

# KEY DISCLOSURE ISSUES FOR LIFE SCIENCES COMPANIES: FDA PRODUCT APPROVAL, CLINICAL TEST RESULTS, AND GOVERNMENT INSPECTIONS†

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Cite as: William O. Fisher, *Key Disclosure Issues for Life Sciences Companies: FDA Product Approval, Clinical Test Results, and Government Inspections*,

8 MICH. TELECOMM. TECH. L. REV. 115 (2002)  
available at <http://www.mttl.org/voleight/Fisher.pdf>

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This article takes all factual descriptions from the sources cited. The reader should note that most of the cases cited address motions to dismiss, where the court assumes the truth of the plaintiffs’ allegations, or defense motions for summary judgment, where the court draws inferences in plaintiffs’ favor. The “facts” recounted in those opinions are the facts as the court must take them under the applicable procedural rule and may not reflect the events that actually occurred.

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The government, particularly the Food and Drug Administration (“FDA”), heavily regulates the life sciences industry. FDA actions can have an extraordinary influence on the fortunes of biotechnology companies. Timely FDA approval of a drug or medical device can permit a company to exploit an inviting market window. FDA product approval is, in turn, tied to clinical test results which demonstrate “efficacy” and safety. Delayed approval, unfavorable test results, or the denial of an FDA application may ruin a company.

Beyond the FDA product approval process and related testing lie FDA inspections and the possibility that the government will investigate charges such as the submission of false data. Problems found by inspection or revealed by investigation can, in turn, influence FDA action on further product approvals.

All of this makes regulatory events and clinical testing matters of great concern to both the managers of life sciences companies and investors in those companies. What biotechnology companies disclose—and decide against disclosing—about such events can influence the price of those companies’ stocks. These disclosure decisions, therefore, can have important securities law implications. Inaccurate statements—and, under some circumstances, decisions to keep information about regulatory and testing developments within the company rather than including it in a public statement—may lead to private lawsuits, Securities and Exchange Commission (“SEC”) enforcement actions, and even criminal prosecutions.

This article addresses issues arising from disclosures about:

- a) FDA product approval, particularly predictions about such approval;
- b) Clinical tests;

- c) Communications with the FDA before product approval; and
- d) FDA inspections, government investigations, and the possible consequences of such actions.

The recent adoption of Regulation FD<sup>1</sup> emphasizes that life sciences companies must communicate information on these four key subjects directly, often making announcements in these critical areas to a market that has not been alerted by analysts who have anticipated the news. All of this increases the pressure on biotech executives who address the investment community.

The Private Securities Litigation Reform Act (the “Reform Act”)<sup>2</sup> does not remove the possibility that shareholders will sue on allegations of inaccurate or incomplete disclosures. Some Reform Act protections require disclosing companies to take affirmative steps. Life sciences executives can find it difficult, in the particular circumstances they face, to take full advantage of the Reform Act’s necessarily general provisions. Moreover, the Reform Act applies only to private suits by shareholders, not to enforcement actions by the SEC, which has been active in the biotech arena.<sup>3</sup>

## I. PREDICTING FDA APPROVAL

FDA approval is critical to a biotechnology product. Investors want to know when such approval is likely. While there is no requirement that life sciences companies forecast when the FDA will approve a product or even the timing of intermediate events in the FDA application process,<sup>4</sup> companies may nevertheless make predictions about approval to keep shareholders informed. Even putting aside express predictions of FDA

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1. Reg. FD, 17 C.F.R. § 243.100 (2001). Reg. FD forbids companies from selectively disclosing material developments to certain market participants, such as analysts. Instead, companies must broadly disseminate such news so that it is available to all investors simultaneously.

2. Pub. L. No. 104-67, 109 Stat. 737 (1995).

3. See *infra* Part II.D.

4. See, e.g., *In re Lyondell Petrochemical Co. Sec. Litig.*, 984 F.2d 1050 (9th Cir. 1993) (affirming dismissal of complaint based on defendants’ asserted failure to disclose financial projections. The court quoted the SEC regulation that “[r]egistrants are encouraged, but not required, to supply forward-looking information.” 984 F.2d at 1053 n.6, quoting 17 C.F.R. § 229.303(a) Instruction 7). This principle should similarly foreclose any duty to publicize internal company predictions that the FDA will deny product approval. See, e.g., *In re Cryomedical Sciences, Inc. Sec. Litig.*, 884 F. Supp. 1001 (D. Md. 1995) (“Plaintiffs plead no facts . . . which would lead the Court to believe that Cryomedical *knew* prior to FDA’s official denial that a denial . . . would be forthcoming. *Even if Cryomedical had suspicions, the securities laws do not require disclosure of suspicions.*”) (emphasis added). *Id.* at 1020.

action, biotech companies releasing financial forecasts frequently base those predictions on assumptions about FDA approval.<sup>5</sup>

#### A. *When Is a Prediction False?*

A company must make a “false” statement in order to be liable under the securities laws. The mere circumstances that a company predicts the FDA will approve a given product by a stated date, and that date passes without any such approval, do not combine to make the prediction necessarily “false.” A prediction is not “false” under the securities laws simply because it does not come true<sup>6</sup> or because in hindsight a different prediction would have been a more reasonable forecast.<sup>7</sup> Courts find a prediction “false” if at the time the company made the prediction there was no good faith, reasonable, objective basis for it, or (under some tests) if those making a forecast knew some undisclosed fact that seriously threatened the predicted event.<sup>8</sup>

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5. FDA product approval action may also affect other disclosures, including descriptions of contracts and reserve figures in financial statements. *See SEC v. Diagnostics Data Inc.*, Litigation Rel. No. 9206 (S.E.C. Oct. 21, 1980) (consent injunction in settled action where the SEC alleged a pharmaceutical research company falsely stated in proxy solicitations that licensing agreement-in-principle for anti-inflammatory drug was worth \$5 million over the next two years when, in fact, it contained provisions totaling only \$2.5 million, \$1.8 of which was contingent upon FDA approval); *Genentech, Inc. Sec. Litig.*, [1989–1990 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 94,901, at 94,968–69 (N.D. Cal. Jan. 19, 1990) (denying in part a motion to dismiss where plaintiffs claimed the company failed to establish a reserve for excess inventory when “defendants knew over a year in advance, based on the FDA’s delay in approving Activase for sale and its limited shelf life, that a large write-off for Activase inventory would eventually be necessary.”).

6. *In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 926 (9th Cir. 1996) (“[T]he fact that the prediction proves to be wrong in hindsight does not render the statement untrue when made.”); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1231 (S.D. Cal. 2001) (FDA’s subsequent rejection of company’s application does not render earlier statements of optimism false or misleading, when defendants had reasonable basis for statements.).

7. *Ronconi v. Larkin*, 253 F.3d 423, 433 (9th Cir. 2001) (“The statement, ‘the storm is passing and it will be sunny tomorrow,’ when it in fact continues to snow the next day, may be bad forecasting, but it is not necessarily a lie. Without more, it does not raise a strong inference of intentional or deliberately reckless falsity or deception.”); *Grassi v. Info. Res., Inc.*, 63 F.3d 596, 599 (7th Cir. 1995) (“Projections which turn out to be inaccurate are not fraudulent simply because later events show that a different projection would have been more reasonable.”); *Sakhrani v. Brightpoint, Inc.*, [2001 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 91,422, at 96,426 (S.D. Ind. Mar. 29, 2001) (granting motion to dismiss where plaintiffs’ “allegations are as consistent with a failure to predict the future accurately as they are with fraud.”).

8. Some courts have in the past relied on a three-part test to determine whether a prediction is false:

A projection or statement of belief contains at least three implicit factual assertions: (1) that the statement is genuinely believed, (2) that there is a reasonable basis for that belief, and (3) that the speaker is not aware of any undisclosed facts tending to

*B. The Private Securities Litigation Reform Act Protections  
for Predictions: Cautionary Language and  
Liability Only for Knowing Falsity*

The Reform Act added sections to both the Securities Act of 1933 and the Securities Exchange Act of 1934 to provide a “safe harbor” for “forward-looking statements” that SEC-filing companies make.<sup>9</sup> Predictions of FDA approval should fall within the statute’s definition of “forward-looking statements.”<sup>10</sup>

The safe harbor provides two principal protections. First, a company is not liable for a forward-looking statement that is identified as such “and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially”

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seriously undermine the accuracy of the statement. A projection or statement of belief may be actionable [i.e., “false” under the securities laws] to the extent that one of these implied factual assertions is inaccurate.

*In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1113 (9th Cir. 1989), *cert. denied*, 496 U.S. 943 (1990); *see also* *Rubinstein v. Collins*, 20 F.3d 160, 166 (5th Cir. 1994) (employing the same test); *Helwig v. Vencor, Inc.*, 251 F.3d 540, 557 (6th Cir. 2001) (employing the same test). Other courts have used an alternate test that appears to include only the first and second *Apple* prongs, and these seem to be the common elements of the various definitions. *Stransky v. Cummins Engine Co., Inc.*, 51 F.3d 1329, 1333 (7th Cir. 1995); *Kowal v. MCI Communications Corp.*, 16 F.3d 1271, 1277 (D.C. Cir. 1994) (“projections . . . are false . . . if they were issued without good faith or lacked a reasonable basis when made.”); *Herskowitz v. Nutri/System, Inc.*, 857 F.2d 179, 184 (3d Cir. 1988), *cert. denied*, 489 U.S. 1054 (1989). Disbelief in a projection by itself, however, should be insufficient to establish falsity after *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1095–96 (1991) (holding in a section 14 context that opinions are not actionable simply because disbelieved). At least one decision holds that projections of future performance not worded as guarantees are generally not actionable under the federal securities laws at all. *See Raab v. General Physics Corp.*, 4 F.3d 286, 290 (4th Cir. 1993).

9. 15 U.S.C. § 77z-2 (1994 & Supp. III 1997); 15 U.S.C. § 78u-5 (1994 & Supp. III 1997).

10. 15 U.S.C. § 77z-2; 15 U.S.C. § 78u-5. The new law defined the term “forward-looking statement” to include

a statement containing a projection of revenues, income . . . earnings . . . per share, capital expenditures, dividends, capital structure, or other financial items . . . a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer . . . a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to rules and regulations of the Commission . . . [and] any statement of the assumptions underlying or relating to any [of the foregoing.]

15 U.S.C. § 77z-2(i)(1)(A)–(D); 15 U.S.C. § 78u-5(i)(1)(A)–(D). While a prediction of an FDA approval date for a particular biotechnology product is not a projection of any of the listed financial figures, it could certainly be phrased as an “objective of management,” and could also be disclosed as an assumption underlying predicted future financial performance.

from those predicted.<sup>11</sup> Second, the Reform Act restricts the companies and executives liable for predictions to those who meet a high and strict standard of culpability. Where a life sciences company makes a prediction outside offering documents, shareholders are most likely to challenge the prediction in a private securities lawsuit under section 10(b) of the Securities Exchange Act and SEC Rule 10b-5.<sup>12</sup> In addition to falsity, plaintiffs in such lawsuits must plead and prove that the defendants had “scienter,” which the Supreme Court has defined to mean “a mental state embracing intent to deceive, manipulate, or defraud.”<sup>13</sup> A majority of circuit courts have held that scienter encompasses some form of extreme recklessness.<sup>14</sup> Under the Reform Act, however, a company and its executives are not liable for a “forward-looking statement” in a private shareholder lawsuit unless the plaintiff pleads and proves that the defendants made the statement “with actual knowledge . . . that [it] was false or misleading.”<sup>15</sup>

Turning to the first protection, if a life sciences enterprise accompanies a forward-looking statement predicting FDA approval with “meaningful cautionary” language, the company should be able to

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11. 15 U.S.C. § 77z-2(c)(1)(A)(i); 15 U.S.C. § 78u-5(c)(1)(A)(i).

12. 15 U.S.C. § 78j (1934); 17 C.F.R. § 240.10b-5 (1948).

13. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 n.12 (1976).

14. VIII L. LOSS & J. SELIGMAN, *SECURITIES REGULATION* 3665 n.521 (3d ed. 1991). Most courts have defined recklessness for 10b-5 purposes as “highly unreasonable” conduct representing “an extreme departure from the standards of ordinary care . . . [so that the] danger of misleading buyers or sellers . . . is either known to the defendant or is so obvious that the [defendant] must have been aware of it.” The Seventh Circuit adopted this standard in *Sunstrand Corp. v. Sun Chem. Corp.*, 553 F.2d 1033, 1044–45 (7th Cir. 1977), *cert. denied*, 434 U.S. 875 (1977). At least one Court of Appeals decision appears to interpret the Reform Act to heighten that standard. See *In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 976–77 (9th Cir. 1999) (viewing 10b-5 recklessness “as a form of intentional or knowing misconduct” applicable where the facts suggest “consciousness or deliberateness”); *but see* *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1064 (9th Cir. 2000) (commenting that the Reform Act “did not alter the substantive requirements for scienter under § 10(b)”). A number of post-Reform Act opinions continue to employ the *Sunstrand* definition. See *Florida State Board of Admin. v. Green Tree Financial Corp.*, 270 F.3d 645, 653 (8th Cir. 2001); *Nathenson v. Zonagen, Inc.*, 267 F.3d 400, 408 (5th Cir. 2001); *City of Philadelphia v. Fleming Cos., Inc.*, 264 F.3d 1245, 1258 (10th Cir. 2001); *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000), *cert. denied*, 121 S. Ct. 567 (Nov. 27, 2000); *Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1282 n.18 (11th Cir. 1999) (also invoking the term “severe recklessness”); *In re Comshare, Inc. Sec. Litig.*, 183 F.3d 542, 550 (6th Cir. 1999); *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 198, 200 (1st Cir. 1999); *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 535 (3d Cir. 1999). The Supreme Court itself left open the question of whether recklessness would in any form satisfy the 10b-5 scienter element. See *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 n.12 (1976).

15. 15 U.S.C. § 77z-2(c)(1)(B) (if the statement is made by a natural person, a plaintiff must prove that that individual had actual knowledge that the statement was false or misleading; if made by a business entity, a plaintiff must prove that it was made with the approval of an executive officer who had actual knowledge that the statement was false or misleading).

dismiss a lawsuit based on the circumstance that FDA approval did not materialize at the predicted time. This should be true regardless of plaintiffs' allegations about the defendants' mental state when they made the prediction, and regardless of whether the factors expressly identified by the company's cautionary language were the ones that eventually caused the FDA to delay or deny approval. Congress expected

that the cautionary statements [will] identify important factors that could cause results to differ materially—but not all factors. Failure to include the particular factor that ultimately causes the forward-looking statement not to come true will not mean that the statement is not protected by the safe harbor. The Conference Committee specifies that the cautionary statements identify “important” factors to provide guidance to issuers and [this is] not to provide an opportunity for plaintiff counsel to conduct discovery on what factors were known to the issuer at the time the forward-looking statement was made.

The use of the words “meaningful” and “important factors” are intended to provide a standard for the types of cautionary statements upon which a court may, where appropriate, decide a motion to dismiss, without examining the state of mind of the defendant. The first prong of the safe harbor requires courts to examine only the cautionary statement accompanying the forward-looking statement. Courts should not examine the state of mind of the person making the statement.<sup>16</sup>

As significant as this first protection is, it is uncertain how effective it will be in stopping lawsuits based upon inaccurate forecasts of FDA approval. The Conference Report made this comment on the cautionary language needed to bring the first protection into play:

[B]oiler plate warnings will not suffice . . . . The cautionary statements must convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statement, such as, for example, information about the issuer's business.<sup>17</sup>

The central question is what cautionary language courts will find “meaningful” and what they will consider “boilerplate.” As this article

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16. H.R. CONF. REP. NO. 104-369, at 44 (1995) (“The applicability of the safe harbor provisions [regarding cautionary statements] . . . shall be based upon the sufficiency of the cautionary language under those provisions and does not depend on the state of mind of the defendant.” *Id.* at 47).

17. *Id.* at 43.

sets out below, some pre-Reform Act decisions considering the “bespeaks caution” defense gave short shrift to express warnings that the company was not making bankable predictions about FDA actions.<sup>18</sup> While the Reform Act’s first protection for forward-looking statements is stronger than the “bespeaks caution” doctrine,<sup>19</sup> it remains unclear what language will suffice to shield forecasts from future lawsuits.

*In re PLC Systems, Inc. Securities Litigation*<sup>20</sup> applies this first protection. The opinion found a number of statements, including that the company believed its FDA application was “on track for approval this year,” to be within the Reform Act’s safe harbor.<sup>21</sup> The court quoted the

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18. See discussion of *Xoma* and *Marion Merrell Dow* *infra* notes 74–78, 86–87 and accompanying text.

