some point a chief financial officer will be confronted with a psychopathic [CEO]").

[14] LaCroix, *infra* note 201; *see also* SECURITIES CLASS ACTION FILINGS, 2019 YEAR IN REVIEW, CORNERSTONE RSCH. 1 (2020), https://www.cornerstone.com/Publications/Reports/Securities-Class-Action-Filings-2019-Year-in-Review (stating that "[c]ompanies in the Health Care sector were the most frequent targets of new core federal filings"). Additionally, there appears to be a rise in securities class action filings in the life sciences sector in 2019 over 2018. *See* MICHELE JOHNSON, COLLEEN SMITH & AMANDA BETSCH, RISE IN SECURITIES CLASS ACTION FILINGS IN LIFE SCIENCES SECTOR, IN VIVO 2 (2020), https://www.lw.com/thoughtLeadership/rise-securities-class-actions-life-sciences.

[15] Nicki Locker & Laurie B. Smilan, *2019 Life Sciences Securities Litigation Roundup*, WILSON, SONSINI, GOODRICH, & ROSATI (Apr. 28, 2020), https://www.wsgr.com/en/insights/2019-life-sciences-securities-litigation-roundup.html.

Drug Administration (FDA)[16] for approvals, life science companies—and their managers—are beholden to a strange array of deadlines, inspections, and notifications that ultimately makes or breaks the business.[17] Determining when and how to notify investors presents a myriad of ethical and, ultimately, legal dilemmas.[18]

The failure to disclose material changes to investors, either through misrepresentations or omissions, is a significant trigger for class action suits in this sector. Under the Securities and Exchange Act of 1934 (SEA), companies have disclosure obligations designed to encourage truthful disclosures and discourage the misrepresentation or omission of material facts to the investing public.[19] Violations of the key statute—SEA's Section 10(b)—are limited by a mindset requirement: often this requires the court to look at the facts and the circumstances surrounding the disclosures managers and directors make to assess whether they have the requisite scienter.[20] The general internal corporate processes that lead to running afoul of Section 10(b)—and thus raising a cognizable claim of harm against managers and directors on the part of investors[21]—are strangely similar in a myriad of cases. While it is occasionally a matter of willful fraud or innocent confusion as to the effect of an FDA notice, it is frequently a more complicated, convoluted web of ego, confusion, loyalty, and bravado that plays out between a variety of key corporate players. Where, exactly, the manager—or managers—cross the line into the requisite scienter is not always clear because a slow shuffle across the line is often harder to catch in action but is still answerable in a suit.[22]

This Comment proposes that a significant percentage of securities violations in the life sciences industry may be caused not by willful fraud

16 The FDA is a regulatory agency that regulates under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. §§ 301–399.

17 *See infra* Section III.A.

18 *See* Locker & Smilan, *supra* note 15.

19 It is unlawful "[t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement[,] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." *See* Securities and Exchange Act of 1934, 15 U.S.C. § 78j ("Section 10(b)").

20 *See infra* note 41 and accompanying text.

21 Investors bring civil claims under Section 10(b) of the SEA against managers and directors who cause harm to investors through misrepresentations and omissions. *See* 15 U.S.C. § 78j.

22 Donald C. Langevoort, *Disasters and Disclosures: Securities Fraud Liability in the Shadow of a Corporate Catastrophe*, 107 GEO. L.J. 967, 1004 (2019) (stating that most courts look for a minimum mens rea of "conscious disregard" when establishing scienter under a Section 10(b) suit).

or innocent confusion, as other scholars have theorized,[23] but by corporate cognitive dissonance.

Cognitive dissonance exists when a person intakes two mutually opposing facts.[24] An individual is, by nature, uncomfortable maintaining opposing facts, and, therefore, the brain seeks to eliminate this differential.[25] The discomfort created by dissonance is a driving force, like hunger, that motivates an individual to seek resolution to the discrepancy; that resolution is called consonance.[26] Dissonance is eliminated by (1) discarding old information or (2) distinguishing or rejecting new facts.[27] This process occurs regularly and is an essential mental tool for organizing new information.[28] Typically, the process resolves by leaving the individual in internal consonance and relative harmony with objective reality.[29] But when an individual reaches consonance falsely by manufacturing new facts, disregarding the scope of new information, or wrongly distinguishing dissonant information, that individual has lost the driving force to resolve the issue and may, in ignorance, persist in believing his or her newly manufactured reality.[30] The more complex the new information may be and the smaller the objective difference between the dissonant facts, the easier it is to distinguish the new information from the old without curing the disconnect with reality.[31] The individual may not be conscious or aware of this process and that may inhibit his or her ability to course-correct and avoid potential liability. [32] Cognitive dissonance may make many violators of Section 10(b) unaware of their own missteps to the point where the law loses effectiveness as a deterrent.[33]

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[23] *Fraud or Confusion*, *infra* note 90, at 1901.

[24] FESTINGER, *infra* note 127, at 3.

[25] *Id.*

[26] *Id.*

[27] *Id.* at 5–6.

[28] *Id.* at 4–5.

[29] If an individual is "more or less" in harmony with objective reality, the individual in question does not believe any inherent falsehoods or fundamentally misunderstand material facts about their environment, task, or conduct. For a discussion about eliminating dissonance, see *id.* at 5.

[30] By eliminating dissonance, the individual has lost the "hunger" to resolve a problem and will now not seek a resolution, as the individual feels as though the issue is resolved. *See* FESTINGER, *infra* note 127, at 3–5.

[31] *See* discussion *infra* Sections V.A–D.

[32] *See* Wright, *infra* note 119.

[33] In addition, systematic deterrence reducers—such as indemnification and insurance—look to lift the weight from managers and directors who may be concerned about potential malfeasance. The indemnification and insurance provided to directors and managers may reduce the financial threat intended to create deterrence. David B. Shulz, Comment, *Indemnification of Directors and Officers Against Liabilities Imposed*

A common example of this effect may occur in a *victim* of ongoing fraud—such as a victim of Bernie Madoff[34]—who believes that the perpetrator is a friend. But then the victim discovers new information indicating that the victim has been misled. This information would be sufficient to cause an objective person great concern and likely motivate them to take action. But due to cognitive dissonance, if the prior belief of friendship is strong enough, it can cause the new information to be disregarded or distinguished in such a way that it loses all effect. Thus, the victim is brought back into consonance. The result is that the victim believes the friendship still exists and that the new fact was somehow (1) false, (2) misleading, or (3) misunderstood. The victim has reduced his dissonance—and the driving force to take action—but remains out of sync with objective fact.

Rather than looking at how cognitive dissonance can enable prolonged victimization, by affecting the victim, this Comment will turn towards how cognitive dissonance can play a role in the wrongful conduct itself. The purpose of this Comment is to develop an understanding of the interactions between cognitive dissonance, FDA notifications, and securities disclosures to (1) focus the law into a better deterrent and (2) serve as a guide for counsel representing actors in this space.

Public life sciences companies have a duty to make disclosures under the SEA, and that duty includes refraining from omitting necessary material facts.[35] But determining the timing and scope of disclosure may be difficult due to the complex multi-step process life science companies commonly engage in with the FDA: information may be disbursed in smaller-step changes, and its impact may be opaque.[36] Subsequently, this Comment will focus on the effect of securities laws in the life sciences sector: the combination of the two regulatory schemes tends to produce a unique, partially repeatable pattern of behavior that has, statistically, led to a higher rate of securities violations.

One of the key purposes of Rule 10b-5 is to deter fraudulent actors, as violations negatively impact investor confidence, fluidity of capital

*Under Federal Securities Laws*, 78 MARQ. L. REV. 1043, 1065 (1995). Also, the stakes are too high: over-disclosing to investors could cut managers off from the additional capital they require to complete the task, risking the business; the indemnification-stifled potential cost—and a seemingly remote chance of enforcement—may not be enough to offer true deterrence. S. P. Kothari, Susan Shu & Peter D. Wysocki, *Do Managers Withhold Bad News?*, 47 J. ACCT. RSCH. 241, 242 (2009).

[34] A victim who has used an investor for a long period may form a trusting relationship. *See Madoff*, *supra* note 2.

[35] *See supra* notes 19–21 and accompanying text.

[36] *See infra* notes 61–89 and accompanying text.

raises, and overall economic growth.[37] Practitioners should be aware of the hurdles cognitive dissonance places in front of relevant clients. Changes to both securities laws and FDA regulations should take the potential for cognitive dissonance into account to maximize the effectiveness of securities law as a deterrent. The combination of the engrained high-stakes of corporate management and cognitive dissonance leads to a highly incentivized actor who is able to rationalize each micro-step by employing mental tools to nullify cognitive dissonance—and thus prospectively underestimate her own malfeasance. This grave underestimation transforms high-stakes to high-risk: one now has an actor who is despondent to deterrence because she is unaware she is violating the law. Therefore, this Comment proposes key modifications to the FDA, SEC, and corporate charters that will encourage engagement throughout the slow-burn of the FDA approval process in a manner that increases beneficial disclosures and, by doing so, decreases lawsuits.

Part II of this Comment will provide background on the law surrounding SEC disclosures and the impact of the FDA approval process on public life sciences companies. Part III will discuss the pitfalls that public life science companies face in determining how to make proper SEC disclosures and how to keep the investing public apprised of their status given any FDA notifications they may receive while still driving investment in the company. Part IV will discuss the commonly considered mindsets that contribute to Section 10(b) liability, such as fraud or mistake. Part V will develop a third possibility—cognitive dissonance—as a mildly opaque but frequent psychological process that may account for a thus-far unrecognized category of Section 10(b) violations. Part VI will explore a variety of paths forward, including how the market and courts currently handle this issue, as well as some additional considerations that could deter additional violations. Part VII will conclude the Comment by recommending a mixed approach to maximizing deterrence.

## II. BACKGROUND

For public companies in the life sciences that depend primarily on approvals from the FDA to generate revenue, the intersection of securities disclosure requirements and FDA notifications creates a challenging road for corporate managers to navigate—a road that, with

[37] *See* 5B DISCLOSURE & REMEDIES UNDER THE SECURITIES LAWS § 6:4 (2011) (stating that the purposes of Rule 10b-5 include "deterring violations while compensating victims" and "building investor confidence" while "assuring fairness"). *See infra* note 39 for a description of Rule 10b-5, derived from Section 10(b).

some frequency, ends in securities litigation under the SEA's Section 10(b).[38] The SEA also created the Securities and Exchange Commission (SEC), which administers and promulgates regulations, such as Rule 10b-5, which provides additional contours to Section 10(b).[39] Public corporate directors and managers, under the SEC regulations, have a duty to disclose to the investing public "material events and uncertainties known to management" that might reveal that publicly reported financial information is not truly indicative of the corporation's condition within quarterly 10-Q and annual 10-K submissions.[40] Company managers are often faced with product imperfections—and subsequent related communications from the FDA—that require additional resources to overcome. Managers may often need to respond to these "speed bumps" by raising additional capital. But some of the product imperfections may eventually rise to material issues that, should they not be disclosed, expose the company to liability. This presents a conundrum to operators who cannot fix the problem without capital but cannot raise capital if they disclose the problem—and, frequently, when operators fail to thread this needle, class action securities litigation occurs.

For a complaint to survive a motion to dismiss, six factors must be properly pleaded to make a prima facie case—but only two of those factors are fertile grounds for conflict. The plaintiff must allege that each defendant had the required scienter and that the facts that were omitted or misrepresented were material. In order for a plaintiff to successfully allege violations under Section 10(b) and Rule 10b-5, the plaintiff must allege—particular to each defendant—that (1) the defendant made a material misrepresentation or omission; (2) had scienter in doing so; (3) the misrepresentation or omission had a connection to the purchase or sale of a security by the plaintiff; (4) the plaintiff relied on said misrepresentation or omission; (5) the plaintiff suffered economic loss; and (6) there was a causal link between the misrepresentation or omission and the plaintiff's economic loss.[41] The

[38] 15 U.S.C. § 78j.