19. The “bespeaks caution” doctrine “provides a mechanism by which a court can rule as a matter of law (typically in a motion to dismiss for failure to state a cause of action or a motion for summary judgment) that defendants’ forward-looking representations contained enough cautionary language or risk disclosure to protect the defendant against claims of securities fraud.” *In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1413 (9th Cir. 1994), *cert. denied*, 516 U.S. 868 (1995), quoting Donald C. Langevoort, *Disclosures that “Bespeak Caution”*, 49 BUS. LAW. 481, 482-83 (1994). It “has developed to address situations in which optimistic projections are coupled with cautionary language—in particular, relevant specific facts or assumptions—affecting the reasonableness of reliance on and the materiality of those projections.” *Id.* at 1414, quoting *Rubinstein v. Collins*, 20 F.3d 160, 167 (5th Cir. 1994) (footnotes omitted). As applied by the Ninth Circuit in *Worlds of Wonder*, it comes into play where defendants have employed “precise cautionary language which directly addresses itself to future projections, estimates or forecasts.” *Id.*, quoting *In re Worlds of Wonder Sec. Litig.*, 814 F. Supp. 850, 858 (N.D.Cal. 1993). Some commentators and cases suggest that the first Reform Act protection for forward-looking statements is similar to the “bespeaks caution” doctrine. John C. Coffee, Jr., *The Future of the Private Securities Litigation Reform Act: Or, Why the Fat Lady Has Not Yet Sung*, 51 BUS. LAW. 975, 988 (1996); *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1121 (10th Cir. 1997); *Shaw v. Digital Equipment Corp.*, 82 F.3d 1194, 1213 n.23 (1st Cir. 1996). However, “bespeaks caution” is limited by many decisions to instances in which the cautionary statements identify the precise risks that matured to thwart the predicted result. See, e.g., *In re NationsMart Corp. Sec. Litig.*, 130 F.3d 309, 318 (8th Cir. 1997), *cert. denied*, 524 U.S. 927 (1998). In contrast, the first Reform Act protection requires only that the defendant identify “important factors” that could cause actual results to differ materially from a prediction and does not require that the language include the exact risk that in fact caused the prediction to fail. See H.R. CONF. REP. NO. 104-369, *supra* note 16, at 44; see also *Harris v. Ivax Corp.*, 182 F.3d 799, 807 (11th Cir. 1999), *rehearing denied*, 209 F.3d 616 (11th Cir. 2000), questioning whether

To be ‘meaningful’ . . . must the cautionary language explicitly mention *the* factor that ultimately belies a forward-looking statement? We think not . . . [W]hen an investor has been warned of risks of a significance similar to that actually realized, she is sufficiently on notice of the danger of the investment to make an intelligent decision about it according to her own preferences for risk and reward.

20. *In re PLC Systems, Inc. Sec. Litig.*, 41 F. Supp. 2d 106 (D. Mass. 1999).

21. *Id.* at 117–18. (footnote omitted). The court characterized the following statements, among others, as “aspiratory” and found them safe harbor-protected:

- (1) “[T]he Company *believes* that this data will satisfy the FDA’s request;”
- (2) “PLC believes its . . . application . . . is on track for approval this year;”

following words as an example of the cautionary language PLC had included in a 10-Q filing:

Although The Heart Laser has been granted “expedited review” by the [FDA], given the current uncertainties of the time required by the FDA to approve a Pre-market Approval (“PMA”) application, the Company cannot project when, if at all, such approval would be granted. Until PMA approval, continued profitability will likely be determined by the number of international shipments and the related mix of sales and placements.<sup>22</sup>

Whether another court would find such language adequate to invoke Reform Act protection might well depend on the court’s view of whether such phrases provide, under the circumstances, a fair warning. Life sciences companies may wish to include additional details, cautioning investors that FDA approval is contingent on many factors—including clinical test results and the evaluation of those results<sup>23</sup>—that make it impossible to accurately predict when or whether the FDA will approve the drugs or devices that the companies are developing. Companies may wish to add further details, including that tests are based upon certain protocols and are subject to human errors; that there may be several ways in which to evaluate test results; and that even if the companies conclude that tests provide evidence of a drug’s or device’s effectiveness and safety, the agency may not agree because it may conclude that the protocols were not sufficiently enforced, may evaluate the significance of the test results differently, or may take a different view concerning the effect of any human errors on those results during the trials.

While the first Reform Act protection for forward-looking statements is straightforward and objective, the second protection—no

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(3) “[E]xpeditious review . . . may compress the remaining process time . . . . We believe the recent filing . . . allows PLC Systems to remain on track for an FDA approval this year;” and (4) “[W]e expect that full approval could be granted in the summer months.”

*Id.* (alteration and emphasis in original).

22. *Id.* at 118 n.7 (alteration in original).

23. See also *In re Columbia Lab., Inc. Sec. Litig.*, 144 F. Supp. 2d 1362 (S.D. Fla. 2001), where the court wrote:

Defendants state that they [were] optimistic Advantage-S would pass all the UNAIDS study . . . and that they believed Columbia would receive FDA approval within six months. *Id.* at 1368.

The Court finds that the language accompanying these forward-looking statements qualif[ies] as meaningful cautionary language. The disputed statements were consistently accompanied by language indicating that the product and projected results depended on the successful completion of the UNAIDS study. *Id.* at 1369.

liability absent “actual knowledge” that the prediction is false and misleading—implicates the defendant’s mental state. The Reform Act requires that 10b-5 plaintiffs plead “with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.”<sup>24</sup> Defendants may test such pleading with a motion to dismiss before any discovery occurs because the Act imposes a discovery stay during the pendency of such motions.<sup>25</sup>

Many decisions interpret the “particularity” requirement strictly so that, without any discovery, plaintiffs relying on “internal” documents or discussions to show that defendants knew damning facts need to identify and describe those documents or discussions in significant detail.<sup>26</sup> Even pre-Reform Act cases evinced concern that plaintiffs should plead the details of internal documents instead of referring to them generally.<sup>27</sup> Moreover, to the extent that plaintiffs rely on oral information, under the Reform Act they must plead some facts about their sources,<sup>28</sup> although the required particularity of identification is still in dispute.<sup>29</sup>

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24. 15 U.S.C. § 78u-4(b)(2) (1994 & Supp. III 1997).

25. 15 U.S.C. § 78u-4(b)(3)(B) (1994 & Supp. III 1997).

26. See *In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 984–85 (9th Cir. 1999) (affirming dismissal of a complaint where allegations were based on internal reports, but plaintiff failed to “mention . . . the sources of her information with respect to the reports, how she learned of the reports, who drafted them, or which officers received them. . . . We would expect that a proper complaint which purports to rely on the existence of internal reports would contain at least some specifics from those reports as well as such facts as may indicate their reliability.”); *In re Peritus Software Services, Inc. Sec. Litig.*, 52 F. Supp. 2d 211, 228 (D. Mass. 1999) (“Stating that unnamed ‘defendants’ discussed ‘major problems with the acquisition,’ does not raise a strong inference that [a defendant] knew of the misleading nature of his statement at the time it was made.”).

27. See *Arazie v. Mullane*, 2 F.3d 1456, 1467 (7th Cir. 1993); *Weisburgh v. St. Jude Medical, Inc.*, 158 F.R.D. 638, 643 (D. Minn. 1994), *aff’d*, 62 F.2d 1422 (8th Cir. 1995) (unpublished table decision). Cf. *Provenz v. Miller*, 102 F.3d 1478, 1487–88 (9th Cir. 1996), *cert. denied*, 118 S. Ct. 48 (1997) (reversing district court dismissal of a complaint based on internal spreadsheet accompanied by deposition testimony of company employees that the forecast in the spreadsheet represented “the best, most accurate representation as of the time it was prepared of what the company’s financial results [would] be like for the prospective quarter”).

28. *In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1080 n.15 (N.D. Cal. 2001) (granting motion to dismiss in part because “[t]he S[econd] A[mended] C[omplaint] alleges that ‘confidential informants’ provided some of the information alleged therein, but does not specify what type of information they provided. Nor does it supply any information that the Court might use to evaluate the confidential informants’ basis for alleging that the defendants had access to adverse information.”).

29. In *Novak v. Kasaks*, 216 F.3d 300, 313–14 (2d Cir.), *cert. denied*, 121 S. Ct. 567 (2000), the Second Circuit wrote that, while the Reform Act “may compel revelation of confidential sources under certain circumstances,” its “reading of the [Reform Act] reject[ed] any notion that confidential sources must be named as a general matter.” The court added that “even if personal sources must be identified, there is no requirement that they be named, *provided they are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information*

Putting all of this together, the Reform Act requires plaintiffs attacking predictions of FDA approval to, at the outset of the case and without any discovery, plead factual details giving rise to a strong inference that defendants had “actual knowledge” that the prediction was false or misleading.<sup>30</sup> Plaintiffs will find this a substantial hurdle to clear.<sup>31</sup>

It bears emphasis, however, that the Reform Act protections for “forward-looking statements” do not apply at all to some statements, such as those made in documents for an initial public offering.<sup>32</sup> The

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*alleged.*” [emphasis added]. *Novak* disagreed with district court decisions that appeared to require naming sources.

30. *Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001) (“The complaint must . . . ‘state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind’—that is . . . where the challenged act is a forward looking statement, with ‘actual knowledge . . . that the statement was false or misleading.’ ”); *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 536 (3d Cir. 1999) (affirming dismissal where plaintiffs did “not plead any specific facts to support an inference that . . . [the individual speaker], or anyone else at Advanta, had actual knowledge of her statement’s falsity”); *In re Ciena Corp. Sec. Litig.*, 99 F. Supp. 2d 650, 661–62 (D. Md. 2000) (granting motion to dismiss because “plaintiffs have not alleged any particularized facts showing that defendants had actual knowledge that any of the forward-looking statements were false or misleading—the substantive standard they must meet to blow the statements out of the safe harbor”).

31. *See, e.g., In re Technical Chemicals Sec. Litig.*, [2000 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 91,045 (S.D. Fla. July 3, 2000) (dismissing a complaint including allegations that the company’s “own scientists warned management that completion of the product could take years. . . . Key measurement correlations . . . still need[ed] to be developed. . . . [Company] scientists also informed management that it was impossible to predict a time for submission of the product for FDA approval, and that numerous and significant scientific breakthroughs would have to be made.” *Id.* at 94,862. Plaintiffs also alleged “repeated warnings from the on-site developers.” *Id.* The court found even these allegations too general:

Plaintiffs here fail to adequately explain the information in the scientists’ possession, why it was reliable, or any other relevant details. What breakthroughs would have to be made? Who were the on-site developers? More important, what specific facts support the allegation that the company’s development projections were unsupported by facts in [the company’s] possession at the time the company made the projections?

*Id.* Overall, the court ruled that plaintiffs “failed to plead sufficient facts to give rise to a strong inference that the statements, if false, were made with actual knowledge of their falsity.” *Id.* at 94,864.).

32. 15 U.S.C. § 77z-2(b)(2)(D) (1994 & Supp. III 1997); 15 U.S.C. § 78u-5(b)(2)(D) (1994 & Supp. III 1997). Forward-looking statements in documents filed with the Commission do enjoy the protection of Rule 175 under the 1933 Act and Rule 3b-6 under the 1934 Act. 17 C.F.R. § 230.175 (2001), 17 C.F.R. § 240.3b-6 (2001). These rules provide that such a statement “shall be deemed not to be . . . fraudulent . . . unless it is shown that such statement was made . . . without a reasonable basis or was disclosed other than in good faith.” These rules apply to initial public offerings. 1C HAROLD S. BLOOMENTHAL, *GOING PUBLIC AND THE PUBLIC CORPORATION* § 10.08, at 10-277 (2001). However, they provide less protection than the Reform Act in part because they require investigation of the defendant’s state of mind (to determine “reasonable basis” and “good faith”) and do not include anything like the first Reform Act protection, which is a complete defense if the forward-looking statement is accompanied by meaningful cautionary language.

protections are similarly inapplicable to financial statements prepared in accordance with generally accepted accounting principles (“GAAP”).<sup>33</sup> If a faulty prediction of FDA approval leaves a company with unsalable inventory<sup>34</sup> for which it has not reserved in GAAP-prepared financials, defendants cannot rely upon the forward-looking statement protections to defend against a lawsuit charging that the failure to reserve was fraudulent. In addition, the protections apply only in private actions,<sup>35</sup> not in SEC enforcement proceedings.

Finally, some decisions permit plaintiffs to avoid the Reform Act protections by crafting their complaints to allege omission of the facts causing predictions to fail rather than attacking the predictions as affirmative misstatements. In *In re Cell Pathways, Inc. Securities Litigation*, the court denied a motion to dismiss in a case based, among other things, on statements that a Phase III trial was on schedule and that the company expected to file an application with the FDA in the first half of 1999. Plaintiffs claimed the company failed to reveal that the trial included many patients who did not meet the criteria for inclusion in the study. When defendants argued that “statements regarding . . . plans and expectations for the NDA filing . . . [were] forward-looking,” the court responded that “‘allegations based upon omissions of existing facts or circumstances do not constitute forward looking statements protected by the safe harbor of the Securities Act.’”<sup>36</sup>

Courts should be skeptical of plaintiff efforts to convert a case based on an allegedly false prediction into one assertedly based on the nondisclosure of the facts that supposedly made the prediction false. Plaintiffs could so characterize most prediction cases. If such a characterization routinely disables the Reform Act protections for forward-looking statements, those protections will be meaningless. Congress could not have intended that result.

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33. 15 U.S.C. § 77z-2(b)(2)(A); 15 U.S.C. § 78u-5(b)(2)(A).

34. *See, e.g.*, *Genentech, Inc. Sec. Litig.*, [1989–1990 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 94,901, at 94,968–69 (N.D. Cal. Jan. 19, 1990).

35. 15 U.S.C. § 77z-2(c); 15 U.S.C. § 78u-5(c).

36. *In re Cell Pathways, Inc. Sec. Litig.*, [2000 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 91,001, at 94,499 (E.D. Pa. June 20, 2000), quoting *In re Mobilemedia*, 28 F. Supp. 2d 901, 930 (D.N.J. 1998). *See also* *Walsingham v. Biocontrol Tech., Inc.*, 66 F. Supp. 2d 669, 679 (W.D. Pa. 1998) (court denied motion to dismiss based in part on the argument that the “be-speaks caution” doctrine or the Reform Act safe harbor protected company statements, finding these protections inapplicable where “plaintiff’s claims . . . are based upon an allegation of misrepresented historical or current facts . . . for example, that at the time the defendants’ [sic] made the statements . . . each defendant already knew of the inadequate test results but concealed such information from the public.”).

That said, companies cannot afford to ignore the possibility that plaintiffs may convince courts to categorize allegations that are actually based on a published prediction as an omissions case. To guard against this possibility, life sciences companies should review carefully what they know when they make a prediction of FDA approval or financial results assuming such an approval. They may decide to disclose—perhaps as part of their cautionary language—facts which, although they do not reduce the probability of anticipated outcomes so greatly that the companies should not make the predictions, nevertheless might develop into factors that could significantly change future results.

This article now considers other cases in which courts evaluated securities claims based upon (1) express predictions of FDA approval and (2) financial projections assuming such approval. While some of these cases pre-date the Reform Act, they still yield helpful insights.

### C. Express Predictions of FDA Approval

Two Ninth Circuit decisions and a district court case in Missouri—all pre-Reform Act—dealt explicitly with projected FDA approvals. The defendants in *In Re Syntex Corporation Securities Litigation*<sup>37</sup> won, defeating plaintiffs on a motion to dismiss. The defendants in *Warshaw v. Xoma Corporation*<sup>38</sup> prevailed on a motion to dismiss in the district court, but the Ninth Circuit reversed. The defendants in *In re Marion Merrell Dow Inc. Securities Litigation*<sup>39</sup> lost their motion to dismiss in the trial court. More recently, the SEC, in *In re Zila, Inc. and Joseph Hines*, entered a cease and desist order against a company in a settled SEC administrative proceeding for persisting in predictions of FDA approval after receiving a communication that FDA staff would recommend that approval be denied.<sup>40</sup>

Syntex produced a patented prescription drug called Naprosyn, used to treat arthritis inflammation and pain. The Naprosyn patent was to expire in late 1993. In January 1992, Syntex predicted that the FDA would approve an over-the-counter (“OTC”) version of Naprosyn “well in advance of” the patent expiration.<sup>41</sup> Plaintiffs claimed this prediction was

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37. *In re Syntex Corp. Sec. Litig.*, 95 F.3d 922 (9th Cir. 1996).

38. *Warshaw v. Xoma Corp.*, 74 F.3d 955 (9th Cir. 1996) [hereinafter “Xoma II”].

39. *In re Marion Merrell Dow, Inc. Sec. Litig.*, [1993 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 97,776 (W.D. Mo. Oct. 4, 1993).

40. *In re Zila, Inc. and Joseph Hines*, Administrative Proceeding File No. 3-10657, Order Instituting Public Administrative Proceedings Pursuant to Section 21C of the Securities and Exchange Act of 1934, Making Findings, and Imposing a Cease-And-Desist Order (Dec. 19, 2001) [hereinafter “Zila Admin. Order”], <http://www.sec.gov/litigation/admin/34-45169.htm>.

41. *In re Syntex*, 95 F.3d at 930.

“false” because Syntex had information that the investing public did not possess about “deficiencies in . . . testing procedures for the [over-the-counter] drug such as problems with dosages and differences between the drugs tested (which lacked sodium) and the OTC version of Naprosyn (which contained sodium).”<sup>42</sup>

In affirming the district court’s decision to grant Syntex’s motion to dismiss, the Ninth Circuit emphasized that the prediction was a long-term one and that plaintiffs had failed to plead how any difficulties in testing undermined that prediction. The Ninth Circuit even suggested circumstances that could reconcile the alleged testing problems with the projected approval date:

In estimating a date for FDA approval of OTC Naprosyn, Syntex was making a prediction far in advance, while the drug was still in the testing stage, about an approval decision that lies in the hands of a regulatory body. Thus, Syntex was forecasting a future event. Any alleged deficiencies in the testing procedures do not indicate that Syntex’s prediction of an FDA approval date was false when made. Instead, the company could have known of problems in the testing procedures, planned to remedy those deficiencies, and still thought it would achieve FDA approval by the estimated date. Clearly, Defendants’ prediction of a date for a regulatory decision over which they did not have control, made that far in advance, for a drug that was still in the testing stages, could not carry a guarantee of accuracy or reliability. . . .

Nothing in this case indicates that the company had knowledge contradicting its ability to achieve FDA approval within two years and prior to the expiration of prescription Naprosyn’s patent.<sup>43</sup>

Three points merit discussion. First, the *Syntex* defendants made their prediction quite some time before the approval date they forecasted.<sup>44</sup> The Ninth Circuit was properly more lenient in evaluating such long-term projections, as compared to predictions of more immediate

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42. *Id.*

43. *Id.*; see also *Schuster v. Symmetricon, Inc.*, [2000–2001 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 91,206, at 95,031 (N.D. Cal. Aug. 1, 2000) (granting dismissal where “internal communications speak of problems and even periodic ‘failures’ (or in one case a ‘debacle’ during the Birmingham testing), but nowhere do they indicate a sense that the project would not ultimately come through”).

44. In addition, the FDA actually issued its approval for the over-the-counter drug only three weeks after the Naprosyn patent expired. “Apparently the company was able to remedy any defects in the testing procedures and in the drug itself.” *In re Syntex*, 95 F.3d at 930–31.

concern. The significance of an estimate that the FDA will approve a given product by a specific date can be stated, in a statistical sense, in terms of a “confidence interval”—e.g., that the company is 90% confident that the FDA will approve the product within a certain range of months, with the stated date falling inside that range.<sup>45</sup> Generally, the farther out the prediction is made, the larger the time interval for any given level of confidence will be. In less formal terms, common sense argues for more leeway when a company predicts that an event will occur two years from today than when it predicts that an event will occur tomorrow.

Second, plaintiffs may argue that such long-term predictions impose a “duty to update.”<sup>46</sup> For example, if a company has predicted FDA approval for a product by a certain date and then, before that date arrives, concludes that test results fail to demonstrate efficacy, plaintiffs may argue that the company has a duty to publicly update its forecast of regulatory approval if the company concludes that the test results will delay approval beyond the forecasted time or mean that the FDA will not approve at all.

It is unclear to what extent there is any duty to update under the securities laws. Some decisions suggest the possibility of such a duty where the subject of the first statement is an extraordinary corporate transaction or some such similarly important and out-of-the-ordinary fact. But the Reform Act specifically stated that it was not imposing any

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45. See *Wielgos v. Commonwealth Edison Company*, 892 F.2d 509, 514 (7th Cir. 1989) (“Commonwealth Edison made point estimates: [the two nuclear reactors] will cost \$3.34 billion and start in 1984 and 1985. Everyone understands that point estimates are almost certainly wrong. Things will not go exactly as predicted, and any deviation will cause the future to diverge from the estimate. Statisticians—and stock analysts—need confidence intervals to go with the maximum-likelihood estimate. Commonwealth Edison might have said, for example, that there is a two-thirds chance that the cost will fall in a given range, identifying the events that would push the cost up or down within (or outside of) that range.”).

46. *Backman v. Polaroid*, 910 F.2d 10, 17 (1st Cir. 1990) (“We may agree that, in special circumstances, a statement, correct at the time, may have a forward intent and connotation upon which parties may be expected to rely. If this is a clear meaning, and there is a change, correction, more exactly, further disclosure, may be called for.”); *In re Time Warner, Inc. Sec. Litig.*, 9 F.3d 259, 268 (2d Cir. 1993), *cert. denied sub nom. Ross v. ZVI Trading Corp. Employees’ Money Purchase Pension Plan and Trust*, 511 U.S. 1017 (1994) (company making statements that could have been understood to mean that it hoped to solve its entire debt problem through strategic alliances may have been under duty to disclose consideration of dilutive equity offering as an alternative means of raising capital); *Weiner v. Quaker Oats Co.*, 129 F.3d 310, 317 (3d Cir. 1997) (company subject to takeover rumors had announced intended debt/capitalization ratio, then made acquisition that increased the ratio and made the company less attractive as a takeover target; “it was reasonable for an investor to expect that the company would make another such prediction if it expected the ratio to change markedly in the ensuing year.”), *on remand* [2000–2001 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 91,266, at 95,468–69 (N.D. Ill. Nov. 9, 2000) (denying defendants’ motion for summary judgment).

duty to update.<sup>47</sup> At least one Court of Appeals has questioned whether a duty to update survives this legislation even when a company is involved in an extraordinary transaction.<sup>48</sup> Moreover, many recent cases are hostile to a “duty to update,” particularly outside the context of company-transforming transactions. *In re Burlington Coat Factory Securities Litigation*<sup>49</sup> affirmed dismissal of complaint insofar as it alleged defendants had a duty to update a statement by the issuer’s chief accounting officer that he was comfortable with certain analysts’ earnings estimates.<sup>50</sup> More recently, *Gallagher v. Abbott Laboratories*<sup>51</sup> rejected the notion that companies have “an absolute duty to disclose all information material to stock prices as soon as news comes into [the issuer’s] possession.”<sup>52</sup>

A prediction of FDA approval seems closer to an earnings estimate than an extraordinary corporate transaction and, accordingly, should not be subject to a duty to update. Moreover, issuers may be able to avoid any “duty to update” by including cautionary statements to the effect that a projection of FDA approval speaks only as of the date that the company releases the forecast and that the company is not assuming any duty to update that projection.

Third, *Syntex* recognized that there are inherent uncertainties in the FDA approval process, of which the market is well aware. This is important because most shareholder class actions are based on the fraud-on-the-market theory. Under that theory, individual shareholders need not show they personally relied upon a misstatement, such as a prediction of FDA approval. Instead, this economic construct assumes that the price of

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47. 15 U.S.C. § 78u-5(d) (1994 & Supp. III 1997).

48. *Eisenstadt v. Centel Corp.*, 113 F.3d 738, 746 (7th Cir. 1997).

49. 114 F.3d 1410 (3d Cir. 1997).

50. “[W]e do not think it can be said that an ordinary earnings projection contains an implicit representation on the part of the company that it will update the investing public with all material information that relates to that forecast. . . . We conclude that ordinary, run-of-the-mill forecasts contain no more than the implicit representation that the forecasts were made reasonably and in good faith.” *Id.* at 1433.

*Burlington Coat Factory* distinguished the case in which a forward-looking statement involves a fundamental change in the nature of a company, but noted that even then any duty to update “would be a narrow one to update the public as to extreme changes in the company’s originally expressed expectation of an event such as a takeover, merger, or liquidation.” *Id.* at 1434 n.20. (emphasis in original); *See also* *Grassi v. Information Resources, Inc.*, 63 F.3d 596, 599 (7th Cir. 1995); *Stransky v. Cummins Engine Co.*, 51 F.3d 1329, 1332, 1333 n.9 (7th Cir. 1995).

51. 269 F.3d 806 (7th Cir. 2001).

52. *Id.* at 808. “We do not have a system of continuous disclosure.” *Id.* Instead, the 1933 Act “requires firms to reveal information only when they issue securities.” *Id.* The 1934 Act and accompanying regulations require issuers to file annual and other periodic reports, but “contemplate that these reports will be snapshots of the corporation’s status on or near the filing date, with the updates due not when something ‘material’ happens, but on the next prescribed filing date.” *Id.* at 809.

a security reflects all publicly disclosed information, including any predictions. “Market professionals” closely monitor company information and react to it. Their recommendations and decisions drive the price.<sup>53</sup> These market professionals presumably know the rigors and difficulties of FDA approval and discount a company’s prediction, as the *Syntex* court put it, “of a date for a regulatory decision over which [the company does] not have control . . . for a drug that [is] still in the testing stages.”<sup>54</sup>

In *Xoma*, plaintiffs alleged very different facts. Xoma was developing a drug called E5, an antibody designed to treat gram-negative sepsis. The critical events began on March 2, 1992, when an Oppenheimer analyst issued a report based on his review of two Phase III tests<sup>55</sup> raising the possibility that “E5 actually increases mortality in a large percentage of gram-negative sepsis patients.” The analyst opined that Xoma had “no hope” of winning FDA approval for E5.<sup>56</sup> Xoma’s president responded by publicly stating that the analyst report was “scientifically wrong” and “irresponsible,” and that “everything is going fine” in the FDA review. The president went on to say that E5 “decreases mortality as proven by results from 1,300 patients including two Phase III studies, and four other smaller studies.”<sup>57</sup>

On April 14, 1992, Xoma disclosed that the FDA had said “a review of the first [Phase III] clinical study of . . . E5 . . . does not, by itself, provide sufficient evidence of efficacy to support product licensure.” Xoma said that the FDA had advised “it is continuing its review of the

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53. The Supreme Court endorsed the fraud-on-the-market theory in *Basic, Inc. v. Levinson*, 485 U.S. 224, 241–50 (1988), and commented specifically on the importance of “market professionals.” *Id.* at 247 n.24.

54. *In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 930 (9th Cir. 1996). The Ninth Circuit has, in other contexts, similarly found that the market is aware of certain inherent problems in the high technology industry. *In re Convergent Tech. Sec. Litig.*, 948 F.2d 507 (9th Cir. 1991) (“The market clearly knew demand for the [first generation] workstation would decrease as Convergent began to make [the second generation workstation] available to its customers. As a general matter, investors know of the risk of obsolescence posed by older products forced to compete with more advanced rivals.” *Id.* at 513).

55. For a description of the FDA testing process, see *Padnes v. Scios Nova Inc.*, No. C 95-1693, 1996 WL 539711 at \*10 n.1 (N.D. Cal. Sept. 18, 1996) (“New drugs typically proceed through three levels of testing prior to approval by the FDA. A Phase I study is conducted in healthy patients and is designed to measure the safety of the drug. A Phase II study is intended to gain preliminary evidence of the efficacy of the drug within a range of dosages. Phase III studies are intensive clinical trials, with testing protocol controlled by FDA standards. A Phase III study is conducted to obtain sufficient data for statistical proof of both safety and efficacy.”).

56. *Warshaw v. Xoma Corp.*, 74 F.3d 955, 957 (9th Cir. 1996).

57. *Xoma-OpCo-3: Xoma President Disputes Oppenheimer E5 View*, Dow Jones News Service, Mar. 2, 1992.

company's second [Phase III] study of E5."<sup>58</sup> In a second press release, Xoma stated that it continued to believe that the two Phase III trials, considered together, showed effectiveness and that the FDA notification was not a setback in the review process. The CEO/chairman of the board said the notification was a sign that the FDA was moving forward.<sup>59</sup>

The next day, the media quoted Xoma's chairman/CEO as saying, "We are confident that the drug is safe and efficacious and that it is moving forward well" in the review process.<sup>60</sup> Xoma issued a press release saying that the FDA notification "doesn't imply 'a delay or setback in the agency's review of E5.' [The] Xoma Chairman and Chief Executive . . . said, 'Our announcement yesterday led to concerns in the market that a significant problem had arisen in the FDA's review of E5. Those concerns are unfounded; we think the market misunderstood the earlier announcement and overreacted to it.'"<sup>61</sup> Xoma's stock dropped 4 points to 14 1/2.<sup>62</sup>

Three weeks later, Xoma's chairman/CEO again noted the "positive forward progress" of the FDA review.<sup>63</sup> A Dow Jones News Service article reported that he said Xoma remained confident of FDA approval and convinced that E5 was safe and effective and would be widely used to treat patients suspected of having sepsis who had organ failure but were not in refractory shock. The chairman/CEO reportedly said the Phase III clinical trials of E5 demonstrated statistically significant decreases in mortality and organ failure, that FDA inspections of the E5 manufacturing facilities had been completed, and that inventories of the drug were in place and ready for commercial shipment.<sup>64</sup>

One month later, however, Xoma announced on June 4 that the FDA had concluded additional testing might be necessary on E5.<sup>65</sup> A story quoted the chairman and CEO as saying that the FDA "felt there wasn't

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58. *FDA Review of Xoma Drug Study Doesn't Find License Evidence*, Dow Jones News Service, Apr. 14, 1992.

59. *Warshaw v. Xoma Corp.*, 856 F. Supp. 561, 563 n.1 (N.D. Cal. 1994) [hereinafter "Xoma I"].

60. *Id.*; *FDA Review of Xoma Drug Study Doesn't Find License Evidence*, Dow Jones News Service, Apr. 14, 1992 (corrected 4/15, 9:38 a.m.).

61. *Xoma-FDA Review of E5 . . . Says Market Overreacted to News*, Dow Jones News Service, Apr. 15, 1992.

62. IDD Information Services, *Tradeline*, CUSIP no. G9825R10, available at LEXIS, Quote Library.

63. *Warshaw v. Xoma Corp.*, 74 F.3d 955, 958 (9th Cir. 1996).

64. *Xoma I*, 856 F. Supp. at 563 n.1; Phillip E. Nalborne, *Xoma Corp. Remains Confident FDA Will Approve E5 Drug*, Dow Jones News Service, May 5, 1992.

65. *Xoma Says FDA May Require Added Clinical Testing of E5*, Dow Jones News Service, June 4, 1992.

sufficient efficacy.”<sup>66</sup> Xoma’s stock, which had rebounded to close at 20 on June 3, fell to 15 1/4 the next day.<sup>67</sup> On June 11, Xoma announced it would give the FDA additional information and analyses from clinical studies, but acknowledged that “there can be no assurance that the FDA will license E5 on the basis of the already-completed studies or on the basis of any additional clinical trials.”<sup>68</sup>

Shareholders sued, claiming Xoma had misrepresented the facts from March 2 through June 3. The district court granted the company’s motion to dismiss on the grounds that:

Plaintiffs do not allege that any of Defendants’ statements are false. Rather, Plaintiffs contend that the statements are misleading because they imply that FDA approval is imminent. However, Plaintiffs do not point to a single instance where Defendants speculated on when FDA approval might come. Plaintiffs rely exclusively on statements of general optimism, without alleging any basis for inferring that Defendants did not genuinely believe, or had no reason to believe, their optimistic statements. Given that the results of the two Phase III trials were publicly available, and Defendants repeatedly disclaimed any ability to predict the actions of the FDA, Plaintiffs fail to state a claim under the federal securities laws.<sup>69</sup>

The Ninth Circuit reversed. Like the district court, it characterized plaintiffs’ case as asserting that Xoma had assured the public of E5’s “imminent” approval.<sup>70</sup> The Ninth Circuit held, however, that the complaint could stand because plaintiffs alleged “that Xoma knew, based on its clinical studies, that E5 might not work and would never be approved by the FDA.”<sup>71</sup>

It is difficult to understand the Ninth Circuit’s decision. The opinion does not cite any Xoma statement that FDA approval was “imminent.” The opinion fails to identify just *what* facts Xoma allegedly knew—and concealed—that supposedly showed that E5 did not work. This silence is

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66. Scott Wenger, *Xoma to Meet with FDA to Review Status of E5 Antibody*, Dow Jones News Service, June 4, 1992; *Xoma II*, 74 F.3d at 958.

67. IDD Information Services, *Tradeline*, CUSIP no. G9825R10, available at LEXIS, Quote Library; *Xoma I*, 856 F. Supp. at 563.