[39] 15 U.S.C. § 78d (creating the Securities and Exchange Commission). Additional regulations promulgated by the SEC under 17 C.F.R. § 240.10b-5 ("Rule 10b-5") make it unlawful for companies to make an "untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances . . . not misleading." 17 C.F.R. § 240.10b-5 (2021).

[40] Katherine Cohen, Joseph W. Cormier & Mahnu V. Davar, *Predictable Materiality: Need for Common Criteria Governing Disclosure of Clinical Trial Results by Publicly-Traded Pharmaceutical Companies*, 29 J. CONTEMP. HEALTH L. & POL'Y 201, 215 (2013) (citing 17 C.F.R. § 229.303) [hereinafter *Predictable Materiality*].

[41] Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 38 (2011) (citing Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc., 552 U.S. 148, 157 (2008)); *see also* 15 U.S.C.

plaintiff, however, is relieved from pleading with any great detail whether or how the misrepresentation or omission had a connection to the sale, or if the plaintiff justifiably relied on the misstatement or omission, by the "fraud on the market" theory: it is enough to say that the misstatement occurred, and the plaintiff, subsequently, made a stock transaction, and that there was causation that triggered an economic loss.[42] This leaves, as the primary challenge for plaintiffs to survive a motion to dismiss, alleging that the facts omitted or misstated were material and that the defendants had the required scienter when the omissions or misstatements were made.

There is a complex interplay between materiality of facts and the corporate managers' scienter.[43] Scienter requires that the defendants have a mindset of knowledge or recklessness—this is frequently interpreted by courts as a "conscious disregard" standard: the defendant had some awareness that the behavior was improper, but decided to disregard the information and move forward despite it.[44] Scienter has been adequately alleged in a complaint "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged."[45] The materiality of facts can circumstantially inform the level of scienter the defendants are accused of having acted with.[46] Therefore, the determination of the materiality of facts, and any circumstantial evidence as to the knowledge or awareness of the defendants of the materiality of those facts, will be highly probative as to the defendant's scienter.

§ 78u-4. Given the relatively low bar for surviving a F.R.C.P. 12(b)(6) motion to dismiss—which is the primary way to keep litigation costs low for defendants—it is vitally important to be aware of the line created by the Court's interpretation of Rule 10b-5. *See Matrixx*, 563 U.S. at 45 n.12. Additionally, it must be noted that the Supreme Court has allowed the standard of recklessness to be assumed without being "decided." *Id.* at 48.

[42] *Basic* affirmed the "fraud on the market" theory, which relieves plaintiffs of the burden of proving that they specifically relied upon the material omission or misstatement in their purchase; it only requires that the misleading statement was made and that the stock purchase occurred. Basic Inc. v. Levinson, 485 U.S. 224, 242, 247 (1988).

[43] Thomas M. Madden, *Significance and the Materiality Tautology*, 10 J. BUS. & TECH. L. 217, 225 (looking at the "close relationship" between materiality and scienter, as explored by the First Circuit).

[44] Langevoort, *supra* note 22 at 1004 (stating that most courts look for a minimum mens rea of "conscious disregard" when establishing scienter under a § 10(b) suit).

[45] *Matrixx*, 563 U.S. at 48 (internal quotations omitted).

[46] Madden, *supra* note 43 (quoting Miss. Pub. Emp.'s Ret. Sys. v. Bos. Sci. Corp., 549 F.3d 5, 20 (1st Cir. 2011)) ("Knowingly omitting material informative is probative, although not determinative, of materiality.").

For example, in *Matrixx v. Siracusano*, the Court decided it was a "cogent and compelling" inference that there was scienter when the company chose not to disclose reports; it was not because they thought they were immaterial, but rather because they "understood their likely effect on the market."[47] Additionally, the Court, in *Matrixx*, made an express point of noting, "[m]ost significantly," that Matrixx issued a press release referring to non-existent studies that proved its medication, Zicam, did not cause the adverse effects it was accused of causing.[48] The indication here is that the level of materiality of the issue will inform the Court's interpretation of the defendant's scienter—the more important the matter is to the operations of the business, the more likely a manager or director is aware of the "likely effect" on the market.[49]

This prompts a much needed look into materiality: a helpful first step in determining materiality for SEC disclosures is to examine the Supreme Court's opinion in *Basic v. Levinson*.[50] In *Basic*, the Court established a standard that eliminated "certain information . . . of 'dubious significance'" that would risk overwhelming investors with "an avalanche of trivial information."[51] The Court tightened-up the materiality standard so that, while it is still what is material from the viewpoint of a "reasonable investor," it requires the information to have a "*substantial* likelihood" that it will have "*significantly altered* the '*total mix*' of information available."[52] This at least works to account for the fact that *any* reasonable investor would likely want to claim that *any* detrimental fact not disclosed is material. But this "total mix" standard only goes so far as a protection for most companies, and for pharmaceuticals where a single FDA approval will gravely impact the bottom line, this does not provide a lot of leeway. The "total mix" of information for a public, small-cap pharmaceutical is information organized around a product line of one, two, or three products; any meaningful FDA feedback could jeopardize the very existence of one of those products—or require a significant recapitalization in order to

47 *Matrixx*, 563 U.S. at 49 (citing Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 323–24 (2007)).

48 *Id.*

49 *Id.*

50 *See* Basic Inc. v. Levinson, 485 U.S. 224, 231–32 (1988) (quoting TSC Indus. v. Northway, 426 U.S. 438 (1976)) (holding that there "must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available").

51 *Id.* at 231 (quoting TSC Indus. v. Northway, 426 U.S. 438 (1976)).

52 *Id.* at 231–32 (quoting TSC Indus. v. Northway, 426 U.S. 438 (1976)) (emphasis added).

redevelop the product.[53] Due to the grave impact of that information, it tends to take on a high level of importance in the overall scheme of information available on the company, and it is, therefore, likely to exceed the "total mix" standard.[54] The Court, in *Matrixx*, upheld its fact-intensive analysis of materiality in the context of pharmaceuticals.[55]

Over the last several decades, both Congress and the judicial branch have sought to refine the contours of the burdens placed on both plaintiffs and defendants in the initial phases of Section 10(b) cases. Congress enacted the Private Securities Litigation Reform Act ("PLSRA") in 1995 to reduce meritless class action securities actions by increasing the pleading standard.[56] But these suits have continued.[57] The United States Supreme Court has, through *Basic* and *Matrixx*, made it easier for plaintiffs to file these suits.[58] While *Halliburton v. Erica P. John Fund* provided defendants with the ability to rebut the plaintiff's presumption of reliance,[59] other cases, like *Arkansas Teacher Retirement System v. Goldman Sachs*, have expanded potential liability for defendants: the Second Circuit, in *Goldman Sachs*, lowered the bar necessary to establish harm through an "Inflation Maintenance Theory" that allows for plaintiffs to establish harm without showing a change in the market.[60]

## III. PITFALLS LIFE SCIENCE COMPANIES FACE SURROUNDING SEC DISCLOSURES

While Section 10(b) presents challenges to various industries, there are unique challenges to public life science companies, particularly companies on the smaller capitalized side that rely on one or two products—and the FDA to approve those products—to provide

53 *See* discussion *infra* Section III.A (discussing the impact of a CLR).

54 *See infra* note 74 for an example of FDA notifications triggering high-media coverage in small-cap pharmaceuticals.

55 *See* Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 39 (2011).

56 *Consequences*, *supra* note 10, at 5.

57 *Id.* at 7.

58 By instituting a "total mix" approach in *Basic*, and then supporting that same approach in the context of life science companies in *Matrixx*, the Court increased the likelihood of small-capitalized public life science companies having any change in one product be material. *See supra* notes 42–55 and accompanying text. *Basic* also affirmed the "fraud on the market" theory, which eliminates the need for the plaintiff to prove reliance on the disclosure or omission. Basic Inc. v. Levinson, 485 U.S. 224, 242, 247 (1988).

59 Halliburton Co. v. Erica P. John Fund, Inc., 573 U.S. 258, 279 (2014) (holding that a defendant may rebut the presumption of price impact at the class certification stage).

60 The "Inflation Maintenance Theory" operates on the assumption that, if the company had not made the materially misleading disclosure (or omission), the price would have dropped earlier, and thus the purchaser of that stock has overpaid, and that is the harm. *See* Ark. Teacher Ret. Sys. v. Goldman Sachs Grp., Inc., 955 F.3d 254, 265–66 (2d Cir. 2020).

profits to their shareholders. It is important to look at two key elements: first, the requirements to gain—and retain—FDA approval for life sciences products; and second, how the SEC disclosure requirements interact with FDA notifications.

### A. *The FDA Approval Process: A Tale of Inspections and Notifications*

The FDA approval process can vary depending on the particular piece of biotechnology, traditional drug, or biologic a company is attempting to bring to market.[61] As an example, this Comment will focus on the application process for biologics: these are large molecule, complicated medicines created through a biological process; this means that the company creating the molecule and the subsequent approval process is firmly tied to the manufacturing facility in which it is created.[62] While this Comment will focus on issues that occur during the approval process of new biologics, there are other areas, including post-approval actions, where similar issues may arise between companies and the FDA relevant to this discussion.

Pharmaceutical research and development is a costly endeavor. The mean cost to bring a single drug to market between 2009 and 2018 was $1.33 billion.[63] And when one adds the additional manufacturing specifications, approvals, and location-commitments, biologics are high cost with low mobility, as a company's approval process is anchored to the manufacturing facility in which it chooses to root its business.[64] If problems present themselves down the road—after a company is tied to a particular facility—the sunk costs can present a major mental obstacle to forsake.

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[61] *Industry Frequently Asked Questions*, FOOD & DRUG ADMIN. (June 26, 2018), https://www.fda.gov/industry/fda-basics-industry/industry-frequently-asked-questions (offering approval paths for Animal & Veterinary Drugs, Medical Devices, Radiation-Emitting Products, and Drugs).

[62] *What Are "Biologics" Questions and Answers*, FOOD & DRUG ADMIN. (Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers; Emily Singer, *Why is Biomanufacturing So Hard?*, MIT TECH. REV. (July 15, 2011), https://www.technologyreview.com/2011/07/15/192981/why-is-biomanufacturing-so-hard/ (stating that not only must the drug itself be approved, but "the manufacturing procedure must be approved as well").

[63] *Millions*, *infra* note 64.

[64] Mark Terry, *The Median Cost of Bringing a Drug to Market is $985 Million, According to New Study*, BIOSPACE (Mar. 4, 2020) [hereinafter *Millions*], https://www.biospace.com/article/median-cost-of-bringing-a-new-drug-to-market-985-million/; Singer, *supra* note 62 (stating that not only must the drug itself be approved, but "the manufacturing procedure must be approved as well").