68. *Xoma-FDA -2-: FDA Had Said It Might Require Added Testing*, Dow Jones News Service, Jun. 11, 1992; see also *Xoma II*, 74 F.3d at 958 (Ninth Circuit said plaintiffs alleged that this meant approval would be delayed for months or years and that the delay greatly diminished Xoma’s chances of capturing the sepsis treatment market).

69. *Xoma I*, 856 F. Supp. at 564.

70. *Xoma II*, 74 F.3d at 957.

71. *Id.* at 959.

particularly troublesome because—even before the Reform Act—Rule 9(b) required that fraud be pleaded with particularity.<sup>72</sup> And well before *Xoma*, the Ninth Circuit interpreted that rule to mean that plaintiffs in securities fraud cases must allege specifically *why* a statement was false.<sup>73</sup>

Moreover, the *Xoma* defendants pointed to many qualifying statements the company and its officers had made that expressly disclaimed any intent to predict when the FDA would approve E5. *Xoma*'s 10-Q for the quarter ended September 30, 1991, included this warning:

The Company's liquidity and future financial position will be materially impacted by both the timing of approval and the ultimate commercial success of E5 and [another drug]. Both products are currently under active review with the U.S. Food and Drug Administration ("FDA"). The FDA has substantial discretion in the product approval process and therefore, *it is not possible to predict at what point, or whether, the FDA will be satisfied with the Company's submissions or whether the FDA will raise issues which could significantly delay product approvals.*<sup>74</sup>

Both *Xoma*'s April 6, 1992 10-K<sup>75</sup> and its May 4, 1992 10-Q<sup>76</sup> contained similar cautions. News stories noted that *Xoma*'s board chairman voiced like disclaimers.<sup>77</sup> The defendants argued that these express disavowals entitled them to rely on the "bespeaks caution" doctrine. The Ninth Circuit simply brushed this defense argument aside.<sup>78</sup>

It is quite possible *Xoma* would be decided differently today. The Reform Act requires complaints to "specify . . . [the] reasons why [each allegedly false] statement is misleading"<sup>79</sup> and imposes liability on predictions only when the speaker had actual knowledge that they were

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72. FED. R. CIV. P. 9(b).

73. *In re Glenfed, Inc. Sec. Litig.*, 42 F.3d 1541, 1547–48 (9th Cir. 1994) (superseded by statute to the extent it held that scienter could be pled generally in private 10b-5 actions).

74. *Xoma Corp.*, 10-Q Quarterly Report for quarter ending Sept. 30, 1991, at 8. (emphasis added).

75. *Xoma Corp.*, 10-K Annual Report for year ending Dec. 31, 1991, at 10.

76. *Xoma Corp.*, 10-Q Quarterly Report for quarter ending March 31, 1992, at 6.

77. The district court decision quotes a Reuter's April 14, 1992 story as saying that *Xoma*'s CEO "declined to speculate if or when the drug would be approved by the agency;" a Dow Jones News Service report of May 5, 1992, as saying that the CEO "didn't speculate on when approval might come;" and a Reuter's piece on May 15, 1992, as reporting that the CEO "declined to speculate on if and when the drugs will be approved." *Xoma I*, 856 F. Supp. 561, 564 n.3 (N.D. Cal. 1994).

78. *Xoma II*, 74 F.3d 955, 959 (9th Cir. 1996).

79. 15 U.S.C. § 78u-4(b)(1) (1994 & Supp. III 1997).

false.<sup>80</sup> Plaintiffs might have been unable to plead specific facts raising a strong inference that Xoma executives actually knew the FDA would not approve E5. Moreover, the cautionary language in Xoma's securities filings might have shielded the company under the Reform Act's first safe harbor protection. Nevertheless, *Xoma* suggests three important considerations for companies formulating predictive public statements.

First, rightly or wrongly, the court understood the company's statements to predict *imminent* FDA approval and, in this respect, to differ from the long-term prediction in *Syntex*.<sup>81</sup> Second, Xoma's statements appeared to be directed at the market and designed to affect the market price of the stock. The first challenged statement directly refuted a securities analyst's report. Xoma later stated that the market had "misunderstood" the significance of FDA action when Xoma's stock price fell after the FDA found the first Phase III study insufficient to support product approval. Third, the court may have interpreted Xoma's statements—taken in the context of the chronology—as excessive "spin control." The FDA's advice that the first Phase III study did not provide sufficient efficacy evidence was bad news. The company, however, embarked on a public effort to erase that impression.

*In re Marion Merrell Dow Securities Litigation*<sup>82</sup> is a third case in which defendants predicted FDA approval. Their statements suggested that approval of Seldane as an over-the-counter medication was only a matter of time. They also made a specific prediction, in September 1990, that the drug would be available OTC sometime in 1991.<sup>83</sup> The company allegedly failed to disclose:

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80. 15 U.S.C. § 78u-5(c)(1)(B) (1994 & Supp. III 1997). A company saying an FDA approval is "imminent" would seem to be making a statement about the future. A recent case addressing allegations about "imminent" contracts, however, casts some doubt on this proposition. *EP MedSystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 876 (3d Cir. 2000) holds that an issuer announcing that certain contracts "were ready to take place" could be found to be making "a representation about the current state of negotiations . . . rather than a prediction of future events."

81. See *H.A.B. Assocs. v. Hines*, [1990–1991 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 95,665, at 98,116 (S.D.N.Y. Oct. 26, 1990) (denying motion to dismiss securities claims where defendant "purportedly represented to the HAB partners that he had direct information that Thermascan would *soon* be receiving approval from the Food and Drug Administration . . . for its unique in-office AIDS test." [emphasis added]).

82. *In re Marion Merrell Dow Inc., Sec. Litig.*, [1993 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 97,776 (W.D. Mo. Oct. 4, 1993).

83. *Id.* Plaintiffs alleged that on January 9, 1990, the chairman said, "once Seldane . . . is approved on a non-prescription basis, the greatest absolute sales growth will continue to be in prescription drugs." On May 8, 1990, one individual defendant said that the company was "working hard . . . to be sure that we are ready when we do get the approval." In September 1990, a company spokesperson said, "Seldane will represent the largest Rx-to-OTC switch in U.S. pharmaceutical history." The company publicly projected that Seldane would go OTC

- (1) that 773 reactions to Seldane had been reported in England, including one arrhythmia, one extrasystole, one cardiac arrest, one report of convulsions and two cases of aggravated epilepsy.
- (2) that on June 11, 1990, the FDA's Pulmonary-Allergy Drugs Advisory Committee met to discuss the cardiovascular effects of Seldane and reported that as of June 1990 the FDA had received 61 reports of adverse Seldane cardiac events, including 25 that Marion's own personnel acknowledged as serious cases. At the meeting, Dr. Leslie Hendeles, a member of the committee, stated, among other things, that "obviously, it goes without saying that this is a drug that could not possibly be over-the-counter for self-administration."
- (3) that by mid-May 1991, Marion had received 47 reports of serious cardiovascular events in patients taking Seldane.
- (4) that by May of 1992, four deaths had been attributed to Seldane use, and one additional death was attributed to the use of Seldane with another drug. In addition, Marion had learned of a significantly greater number of serious cardiovascular events in patients taking Seldane, causing Marion to make even stronger warnings about using Seldane as a prescription drug.<sup>84</sup>

Plaintiffs' "inference [was] that the defendants knew that there was little or no chance the FDA would approve Seldane for OTC status, but that the defendants continued to make statements that approval was certain."<sup>85</sup> The court denied the motion to dismiss even though the 1991 Annual Report stated twice that "there can be no assurance that . . . approval will be received from the FDA for the switching of any prescription product, including Seldane, to OTC status," and despite statements by an individual defendant that "[w]e will not guess the timing of the FDA approval" and that "we don't predict the FDA's actions."<sup>86</sup> For purposes of the motion to dismiss, the court found these to be

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sometime in 1991. On February 26, 1991, an individual defendant told financial analysts, "[T]he anticipated conversion of Seldane to an over-the-counter product potentially represents the largest prescription-to-OTC switch in pharmaceutical history." In March or April 1992, he said that when Seldane switched to the OTC market, it was likely to become "the largest product in the OTC marketplace in the United States." *Id.* at 97,763.

84. *Id.* at 97,763.

85. *Id.* at 97,765.

86. *Id.* at 97,763; 97,768.

“generic warning[s] that Marion would provide for any drug,” and held it was “not enough that plaintiffs recognized a risk; rather, given the plaintiffs’ allegations, the statements did not sufficiently warn the plaintiffs of the magnitude of the risk or the risk factors relevant to Seldane.”<sup>87</sup>

More recent decisions dealing directly with undisclosed side effects clarify that they are not material (or, alternatively, that a company does not intend to defraud by failing to disclose them) until the adverse reactions are statistically significant.<sup>88</sup> Again, it is uncertain whether *In re Marion Merrell Dow* would be decided for plaintiffs today when the Reform Act requires specific pleading that a defendant actually knew that its prediction was misleading when made.

*In re Marion Merrell Dow* nevertheless illustrates the danger in predicting FDA approval, even in a careful manner. The company’s only time-specific statement—a prediction in 1990 of OTC status sometime in 1991—was relatively long-term and imprecise. Its other statements were, as the court understood them, merely expressions of the company’s belief that the drug would eventually receive over-the-counter approval. All of these statements should have been relatively low-risk. Perhaps this case is best understood as one combining *both* an undisclosed, and on its face quite discouraging, FDA comment (that the drug “obviously . . . could not possibly be over-the-counter for self-administration”) and assumedly undisclosed underlying facts (the extent of the reported adverse reactions).<sup>89</sup> *In re Marion Merrell Dow* also demonstrates again that plaintiffs can turn a case about an affirmative forward-looking statement into a case about alleged omissions. As set out above, plaintiffs have employed this technique on occasion in more recent cases to elude Reform Act protections.

The SEC recently addressed predictions of FDA approval in an administrative proceeding against Zila, Inc. Zila had developed OraTest, a mouth rinse to diagnose oral cancer.<sup>90</sup> In November 1998, the company announced that the FDA had agreed to review Zila’s New Drug Application for OraTest, and in December the FDA said that its Oncologic

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87. *Id.* at 97,768.

88. *See* *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000); *see also In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153 (2d Cir. 1998).

89. *In re Marion Merrell Dow*, [1993 Transfer Binder] Fed. Sec. L. Rep. (CCH) at 97,763. It is important to remember that this case was decided on a motion to dismiss. The defendants argued that the allegedly omitted facts had been publicly reported. *Id.* at 97,769. The court ruled, however, that the record was not sufficiently developed at the pleading stage to address such a “truth-on-the-market” defense. *Id.* at 97,769–70.

90. Zila Admin. Order, *supra* note 40, Part III.C.1. All facts are from SEC findings, which respondents neither admitted nor denied in the settlement leading to the order.

Drugs Advisory Committee (ODAC) would do so at a January 13, 1999 public meeting.<sup>91</sup>

On December 10, Zila issued a press release containing financial information. The release expressed the view that “we expect the committee will recommend approval of our inexpensive and potentially life-saving technology.”<sup>92</sup> The company’s 10-Q, filed on December 11, contained a similar statement.<sup>93</sup> But around December 28, Zila received a draft copy of the review the FDA staff had submitted to ODAC, which stated that Zila’s study supporting OraTest was “incomplete, seriously flawed, [and] of questionable quality.” The draft added that, “definitive conclusions regarding the efficacy of OraTest cannot be drawn.”<sup>94</sup> The staff opined that the OraTest NDA was not approvable.

After the company received that draft report, Zila’s public relations spokesperson continued to make optimistic statements about FDA approval to Zila shareholders, brokers, and the media, *without* disclosing the fact and substance of the FDA report.<sup>95</sup> When an analyst initiated Zila coverage with a sell rating and offered the opinion that OraTest would have a difficult time until an ongoing clinical trial produced conclusive results, Zila responded with a statement calling the analyst’s report “inaccurate and misleading.”<sup>96</sup> Zila’s statement referenced two other analyst reports and asserted that they “more accurately reflect the status of OraTest.”<sup>97</sup> Again, Zila did not disclose the FDA staff draft or what it said.<sup>98</sup>

The ODAC voted unanimously against approving OraTest.<sup>99</sup> The SEC found that the optimistic statements Zila made after receiving the staff draft violated Rule 10b-5 because they did not tell investors about the adverse FDA paper.<sup>100</sup>

The *Zila* administrative proceeding is important in three respects. First, it demonstrates that the SEC itself may pursue life sciences companies for predictions of FDA approval. When the Commission does so, issuers are not protected by the Reform Act’s safe harbor provisions, which apply only to private actions. Second, *Zila* illustrates the impor-

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91. *Id.* Part III.C.2.

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.* Part III.C.3.

96. *Id.*

97. *Id.* One of those reports said that the analyst was “confident that Zila would obtain FDA approval to market OraTest in the United States.” *Id.*

98. *Id.*

99. *Id.*

100. *Id.* Part III.D.1.

tance of reviewing the facts in the company's possession each time the company forecasts FDA approval. Even if the forecast uses the same language and is surrounded by the same cautions as before, some new development (such as the receipt of the FDA staff draft in *Zila*) can make a forecast inappropriate or require different language or some further disclosure. Finally, under some circumstances, forecasts can themselves trigger the obligation to publicly reveal communications with the FDA staff.

#### D. Financial Projections Anticipating FDA Approvals

A small step away from express predictions of FDA approval lie financial forecasts that assume such approval. Those forecasts may raise securities law issues if the company possesses material, undisclosed information seriously undermining the chances that FDA approval will occur in time to produce the projected results. Two cases—involving Zenith Laboratories and Sabratek—illustrate this issue.

Plaintiffs survived a motion for summary judgment in *In re Zenith Laboratories Securities Litigation*,<sup>101</sup> where they alleged the company expressed confidence that it would exceed the 15–20% annual growth rate projected for the generic drug industry. More specifically, Zenith had, in its first quarter 1986 report, forecasted profits from “the introduction in the second quarter of additional new products which are pending approval by the U.S. Food and Drug Administration,” and that results for the year 1986 would “meet or exceed current expectation.”<sup>102</sup> The company had received a Form 483 from the FDA, however, which apparently included a long list of problems: selling drugs without approval, changing the manufacturing or composition of drugs without approval, absence of data to justify listed expiration dates, failure to validate manufacturing processes, and neglect of annual drug reviews, equipment maintenance and record keeping.<sup>103</sup> Zenith did not disclose these FDA complaints.

A company need not publicize the results of every FDA inspection the company endures.<sup>104</sup> In this case, however, the FDA had conducted a four-month review of Zenith operations, and there were indications that the Form 483 was significant. One board member testified that he was

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101. *In re Zenith Labs. Sec. Litig.*, [1993 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 97,617, at 96,814 (D.N.J. Feb. 11, 1993).

102. *Id.* at 96,817.

103. *Id.* at 96,816.

104. See *infra* text accompanying notes 217–221.

“shocked” when he read the FDA report,<sup>105</sup> and stock price movement arguably supported its importance. On July 14, *Barron’s* published an article, written by an author who had obtained a copy of the Form 483 through the Freedom of Information Act. The article summarized the deficiencies that the FDA identified, and Zenith’s stock price modestly declined.<sup>106</sup>

Although Zenith attacked the *Barron’s* article in a press release, it announced on August 6 that second quarter earnings would likely drop by 25–38% from the same quarter the previous year. Plaintiffs alleged that noncompliance with FDA regulations directly and substantially caused this financial reversal.<sup>107</sup> The district court denied motions for summary judgment by a member and former chairman of Zenith’s board and a former vice president of medical affairs.

In contrast to *Zenith Laboratories*, Sabratek won its securities case, at least insofar as plaintiffs claimed that financial forecasts improperly assumed an FDA approval. Sabratek produced flush syringes. While the syringes had previously been regulated as drugs, the FDA informed Sabratek in April 1997 that the company would have to submit a 501(k) application for approval of the syringes as a medical device. The company did so, and while the FDA considered that application, the agency twice inspected the syringe manufacturing facilities and advised Sabratek that the facilities did not comply with federal regulations. Some months after the second inspection, the company suspended production of the syringes for a time, but the FDA ultimately approved a revised 501(k) application.<sup>108</sup> When shareholders sued Sabratek, their case was dismissed to the extent that it attacked financial projections the company made while these events unfolded. The decision recognized that, in the heavily regulated health care industry, the FDA will sometimes give a company unfavorable reviews. But this does not necessarily mean the company must abandon its financial projections.

Simply receiving a number of letters from the FDA listing regulatory shortcomings does not portend ultimate FDA denial of the recipient’s application, as demonstrated by the FDA’s ultimate approval of Sabratek’s revised 501(k) application . . . . [T]here is no basis for the plaintiffs’ claim that Sabratek’s optimistic finan-

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105. *See In re Zenith Lab.*, [1993 Transfer Binder] Fed. Sec. L. Rep. (CCH) at 96,817.