Companies must begin by conducting their own testing and development phase—taking an average of over eight years—ranging from computer modeling to microorganism and animal testing.[65] A company must then go through the Investigational New Drug (IND) process in order to conduct human testing to determine if its product is safe.[66] Once early human trials are complete, the company files a Biologics License Application (BLA) with the FDA to indicate that they are ready to bring the drug into interstate commerce.[67] The FDA then conducts inspections on the manufacturing facility.[68] If the FDA determines there may be a violation of applicable law—through inspection of the facility, reports, lab results, or other findings—the FDA will issue a Form 483 to management.[69] The Form 483 is "discussed with [the] company's management at the conclusion of the inspection . . . [and] each observation is read and discussed so that there is a full understanding of what the observations are and what they mean."[70] The FDA follows the Form 483 by sending an Establishment Inspection Report (EIR) that details the precise issues uncovered in the inspection.[71] The company can then submit a response to the FDA, and

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[65] *The Beginnings: Laboratory and Animal Studies*, FOOD & DRUG ADMIN. (Apr. 27, 2015), https://www.fda.gov/drugs/drug-information-consumers/beginnings-laboratory-and-animal-studies; *How Do I Go About Getting a Drug Approved?*, FOOD & DRUG ADMIN. (Feb. 1, 2016), https://www.fda.gov/industry/fda-basics-industry/how-do-i-go-about-getting-drug-approved.

[66] *Development & Approval Process (CBER)*, FOOD & DRUG ADMIN. (June 25, 2020), https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber (stating that an "Investigational New Drug Application (IND) is a request for authorization from the [FDA] to administer an investigational drug or biological product to humans"); *see also* U.S. DEP'T OF HEALTH & HUM. SERVS., FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RSCH. (CDER), GUIDANCE FOR INDUSTRY AND REVIEWERS: EXPLORATORY IND STUDIES 3–4 (2006), https://www.fda.gov/media/72325/download (explaining the purpose and scope of an IND).

[67] *Development & Approval Process, supra* note 66 (citing 21 C.F.R. § 601.2); *see also Biologics License Applications (BLA) Process (CBER)*, FOOD & DRUG ADMIN., https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber (last visited Oct. 24, 2021).

[68] *See, e.g.*, Mulligan v. Impax Lab'ys, Inc., 36 F. Supp. 3d 942, 948 (N.D. Cal. Apr. 18, 2014). Additionally, once a biologic is certified by the FDA, biennial inspections will commence; therefore, a Form 483, and the subsequent string of FDA actions, can commence later in a product's lifecycle, should the manufacturing conditions change. FOOD & DRUG ADMIN., BIOLOGIC COMPLIANCE PROGRAM 5 (2010), https://www.fda.gov/media/73834/download (last visited Oct. 24, 2021).

[69] *Form 483 Frequently Asked Questions*, FOOD & DRUG ADMIN. (Jan. 9, 2020) [hereinafter *FDA FAQ*], https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions.

[70] *Id.*

[71] *Id.*

if the FDA finds that response lacking in regard to a violation of regulatory significance, it will issue a "Warning Letter."[72] Finally, the company either receives an approval letter, or the company receives a Complete Response Letter (CRL)—which effectively denies the drug's approval.[73]

There can be a month-long or a many month-long gap between the receipt of a Form 483 and a CRL.[74] When a company is caught in such a window, the company faces some degree of knowledge regarding the challenge it faces to right the ship as well as the need to fund solutions. The FDA has a process, after a Form 483 is submitted, to allow a company to make corrections.[75] This process is essential—but also dangerous—because, as discussed below, it is fertile earth for the induction of cognitive dissonance[76] due to the opaqueness, malleability, and, often, the small-step changes required to mend a perceived problem. The process, thus, creates opportunities for managers to subconsciously self-manipulate their own understandings of the viability of the product.

### B. *How SEA Disclosures Interact with The FDA Approval Process*

Against the backdrop of securities law, when FDA-related interactions—clinical results, positive or negative, or FDA notices—occur, how do managers of smaller public corporations determine their materiality? Negative clinical results can lead to questions of materiality if a reasonable investor would be impacted by knowledge of that result, if that result would have a grave effect on the "total mix" of information

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[72] *Mulligan*, 36 F. Supp. 3d at 947–48 (quoting FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL 4.1 (2012)) ("The FDA's policy states that a Warning Letter 'should not be issued if the agency concludes that a firm's corrective actions are adequate and the violations that would have supported the letter have been corrected.'").

[73] *What is an FDA Complete Response Letter?*, MOTLEY FOOL (Feb. 16, 2017), https://www.fool.com/knowledge-center/what-is-a-fda-complete-response-letter.aspx.

[74] Immunomedics is an example of a small-cap public pharmaceutical that endured a progression of Form 483 difficulties over many months, making multiple public disclosures while managing the evolving FDA notifications. *See, e.g.*, Eric Palmer, *Troubled Immunomedics Now Hit with CRL for Breast Cancer Drug Candidate*, FIERCE PHARMA (Jan. 18, 2019), https://www.fiercepharma.com/manufacturing/troubled-immunomedics-now-hit-crl-for-breast-cancer-mab; Odeh v. Immunomedics, Inc., No. 18-17645, 2020 U.S. Dist. LEXIS 135917, at *10–11 (D.N.J. July 31, 2020) (receiving Form 483 in August 2018 and a CRL in January 2019).

[75] *What Should I Expect During an Inspection?*, FOOD & DRUG ADMIN. (Apr. 26, 2016), https://www.fda.gov/industry/fda-basics-industry/what-should-i-expect-during-inspection.

[76] *See* discussion *infra* Section V.E.

about the business.[77] But even *positive* clinical results can present a liability to the company if that result is given outsized weight in communications and is eventually not dispositive of the product's viability.[78] Yet, the real landmine is the Form 483[79]—and the subsequent threat of a CRL[80]—because a Form 483 can signify a range of problems (scaling from solvable to unsolvable). And, since the number of opportunities the FDA will provide to correct the error is unknowable, the value of the Form 483 can be an unknown variable.[81] A Form 483 presents a tangible problem—but a problem that can possibly be solved, per FDA protocol.[82] By presenting a cryptic pathway to success—difficult to understand in scope, course, number of permissible attempts, and time to act—a Form 483 notice can open the door to a slippery slope that could end in a CRL. And, notably, the road from the former to the latter has plenty of opportunities to run afoul of the material disclosure requirements along the way.

Like all public companies, public, small-capitalized pharmaceutical companies have a duty to disclose [83] in their quarterly Form 10-Q and annual Form 10-K submissions "material events and uncertainties known to management that would cause reported financial information

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[77] *Predictable Materiality*, *supra* note 84, at 222–27 (discussing the materiality of negative clinical trial results).

[78] When a manager overemphasizes positive clinical results, this may happen while excluding other, less favorable data—and should the product, in the end, fail, investors may perceive the positive clinical results as a biased way of manipulating investor response. *Predictable Materiality*, *supra* note 84, at 220–22 (discussing the effect of overstating positive clinical results).

[79] A notice provided by the FDA that finds faults in the drug approval process that must be rectified. *See supra* notes 67–69 and accompanying text.

[80] A Complete Response Letter (CRL) is a final notice by the FDA that a drug or biologic application is denied. *See* MOTLEY FOOL, *supra* note 73 and accompanying text.

[81] *See supra* notes 61–64 and accompanying text.

[82] Misleading mandatory disclosures that follow from a Form 483 are, on their own, *insufficient* to find a mandatory Form 10-K disclosure misleading. *See* Schaeffer v. Nabriva Therapeutics PLC, No. 19-4183, 2020 U.S. Dist. LEXIS 78035, at *31–32 (S.D.N.Y. Apr. 28, 2020) (citing *In re* Discovery Lab'ys Sec. Litig., No. 06-1820, 2007 U.S. Dist. LEXIS 18163 (E.D. Pa. Mar. 15, 2007)). But a Form 483 "represents a risk that the FDA may take corrective action, . . . and thus a company is obligated to assess the seriousness of the risk and disclose such information to potential investors if it also represents it is in compliance with the FDA regulations . . . ." Pub. Pension Fund Grp. v. KV Pharm. Co., 679 F.3d 972, 982 (8th Cir. 2012). If a Form 483 is not likely to, on its own, create liability, it can frequently be a key piece in the beginning of misleading material disclosures. *See, e.g.*, Odeh v. Immunomedics, Inc., No. 18-17645, 2020 U.S. Dist. LEXIS 135917, at *6 (D.N.J. July 31, 2020); Mulligan v. Impax Lab'ys, Inc., 36 F. Supp. 3d 942, 947–48 (N.D. Cal. Apr. 18, 2014).

[83] *See generally* Stuart R. Cohn & Erin M. Swick, *Sitting Ducks of Securities Class Action Litigation: Bio-Pharmas and the Need for Improved Evaluation of Scientific Data*, 35 DEL. J. CORP. L. 911, 912 (2010).

not to be necessarily indicative of future operating results or of future financial condition."[84] Additionally, should circumstances change by way of a "reportable event," companies are required to disclose material changes in a Form 8-K.[85] Finally, asynchronous "voluntary disclosures" that many managers make—whether on an investors' call, to the media, or at an event—still carry the burden of not being materially misleading.[86] It is essential to note that the timing of the Form 10-Q and Form 10-K reports have no bearing whatsoever on potential notifications from the FDA: FDA notifications are correlated to the BLA application process and inspection timing, and the SEC notifications are scheduled against the company's fiscal year.[87] This means, on receipt of an FDA notification, management may already be in progress of releasing a scheduled Form 10-Q or Form 10-K, or a voluntary Form 8-K. Therefore, receipt of any Form 483s, EIRs, or CRLs will often lead to a two-prong decision: (1) what action is required to correct the business or scientific problem? And (2) is this a material change to the business—also known as: Must I disclose this? The more substantial the level of difficulty rendered by the former seems to implicate a higher likelihood of the latter; however, it is not clear *when* disclosure is required. Therefore, the manager might lobby for time to neutralize the problem before making a disclosure that would risk upsetting the apple cart—and subsequently losing shareholder value and the potential to raise additional capital. After all, if this is part of the natural—perhaps even typical—progression of the FDA approval process, is it essential or wise to disclose immediately? Additionally, if disclosures are already pending, the timing of this notice can make it difficult to withdraw or edit a currently outbound disclosure.

And a recent disclosure that is now rendered incorrect creates a second problem. Even providing that it may be permissible not to disclose specific information on the prior date of disclosure, the company may move on to make *other*, unrelated disclosures. But, not only must those disclosures not contain materially misleading information, but they cannot "omit . . . a material fact necessary in order to make the statements made, in [ ] light of the circumstances under

84 *Predictable Materiality*, *supra* note 40, at 215.

85 *Id.* at 216.

86 Langevoort, *supra* note 22, at 979 (stating that many disclosure issues arise from voluntary disclosures).

87 *See Predictable Materiality*, *supra* note 40, at 224–225 (discussing the duty to disclose under SEC regulations); *see also supra* notes 65–75 and accompanying text (discussing the unscheduled and unpredictable FDA process, in order to infer that there is no correlation between these two processes).

which they were made, not misleading."[88] Therefore, should the company make a disclosure, ignoring the issue at hand, it is possible that making an otherwise neutral statement about the company may imply that the "problem"—which the company is now aware of—does not exist, and therefore, has been omitted in violation of Rule 10b-5.[89]

## IV. TRADITIONAL FRAMEWORK OF CORPORATE MINDSETS THAT LEAD TO SECTION 10(B) VIOLATIONS

Given the difficulties expressed in the sections above, it can be easy to see how the traditional perspectives on corporate mindsets have dwelt on two extreme ends of the spectrum: managers acting either fraudulently or innocently, due to confusion. This section will briefly look at Eric Schmid's *Fraud or Confusion*, which looks to bifurcate the possible managerial mindsets into two distinct categories: fraud and confusion.[90] The Note sophisticatedly proposes these two opposite polls and then suggests a variety of solutions for each cause.[91] This section will briefly touch on a willfully fraudulent mindset and a confusion-driven innocent mindset.