106. The opinion states that *Barron’s* published the article on July 14, 1986. *Id.* at 96,818. Zenith stock closed at 14-1/4 on Friday, July 11, 1986. It closed down at 13-1/8 on July 14, 1986, and declined unevenly to 10-1/2 by the close of trading on August 6, 1986. *Id.* at 96,824.

107. *Id.* at 96,818.

108. *Chu v. Sabratek Corp.*, 100 F. Supp. 2d 827, 831 (N.D. Ill. 2000).

cial predictions were unreasonable in light of the FDA's actions regarding the flush syringes.<sup>109</sup>

*Sabratek* represents a more realistic view than *In re Zenith*. Imposing liability when financial predictions go unrealized because the FDA did not approve new products on the schedule the predictions assume is often unfair because FDA approval is so unpredictable. Even if a company is experiencing some regulatory difficulty with the agency when it makes predictions, it may be unclear at the time whether that difficulty will derail or significantly slow new licenses. *Sabratek* was a Reform Act case. *Zenith* was not. Hopefully, the Act will prompt courts to focus on, and critically evaluate, specific facts behind claims that a life sciences company knew, when it predicted FDA approval of a particular product at an identified time, that regulatory issues would frustrate that prediction.

It is important to note, however, that financial projections cases may be characterized as omission, rather than misrepresentation, cases. The *In re Zenith* court saw that case in part as one in which the defendants failed to disclose FDA problems, including the Form 483. As with cases involving express predictions of FDA approval, courts may determine that an omission analysis is unaffected by the Reform Act's protections for "forward-looking statements."

#### E. Final Thoughts on Predictions of FDA Approval

Considered together, the FDA prediction decisions prompt three final comments. First, courts generally should and likely will give companies considerable leeway in predicting agency approval. The decisions of government bureaucracies, like the FDA, are inherently difficult to predict.<sup>110</sup> While courts will give more latitude to companies

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109. *Id.* at 835. It is difficult to tell from the opinion exactly what financial projections *Sabratek* made. It is also worth noting that the complaint cited newspaper articles about the warning letters from the FDA. *Id.* at 834. The regulatory problems at the syringe manufacturing facilities must have been publicly known.

110. The Ninth Circuit has recognized the great difficulties in predicting regulatory actions, albeit in a different context. In *Epstein v. Washington Energy Co.*, 83 F.3d 1136, 1141–42 (9th Cir. 1996), the court observed that:

[R]eliance on predictive statements in the context of regulatory proceedings is inherently unreasonable. Basing an investment decision on an anticipated and contingent outcome of a litigated regulatory proceeding, even *with* full knowledge of the prior history of the parties, is tantamount to sheer speculation; and guessing wrong hardly suggests fraud.

Accordingly, an investor who relies on such information cannot be said to be misled by an "untrue statement of material facts." [Citation omitted]. The context of the regulatory process does not ordinarily invoke a duty to disclose or provide a basis

predicting approval farther out in time, even companies making shorter-term predictions should be able to avoid liability, unless the company acts in a manner that raises the court's suspicion. In *Xoma*, the company's very direct campaign to support the price of its stock by publicly contesting the significance of bad news may have been its undoing.

Second, courts and the investment community need a deeper understanding of the entire FDA approval process. Biotechnology is based on science and, to the lay person, science suggests certainty. Yet certainty may be unattainable in biotechnology reality. A company may undertake tests designed to show the effectiveness of a drug over a large patient population, only to find that the tests do not show efficacy for that population as a whole, but may show a statistically significant positive effect on a subset of the patients in the clinical trial. Interpretation of the test results may be a matter of judgment and different reviewers may hold differing opinions, each of which is reasonable. All of this adds uncertainty in the scientific sense which, added to the unpredictability of bureaucratic decisions, compounds the difficulty of forecasting FDA actions. The section of this article discussing disclosure of test results suggests an approach that may help courts and companies wrestle with this problem.

Third, drug and medical device manufacturing businesses engage in a near-constant dialogue with the FDA. A communication from the FDA that criticizes the company may simply be a part of that dialogue. The fact that plaintiffs' lawyers later seize upon that communication does not necessarily mean the life sciences company erred at the time in concluding that the letter, comment, or notice raised issues the company could address successfully without damage to the prospects for, or timing of, an FDA approval.

## II. DISCLOSING TEST RESULTS

Test results can determine whether the FDA grants a license or not. They can also reveal what patient populations a new product can benefit and, by extension, the size of the available market for the drug or device. As a life sciences product proceeds through different stages of its testing,

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for a securities fraud claim. Thus, a utility that has announced it has submitted an application for a rate increase normally has no duty to inform the public of any facts or circumstances in addition to those set forth in the application.

(emphasis in original).

the company developing it may wish to comment publicly upon testing progress.

Such comments pose at least two securities law problems. The first is how to announce “good” news that test results suggest a product is safe and efficacious. The second is whether, and when, to reveal “bad” news, such as that a product’s success rate is less than the company hoped, that its success is limited to a relatively small subset of the patient population suffering a particular combination of medical problems, or that a test population is experiencing a harmful side effect at a statistically significant rate.

#### A. *The Possible Ambiguity of Test Results*

Before discussing these issues directly, it is important to acknowledge that even experts can find test results difficult to interpret. Two researchers or evaluators looking at the same test results sometimes reach different conclusions. The FDA recognizes this fact. In explaining to Congress why the FDA insists that applicants provide all test data to the agency instead of only summaries, the agency has stated that

summary data has necessarily been processed, and that processing includes interpretation. When data is summarized, a decision must have already been made to look at it in some particular way. A review of the actual data provides the opportunity for that data to be examined and processed by different tests and procedures, and thus may allow the data to reveal information that would not be evident from the single perspective.<sup>111</sup>

One district court stated more bluntly:

Medical researchers may well differ over the adequacy of given testing procedures and in the interpretation of test results.<sup>112</sup>

Interpretation of test results is, to a significant degree, an art as well as a science. There may exist a range of reasonable interpretations. In a

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111. *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 1997: Hearings Before a Subcomm. of the House Comm. on Appropriations*, 104th Cong., 2d Sess. at 512 (1996) (written responses by FDA to questions from Congresswoman Kaptur).

112. *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995), *quoted in* *Nathenson v. Zonagen, Inc.*, 267 F.3d 400, 420 (5th Cir. 2001), *In re PLC Systems, Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 121 (D. Mass. 1999), and *In re Biogen Sec. Litig.*, 179 F.R.D. 25, 38 (D. Mass. 1997). *See also* *Padnes v. Scios Nova Inc.*, No. C 95-1693, 1996 WL 539711 at \*5 n.1 (N.D. Cal. Sept. 18, 1996). (“Medical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols.”).

given case, the life sciences company may be sincerely committed to one interpretation within that range, which shows product efficacy, while the FDA might select another interpretation within that range, which shows that the drug is not effective or at least that the particular test results do not prove efficacy. Even within a company, different individuals, or even the same researchers and evaluators at different times, may reach different conclusions from the same test data.<sup>113</sup> Courts should, therefore, understand that after-the-fact analyses may not reveal the tests' true significance and certainly may not accurately reflect the defendants' interpretation at the time they described test results in a manner allegedly violating the securities laws.<sup>114</sup> Critically, if a company's positive interpretation of clinical tests is within the range of reasonable science, courts should not find the interpretation "false" within the meaning of

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113. In *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212 (S.D. Cal. 2001), the court granted a motion to dismiss where plaintiffs, among other things, alleged that statements about test results made in June and July 1996 were false because they referred to "25 evaluable patients" whereas a later presentation referred to 22 such patients. *Id.* at 1228. The court explicitly recognized that review of data could change the number:

Much occurred in the 18 months that separated the issuance of [the] June 1996 press release and the ODAC meeting in December 1997, including the data cutoff for the NM clinical trials, further statistical analysis of clinical data, and the filing of the complete New Drug Application with the FDA. *Nothing in the Second Amended Complaint negates the reasonable inference that the removal of evaluable patients from the DepoCyt group resulted from subsequent statistical refinements of the clinical data.*

*Id.* (emphasis added).

114. *McNamara v. Bre-X Minerals Ltd.*, 57 F. Supp. 2d 396 (E.D. Tex. 1999), *reconsideration denied as to other matters*, 68 F. Supp. 2d 759 (E.D. Tex. 1999), addressed this issue in the context of a gold mining venture. Plaintiffs sued on the basis that one of defendant's public statements was misleading because tests the company ran on waste core samples found no gold content in 130 of the 135 samples. In dismissing the complaint, the court wrote:

In order for the Plaintiffs' theory to survive this motion to dismiss, the allegations in the complaint must give rise to a reasonable inference that Barrick's awareness of these negative test results is equivalent to Barrick's learning definitively or recklessly disregarding the fact that there was no gold at Busang. Such an inferential leap is not supported by the Complaint. . . . Without more facts from which to draw reasonable inferences, the Court finds that the Plaintiffs have failed to identify actionable misstatements of Barrick.

*McNamara*, 57 F. Supp. 2d at 415. In a later opinion, the court found that a further amended complaint stated a 10b-5 claim against Barrick, in part because plaintiffs alleged that Barrick submitted the test results described above to a mineral sampling expert who concluded that it was highly improbable that chance or accident could explain the discrepancy between these results and the high-gold content assay results that the project's developers had submitted to Barrick. *McNamara v. Bre-X Minerals Ltd.*, [2001 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 91,418, at 96,367-68, 96,391-92 (E.D. Tex. Mar. 30, 2001).

the securities laws,<sup>115</sup> should not find scienter and accordingly should not find a 10b-5 violation if the company publishes its view.<sup>116</sup>

### B. Disclosing Positive Test Results

When test results arrive, they frequently include some good news. The news may be tempered by limited statistical significance, by now-apparent problems in study design, or by the fortuitous discovery that a drug did not demonstrate efficacy against the prospective endpoints but appears to show promise in other ways. All of these factors enter into a company's analysis of the results and what the company decides to say about them.

The company will want to emphasize the positive. But if the drug is ultimately unsuccessful, or if its licensing suffers delays, shareholders may question the decision to disclose favorable data. Cases arising from such circumstances address three issues: (1) disclosure of selected information about tests; (2) internal company disputes over what test results prove; and (3) confusion created by the publication of "hard data."

#### 1. Disclosing Selected Information About Clinical Tests

Absent publication of virtually all documents created in a clinical trial, every disclosure about such a trial will be limited to the pieces of information that management elects to disclose. The company may provide some description of test protocols, but may not supply all details. While a study may have recorded many different patient variables (from heart attacks to blood pressure and temperature), and may have measured multiple "endpoints," the company normally publishes data on only some variables and may announce the results only as to some endpoints. Deciding what to disclose is a matter of judgment. Three cases illustrate how such a judgment may itself later be judged: *Padnes v. Scios*, *In re PLC Systems*, and *In re Biogen*.

Scios Nova collaborated in a Phase II study of Auriculin—a proprietary form of atrial natriuretic peptide ("ANP")—a drug to treat acute renal failure ("ARF"). The study was conducted in Colorado, and after it was complete, Scios Nova issued a November 16, 1993 press release stating that the study "demonstrated" that ANP provided a

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115. The interpretation of test results is an opinion, and courts should evaluate its truth or falsity in much the same manner as a forecast. See *supra* text accompanying note 8.

116. It was precisely on this basis that the court in *In re MedImmune*, 873 F. Supp. at 966, found that plaintiffs had not "fairly ple[d] the manner in which Defendants acted with reckless disregard as to the validity or invalidity of the data."

statistically significant reduction in the need for dialysis in ARF patients and increased creatinine clearance.<sup>117</sup> Its President/CEO/Chairman said that Auriculin would reverse the course of acute kidney failure.<sup>118</sup> Scios Nova's annual report in March 1994 repeated the representation that the Colorado study showed a "statistically significant reduction in the number of patients requiring dialysis."<sup>119</sup> In May 1995, however, the company announced that preliminary Phase III results failed to show that Auriculin reduced dialysis or mortality.<sup>120</sup>

Shareholders sued, alleging fraud in Scios Nova's reports of the Phase II results. In particular, they asserted that the company's statements had failed to reveal:

that Auriculin did not increase urine flow rates, that Auriculin had no substantial effect on glomerular filtration rate or changes in serum creatinine, that different dosages and routes of administration were used, that a higher percentage of control-group patients received vasopressors, that diuretics were not administered to control-group patients after the first 24 hours, and that the difference in the dialysis rates between surviving control-group and surviving treatment-group patients was not statistically significant.<sup>121</sup>

In dismissing the complaint, the court noted the shareholders did not dispute that Scios Nova's summaries of the Colorado study "were factually accurate in the sense that they faithfully reported the study's conclusions."<sup>122</sup> Instead, the court viewed the complaint as charging that the company "should have disclosed details of the study which they characterize as design defects . . . and should have included different measurements of the study's outcome than those performed by the Colorado researchers."<sup>123</sup> The court rejected such claims, recognizing that a life sciences company cannot publicly report every fact from a clinical trial, and embracing the notion that a company does not commit fraud so long as it selects the facts it discloses in a reasonable way:

The securities laws do not impose a requirement that companies report only information from optimal studies, even if scientists could agree on what is optimal. *Nor do they require that*

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117. *Padnes*, 1996 WL 539711 at \*1-2.

118. *Id.* at \*2.

119. *Id.*

120. *Id.* at \*1.

121. *Id.* at \*2.

122. *Id.* at \*5.

123. *Id.*

*companies who report information from imperfect studies include exhaustive disclosures of procedures used, including alternatives that were not utilized and various opinions with respect to the effects of these choices on the interpretation of the outcome data.*

*Defendants, like any other company wishing to publicly discuss the results of a scientific study, had to make a judgment as to which specific bits of information about the study and its conclusions to disclose. With the advantage of hindsight, defendants' judgment as to which information to disclose is subject to challenge; however, this does not amount to "facts explaining why the difference between the earlier and later statements is not merely the difference between two permissible judgments, but rather the result of a falsehood." [Citation omitted.] The fact that plaintiffs disagree with the Colorado researchers and with defendants about the import of the Colorado data does not make defendants' summaries of the study false or misleading. The court finds that defendants' statements were within the realm of permissible judgment.*

Reasonable minds could differ with respect to the value of the Colorado study in determining the therapeutic effects of Auriculiculin. *Reasonable minds cannot conclude, however, that defendants' failure to exhaustively catalogue those possibilities was fraudulent.*<sup>124</sup>

*In re PLC Systems, Inc. Securities Litigation*<sup>125</sup> is a similar case. PLC reported positive results from clinical tests of its Heart Laser device in Transmyocardial Revascularization ("TMR"). Plaintiffs criticized one press release "for stating that 'the TMR data . . . confirms that TMR may

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124. *Id.* (emphasis added). The court noted that "the Colorado study was published in a peer-reviewed journal, indicating that specialists in the field believed it had some scientific value." *Id.* at \*6. As for Scios Nova's optimistic opinions about the drug—such as its estimate that it could be used to treat 130,000 patients annually—the court ruled that "neither facts showing reasonable people could have disagreed with defendants' beliefs nor the mere fact that the Phase III tests were unsuccessful, even when coupled with a list of supposed protocol defects, amount to allegations that there was no reasonable basis for the opinions which were expressed." *Id.* at \*6.

*See also* DeMarco v. DepoTech Corp., 149 F. Supp. 2d 1212, 1230 (S.D. Cal. 2001) (dismissing complaint alleging that press release reporting comparative survival numbers for company's product versus a competing product for "evaluable" patients was misleading because, if the company had reported the comparative survival numbers for all enrolled patients, the comparison would have been less favorable. The court found plaintiffs' suggested reason for patients dropping out of the evaluable category wholly speculative).

125. *In re PLC Systems, Inc. Sec. Litig.*, 41 F. Supp. 2d 106 (D. Mass. 1999).

be an effective therapy' without disclosing the fact that for terminal patients suffering from unstable angina, TMR appeared to hasten death. Plaintiffs fault[ed] the same release for not disclosing that the clinical trial had been designed for 200 (not 100) patients."<sup>126</sup> Dismissing these claims, the court called them "more quibble than material."<sup>127</sup>

A reasonable investor would be interested in whether TMR might prove to be an effective therapy for the majority of patients suffering from end-stage coronary disease without being overly concerned that it might offer little or no benefit to a small subset of patients suffering from unstable angina. Similarly, whether the data was derived from a study of 100 or 200 patients might interest a medical researcher, but would not be an influential factor in making an investment decision.<sup>128</sup>

*In re Biogen Securities Litigation*<sup>129</sup> presented a somewhat different issue. Biogen developed a drug called Hirulog ("HLOG"), an anti-clotting agent the company hoped would replace Heparin. The Thrombolysis in Myocardial Infarction ("TIMI") office of the National Heart, Lung and Blood Institute conducted a Phase II study of the drug. The primary prospectively defined endpoint, called "unsatisfactory outcome," included any of four adverse events: (1) death, (2) myocardial infarction ("MI"), (3) failure-of-initial therapy and (4) rapid clinical deterioration. The study included 24 prospectively defined secondary endpoints.<sup>130</sup>

The study failed to show efficacy at any of these endpoints. After analyzing the data, however, Biogen determined that death or nonfatal myocardial infarction was less frequent in the group of patients who received the higher three doses of Hirulog than in the group receiving the lowest dose.<sup>131</sup> The drug appeared to be effective when evaluated against this retrospectively defined endpoint.