### A. *The Frequency of Willful Fraud*

Willful fraud—a term that exceeds any statutory mens rea requirement concerning Section 10(b)—may well exist on the market, but it is a "more radical conclusion."[92] We can look at a host of cases through the ages—*ZZZZ Best*,[93] *Enron*,[94] *HealthSouth*[95]—and determine that willful fraud exists. The enormity of the scale, both in impact and

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88 17 C.F.R. § 240.10b-5 (2021).

89 *See* Levie v. Sears Roebuck & Co., No. 04-7643, 2006 U.S. Dist. LEXIS 12725, at *15–16 (N.D. Ill. Mar. 22, 2006) (stating that omitting the fact that merger negotiations were taking place from an announcement about a store purchase could rise to a material fact omission under Rule 10b-5 and was enough to deny a motion to dismiss).

90 Eric Schmid, *Fraud or Confusion: A Pill for Chronic Securities Litigation in The Life Sciences Sector*, 61 B.C. L. REV. 1899, 1928 (2020) [hereinafter *Fraud or Confusion*].

91 *Id.* at 1901.

92 *Id.* at 1927–28.

93 *See In re* ZZZZ Best Sec. Litig., 864 F. Supp. 960, 964 (C.D. Cal. 1994) (plaintiffs allege "[ZZZZ] Best's glamorous aura was a sham, and that a massive fraud was perpetrated in connection with the public trading of [the company]").

94 *In re* Enron Corp. Sec., 235 F. Supp. 2d 549, 637 (S.D. Tex. 2002) (stating that the materially "False and misleading Statements" were a "*deliberate* failure" on Enron's part) (emphasis added).

95 *In re* Healthsouth Corp. Ins. Litig., 308 F. Supp. 2d 1253, 1259 (N.D. Ala. Mar. 16, 2004) ("[G]uilty pleas entered by former HealthSouth officers and employees indicate that much of HealthSouth's unprecedented growth may have been the result of unprecedented fraud.").

in the array of complicit actors,[96] makes Enron (and frauds like it) a challenging story for the public to understand for a multitude of reasons, including that it conflicts with the rational actor theory.[97]

Willful fraud cases commonly appear to have a central bad actor or small group of bad actors operating knowingly. Conflicts of interest often mire cases of willful fraud.[98] For example, in *WorldCom*, Bernard J. Ebbers, the CEO of WorldCom, became overleveraged when, after engaging in margin calls with his WorldCom stock, the price dropped due to a merger denial by the Department of Justice (DOJ).[99] The facts, as alleged by the plaintiffs, state that an agreement between senior staff at the company started in 2000 when they were directed to "do whatever was necessary to get WorldCom's 'margins back in line.'"[100] WorldCom manipulated its books to inflate its earnings.[101] This fraud persisted until it unraveled in 2002.[102] Ebbers was conflicted between his obligations to his company and saving himself from potential legal action; on the other hand, Ebber's employees and Board of Directors were conflicted between their obligations to the company and their loyalty to Ebbers.[103]

While Enron's key actors may have been actively aware of the fraudulent accounting practices they were engaging in, Professor Robert Prentice suggested that their direct reports may not have come forward to expose the fraud due to cognitive dissonance.[104] He proposed that cognitive dissonance allowed many of the employees who were not acting willfully fraudulently to continue to act in the business despite conflicting facts.[105] This Comment will explore, below, how cognitive dissonance can be a factor in the primary actor's conduct.

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96 *See History: Famous Cases & Criminals: Enron*, FED. BUREAU OF INVESTIGATIONS, https://www.fbi.gov/history/famous-cases/enron (last visited Oct. 24, 2021).

97 Robert Prentice, *Enron: A Brief Behavioral Autopsy*, 40 AM. BUS. L.J. 417, 427–28 (2003).

98 *Crucible*, *infra* note 122, at 4.

99 Troy Segal, *5 Most Publicized Ethics Violations by CEOs*, INVESTOPEDIA (May 9, 2020), https://www.investopedia.com/financial-edge/0113/5-most-publicized-ethics-violations-by-ceos.aspx.

100 *In re* WorldCom, Inc. Sec. Litig., 294 F. Supp. 2d 392, 402 (S.D.N.Y. 2003).

101 *Id.* at 400.

102 Segal, *supra* note 99.

103 *Id.*

104 Prentice, *supra* note 97, at 431.

105 *Id.*

B. *Confusion About FDA Policy as a Defense*

Looking at the other end of the spectrum, there exists the notion that managers are merely confused by the specifics of the FDA approval process, and such confusion leads to incidental fraud on the market. In *Fraud or Confusion*, Schmid suggests that FDA notifications are inherently confusing, and that makes it impossible for managers, in some instances, to be aware of potential disclosure errors.[106]

*Fraud or Confusion* looks to *Levi v. Atossa Genetics, Inc.*,[107] out of the Ninth Circuit, as a case involving FDA related confusion.[108] In one instance, Atossa correctly described the FDA clearance of its MASCT System in its IPO documents, stating that it had received limited FDA-certification for an express purpose.[109] But in a separate instance in the IPO documents, the company described the MASCT System as fully "FDA-cleared."[110] This made the product appear further along and more imminently profitable—the court described this as Atossa using "less precise language" ("Incident Two").[111] Schmind, in *Fraud or Confusion*, discusses the implications of this confusion as "creat[ing] liabilit[ies] for life science companies that unintentionally misinterpret materiality in one of the most complex, highly regulated sectors."[112] Schmind leaves us with a rational concern that, scientifically, "reasonable minds may differ," and such "disagreements could equate to misstatements of material fact under SEC regulations."[113] The issues raised in *Atossa*, however, were more extensive than a single misstatement. And curiously, all misunderstandings seemed to err in favor of Atossa. This Comment will review this case, with a new perspective, after discussing cognitive dissonance in depth.

## V. CORPORATE COGNITIVE DISSONANCE: QUANTITATIVE EASING FOR MANAGERS' MINDSETS

This Part looks at the spectrum that exists between the opposite poles of confusion and willful fraud. This grayscale can exist as a static construct—the actor never fully innocent nor willfully fraudulent—and it can exist as a course of action, over time, building to knowingly or

106 *See Fraud or Confusion*, *supra* note 90, at 1925–26.
107 Levi v. Atossa Genetics, Inc., 868 F.3d 784, 789–90 (9th Cir. 2017).
108 *Fraud or Confusion*, *supra* note 90, at 1925–26.
109 *Atossa*, 868 F.3d at 796.
110 *Id.*
111 *Id.*
112 *Fraud or Confusion*, *supra* note 90, at 1926.
113 *Id.*

recklessly fraudulent behavior. C-Suite-wide cognitive dissonance[114] is a product of groupthink[115] and the individual manager or director's desire to eliminate conflicting inputs while maintaining forward momentum. The elimination of these dissonant elements may occur consciously or unconsciously. Notably, the less conscious the behavior, the more difficult the behavior is to deter. As securities laws are designed to deter harmful behaviors and to remediate when deterrence has failed,[116] understanding how cognitive dissonance may impede deterrence is relevant to evaluating the effectiveness of existing securities law.

Securities laws are designed to deter harmful behaviors and to remediate when deterrence has failed.[117] Remediation functions by compensating victims and reaffirming notions of justice, which, in turn, boosts confidence in the marketplace.[118] Deterrence, by its very nature, requires a level of knowledge about one's own actions prior to or in the course of the conduct.[119] Traditionally, mens rea creates a demarcation point for culpability: it can be seen as "just" to punish the behavior when the actor had some level of awareness, and thus, an ability to have avoided the conduct.[120] This makes mens rea a focal point for both just ex post remediation and prospective deterrence. Looking at a series of events retrospectively, it may be possible to find the necessary mens rea at the point of action. But looking at that same series of events prospectively—from the vantage point of the actor *prior* to taking the action—cognitive dissonance may make it nearly impossible for an actor to understand the conduct and its consequences prior to and

114 Merriam-Webster defines "cognitive dissonance" as "psychological conflict resulting from incongruous beliefs and attitudes held simultaneously." *Cognitive Dissonance*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/cognitive%20dissonance (last visited Oct. 24, 2021).

115 *See infra* note 164 and accompanying text.

116 5B DISCLOSURE & REMEDIES UNDER THE SECURITIES LAWS § 6:4 (2011) (stating that the purposes of Rule 10b-5 include "deterring violations while compensating victims" and "building investor confidence" while "assuring fairness").

117 *Id.*

118 *Id*.

119 When people lack awareness that their behavior is criminal, there is likely no deterrent effect. *See* VALERIE WRIGHT, SENT'G PROJECT, DETERRENCE IN CRIMINAL JUSTICE: EVALUATING CERTAINTY VS. SEVERITY OF PUNISHMENT 2 (2010) (stating that people with a "temporarily impaired capacity to consider the pros and cons of their actions" lack the ability to be deterred from the conduct).

120 In order to avoid conduct, one must have self-awareness of the conduct. *See* Jeffrey S. Parker, *The Economics of Mens Rea*, 79 VA. L. REV. 741, 744–45 (1993) (stating that mens rea effectively imposes "a requirement that the person charged possessed, at the time of the offense, subjective awareness of the 'true' or objective nature of his or her own conduct").

including the moment of the conduct. Mens rea may only look to the moment of actus reus, but the more time, prior to the act, an actor has, the more opportunity that actor has to choose not to do the action: hence, more prospective awareness can aid in maximizing the deterrent effect. Understanding how this behavior develops over time is highly relevant in modeling how to prevent the behavior.

For example, in the framework of a bank robbery, there are clear, possible steps of escalation: attaining a gun (legally or illegally); assembling a group to act; walking into a bank; and pulling out the gun inside a bank branch. Each substantial step leads to another and requires a relatively significant choice—and thus an inferable mindset.[121]

In securities law, each choice can be much smaller: for example, stalling a disclosure for a few days until more information is available; not disclosing a third Form 483 when the manager is convinced some progress was made; hosting an investors' call and explaining away a very negative Form 483 as "part of the normal process;" or issuing a press release explaining that the company is still on track for approval, even though some advisors have suggested a Warning Letter may be on its way. Instead of a series of significant steps, the path to violating Section 10(b) begins to look more like a smooth curve. The practical result of which is that you may have a culpable mens rea retrospectively: a factfinder may review a pattern of behavior and determine that, at the time of the wrongful act or omission, the individual was exhibiting a conscious disregard of their known duty to disclose—and therefore, the law can remediate appropriately. But because the steps are infinitely smaller, the effectiveness of the law as a deterrent drops precipitously because the actor will have difficulty differentiating between the steps due to cognitive dissonance. Because of this slow progression, the actor may or may not consciously understand the level of his or her violation.

Therefore, this Part will analyze the effect of cognitive dissonance in the C-Suite of small-capitalized, public life science companies in order to understand where adjustments may be made in the law, or via advice from counsel, that would reinforce the deterrent effect of Section 10(b). Moving forward, we will exclude sociopaths, psychopaths, and any other person who is "uninhibited" by a typical set of moral, social, or ethical limitations. This is, by no means, to suggest that the C-Suite is magically insulated from such individuals, but statistically, we are dealing with a

121 *See* Steven R. Morrison, *The System of Modern Criminal Conspiracy*, 63 CATH. U. L. REV. 371, 408–10 (2014) (discussing how otherwise innocent acts may establish mens rea independently or through a series of actions and subsequent inferences).

broader problem.[122] First, this Part will look at how cognitive dissonance is a driving force for an individual to seek consonance through behavioral or belief changes. Second, this Part will discuss cognitive dissonance as a subjective state of mind—and a driving force for self-resolution—juxtaposed against external, objective cognitive dissonance. Third, this Part will analyze how an individual can maintain dissonance, despite the inevitable drive to consonance. Fourth, this Part will develop the theory that cognitive easing can work to ease subjective cognitive dissonance at the cost of losing objectivity both individually and as a management group. Fifth, this Part will analyze how those tools apply to both the corporate environment and public life science companies. Sixth, this Part will take a fresh look at *Atossa*. And lastly, this Part will explain why this is a relevant determination.

### A. *What is Cognitive Dissonance?*

For an individual, cognitive dissonance develops when new information conflicts with existing information.[123] Cognitive dissonance compels the mind to eliminate or diminish the dissonance, reaching consonance.[124] Individuals lose objectivity when new, conflicting information is distinguished and subsumed into the former fact, eliminating internal dissonance, but establishing an objectively incorrect belief in the process.[125] Corporate cognitive dissonance may result in an actor having the necessary mens rea to be culpable under Section 10(b), but it inhibits the actor from recognizing the conduct prospectively and, therefore, greatly reduces the potential deterrence effect.

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122 *See* Scott Killingsworth, *'C' is for Crucible: Behavioral Ethics, Culture, and the Board's Role in C-Suite Compliance*, RAND CENTER FOR CORPORATE ETHICS AND GOVERNANCE SYMPOSIUM WHITE PAPER SERIES, SYMPOSIUM ON "CULTURE, COMPLIANCE & THE C-SUITE: HOW EXECUTIVES AND POLICYMAKERS CAN BETTER SAFEGUARD AGAINST MISCONDUCT AT THE TOP" 1 (May 29, 2013) [hereinafter *Crucible*], https://ssrn.com/abstract=2271840 (suggesting that "C-Suite psychopaths exist and do great damage, but they are not the source of most corporate compliance failures").

123 *See* FESTINGER, *infra* note 127, at 3–4.

124 *Id*.

125 See Clay Halton, *Cognitive Dissonance*, INVESTOPEDIA (July 19, 2019), https://www.investopedia.com/terms/c/cognitive-dissonance.asp, for an explanation of cognitive dissonance within an investment setting.

B. *Cognitive Dissonance is Like Hunger*

Cognitive dissonance, like hunger, has a natural desire to eliminate itself.[126] Cognitive dissonance frequently occurs; however, it is typically resolved instantaneously, placing the individual back into consonance.[127]

For a simplistic example, person A was told by person B yesterday that it would be sunny today.[128] Person A believes person B and, therefore, intends to go to the park.[129] Upon looking out the window, person A discovers that it is not sunny, but storming. This new fact creates dissonance; for a moment, the competing information exists simultaneously within person A's mind—maintaining both the belief of the day as it *should* have been and the day that it appears to be.[130] But typically, rationality prevails, eliminating the *dissonance*.[131] Despite the desire to go to the park, the superior, clear facts win out over the personal motivation.

But sometimes, facts are not easy to reconcile. As an alternative to the example above, one might imagine a scenario where a victim of a sophisticated, fraudulent investment scheme might be tempted to follow the adage "in for a penny, in for a pound," despite discovering worrisome facts about their would-be defrauder. Even with clear, superior facts—for instance, a news report on the fraud—the victim might find that many pressures—such as financial dependencies or interpersonal relationships—deter an easy resolution of the factual dilemma. This creates persistent dissonance that the victim will be instinctually drawn to eliminate, per Dr. Leon Festinger above, bringing himself back into consonance.

The magnitude of the fact misalignment amplifies the uncomfortable dissonance. Festinger states that "[c]ognitive dissonance can be seen as an antecedent condition which leads to activity oriented towards dissonance reduction just as hunger leads to activity oriented toward hunger reduction."[132] Each fact, internalized by the individual, becomes a "cognitive element," and the greater the significance attributed to the competing cognitive elements, the greater

126 FESTINGER, *infra* note 127, at 3.

127 *See* LEON FESTINGER, A THEORY OF COGNITIVE DISSONANCE 4–5 (1957).

128 *Id*.

129 *Id*.

130 *See, e.g.*, *id.*

131 *Id*.

132 *Id.* at 3.

the *magnitude* of the dissonance.[133] Generally, a greater *magnitude* of dissonance leads to a stronger drive to reduce or eliminate the dissonance.[134]

In the case of our hypothetical fraud victim, the magnitude of the dissonance is high because the informational differential and the value of the information are both high. The informational differential is high because the distance between the competing cognitive elements of (1) "this person is a friend" and (2) "this person is trying to defraud me" is significant, and the value of the information is significant because the information is of a type that would have a material effect on the victim's life.

### C. *Finding Consonance at the Cost of Objectivity*

There are methods to reduce dissonance constructively, keeping the subject in alignment with the objective reality.[135] This usually requires an active approach: (1) changing a behavior, (2) changing a belief, or (3) changing an environmental element.[136]

A rational approach allows for consonance and objective clarity. When the above changes are made rationally—for example, our victim of fraud from above, motivated by the news report, undertakes a course of action to investigate the issue to determine which of the two beliefs is objectively truthful—the individual can resolve the conflicting information by eliminating the false cognitive element, allowing a return to consonance.

But sometimes, cognitive dissonance fails the individual. By Festinger's model—consciously or unconsciously[137]—a person can *create* new facts or beliefs that reduce or eliminate the dissonance, placing them internally—psychologically—in consonance.[138] When a change in belief is discordant with reality—when a person distinguishes a fact by inventing new facts or investing belief in low-quality

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133 FESTINGER, *supra* note 127, at 16. A "cognitive element" is largely undefined but consists of fact, impression, belief, or groups thereof. *See id.* at 9–11.

134 *Id.* at 18.

135 For the purposes of this Comment, not seeking to become "too philosophical," we will refer to objective reality as the standard by which offenders will be measured in suit, as opposed to their own subjective machinations.

136 *See* FESTINGER, *supra* note 127, at 19–23 (discussing changing behavior and environment, and then using a literature-based hypothetical model in discussing options to bring a population back to objectivity, and why an alternative may prevail).

137 *See Conscious and Unconscious*, *infra* note 143.

138 *See* FESTINGER, *supra* note 127, at 23 (describing how a community imagines ghosts as a way to eliminate the cognitive dissonance created between a belief in humanity's inherent goodness and adolescent malevolence).

information—this reduces the individual's internal dissonance but still leaves the individual at odds with objective reality.[139]

Why create new information instead of resolving things objectively? Practical limitations—such as a high cost or a sunk investment—may offer strong incentives against changing a behavior or a belief.[140] And environmental elements—such as the status of a product or an FDA decision—may be clear and unchangeable, like the weather at the park, but frequently environmental elements are ambiguous and difficult to navigate, like an agency's recommendation or a scientific result; additionally, environment elements are often external and, therefore, inherently resistive to change.[141] Finally, another roadblock to changing behavior, belief, or environment is that changing one cognitive element may place that element in dissonance with another cognitive element, creating integrated resistance to change.[142]

But what of our victim of fraud from above? The weight of old information may cause the victim to invent a new fact to distinguish the dissonant information: perhaps someone is targeting the fraudster with a smear campaign, the accuser has a case of mistaken identity, or this was malicious reporting. That new fact allows the victim to continue to operate without compromising his existing beliefs—placing the victim in relative consonance. The path of least resistance may lead the victim to decide[143] that this was "fake news," and the defrauder has been maligned or slandered. This fraud victim may keep investing. To the outside world, it may seem as though the victim *should* know the truth, but the victim continues to invest with the fraudster.

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139 *See id.* at 23 (detailing how the creation of a new belief can eliminate the original dissonance, but potentially at the cost of objective reality). Festinger discusses individuals who manufacture the concept of "ghosts" in order to diminish their internal cognitive dissonance, *id.*—but by inventing ghosts, the individuals have inherently put themselves out of phase with objective reality.

140 *See id.* at 24–26 (discussing resistance to changing behaviors).

141 *See id.* at 20–21, 26–27 (discussing changing an environmental element and the resistive nature of making the change).

142 *Id.* at 27.

143 The level at which the manufacturing of this new fact is conscious, or subconscious, is not necessarily clear: there are competing theories. *See* Jack Anthony Cole, *Individual Differences in Conscious and Unconscious Processes in Cognitive Dissonance*, 1–2 (Aug. 2004) [hereinafter *Conscious and Unconscious*] (unpublished Ph.D. dissertation, University of Southern Mississippi) (on file with author) (stating that the study's "overall results were consistent with the Defense-mechanism model," a model which points towards unconscious choices as the driving mechanism for dissonance reduction). If these behaviors were entirely subconscious, this would raise concerns about the applicable mens rea because the actor would not be capable of having awareness of his or her own recklessness.

D. *Maintaining Dissonance*

Individuals can maintain states of internal dissonance under certain circumstances. Countervailing forces—other cognitive elements with a higher *magnitude* of dissonance—may also enable an individual to maintain a state of cognitive dissonance internally, which would also be dissonant from an objective third-party observer.[144]

Looking to our above victim of investment fraud, the victim may not be able to rectify the dissonance, as there may be other dissonant facts that the new fact balances against. For instance, the original dilemma was the conflict between (1) the belief that the fraudster was actually a friend who was looking out for your best interests, and (2) a news report that the fraudster was, in fact, a fraudster. Now imagine the victim hears from his brother who says (3) the brother made a lot of money from the fraudster: it worked! And then (4) another colleague reports that the fraudster is being indicted. Now there are four dissonant facts, some balancing against each other. The victim must weigh the value of each fact—the source of the information and the authoritative quality—but those are also balanced against the outcome the victim may be reliant on seeing: not being defrauded by the fraudster. This victim may live in an uncomfortable state of internal dissonance for a prolonged period, looking for more information to "tip the scales."

Keeping the above in mind, we have identified two potential routes to functioning in an objectively external state of cognitive dissonance: (1) significant leverage provided by a competing cognitive element with greater *magnitude* or (2) successfully distinguishing the dissonant elements by generating new facts or beliefs or reprocessing ambiguous, existing facts. From an external, impartial, third-party observer, the conclusion can appear the same: the subject is functioning while relying on the "truth" of two conflicting cognitive elements. But internally, friction and self-awareness are reduced under the latter option as the dissonance is eliminated or significantly reduced, squashing the drive in the subject to identify and rectify the problem. This means the victim under route one is uncomfortable and seeking resolution, while the victim who takes route two has eased his discomfort and has ceased to look for an alternative solution.

144 *See* FESTINGER, *supra* note 127, at 27.

### E. *Cognitive Easing: Leveraging Induction to Artificially Reduce Dissonance*

Just as the government uses quantitative easing to buoy the economy while avoiding direct handouts, corporate managers can use *cognitive easing* to adjust facts to suit their needs at the time without electing to "lie."

Quantitative easing allows the government to print up new money and disburse it to a bank through a private securities purchase.[145] Then that bank applies the money to businesses to slowly buoy the economy, allowing the government to avoid treacherous economic dips without directly addressing the problem.[146]

Similarly, cognitive dissonance can be reduced by a form of *cognitive easing*,[147] allowing the brain to generate new facts—or distinguishing features—and apply them to dissonant cognitive elements to gently bring them into consonance.[148] The higher the magnitude of dissonance the more difficult it will be to ease the two elements into consonance,[149] and thus, likely, the more cognizant the actor will be of the process due to the difficulty in rectifying the differential. Like tension on a suspension bridge, dissonance can be maintained when the resolution of that dissonance—consonance—comes at a cost of greater dissonance between other cognitive elements.[150]

Imagine the typical manager of a public company: while that individual has been forged through the challenging process of rising to the C-Suite, it is likely that person—like a statistically significant number of people—believes herself to be "psychologically normal,"

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145 *See Quantitative Easing*, INVESTOPEDIA (Oct. 15, 2021), https://www.investopedia.com/terms/q/quantitative-easing.asp.