Biogen's CEO/President stated on January 11, 1994, that the test results looked "very good," that the company had received "good results

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126. *Id.* at 119.

127. *Id.*

128. *Id.* at 119–20. On the other hand, another court might have found that such information—possibly including the number of patients in a test, if that number was relevant to determining the statistical significance of test results—was important to sophisticated investors or analysts and therefore "material" in the context of an efficient market. *See In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 156 (2d Cir. 1998) (holding that a court could find statements in technical journals to be made "in connection with" securities transactions and observing that "[i]n an economy that produces highly sophisticated products, technical information is of enormous importance to financial analysts").

129. *In re Biogen Sec. Litig.*, 179 F.R.D. 25, 30 (D. Mass. 1997).

130. *Id.* at 30.

131. *Id.*

from the preliminary Phase II trials,” and “that given positive clinical results we have a very large potential market for the drug.” All of these statements were made without saying that the drug showed no efficacy with respect to the study’s primary or secondary endpoints as prospectively defined.<sup>132</sup> In February 1994, the American College of Cardiology (“ACC”) published an abstract that the company approved. The abstract revealed that the Phase II study had not shown efficacy as to the primary endpoint, said nothing about the prospectively defined secondary endpoints and stated that “[d]eath or nonfatal MI was significantly reduced in [patients] treated with HLOG sub2, 3, 4 compared to Lo HLOG at both hospital discharge . . . and at 6 weeks.”<sup>133</sup> The abstract did not say that the reported success was uncovered only by reviewing the data after the trial had ended and defining a new, retrospective endpoint.

On March 14, 1994, the TIMI Study Office presented the results of the Phase II study to an ACC conference. The presentation discussed both the primary endpoint failure and the reduction in the incidence of death and nonfatal heart attacks. Biogen published a press release on the same day stating that the company was “encouraged by the results of [the Phase II study], which showed a significant reduction in death and heart attacks among patients treated with Hirulog.”<sup>134</sup> Again, Biogen said nothing about the secondary endpoints, and the company did not disclose that the drug experienced success only as to an endpoint retrospectively defined. The company planned an expensive Phase III trial to compare the efficacy of Hirulog to Heparin, but then discontinued the entire Hirulog program when another Phase III trial, testing Hirulog for treatment of patients undergoing angioplasty, yielded no positive results.<sup>135</sup>

The subsequent securities complaint charged fraud in the January 11, 1994, statement, the February abstract, and the March press release. The court denied summary judgment as to the January 11 statement because the positive remarks did not reveal that Hirulog had failed as to the study’s primary endpoint.<sup>136</sup> The court did, however, grant defendants’ motion as to the February abstract and the March press release. The court found no evidence that the drug’s failure with respect to secondary endpoints was material.<sup>137</sup> As to the failure to disclose that the one successful endpoint was retrospectively defined, the court found that

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132. *Id.* at 30–31.

133. *Id.* at 31.

134. *Id.* at 32.

135. *Id.* at 30, 33.

136. *Id.* at 36.

137. *Id.* at 39.

“[g]iven the split of expert opinion regarding the importance of prospectively defined endpoints, the plaintiffs cannot demonstrate either fraudulent intent or recklessness in Biogen’s failure to fully publicize the [Phase II] methodology.”<sup>138</sup>

As *Scios Nova, PLC*, and *Biogen* demonstrate, disclosure of one aspect of clinical test results does not mean a life sciences company must publish all other details of those trials. These holdings accord with securities decisions from other industries. The rule that a voluntary disclosure must be complete and accurate “does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting . . . but means [that defendants must disclose] only such others, if any, that are needed so that what was revealed would not be ‘so incomplete as to mislead.’ ”<sup>139</sup>

Liability for failing to disclose an aspect of clinical tests should depend in part on science, recognizing that science often permits differing judgments in this complicated setting. If it is within the range of reasonable medical, health care, and statistical science to conclude that one aspect of test results is important independent of other aspects, then reporting that one aspect without the others should impose no securities liability, either because the omitted aspects were not material or because the reporting company did not intend to defraud by the selective reporting and was not reckless in creating any misimpression.

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138. *Id.* at 38. The court further observed that:

By all accounts, scientists working for the TIMI office and Biogen were genuinely enthusiastic about the results of [the Phase II test] with regard to the retrospectively-defined endpoint . . . [Dr.] Braunwald [of Harvard Medical School], the Chairman of the TIMI study . . . testified that the retrospective scrubbing of clinical trial data is not only acceptable, but “part of the due diligence in looking at data.” Braunwald further testified that while death and non-fatal heart attack were not listed as a pre-specified secondary endpoint, “[d]eath and MI is a very common analysis. It’s one that is clinically, probably the most important one. And that obviously was one that we used . . . .” In fact, Braunwald believed that the . . . trial was successful “where it mattered” . . . . The TIMI team, who were not Biogen employees, felt that way.

*Id.*

139. *Backman v. Polaroid*, 910 F.2d 10, 16 (1st Cir. 1990), quoting *SEC v. Texas Gulf Sulphur Co.*, 401 F.2d 833, 862 (2d Cir. 1968), cert. denied, 394 U.S. 976 (1969) (where Polaroid disclosed that product was being sold below cost, it did not mislead by failing to say how much below cost or by failing to report the number of units sold or by failing to state that sales were below expectations). Obviously, there are limits. See *SEC v. Coates*, 137 F. Supp. 2d 413, 424–25 (S.D.N.Y. 2001) (finding misrepresentation where defendant said that “under an internally supervised test, its [engine] far surpassed the emissions standards imposed by the [EPA]” but did not address the company’s “inability to determine through its in-house tests whether its engines could comply with EPA or federal requirements without the use of a dynamometer” and omitted fact that certain other tests “revealed emission levels that were substantially higher than the EPA maximums”).

It should also be no violation of the securities laws for a company to report positive results without reporting what plaintiffs later claim to have been study design flaws, provided that the company either did not know of the alleged flaws at the time of the report, or if it was scientifically and statistically reasonable to believe—on the basis of what the company knew at the time it spoke—that the results were meaningful regardless of the alleged flaws.<sup>140</sup> With the Reform Act, plaintiffs will be required not just to generally state that the reported results omitted problems in the clinical trials, but also to specify those problems and plead with particularity how they affected conclusions from the trials.<sup>141</sup>

Life sciences companies should remember, however, that courts may be troubled if a clinical trial fails as to its prospectively defined primary endpoint, but results in an announcement that includes a statement that the trial was in some sense a success without also disclosing the primary endpoint failure.<sup>142</sup>

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140. See *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 967 (D. Md. 1995) (dismissing complaint based on allegations of test flaws leading to skewed test results, because “plaintiffs ple[d] no specific facts to show why Defendants knew or should have known this to be a problem”). In contrast, *In re Cell Pathways, Inc. Securities Litigation*, [2000 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 91,001, at 94,491 (E.D. Pa. June 20, 2000), denied a motion to dismiss where plaintiffs claimed defendants stated that enrollment for a Phase III trial had been completed, that it was on schedule, and that it could produce data to support an NDA—all without disclosing that, allegedly, only 34 out of 61 patients who completed the one-year course of treatment met the criteria for inclusion in the study. At one point, the court suggests reliance on the notion that “where the alleged fraud relates to the core business of the company, knowledge of the fraud may be imputed to the individual defendants.” *Id.* at 94,495, citing *In re Aetna*, 34 F. Supp. 2d at 953. But this seems wrong, especially in light of the Reform Act’s requirement that plaintiffs plead “with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2). At other points, the court suggests that the company acted “recklessly.” *In re Cell Pathways*, [2000 Transfer Binder] Fed. Sec. L. Rep. (CCH) at 94,494. The case fails to analyze whether, at the time of its statements, the company had departed in an extreme way from consensus precautions to ensure appropriate test patient selection.

141. See *Nathenson v. Zonagen, Inc.*, 267 F.3d 400 (5th Cir. 2001) (plaintiffs alleged that positive results from Phase III test were misleading because of flaws in those tests; Fifth Circuit affirmed dismissal in part because plaintiffs failed to identify “with any degree of detail how these shortcomings impacted the trials”). *Id.* at 419.

142. See *In re PLC Systems, Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 120 (D. Mass. 1999) (refusing to dismiss claim that company violated 10(b) by publishing interim clinical trial results showing decrease in mortality and angina, but failing to disclose “the fact that the six-month data showed no significant improvement in perfusion, the study’s primary endpoint.” The court found this “troubling, as the absence of any such improvement might signify to a sophisticated investor that TMR offered no long-term benefit to end-stage patients generally.”).

## 2. Addressing Internal Disagreements Over Test Results

Whatever positive, selective disclosure a life sciences company makes about clinical results, that disclosure will reflect the company's interpretation of the results. That interpretation will emerge from an internal company dialogue. During that dialogue, different professionals may express different views. If so, some views may be rejected after internal consideration. The inconsistent views may remain in company files, however, and shareholders may later contend that memoranda, notebooks, and emails containing those views show that the company's announced interpretation was "false" and that the company knew, or was reckless in not knowing, that its interpretation was misleading.

*In re Synergen, Inc. Securities Litigation*<sup>143</sup> demonstrates this problem. The company conducted Phase II tests of Antril, a drug to treat sepsis. Synergen's president/CEO and its vice president of clinical research said that Antril "will treat all patients with sepsis syndrome."<sup>144</sup> A report to shareholders referenced data "from the Phase II trial that demonstrated a dose-dependent survival advantage in sepsis syndrome patients treated with ANTRIL."<sup>145</sup>

The patients in Phase II had been divided into four groups receiving, respectively, a placebo, a low Antril dose, a medium dose and a high dose.<sup>146</sup> The company released a media advisory on November 7, 1991, stating that, "[B]aseline characteristics were similar among treatment groups."<sup>147</sup> After Phase III tests failed to satisfy the FDA's statistical criteria for drug approval, shareholders sued. The court denied the defense's motion for summary judgment, in part because of the apparently conflicting statistical views within the company concerning patient characteristics in the Phase II tests. At an April 1992 meeting of Synergen's Product and Project Review Committee, the company's biostatistician discussed imbalances of patient characteristics in the four Phase II treatment groups. He informed the Committee that:

Another covariate examined was the number of patients with organ dysfunction at entry. Organ dysfunction was defined as one or more of the following: ARDS, DIC, liver dysfunction or renal dysfunction. "Normalizing" for these covariates would bring the level of significance of the outcome by dose effect seen in the Phase II results to an unacceptable  $p = 0.062$  from  $p = 0.035$ .

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143. 863 F. Supp. 1409 (D. Colo. 1994).

144. *Id.* at 1413 (emphasis omitted).

145. *Id.* at 1414.

146. *Id.* at 1412.

147. *Id.* at 1414.

[The court commented that a “p-value of 0.05 or less renders the results statistically significant.”]<sup>148</sup>

A short time later, Synergen’s vice president of clinical research sent a report to the board of directors saying that data

suggested that the placebo patients may have had more severe sepsis than the three active treatment groups, as measured by Apache II scores and presence of major organ dysfunction; of the four groups, the high-dose group was the least severe by these two important parameters. None of these differences was statistically significant for the small sample sizes.<sup>149</sup>

Synergen’s final Phase II integrated report, published December 17, 1993, said that the “treatment groups may be somewhat imbalanced with respect to the presence or absence of organ dysfunction at study entry, but not statistically so ( $p > 0.2$ ) . . . [E]ven adjusted for [organ dysfunction], the level of doses is still a statistically significant predictor of survival.”<sup>150</sup> With all of this (and other) evidence before it, the court decided that the case should go forward because “a reasonable jury could conclude . . . that baseline characteristics of the patients in the various treatment groups were dissimilar, not similar.”<sup>151</sup> The apparent difference of opinion within Synergen itself helped create the factual question that permitted plaintiffs to proceed.

In considering what companies may say about test results that can be interpreted in different ways even within the same company, it is useful to draw an analogy to financial projections. Courts recognize that the financial forecasting process often generates differing predictions within a single company. Decisions acknowledge that corporations routinely compare different projections, exercise company judgment, and then reach a corporate decision on the forecast to use for planning purposes, and, in some cases, to release to the public. Provided that the company had a reasonable basis for the forecast it adopted, it is not liable for publishing the one it selects simply because there were other conceivable forecasts, even other forecasts that were committed to paper within the corporation.<sup>152</sup>

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148. *Id.* at 1416.

149. *Id.* at 1417.

150. *Id.*

151. *Id.*

152. *See* *Wielgos v. Commonwealth Edison Co.*, 892 F.2d 509, 516 (7th Cir. 1989) (“Any firm generates a range of estimates internally or through consultants. It may reveal the projection it thinks best while withholding others, so long as the one revealed has a ‘reasonable basis’—a question on which other estimates may reflect without automatically depriving

Moreover, many courts will no longer accept as legally sufficient a plaintiff's conclusion that a forecast was false simply because the plaintiff alleges that an "internal" memorandum, authored by an unidentified company staffer for an unspecified audience, reached a different conclusion. Instead, the better-reasoned decisions require plaintiffs to plead the identity of the author and the recipient, as well as other facts pertinent to deciding whether the referenced document casts some serious cloud on the company's ultimate judgment as expressed in its published projection.<sup>153</sup>

The same principle—that a difference of opinion, even among professionals, does not indicate fraud—applies to at least some numbers in financial statements. Certain accounting decisions are a matter of judgment. Courts recognize that a company's accountants may make one judgment while other accountants would reach a different judgment. This difference of professional opinion does not show fraud, provided that the company's chosen accounting treatment falls within the reasonable options.<sup>154</sup>

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the published one of foundation."); *Freedman v. Value Health, Inc.*, 135 F. Supp. 2d 317, 332–33 (D. Conn. 2001) (fact that initial internal forecast predicted a \$13 million to \$15 million loss on a contract did not show that \$9.6 million estimate in prospectus was false); *In re VeriFone Sec. Litig.*, 784 F. Supp. 1471, 1487 (N.D. Cal. 1992), *aff'd*, 11 F.3d 865 (9th Cir. 1993) ("Plaintiffs must show why the projection disclosed lacked a reasonable basis. The fact that defendants had contradictory projections available to them cannot, by itself, support an inference that the disclosed projection was unreasonable at the time it was made."); *In re Sybase, Inc. Sec. Litig.*, 48 F. Supp. 2d 958, 962 (N.D. Cal. 1999); *Bell Atl. Corp. Sec. Litig.*, [1997 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶99,467, at 97,113 (E.D. Pa. Apr. 16, 1997), *aff'd*, 142 F.3d 427 (3d Cir. 1998) (unpublished table decision) (internal document predicting 4.8% growth for 1990 was not considered reliable by management, so this document did not represent the *company's view*. Such evidence did not undermine the reasonable basis or good faith belief for the defendants' projections of 6–9% earnings growth provided by other internal estimates); *In re Caere Corp. Sec. Litig.*, 837 F. Supp. 1054, 1061 (N.D. Cal. 1993).

153. See *supra* note 26.

154. *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 205 (1st Cir. 1999); *Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1021 (5th Cir. 1996), *quoting* *Godchaux v. Conveying Techniques, Inc.*, 846 F.2d 306, 315 (5th Cir. 1988) (affirming dismissal of complaint. "[T]he fact that Defendants changed auditors because of a difference in judgment about generally accepted accounting principles does not establish conscious behavior on the part of Defendants. The term 'generally accepted accounting principles,' as we have often noted, is a term of art encompassing a wide range of acceptable procedures, such that 'an ethical, reasonably diligent accountant may choose to apply any of a variety of acceptable accounting procedures when that accountant prepares a financial statement.'"); *Lemmer v. Nu-Kote Holding, Inc.*, [Current Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶91,604, at 97,538–39 (N.D. Tex. Sept. 6, 2001); *In re Ikon Office Solutions, Inc. Sec. Litig.*, 131 F. Supp. 2d 680, 701–02 (E.D. Pa. 2001), *aff'd*, 277 F.3d 658 (3d Cir. 2002); *In re Miller Indus., Inc. Sec. Litig.*, 120 F. Supp. 2d 1371, 1382 (N.D. Ga. 2000); *In re Cirrus Logic Sec. Litig.*, 946 F. Supp. 1446, 1457 (N.D. Cal. 1996); *Mathews v. Centex Telemanagement, Inc.*, [1994–1995 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶98,440, at 91,037 (N.D. Cal. June 8, 1994); *SEC v. Price Waterhouse*, 797 F. Supp. 1217 (S.D.N.Y. 1992) (granting judgment for defendants in SEC action where account-

A similar analysis logically applies to test results. A life sciences company will analyze those results and, though there may be internal debate, will reach a corporate view. This view will be reflected in such decisions as allocation of resources in anticipation of the ultimate licensing of a drug or device. Provided the biotechnology company has a procedure or process to reach a *company* judgment on the significance of test results, and provided that the company follows that procedure or process to reach a judgment that is within the range of the scientifically reasonable, the publication of that *company* interpretation should be protected from securities law attack. The fact that there are other internal interpretations, or that company personnel reduced these conflicting interpretations to writing in internal documents, should not render the company-published view “false” within the meaning of the securities laws or taint the company with scienter for releasing its view.