146 *See id.*

147 "Cognitive ease" has been defined by Daniel Kahneman as a state of mental being while engaging in a system of thinking. *See* DANIEL KAHNEMAN, THINKING FAST AND SLOW 59 (2011). Here, *cognitive easing* is being used without attempting to access the depth of analysis Kahneman undertakes, but merely to represent a process in which the brain attempts to mitigate dissonance—this is harmonious with Kahneman's use of the word but not anchored to it.

148 FESTINGER, *supra* note 127, at 21–23. This might be seen as relating to "the path of least resistance."

149 *See infra* note 160 and accompanying text. But, notably, the greater the magnitude, the stronger the drive will be to ease the two items into consonance. FESTINGER, *supra* note 127, at 18.

150 FESTINGER, *supra* note 127, at 28–29.

valuing morality and considering herself ethical.[151] So how does a normal, ethical person misrepresent facts to the investors—to whom she owes fiduciary duties—and thus commit securities violations?

A variety of psychological motivations and states can provide easing functionality and incentives to ease new cognitive elements, such as motivated blindness,[152] time pressure,[153] irrational loss aversion,[154] and overconfidence.[155]

One key mechanism behind cognitive easing is incrementalism. Incrementalism looks at the small steps people take, sequenced over time, that eventually can take managers from ethical street to SEC Blvd.[156] Scholars have referred to incrementalism as the "Slippery Slope of Decision Making."[157] There are two key contributing factors to this process: (1) numbing through repetition and (2) induction.[158] Numbing

[151] *Crucible*, *supra* note 122, at 4 (citing Max H. Bazerman & Francesca Gino, *Behavioral Ethics: Toward a Deeper Understanding of Moral Judgment and Dishonesty*, 8 ANN. REV. L. & SOC. SCI. 85, 85–104 (2012)).

[152] Motivated blindness can allow managers to develop tunnel vision, ignoring key facts under the guise of issues being "unclear, uncertain, deferred, or simply not in the frame of reference" of the given moment. *Crucible*, *supra* note 122, at 6. Notably, this phenomenon does not require dishonesty in the subject's appraisal of the facts but can occur despite good intentions and conflict awareness. *See* Max H. Bazerman & Ann E. Tenbrunsel, *Ethical Breakdowns*, HARV. BUS. REV. (Apr. 2011) [hereinafter *Ethical Breakdowns*] (noting relevant conflicts of interest in an organization and subsequently relying on integrity is not, alone, sufficient "because honest people can suffer from motivated blindness").

[153] The pressure of key launch dates—or IPOs, capital raises, or quarterly reports—can greatly impede a manager's willingness to stop and consider the full ethical ramifications of their actions. *See Crucible*, *supra* note 122, at 6–7 (discussing a social experiment where unhurried people stopped to help a "groaning man collapsed in a doorway"; sixty-three percent of students did so under typical conditions, but under time constraints, only ten percent stopped to help).

[154] Many people are irrationally motivated to *stop* a loss, rather than to achieve an equivalent gain—and will increase their willingness to take risks or violate ethical standards in order to prevent that loss. *Crucible*, *supra* note 122, at 7 (discussing the effect of "prospect theory," and how it applies in the C-Suite).

[155] Overconfidence can lead to managers taking on additional risk; and when that overconfidence is reinvigorated by "early success in high-risk initiatives," that hindsight allows the manager to recalibrate—discounting the prior risk—and then "'double down' on risky business going forward." *Crucible*, *supra* note 122, at 8.

[156] *See id*. at 5.

[157] *Id.* at 5 & n.18 (citing Anne E. Tenbrunsel & David M. Messick, *Ethical Fading: The Role of Self-Deception in Unethical Behavior*, 17 SOC. JUST. RSCH. 223, 228–29 (2004)) (connecting incrementalism—"small steps"—with an article on the "Slippery Slope of Decision Making").

[158] Anne E. Tenbrunsel & David M. Messick, *Ethical Fading: The Role of Self-Deception in Unethical Behavior*, 17 SOC. JUST. RSCH. 223, 228 (2004) [hereinafter *Ethical Fading*].

occurs when actions are repetitious, and one becomes less aware or reflective of the substance of the action.[159]

For example, imagine a pharmaceutical executive who receives a report indicating a small percentage decrease in effectiveness. This executive may note that this is not a material change in efficacy. But over time, there may be many of these reports. Induction allows the executive to perceive the small variable as being imperceptibly different from the original value, and numbness—the repeated application of this induction—can inhibit recognizing a growing downward trend. This compounding error is only more troubling and likely to occur when it involves cryptic soft-data—such as reports, opinions, or more complicated, multi-vector data outputs—instead of clear numeric values that are more likely to be discovered through diligent monitoring.

Induction is the process where the human mind is incapable of accounting for a small enough change in circumstances—the mind determines that this new cognitive element is "almost identical" to a previous cognitive element that was deemed to be acceptable and ethical. Therefore, it allows the mind to accept the new cognitive element as being in alignment with the prior elements.[160]

The above forces tie together to allow, in varying recipes, objective individual cognitive dissonance in the C-Suite. Once competing cognitive elements are introduced—for example, a drug will be successful but requires more capital ("thought 1"), and a new, perceived-to-be adverse FDA notice could, if known, jeopardize the investor confidence needed to raise capital ("thought 2")—time pressure and irrational loss aversion work to establish an immovable force in the mind of the manager. These increase the *magnitude* of the dissonant cognitive elements exponentially as pressure mounts on the manger to perform. The manager is then driven to eliminate the dissonance: that manager may change the belief that a capital raise is required or engage in cognitively reshaping of the dissonant element to eliminate the conflict—either will bring these two thoughts into consonance.[161] On the one hand, to bring these two elements into

159 *Ethical Fading*, *supra* note 158. The more times a person repeats the same action without adverse consequences, the more reaffirmed that action is; therefore, that action may become the new norm, establishing a new baseline prior to the next *induction* step. *See id*.

160 *Id*.

161 *See* FESTINGER, *supra* note 127, at 19–23 (discussing changing behavior and environment, and then using a literature-based hypothetical model, discussing options to bring a population back to objectivity, and why, alternatively, distinguishing the facts

consonance, the manager would have to determine that additional funding is not required, or secure it from a new source: this may be more costly, less rewarding, and it requires a change in course, breaking momentum. On the other hand, motivated blindness may allow the manager to discount environmental, cognitive elements—such as the status of an FDA notice—as being unclear or uncertain.[162] Once the environmental, cognitive element of the FDA notice is distinguished and minimalized, it may be interpreted, through induction, as being equivalent to a prior, insignificant update, unworthy of a mandatory disclosure.[163] Now the problem has been resolved without a change in course—instead, it only required a mild psychological deviation.

But how does one manager's cognitive dissonance expand to encompass the entire C-Suite and the Board of Directors? The culture of each C-Suite is particular in and of itself, and often group norms can set the "dominant reference point for acceptable or expected behavior."[164] It is also essential to note that each manager will have their own sense of ethics—some more than others—which sometimes means knowingly unethical conduct-driven incrementalism might still play a role with some of the actors.[165] Additionally, the stakes are high: even if new information indicates to the person that past actions—taken by them or someone else in management—may have been in error, the person is now forced to choose between surrender—sacrificing career or lifestyle and potentially facing civil or criminal penalties—or trudging ahead, hoping to elude notice of stockholders and regulators.[166] At some point, even if the actor becomes aware of the ethical violation, the stakes may appear too insurmountable to attempt to mitigate or seek help, and thus risking calling attention to the error in the process. Either way, the individual is not only disincentivized from acting at that juncture but also from making herself aware of the scope of the problem altogether.

with new—self-generated—information may provide a more optimal solution to the subject, though it may be objectively invalid).

162 *Crucible*, *supra* note 122, at 6.

163 *See Ethical Fading*, *supra* note 158.

164 *See* "groupthink," described in *Crucible*, *supra* note 122, at 9–10.

165 *See supra* notes 98–103 and accompanying text (discussing a willful fraud perpetrated by one key actor and abetted by other employees who may have had lower mens rea states in their participation).

166 *See Crucible*, *supra* note 122, at 5–6.

F. *Applying Corporate Cognitive Dissonance to Life Science Companies*

Cognitive dissonance in life science companies begins with management doing exactly what they are trained to do: problem solve and maintain a positive disposition to the investors despite any speed bumps.[167] Cognitive dissonance is applicable here in two primary ways: First, cognitive dissonance is required to maintain a separation of self: a person can simultaneously believe they are an ethical person, while making choices that escalate in ethical risk. The Max H. Bazerman and Ann E. Tenbrunsel discuss this phenomenon in the context of the Ford Pinto case:

> [L]ooking at their decision through a modern lens—one that takes into account a growing understanding of how cognitive biases distort ethical decision making—we come to a different conclusion. We suspect that few if any of the executives involved in the Pinto decision believed that they were making an unethical choice. Why? Apparently because they thought of it as purely a *business decision* rather than an ethical one.[168]

There, the two dissonant thoughts involved the individuals' self-perceptions as ethical beings and the knowledge that there was significant potential for death. Bazerman and Tenbrunsel state that the executives decided it was a "business decision," and therefore distinguishable from their own personal moral and ethical compass—and this may be seen as a version of motivated blindness,[169] because it demonstrates the mind working to eliminate the dissonance by redefining the nature of the environmental fact.[170]

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[167] Problem solving includes persistence and "resilience to withstand inevitable pushback from co-workers." *What Are Problem-solving Skills and Why Are They Important?*, CAREERBUILDER (Apr. 13, 2021), https://www.careerbuilder.com/advice/what-are-problemsolving-skills-and-why-are-they-important (a web article designed for instructing younger, would-be-managers on what it takes to be a manager); Margo Reder, *CEO Postings - Leveraging the Internet's Communications Potential While Managing the Message to Maintain Corporate Governance Interests in Information Security, Reputation and Compliance*, 7 DEPAUL BUS. & COM. L. J. 179, 186–87 (2009) ("CEOs necessarily focus on competition, customers, and markets in an effort to achieve maximum returns for the corporation. The temptation to leverage advantages through any means available is nearly irresistible.").

[168] *Ethical Breakdowns*, *supra* note 152 (emphasis added).

[169] Motivated blindness does not necessarily rise to the legal concept of "willful blindness." Motivated blindness is merely suggesting that there is an incentive to remain blind and does not specifically speak to a conscious attempt to remain blind. See *Crucible*, *supra* note 122, at 6, for a discussion of motivated blindness in business ethics.

[170] FESTINGER, *supra* note 127, at 20–21 (noting that environmental cognitive elements can already be ambiguous in nature).

Second, cognitive dissonance can allow managers to, on the one hand, understand the materiality of a problem in order to affect internal operational actions to remedy the problem while mentally declaring the materiality moot in regard to their investor-facing communications. When new, adverse information presents itself to a manager, that manager generally must acknowledge the severity of the issue—for example, a relevant legal notice, an alert triggered by an employee, or a data breach—by taking action to remedy the situation. The level of alarm raised here may be seen to inform the seriousness to which the manager regards the situation. Yet, despite the seriousness of actions required, that manager may then be motivated to disregard the seriousness as it applies to material disclosures under Section 10(b). Objectively, one may imagine a trend to exist: if the element was a serious element in one category, it might likely be of material value to the investors. That is not to declare that these are *always* identical, merely that this should raise the question. But that ambiguity creates room for motivated blindness to repackage the dissatisfactory cognitive element, distinguishing it from a dangerous fact that would induce internal cognitive dissonance. Additionally, incrementalism can be seen here to allow a subject to conflate additional investigative reports regarding an employee's bad actions—where prior notices were deemed immaterial to global operations—as indistinguishable from past notifications through induction and, should these actions repeat, numbness. This incremental "drips and drabs" way of gathering information can appear, on the surface, to keep the manager apprised of the necessary details, but, in reality, it may reduce the manager's ability to comprehend the ultimate severity of the calamity. Whereas, if the full extent of the employee's maleficence was delivered to the manager at one time, it may have been sufficient to register as a material breach. But the slow build to that same fact pattern may allow induction and numbness to eliminate the manager's cognitive dissonance and reduce the manager's objective reaction.

Life science companies typically spend significantly on research and development, so when problems arise with the medication or the manufacturing process, the solution often requires more money.[171] And the problems, at first, may well be immaterial in regard to mandatory investor disclosures. But when the materiality line is incredibly thin and gray, it is easy to succumb to cognitive dissonance: reframing the

171 *See Millions*, *supra* note 64.

adverse facts into a light more favorable and solvable.[172] Given the high-stakes situation of being dependent on the FDA's approval of one or two pharmaceuticals for revenue, it is understandably easy to find oneself faced with hard disclosure decisions.

Specifically, when a Form 483 is presented to the business, the form is fairly clear about *what* issues it is indicating.[173] But the Form 483 will likely not prescribe solutions to those issues.[174] This leaves a manager with a dilemma: the manager needs to fix the issues—and may need capital to do it—but the manager, between time pressure and irrational loss aversion, will be motivated to avoid identifying the Form 483 elements as material to investors—doing so would derail the company's current investor strategy and likely make it impossible to solve the problem, entering into a downward spiral of potential losses. This manager must simultaneously know the problem is serious enough to deploy resources to solve it and believe it is not so serious that it has to be reported. If the pressure of these two items is not enough, the manager can deploy a variety of diffusion tactics to obfuscate the severity: from refusing to anticipate the potential binary (and possibly devastating) outcome of a CLR, to deciding that the FDA parameters or potential outcomes are too confusing to really understand. This is step one for incrementalism. And once there is psychological momentum[175] built up in the manager's mind, objects in motion tend to stay in motion.

### G. *Taking a Second Look at* Atossa *with Cognitive Dissonance in Mind*

Now, after reviewing cognitive dissonance in the life science's C-Suite, a fresh look at *Atossa* calls into question whether Schmid's framing of the case as being driven by "confusion" is entirely satisfactory or whether cognitive dissonance might prove an alternative—if not more likely—explanation.

In *Atossa*, the Ninth Circuit reviewed a motion to dismiss the district court granted in favor of Atossa Genetics.[176] The court affirmed

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[172] *Crucible*, *supra* note 122, at 5 ("In the process of resolving that one internal conflict, [managers] have created, accepted and internalized an ideology for justifying future infractions, especially if they are small and arise in a similar context.").

[173] *FDA FAQ*, *supra* note 69.

[174] *Id.*

[175] James A. Fanto, *Braking the Merger Momentum: Reforming Corporate Law Governing Mega-Mergers*, 49 BUFFALO L. REV. 249, 257–58 (2001) (discussing sophisticated investors being "caught up in the same psychological momentum sweeping over executives and board members" in the context of return-promising mergers and, therefore, not fully scrutinizing transactions).

[176] Levi v. Atossa Genetics, Inc., 868 F.3d 784, 789–90 (9th Cir. 2017).

in part and reversed in part.[177] Atossa had two primary revenue sources: MASCT System and ForeCYTE Test.[178] The MASCT System had received a limited FDA-certification "for use in collecting NAF samples."[179] Steven Quay, Atossa's CEO, made a statement in a Form 8-K report on December 20, 2012, that included an indication that ForeCYTE was "FDA-cleared."[180] Additionally, on News-Medical.net, Quay was quoted as saying that ForeCYTE "has gone through all of the FDA clearance process" ("Incident One").[181] In one instance, Atossa correctly described the FDA clearance of its MASCT System in its IPO documents, stating that it had received limited FDA-certification for an express purpose; but in a separate instance in the IPO documents, the company described the MASCT System as being fully "FDA-cleared;" this made the product appear further along and more imminently profitable—the court described this as Atossa using "less precise language" ("Incident Two").[182] Later, on February 25, 2013, another Form 8-K was filed, "giving notice of the FDA's warning letter."[183] But the notice "omitted the balance of the FDA's alleged serious concerns" ("Incident Three").[184] In a 10-Q report, Atossa made the statement that the company was "'reasonably confident in its responses' to the FDA's warning letter" ("Incident Four").[185] Finally, Quay stated in an interview on March 15, 2013, that the "FDA clearance risk has been achieved" ("Incident Five").[186]

The Ninth Circuit in *Atossa* affirmed the district court's decision from Incident Two and Incident Four—granting the motion to dismiss.[187] But the Ninth Circuit reversed the District Court on Incidents One, Three, and Five.[188] Incidents One and Two were very similar, but with a key distinction: Incident Two appears to have involved more "confusion"—the Ninth Circuit stressed that the issue in the IPO was centered around "less precise language," as Atossa had left out a

177 *Id.* at 790.
178 *Id.* at 795.
179 *Id.* at 796.
180 *Id.* at 794.
181 *Id*.
182 *Atossa*, 868 F.3d at 796.
183 *Id.* at 797.
184 *Id*.
185 *Id.* at 799.
186 *Id.* at 800–01.
187 *Id.* at 793, 797, 800.
188 *Atossa*, 868 F.3d at 793, 796, 799, 802–03.

qualifying fact around the FDA clearance; Incident One, on the other hand, imputed an FDA approval from one key product to the other.[189]

Notably, while there may have been some confusion related to the scope of FDA approval, or the process in which responses to FDA warning letters is handled, by all appearances, the dominant driver in this case was a series of actions that crossed the line from "mere corporate optimism" and waltzed right into a conscious disregard of material, known facts.[190] Over the course of three months, Atossa's management attempted to make their product, ForeCYTE, appear further along and more imminently profitable—it seems like an unlikely coincidence that every "confused" notion about the FDA approval process skewed in Atossa's favor. Looking at this case through the lens of cognitive dissonance, it is easy to imagine convenient cognitive easing that may have led to these beneficial misinterpretations of FDA notices.

H. *Why May Cognitive Dissonance Be Relevant in These Cases?*

When an actor does not understand the nature of his actions, he cannot seek help to avoid current, prevent future, or remedy past incidents. This likely means that deterrents lose effect because when a person cannot understand that the very nature of their actions may trigger a legal consequence, that deterrent does not have value to that individual.[191] And this leaves us with a key difference between a subject affected by *cognitive dissonance* and a subject who acts *knowingly* in order to exploit the system: the person *knowingly* doing it is, in fact, self-aware of the problem and can, therefore, seek legal counsel to best rectify the situation. On the other hand, the person who is experiencing internally consonant, objective *cognitive dissonance* is *not aware* and therefore less likely to realize that she requires counsel, nor would she be willing to entertain the severity of her actions in discussions with counsel. A manager might be the top of her field, supported by a variety of able, intelligent people who know better, yet it is still possible for her to delude herself into believing that the problem is immaterial to investors, despite its materiality to business operations.

Despite the actor's reality-distortion-field, establishing culpability is still possible. Under Section 10(b)'s scienter requirement, as noted

189 *Id.* at 794, 796.

190 *Id.* at 803 (internal citations omitted).

191 When an actor cannot anticipate the impropriety of their action, increased deterrents have little to no effect. *See* Kara M. McCarthy, Note, *Doing Time for Clinical Crime: The Prosecution of Incompetent Physicians as an Additional Mechanism to Assure Quality Health Care*, 28 SETON HALL L. REV. 569, 616–17 (1997) (describing a theory that it is unjust and ineffective to hold doctors liable for inadvertent bad acts).

above, we must look to determine if the actor's mens rea, at the time of the conduct, rose to recklessness. Even the (presently) unaware actor made choices, at the onset of the issue, to eliminate the cognitive dissonance. Given that this is a sophisticated actor, with fiduciary duties to the company, the initial state of dissonance—in concert with the high stakes and knowledge of the situation—would likely make the actor "consciously aware of a substantial and unjustifiable risk."[192] The drive to eliminate internal cognitive dissonance relates to "a desire not to know there is a risk," and indeed, "the causing of the belief is something the person *does* himself," making the actor, if only for that initial fleeting moment, culpable under Section 10(b)'s scienter requirement.[193] This, however, only justifies these civil actions under the law; it does not answer the dominating question: How do we discourage this behavior in an effort to protect investors while decreasing costly litigation?

## VI. POSSIBLE PATHS FORWARD

Despite critics of class action securities litigation,[194] there do appear to be benefits—such as establishing confidence and protection for investors, allowing individual shareholders who otherwise lack the means to bring an action to bring one, and deterring wrongful or misleading actions by directors.[195] Some suggest that the system is generally working.[196]

But even if the system is working, the expense businesses could avoid must be noted: $6 billion is spent in settlements per year[197]—and $1 billion of that constitutes attorney's fees.[198] And yes, billions more are lost trying to prevent expensive litigation or because shareholders deflate value in anticipation of litigation.[199] Expensive "Directors and

192 Michael S. Moore & Heidi M. Hurd, *Punishing the Awkward, the Stupid, the Weak, and the Selfish: The Culpability of Negligence*, 5 CRIM. L. & PHIL. 147, 179 (2011) [hereinafter *Culpability of Negligence*].

193 *Id.* at 155 (emphasis added).

194 *See, e.g.*, John C. Coffee, Jr., *Reforming The Securities Class Action: An Essay On Deterrence And Its Implementation*, 106 COLUM. L. REV. 1534, 1547 (2006) ("[I]t is an open question as to whether the typical securities class action settlement actually produces any net recovery.").

195 *See* Nicole A. Veno, Note, *Class Action Securities Lawsuits Should Survive the Death of a Named Defendant: Why* Baillargeon v. Sewell *was Wrongly Decided*, 25 QUINNIPIAC PROB. L. J. 408, 411–12 (2012).

196 Barbara Black, *Eliminating Securities Fraud Class Actions Under the Radar*, 2009 COLUM. BUS. L. REV. 802, 806 (2009) ("[P]ost-PSLRA securities fraud class action is reasonably effective in achieving both compensatory and deterrence goals.").

197 *Consequences*, *supra* note 10, at 2–3.

198 *Id*.

199 *Id.* at 3.

Officers" insurance coverage increases cost burdens.[200] And in 2019, out of all securities class action lawsuits, twenty-four percent were filed against life sciences companies.[201]

In order to address the peculiar situations that arise with public life sciences companies, this Comment will now look at several narrow opportunities that may provide relief, deterrence, or encourage prevention, with an eye toward diminishing the need for class action securities lawsuits by prophylactically discouraging the harmful behavior. It is important to note that even as the industry looks to make changes, the courts have been altering the burdens placed on both plaintiffs and defendants—and while there are certainly still fair protections for the defendants, as misrepresentations continue, the courts respond in one of the only ways they can: increasing deterrence by allowing plaintiff actions to progress to the merits.[202]

In order to apply the learnings from above, it seems essential to view potential solutions in relation to how they might disrupt the slippery slope of induction that allows for individuals and teams to neutralize their internal cognitive dissonance while remaining objectively out of alignment with reality. The very nature of the FDA approval process creates incredible opportunities for induction, as it is replete with incremental, short-step changes. Globally, solutions that encourage managers to confront these changes by causing disruption would seem to offer a higher efficacy rate. The challenge will be to

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200 *Id.* at 20.