This analysis, however, suggests that a company may wish to adopt a process or procedure for reaching what can truly be called a *company* interpretation of test results. It will be helpful in defending a later lawsuit if the company employs some formality in reaching its judgment and uses the process or procedure consistently.

### 3. Confusion Created by Publication of “Hard” Information From Clinical Trials

Assuming that a biotechnology company has completed its internal analysis of clinical tests, arrived at a company interpretation, and selected the information about the tests that it will release, the company will almost certainly find that some of that information comprises hard facts—statistics for groups of patients and the protocols under which the tests took place. At first blush, it would seem these hard facts, unlike conclusions that involve interpretation, should raise few disclosure issues. Unfortunately, that is not the case, in part because hard data often involve technical terms the financial community—including analysts who profess expertise in life sciences—may not fully understand. The *Synergen*, *DepoTech*, *PLC*, and *MedImmune* cases all demonstrate difficulties arising from disclosure of hard information about positive test results.

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ants differed over residual value for leased equipment. The court held that “this is clearly an area in which reasonable accountants can differ, and such reasonable disagreements cannot support an inference of recklessness or fraud.” *Id.* at 1229. The court acknowledged, however, that 10b-5 recklessness could be found if “the accounting judgments which were made were such that no reasonable accountant would have made the same decisions if confronted with the same facts.” *Id.* at 1240.)

Synergen issued a media advisory on Phase II results reporting that they showed survival to be a linear function of dose at the  $p = 0.015$  level. The advisory stated in capital letters, that Antril “REDUCES MORTALITY IN PATIENTS WITH SEPSIS SYNDROME.”<sup>155</sup> The securities lawsuit against Synergen turned in part on the meaning of “mortality.” There were, in fact, two mortality measures. As the court explained:

Survival curves measure the number of days a patient lives during the 28-day trial. [Citation.] In contrast, “28-day mortality” or “mortality” refers to the percentage of patients who are dead on the 28th day of the trial.<sup>156</sup>

The p-value for survival curves was, indeed, 0.015. The p-value for the percentage dead on day 28 was, however, 0.035.<sup>157</sup> Plaintiffs contended that the media advisory was misleading because it suggested that the 0.015 value applied to the 28-day death measure instead of the survival curves. Defendants submitted one securities analyst report which they said showed the investment community understood the 0.015 value to apply to the survival curves. Plaintiffs submitted a different analyst report which they said showed the investment community understood the 0.015 value to apply to 28-day mortality.<sup>158</sup> The court denied defendants’ motion for summary judgment, concluding that there was a triable issue as to the market’s understanding of the “mortality” data Synergen published.<sup>159</sup>

DepoTech fared better than Synergen in part because it defined the terms it used *in the documents containing those terms*. DepoTech was testing its drug delivery product, DepoCyt, against a standard chemotherapeutic agent, MTX. In a 10-K filing, the company reported interim clinical trial results showing a 47% “response rate” for DepoCyt compared to 6% for MTX. In a later press release, the company reported a 36% response rate for DepoCyt against 17% for MTX.<sup>160</sup> After an FDA Advisory Committee declined to recommend DepoCyt’s approval and DepoTech’s stock fell, plaintiffs contended in a securities lawsuit that the 10-K and the release misled investors because “response” for purposes of these disclosures was different from “response” as defined in the original study protocol. The court dismissed the complaint, in part be-

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155. *In re Synergen, Inc. Sec. Litig.*, 863 F. Supp. at 1418.

156. *Id.* at 1418–19.

157. *Id.* at 1419.

158. *Id.*

159. *See id.*

160. *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1226–27 (S.D. Cal. 2001).

cause the 10-K and release defined “response” as used in the statistics those documents reported, and the definition of “response” in the original protocol had not been publicized at all before the company made the statements the shareholders challenged.<sup>161</sup>

*PLC* and *MedImmune* both concerned the “intention to treat” test protocol. *PLC* published interim results showing 6% mortality in the group provided TMR treatment with the Heart Laser, while the control group suffered 16% mortality. Plaintiffs challenged the two press releases containing this claim, alleging that the data, in fact, demonstrated no mortality benefit because certain patients in the control group received TMR treatment before they died.<sup>162</sup> Defendants responded that the statistics, and the clinical trial itself, employed the “intention to treat” protocol, which accounted for patients according to their initial treatment assignment regardless of whether they received some cross-over treatment during the study. The court denied defendants’ motion to dismiss this part of the case, finding the defense argument depended on materials outside the scope of the pleadings, such as scientific articles and texts.<sup>163</sup>

*MedImmune* developed a drug called *Respivir* to prevent respiratory syncytial virus (“RSV”). After the FDA’s Blood Products Advisory Committee voted against recommending approval for the drug, the company’s stock lost almost two-thirds of its value. Shareholders sued.

Plaintiffs pled that the company had endorsed an article in the *New England Journal of Medicine* stating that a *Respivir* study used the “intention to treat” protocol. Plaintiffs alleged that the protocol required the study to follow all patients who enrolled, even those who did not complete the course of treatment, whereas, plaintiffs contended, the *Respivir* study did not include the outcomes of 17 patients who dropped out.<sup>164</sup> Denying the defense’s motion to dismiss this claim, the court found that the public statement about the study’s protocol might have misled investors by suggesting the trial results were more meaningful than they were:

According to Plaintiffs (as well as the Advisory Blood Products Committee), the absence of reliable outcome data on those 17 dropouts would make it impossible to determine which of the children experienced RSV LRI and which did not and might therefore bias the result. An investor sophisticated enough either to know the meaning of “intention to treat” or to inquire about it could arguably have been led to believe that, since the principle

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161. *Id.* at 1227–28.

162. *In re PLC Systems, Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 118 (D. Mass. 1999).

163. *See id.*

164. *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 968 (D. Md. 1995).

had reportedly . . . been utilized, the statistical dependability of the study was better than it in fact was.<sup>165</sup>

Companies can take at least four steps to avoid securities lawsuits based on the publication of hard data. First, after a company decides what necessarily limited information about a test it will release, the company should scrutinize its announcement to be sure it sufficiently describes that limited information. Synergen might have avoided a lawsuit or won its motion for summary judgment if it had defined what it meant by “mortality” in the advisory it released, just as DepoTech prevailed on its motion to dismiss by defining in its contested documents the “response” that those documents reported. PLC might have avoided a challenge to the press releases publicizing a mortality benefit by stating that the rates in the treatment and control groups were computed on an “intention to treat” basis and describing that protocol.

Second, one person within the company should be responsible for reviewing, prior to their release, all written public statements summarizing test results for any particular life sciences product. Companies should select a reviewer who has studied the test results and protocols, and who is familiar with clinical testing and the statistical analysis of such tests. That individual should have real authority and the strength of personality to wield it.

Third, any members of management who must make oral presentations about test results or provide real-time answers to questions about such results should be armed with precise language. If asked a question or otherwise prompted to make a comment not covered by the pre-approved language, they should make every effort to decline to answer off-the-cuff and to follow up after the company can study the question and carefully phrase an appropriate answer.

In executing this third step, however, management must be careful not to violate the rule against “selective disclosure,” which prohibits disclosing material information to some market participants without simultaneously providing the information to enough other participants so that it can be said to be public.<sup>166</sup> Consider, for example, the biotechnology executive who is confronted in a quarterly conference call with an unanticipated question about test results. Following the recommendation set out above, the executive will decline to provide a definitive answer. He may wish, however, as a matter of courtesy and good relations, to contact the particular analyst who asked the question and provide an an-

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165. *Id.*

166. Regulation FD specifically prohibits selective material disclosures. 17 C.F.R. § 243.100 (2001).

swer after the conference call has been completed and the company has had time to study the question and prepare a response. But if that response provides “material” information, the executive should not disclose that information solely to the one analyst. Instead, some other, broader dissemination will be necessary, e.g., by filing a Form 8-K or disseminating the information “through another method (or combination of methods) . . . that is reasonably designed to provide broad, non-exclusionary distribution . . . to the public.”<sup>167</sup>

Finally, if a company becomes aware of analyst reports or other media stories that provide *inaccurate* “hard facts” about tests, the company *may* wish to publicly correct the inaccuracy. The securities laws generally do not require that a company make such corrections,<sup>168</sup> but in some circumstances the company may be better able to defend a later lawsuit if it publicly corrects the error. Moreover, as a practical matter, plaintiffs in a later lawsuit will attempt to establish that the company was somehow responsible for the public confusion.<sup>169</sup>

If the company learns of the inaccuracy before the report or story is published, the company may wish to contact the analyst or reporter. However, a life sciences company must carefully evaluate this decision with counsel in each instance. If a company contacts a single analyst to correct an error, the company risks violating the prohibition against selective disclosure.<sup>170</sup> If a company provides corrections before

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167. 17 C.F.R. § 243.101(e).

168. *See, e.g.,* Elkind v. Liggett & Myers, Inc., 635 F.2d 156, 162–63 (2d Cir. 1980); VII LOUIS LOSS & JOEL SELIGMAN, SECURITIES REGULATION 3523 & n.175 (3d ed. 1989) (“Normally . . . the mere presence of rumors or of publicly circulating inaccuracies concerning the issuer does not require a response from the issuer.”); Raab v. General Physics Corp., 4 F.3d 286, 288 (4th Cir. 1993) (“The securities laws require General Physics to speak truthfully to investors; they do not require the company to police statements made by third parties for inaccuracies, even if the third party attributes the statement to General Physics.”); *In re Polaroid Corp. Sec. Litig.*, 134 F. Supp. 2d 176, 184 (D. Mass. 2001) (“[T]he First Circuit has not recognized such a broad duty to rectify incorrect statements made by analysts in the marketplace.”).

169. *See, e.g.,* Eisenstadt v. Centel Corp., 113 F.3d 738, 744 (7th Cir. 1997) (“[E]ven if statements by [the issuer] or its investment bankers were garbled by the press, [the issuer] would not be privileged to sit by and allow investors to be misled by the garble.”).

170. The issuer again must bear in mind Regulation FD, which prohibits selective disclosure. *See* 17 C.F.R. § 243.100 (2001) and text accompanying *supra* note 167. If the story is authored by a member of the press, as opposed to a securities analyst, the issuer can privately make the correction without running afoul of FD. FD is not intended to interfere with disclosures to the media. 65 Fed. Reg. 51,716, 51,719–20 (2000). If the report is authored by a securities analyst, the decision to correct by a private pre-publication contact is more complex. If the company is confident that the analyst has not communicated the inaccuracy to others and is confident that others in the investment community have not made the same mistake, then the company may discuss the matter with the analyst alone. If the company does not have

publication, plaintiffs may later argue that the company so “entangled” itself in the article or story as to be legally liable for the statements in it.<sup>171</sup> If a company provides corrections after publication, plaintiffs may argue that the company thereby assumed a “duty to correct” and that the company later violated that duty by failing to correct a subsequent article or report.

### C. *Disclosing Negative Test Results*

Turning from favorable test results that a company wishes to publicize to results that appear, at least initially, to be unfavorable, such “bad” results raise two principal disclosure questions. The first is: when does the company possess “material” information for purposes of the securities laws? The second is: when, after the company has material information, does it have a duty to disclose?

#### 1. When Negative Results Become Material

The first question is complicated by the frequent ambiguity of test results. The results may on first analysis suggest that the new drug or medical device does not produce the desired effect. Additional analysis, however, may suggest or demonstrate that the drug or device is efficacious against certain medical problems or with limited sets of patients who have particular combinations of medical problems or as to endpoints only retrospectively defined. It may take a company some time to review the data sufficiently in order to form a *company* view of what the data reveals.

Accepted authority defines a fact to be “material” if it “would have assumed actual significance in the deliberations of the reasonable shareholder. Put another way, 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.”<sup>172</sup>

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such confidence, then a one-on-one communication with the analyst may constitute a prohibited selective disclosure under FD, and the issuer may decide to correct by a public statement.

171. See *Elkind*, 635 F.2d at 163 (issuer not liable for analysts’ projections because the company “did not place its imprimatur, expressly or impliedly, on the analysts’ projections,” but acknowledging that “a company may so involve itself in the preparation of reports and projections by outsiders as to assume a duty to correct material errors”).

172. *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976); *Basic, Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988) (employing the same definition in section 10(b) and Rule 10b-5 analysis).

Apart from materiality, a life sciences company will only be liable if the plaintiffs can show reliance and loss causation. As a practical matter, this will depend, in a fraud on the market case, on whether plaintiffs can show that the stock price was affected by the issuer’s

In applying this definition to a life sciences company reviewing test results, courts would do well to analogize again to financial projections and reports. A considerable number of cases have held that companies have no duty to disclose financial figures or projections when the information available to the company is incomplete or where the company's analysis is still tentative and subject to further review.<sup>173</sup> Similarly, biotechnology companies evaluating ambiguous test results should be given time to complete their evaluation. Before a company has sufficiently studied the test results to determine what they mean, the company quite arguably does not have "material" information to reveal.

Courts already employ this principle to the disclosure of adverse side effects for drugs approved by the FDA. In these cases, it is only when the incidence of an important side effect becomes statistically significant

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failure to disclose negative results. *See* *Nathenson v. Zonagen, Inc.*, 267 F.3d 400, 414–15 (5th Cir. 2001). But how the stock will move can only be known reliably after the fact. "Materiality . . . looks to likely potential. Reliance, on the other hand, ultimately looks to what *actually* happened." *Id.* at 418. (emphasis in original).

173. While many of these decisions speak in terms of "duty to disclose" or scienter, the same analysis should apply to determine materiality. In *In re HealthCare Compare Corp. Securities Litigation*, 75 F.3d 276 (7th Cir. 1996), plaintiffs argued that a company's statement of comfort with analyst earnings estimates was fraudulent because of an internal memorandum. Among other things, the court found it significant that plaintiffs failed to plead that the figures in the memorandum were final. "The complaint fails to allege even a single fact relevant to the certainty or finality of these figures; nothing in the complaint belies the possibility that the figures reported in the memorandum were subject to revision or verification before they could be made public." *Id.* at 283. *See also In re Convergent Technologies Sec. Litig.*, 948 F.2d 507, 516 (9th Cir. 1991), quoting *Vaughn v. Teledyne, Inc.*, 628 F.2d 1214, 1221 (9th Cir. 1980) ("There is no evidence . . . that the estimates were made with such reasonable certainty even to allow them to be disclosed to the public."); *Wielgos v. Commonwealth Edison Co.*, 892 F.2d 509, 516 (7th Cir. 1989), citing *Panter v. Marshall Field & Co.*, 646 F.2d 271, 291–93 (7th Cir.), cert. denied, 454 U.S. 1092 (1981) ("firms need not disclose tentative internal estimates, even though they conflict with published estimates, unless the internal estimates are so certain that they reveal the published figures as materially misleading"); *Financial Indus. Fund, Inc. v. McDonnell Douglas Corp.*, 474 F.2d 514, 519 (10th Cir.), cert. denied, 414 U.S. 874 (1973); *Sakhrani v. Brightpoint, Inc.*, [2001 Transfer Binder] Fed. Sec. L. Rep. ¶ 91,422, at 96,424 (S.D. Ind. Mar. 29, 2001); *Fitzer v. Security Dynamics Technologies, Inc.*, 119 F. Supp. 2d 12, 39 (D. Mass. 2000); *In re Browning-Ferris Indus., Inc. Sec. Litig.*, 876 F. Supp. 870, 892–93 (S.D. Tex. 1995); *Wright v. International Business Machines Corp.*, 796 F. Supp. 1120, 1125–26 (N.D. Ill. 1992); *Kulicke & Soffa Indus., Inc.*, 747 F. Supp. 1136, 1139–40 (E.D. Pa. 1990), *aff'd*, 944 F.2d 897 (3d Cir. 1991) (unpublished table decision) ("[I]t is not enough that defendants were 'in possession of' data which called a forecast or opinion into question; for defendants to be liable under section 10(b) . . . they must have assimilated and comprehended the significance of that information to the forecast and intentionally failed to disclose it, or they must have recklessly avoided assimilating and comprehending the information.").

that the information about it becomes material under the securities laws.<sup>174</sup>

## 2. When a Company Must Disclose Material Negative Results

Assuming that a company has completed its evaluation and that the analysis contains significant “bad news,” the next question is when the company must reveal it. This involves the “duty to disclose,” for a company cannot be liable for failing to publicize a fact—even a material fact—unless the company has an obligation to disclose it.<sup>175</sup>

Two principal events that may create a duty to disclose nonpublic material facts in this context are:

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174. *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (plaintiffs alleged a drug manufacturer failed to disclose that weight-loss drugs caused heart-valve damage. “Because the link between the two drugs and heart-valve disorders was never definitively established during the relevant period even after the withheld data is taken into account, AHP’s failure to disclose this data cannot render its statements about the inconclusiveness of the relationship materially misleading.”); *see also In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998) (“Drug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings.”). *See* later decision affirming dismissal of case, 220 F.3d 36 (2d Cir. 2000).