201 Kevin M. LaCroix, *A Closer Look at 2019 Securities Litigation Against Life Sciences Companies*, D&O DIARY (Jan. 26, 2020), https://www.dandodiary.com/2020/01/articles/securities-litigation/a-closer-look-at-2019-securities-litigation-against-life-sciences-companies/.

202 Class action securities litigation, even a decade after the PSLR, is still seeing fluctuations in how courts balance the burdens on the plaintiffs and defendants during the initial phases of a suit. For example, the 2010 Supreme Court ruling in *Halliburton Co. v. Erica P. John Fund, Inc.* has changed how defendants must deal with loss causation prior to class certification. 573 U.S. 258, 284 (2014). While it does create a presumption of reliance, making the plaintiff's case easier, it allows the defense to rebut the presumption prior to class action certification. *See id.* at 277–79. In *Halliburton*, the Court held that requiring a plaintiff to prove reliance or "price-impact" created too high of a bar for class action securities litigation to be established. *See id.* at 267–68, 278–79. The Second Circuit pushed to broaden potential plaintiffs through their expanded inflation-maintenance theory; the Supreme Court, reviewing the Second Circuit's decision, discussed the inflation-maintenance theory but did not validate (or invalidate) the theory, instead, remanding the case for the insufficient consideration of the generic quality of statements on the materiality prong. *See* Ark. Tchr. Ret. Sys. v. Goldman Sachs Grp., Inc., 955 F.3d 254, 258 (2d Cir. 2020), *rev'd*, Goldman Sachs Grp., Inc v. Ark. Tchr. Ret. Sys., 141 S. Ct. 1951, 1960–61 (2021). A continued lowering of the barrier to enter a Section 10(b) suit may encourage compliance, but there are likely problems with this as a solution. *See* 20-4 MEALEY'S LITIG. REP.: CLASS ACTIONS 5 (2020).

determine, systematically, how to embed the right disruption points to elicit positive behavior changes, as opposed to generating more bureaucracy.

With that guiding principle in mind, the following sections will briefly identify a few possible, narrow paths forward: (1) opportunities for reformations to the FDA notifications and guidance; (2) mandating disclosures, under the SEA, of any FDA notifications; (3) creating a presumption of disclosure for any—or certain enumerated—communications between the FDA and the business; and (4) creating a "safe harbor" approach for determining appropriate disclosures.

A. *Reform FDA Notifications and Guidance*

The FDA could deploy superior guidance relevant to its notifications and the SEA at either a global level or with a piecemeal approach. *Fraud or Confusion* offers up a version of FDA reform targeted at globally issued guidance:

> The FDA must create comprehensive guidance that establishes and provides examples of best disclosure practices during the drug approval process. Such guidance would help companies determine how the FDA will respond to a fact, which subsequently affects the materiality of that fact. Ideally it would provide strategies *whereby companies could effectively match the scope of their disclosure to the severity of FDA criticism and skepticism.*[203]

The above solution seems very applicable—and helpful—to a rational actor who is *not* swayed by the effects of cognitive dissonance; however, taking the globally issued option and parsing it against the concepts of cognitive dissonance, above, it is challenging to see this as a significant solution on a case-by-case basis. As considered above, an FDA notice is a form of environmental element. Environmental elements, as noted, are external and inherently difficult to change. But the more ambiguous environmental elements are, the easier they become to distinguish because the ambiguity creates opportunities to reshape the facts. Therefore, providing clearer FDA guidance may serve to refine the resolution of information, making it more difficult to falsely distinguish the information.

Alternatively, the second option requires an immense reapportionment of resources on the part of the FDA—this seems too much to ask, given budget constraints. But perhaps an amalgamation of these two concepts: global guidance is issued, and with it a simple

[203] *Fraud or Confusion*, *supra* note 90, at 1932 (emphasis added).

framework is laid out. For example, the guidance would indicate (1) the number of opportunities to correct the problem afforded the company, (2) a simple color code for the severity of the issue, and (3) a clear timeline of events—perhaps simplified, specific example timelines—then, in conjunction with the global guidance that explains these elements, the FDA could include specific color coding and timeline relationships with each notice.

In the context of ethical actors under the influence of cognitive dissonance, clear, bold warnings that may disrupt the regular flow of communication could serve to jar the actor out of complacency.

B. *Mandatory FDA Disclosures Under the SEA*

Another possible path forward is to mandate FDA disclosures.[204] This would work by requiring every company to disclose, in a Form 8-K, the action letter sent by the FDA within a period of time (redactions of intellectual property would be permitted).[205] *Deterring Fraud: Mandatory Disclosure* cites three potential criticisms of this plan: (1) concerns with protecting proprietary data; (2) "information overload" for investors; and (3) concerns about the market overreacting to the disclosure.[206] These may be valid reasons not to execute this plan, but, assuming, *arguendo*, that these are irrelevant, this solution still leaves a glaring flaw: it assumes that the only material information is information sent *to* the company by the FDA, and not messaging the company sends *to* the FDA. As seen above, these action letters often form a sort of "conversation" between the company and the FDA—sometimes the conversation includes actual, verbalized dialogue, as well.

Still, by requiring managers to disclose these FDA notifications, this works to eliminate one of the key decisions that can lead to objective cognitive dissonance in the life sciences sector. It does, however, still leave the potential for misrepresentations or omissions in how the business discloses communications from the business to the FDA. If the mandatory disclosure scheme was extended to require communications that occur both ways, between the company and the FDA, that may go a long way to eliminate potential sticky points for Section 10(b)

[204] Liora Sukhatme, *Deterring Fraud: Mandatory Disclosure and the FDA Drug Approval Process*, 82 N.Y.U. L. REV. 1210, 1236 (2007) [hereinafter *Mandatory*].

[205] *Id.* at 1237.

[206] *Id.* at 1239–42.

violations.[207] Though, on the flip side, there is a potential for increased bureaucracy and information oversaturation for investors.

C. *Presumption of Disclosure*

A variation on the mandatory disclosure approach would be to create a presumption of disclosure. This would create a presumption that, every time there was an FDA notice or communication from the company to the FDA, the company should have disclosed a reasonable rendition of that communication, allowing for the removal of any intellectual property or trade secret. If the company has complied, then the burden is on the plaintiff to show that the company clearly misrepresented a fact—this would allow for significant protections against potential claims of material omissions under Rule 10b-5, should companies comply. If a company has not filed a disclosure, then the burden would shift back to the company to show why a disclosure was not necessary. This acts as a double-edged knife, serving both as a deterrent and an opportunity for safe harbor.

This may be seen as a mild version of the mandatory disclosure scheme. The permissive nature of this plan allows for more flexibility in business management, but, in turn, increases the potential for cognitive dissonance to enable managers to run afoul of disclosure requirements without being fully aware of the misalignment. Still, this works to eliminate some bureaucracy, and potentially reduce the number of disclosures, versus the mandatory disclosure scheme, that would saturate the investors. The safe harbor aspect of this approach allows for businesses to, in a healthy way, take advantage of this law to their own protection while still accomplishing the goal: deterring misrepresentations.

D. *A Special Disclosure Committee*

A committee designed after the Special Litigation Committee ("SLC") model[208] could create a safe harbor opportunity for companies. An SLC can be formed by impartial, Qualified Directors who can assess whether a derivative suit is appropriate against the individual directors of the corporation—by using impartial Qualified Directors, the SLC

[207] This would need to include an ability to redact sensitive, proprietary information and data.

[208] *See* MODEL BUS. CORP. ACT §§ 1.43, 7.44 (1969) (AM. BAR ASS'N, amended 2020) (defining "Qualified Director" and the "Dismissal" power prescribed to a special committee of Qualified Directors).

reduces the burden on the court system by eliminating potentially frivolous suits.[209]

Fashioning a Special Disclosure Committee ("SDC") could have clear benefits by empowering an impartial group to make final disclosure decisions, and, due to their impartiality, offer some level of subsequent liability insulation. But given that the issues here revolve around securities class action litigation—direct actions by shareholders—and not derivative actions, there are some key differences, and thus, clear alterations that must be made between the SLC model and a theoretical SDC. For instance, an SDC, unlike the SLC, would not be capable of dismissing litigation—nor should it.[210] That being said, directors—and thus, Qualified Directors under the Model Business Corporation Act ("MBCA")[211]—would still have fiduciary duties to the shareholders, regardless of the direct action.[212] The end result would be to create an SDC that—similar to how an audit committee requires at least one expert in Generally Accepted Accounting Principles ("GAAP")—might have at least one Qualified Director with a legal background—or legal compliance certification—as well as a Qualified Director who would be deemed an expert in pharmaceuticals or the FDA approval process. Each Qualified Director would have (1) fiduciary duties to the shareholders,[213] (2) no "material relationship"[214] with any of the managing directors, and (3) should not have a "material interest"[215] in the firm itself.

The SDC would function by choosing the scope of disclosure concerning FDA notifications and company correspondence with the FDA. If the procedures are followed correctly, then the presumption—rebuttable by plaintiff—in any dismissal motion or class action certification, is that company directors did not have the requisite

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209 *See id.*

210 Providing the power of dismissal, even if it were possible, would likely give the SDC too much power to eliminate lawsuits.

211 *See* MODEL BUS. CORP. ACT §§ 1.43, 8.30 ("[Q]ualified directors" are a defined subset of directors, and directors must operate "in good faith" and "in a manner the director reasonably believes to be in the best interests of the corporation.").

212 Andrew D. Shaffer, *Corporate Fiduciary - Insolvent: The Fiduciary Relationship Your Corporate Law Professor (Should Have) Warned You About*, 8 AM. BANKR. INST. L. REV. 479, 490 n.39 (2000).

213 MODEL BUS. CORP. ACT § 8.30; *see also* Shaffer, *supra* note 212.

214 MODEL BUS. CORP. ACT § 1.43(b)(1). If the director were otherwise employed by the firm or another director or had a personal or familial relationship with another director, that would disqualify the director from serving in this capacity. *See id.*

215 MODEL BUS. CORP. ACT § 1.43(b)(2). Owning shares should not preclude a director from serving here; however, owning an amount of the firm that "would reasonably be expected to impair the objectivity of the director's judgment," *id.*, should disqualify such a person from serving in this capacity.

scienter. If the SDC procedures are not followed, then safe harbor does not apply. The SDC allows a company to protect itself and ensure it makes the appropriate disclosures to investors as well.

By placing disclosure authority in an independent committee, the SDC, it would migrate the decision from managers who are entrenched with the problem, giving a more objective, third party a different vantage point to see the disclosure issues. By eliminating some of the SDC's potential conflicting interests, the SDC's primary motivation will be to make the correct disclosure decision. This could add more bureaucracy, but it also provides an opportunity for a business that recognizes it is in a risky position to protect itself prospectively.

## VII. CONCLUSION

The essential takeaway of this Comment is that the combination of the current FDA notification process and required SEA disclosure requirements create a perfect storm of circumstances that encourage actors to obviate their cognitive dissonance by small, step-change induction, which allows managers to detach themselves from objective reality, creating material omissions and misstatements along the way.

While cognitive dissonance may not preclude liability under the SEA, Section 10(b), it does diminish the potential for the manager to foresee potential consequences and act to avoid said consequences by positively changing their behaviors. Without this clear view to causality, the theoretically positive effect of deterrence is diminished. Offering businesses additional tools, such as the safe harbor of an SDC, or a presumptive disclosure scheme, may allow businesses to be more proactive in defending these matters. Coordinating FDA notices more closely with SEC disclosure requirements could help to jolt some managers from complacency. Without adjustments to the laws surrounding FDA notifications and the SEC disclosure requirements, small-capitalized public life science sector companies will continue to breed opportunities for managers to, under the influence of falsely obtained consonance, misrepresent and omit material facts to investors without fully comprehending their conduct.