175. Private plaintiffs most frequently sue under section 10(b) of the Securities Exchange Act of 1934, SEC Rule 10b-5, and sections 11 and 12(a)(2) of the Securities Act of 1933. The SEC can sue in district court or initiate administrative proceedings under any of these statutes and a number of others, particularly section 17(a) of the Securities Act of 1933.

In *Chiarella v. United States*, 445 U.S. 222, 228 (1980), the Supreme Court held in a 10b-5 case that “one who fails to disclose material information prior to the consummation of a transaction commits fraud *only when he is under a duty to do so.*” (emphasis added). *See also* *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988) (“Silence, absent a duty to disclose, is not misleading under Rule 10b-5.”); *In re Northern Telecom Ltd. Sec. Litig.*, 116 F. Supp. 2d 446, 459 (S.D.N.Y. 2000) (“Plaintiffs cite no case in which a company has been held to be generally obligated to disclose internal problems merely because those problems were potentially significant. Indeed, courts generally do not impose a duty to disclose in such circumstances.”).

Presumably, the same principle applies to section 17(a) of the 1933 Act, which is phrased in nearly identical language as Rule 10b-5. *Compare* 15 U.S.C. § 77q (1994) and 17 C.F.R. § 240.10b-5 (2001). *See also, e.g.*, *SEC v. Rogers*, 790 F.2d 1450, 1459 (9th Cir. 1986) (appearing to require a “duty to disclose” in an omissions case under either section 17(a) or section 10(b)).

Section 11 of the 1933 Act imposes liability for omissions (and hence enforces a “duty to disclose”) only if the defendant failed “to state a material fact required to be stated [in the registration statement] or necessary to make the statements therein not misleading . . .” 15 U.S.C. § 77k(a) (1994). Section 12(a)(2) similarly creates liability for failure to disclose in a prospectus only where the defendant does not reveal “a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading.” 15 U.S.C. § 77l(a)(2) (Supp. III 1997).

- i) trading in the biotechnology company's stock by the company or its principal officers or its directors,<sup>176</sup> or
- ii) statements by the company (including officers speaking for it) that mislead unless the company also reveals the negative test results.<sup>177</sup>

The first of these events presents a bright line test: a company can easily determine when it is buying or selling its own stock and, in most cases, should be able to determine when its principal officers or its directors buy or sell. In either case, a company having material information about “bad” test results should publicly disclose that information before the trades occur.

The second disclosure trigger is somewhat more difficult to apply. But in a case where a life sciences company has reached a conclusion that test results on a new product are negative, it may, as a practical matter, be difficult to provide any progress report on the product to the investment community that fails to include this “bad” news without the report being arguably incomplete or misleading.<sup>178</sup>

*Walsingham v. Biocontrol Technology, Inc.*<sup>179</sup> makes this point. Biocontrol was developing a noninvasive device to monitor blood glucose levels. The complaint alleged that the company failed to disclose unfavorable test results while touting the effectiveness of the device and

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176. Corporate insiders labor under a duty to “disclose or abstain”—i.e., they must publicize the undisclosed material facts they know or forbear from buying or selling the company's securities. *Chiarella*, 485 U.S. at 227. The same rule applies when the company itself is buying or selling its own securities. *McCormick v. Fund American Companies, Inc.*, 26 F.3d 869, 876 (9th Cir. 1994).

To be analytically precise, where the only trading is by the individual officer or director, the duty to disclose material nonpublic information before trading is his alone and not transferable to the corporation. *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 403 (6th Cir. 1997), *cert. denied*, 523 U.S. 1106 (1998); *Anderson v. Abbott Lab.*, 140 F. Supp. 2d 894, 909–10 (N.D. Ill. 2001), *aff'd sub nom. Gallagher v. Abbott Lab.*, 269 F.3d 806 (7th Cir. 2001); *Chan v. Orthologic Corp.*, No. Civ. 96-1514 PHX RCV, 1998 WL 1018624, at \*20 (D. Ariz. Feb. 5, 1998). As a practical matter, the company may wish to consider disclosure if its directors or top management are going to trade. The company has an interest in avoiding the adverse public and regulatory reaction to improper insider trading by those closely affiliated with it.

177. Sections 11 and 12(a)(2) of the 1933 Act and Rule 10b-5 all expressly impose liability for omitting material facts “necessary” “to make the statements” that are made “not misleading.” Moreover, under section 10(b), cases hold that “[w]hen a corporation does make a disclosure—whether it be voluntary or required—there is a duty to make it complete and accurate.” *See, e.g., Roeder v. Alpha Industries, Inc.*, 814 F.2d 22, 26 (1st Cir. 1987).

178. Putting aside securities law liability, a life sciences company may wish to promptly release such negative news in order to maintain its credibility with analysts and investors.

179. *Walsingham v. Biocontrol Tech., Inc.*, 66 F. Supp. 2d 669 (W.D. Pa. 1998).

expressing optimism about FDA approval. In denying the defense motion to dismiss, the court noted the plaintiffs' specific allegations:

For example, on December 6, 1995, BICO issued a statement in response to a recent newspaper article reporting skepticism as to whether the Diasensor 1000 would be approved by the FDA. BICO stated:

If the device does not work, why struggle so hard to get it to market? Why struggle so hard and long through the FDA approval process and why would eight of the world's leading endocrinologists have gone to the FDA to support the Diasensor 1000™ and urge its approval? The Company will not survive if a product that doesn't work is supplied. Biocontrol will maintain the strictest standards with the Diasensor 1000™ noninvasive glucose sensor and will certainly stand behind the product. The welfare of the diabetic is of the utmost importance.

Compl. at para. 50. The plaintiff alleges that at the time of this and other such positive representations, BICO's test results were dismal. More specifically, the plaintiff alleges that

BICO initially evaluated 85 patients[. I]t excluded 22 of these from the analysis, however, because of machine malfunctions. It excluded an additional 16 patients because the machines could not be calibrated to the patient's physiology (making it impossible to obtain an accurate blood-glucose reading) and while this left 47 patients, BICO used only a subgroup of 23 patients for its testing at [] three sites over a month period . . . BICO considered the device "successful" if, with the patient doing the readings, the Diasensor device produced readings which more than 50% of the time agreed, within 20%, with the readings from the patient's own invasive device. Notwithstanding the flawed nature of the testing, only 8 of the 23 patients monitored using the Diasensor device obtained results which BICO deemed to be "successful" when compared to conventional test methods. The Diasensor 1000 misread glucose levels so often that it could endanger patients.

Compl. at para. 29.<sup>180</sup>

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180. *Id.* at 676–77 n.7.

In rejecting the defense argument that the company had no duty to disclose these test results, the court found it “significant that the defendants’ failure to disclose the test results occurred during a time when they were issuing what can only be described as very positive press releases, one of which was in response to public criticism of the [device].”<sup>181</sup>

It is interesting that the company comments in *Walsingham* did not specifically describe the product’s performance. Indeed, they were phrased largely as rhetorical questions. *Walsingham* emphasizes that any comment by a life sciences company that even implies effective performance may later result in litigation if the company does not simultaneously disclose negative test results that have not been superceded by positive ones.

#### D. Insider Trading Based on Unpublished Test Results and FDA Approvals

This article focuses primarily on the liability of companies and executives in private lawsuits. But the SEC also brings actions against biotechnology professionals who trade while in possession of undisclosed test information.<sup>182</sup> The Commission has also pursued such actions against insiders who trade after learning of an FDA product approval, but before the company or the agency publishes that approval<sup>183</sup> or after learning of a nonpublic delay in an FDA submission.<sup>184</sup>

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181. *Id.* at 677–78.

182. See SEC Litigation Rel. No. 15509, 1997 SEC LEXIS 1997 (Sept. 25, 1997) (announcing SEC insider trading lawsuit against, among others, a clinical investigator and a member of a company’s scientific advisory board for allegedly purchasing, or tipping others to purchase, the company’s stock while in possession of nonpublic positive test results). See also SEC Litigation Rel. No. 15322, 1997 SEC LEXIS 773 (Apr. 10, 1997) (announcing SEC insider trading cases based on allegation that the lead investigator on a clinical trial and his assistant tipped others to sell stock while knowing unfavorable, but nonpublic, clinical test results); SEC Litigation Rel. No. 15905, 1998 WL 655577 (Sept. 24, 1998) (discussing settlement of case).

183. See SEC Litigation Rel. No. 16199, 1999 WL 430865 (June 29, 1999) (announcing SEC lawsuit against former controller of Trimedyne and two family members who bought company stock after allegedly learning that FDA approval to market a medical laser was “imminent”); see also SEC Litigation Rel. No. 16198, 1999 WL 430867 (June 29, 1999) (announcing insider trading case against a lawyer for Trimedyne, retained to represent company in a product liability lawsuit, who allegedly bought Trimedyne stock after learning from a company employee that the FDA had cleared Trimedyne to market the laser but before the company publicly disclosed the clearance).

184. SEC Litigation Rel. No. 15721, 1998 WL 199201 (Apr. 24, 1998) (announcing filing and settlement of an action against an independent consultant who allegedly purchased put options on the stock of a client after the consultant obtained nonpublic information regarding

### III. DISCLOSING FDA ACTIONS AND DISCLOSING COMMUNICATIONS WITH THE FDA

In the course of testing and license application, life sciences companies communicate with the FDA. The agency may not only talk to and write to the company, but it may also take official action by approving test protocols and changes in those protocols. The company may wish to report at least some of these communications and actions, and may be required to do so. Following these disclosures, analysts and investors will want to know what the FDA actions and communications mean for the probability and timing of licensing. They may press the company for its views. But the iterative nature of the licensing process and the unpredictability of agency action can make it difficult to decode the significance of what the FDA says and does. While life sciences companies will internally intuit the agency's rationale and motive, "reading the tea leaves" in public may be perilous.

Reported decisions evaluate: (1) company disclosure (and nondisclosure) of FDA questions about and comments on clinical tests; (2) company interpretation of pre-approval FDA actions; and (3) company statements following FDA denial of a drug or device application.

#### A. *FDA Questions and Comments About Tests*

By letter or comment, FDA staff or Advisory Committee members may express a view, sometimes a negative one, about clinical tests. This will form part of an ongoing dialogue about the tests between the agency and the company. When the FDA makes adverse comments about tests, a life sciences company must decide what, if anything, to say publicly about those comments. This problem becomes acute when the company announces positive test results. At that point, management must decide whether the FDA comments are material and whether the company's positive report on the tests may be misleading if the company does not give at least some warning of the FDA position.

*MedImmune* provides critical guidance. The company positively reported Phase III test results for its Respivir drug to treat RSV LRI. In a November 1993 press release, MedImmune said that the publication of an article on the clinical trial "underscores the potential value of [the drug] in preventing RSV disease" and that the study showed high-dose Respivir "significantly reduced the severity of RSV and significantly

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the company's plans to delay its application for FDA approval of a personal hemodialysis system).

reduced the frequency of RSV-related hospitalizations.”<sup>185</sup> An FDA Advisory Committee voted against recommending approval of the drug the next month and “expressed a concern about the concentration of treatment response at the Denver site, as well as the enrollment procedure used there, which they believed might have compromised random assignment of trial participants to treatment groups.”<sup>186</sup> Shareholders alleged in a lawsuit that the FDA had raised questions about study design and had suggested that there were problems with randomization as early as August, and that the company had violated the securities laws by not revealing these facts.<sup>187</sup> The court dismissed the case insofar as it was based on the defendants’ “enthusiasm ‘about the results from this study and the implications for preventing this serious illness.’”<sup>188</sup> Consistent with the notion that expressing views within the range of the scientifically reasonable does not evince scienter, the court reasoned that MedImmune had a genuine and defensible view that the test results were valid:

[W]hatever may be Plaintiffs’ claim as to the theoretical invalidity of the test data, their complaint falters on the matter of scienter which, in the context of this suit, “refers to a mental state embracing intent to deceive, manipulate, or defraud.” . . . Plaintiffs have pleaded no facts, beyond mere conclusory statements, that would support either an inference of bad faith or an inference that Defendants acted with an intent or recklessly to deceive, manipulate, or defraud . . . .

Nor do Plaintiffs fairly plead the manner in which Defendants acted with reckless disregard as to the validity or invalidity of the data. Medical researchers may well differ over the adequacy of given testing procedures and in the interpretation of test results. . . . Simply to aver that the Advisory Committee, based on theoretical (not to say inappropriate) statistical concerns, eventually challenged the company’s opinion, is not to say that

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185. *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 963 (D. Md. 1995).

186. *Id.* at 958.

187. *Id.* at 959 (following the Advisory Committee decision, “a staff fellow in the same FDA office [of Blood Research and Review] . . . reportedly told [a biotech trade publication] that the FDA had been warning MedImmune ‘for a long time’ about problems with the study design, suggesting that there could have been problems with randomization ‘as early as August, when a letter was sent out asking for more information.’ [She] is reported to have further stated that MedImmune appeared to understand FDA’s position and simply disagreed.” *Id.*).

188. *Id.* at 967.

Defendants should have had knowledge of the theoretical statistical limitations on their assumptions.<sup>189</sup>

Speaking directly to plaintiffs' argument that questions from FDA staffers should have alerted the company to the invalidity of the tests and that the company should have reported the FDA questions to the investing public, the court emphatically disagreed.

Mere questioning by the FDA imposed no duty upon Defendants either to trim back their opinions as to the efficacy of the drug or to report to the public the FDA staffers' questions as they arose. Continuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process. . . . Requiring ongoing disclosure of FDA's questions would not only be disruptive to the review process; it could easily result in misleading the public more than not reporting the questions. Where mere disclosure of a question might cause the company's stock to decline in value, the eventual answer to the question might cause it to rise once again. Investors who sold that stock when the FDA's question was asked but before the company's answer was given might have legitimate cause for concern when a satisfactory answer came forth and the stock's price began to climb again. As defense counsel cogently argues, Defendants might then find themselves defending the opposite of the present lawsuit.<sup>190</sup>

The court denied the motion to dismiss, however, as to a MedImmune statement that there was "absolutely no question about efficacy." This statement went too far because it "might well contain in its sweep a representation that the FDA had raised no question about the efficacy of the drug [before the Advisory Committee decision] when in fact quite possibly it had."<sup>191</sup>

Contrast this lawsuit to *In re Marion Merrell Dow*.<sup>192</sup> There the company made public statements suggesting the FDA would approve a drug for OTC sale. The court denied a motion to dismiss the claim that those statements misled, because Marion Merrell Dow allegedly did not also disclose adverse reactions by some patients or the comment by one Advisory Committee member that "obviously, it goes without saying that this is a drug that could not possibly be over-the-counter for self-

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189. *Id.* at 966–67.

190. *Id.* at 966.

191. *Id.* at 967.

192. *See supra* notes 82–89.

administration.”<sup>193</sup> Note that this Committee member comment, however, was considerably stronger than the implied criticism of test protocol inferred from the staff inquiries in *MedImmune*.

Two other cases—*Biogen* and *British Biotech*—help to refine the analysis. After Biogen retrospectively determined that Hirulog reduced death and nonfatal heart attacks and decided to proceed with a Phase III trial, Biogen representatives met with the Director of the FDA’s Gastrointestinal & Coagulation Drugs Division. The Director warned that the absence of a statistically significant link between Hirulog and the prospectively defined primary endpoint in the Phase II trial “raises concern regarding the efficacy of [the drug].”<sup>194</sup> Nevertheless, the FDA encouraged Biogen to perform a Phase III clinical trial to compare Hirulog against Heparin in the treatment of unstable angina.<sup>195</sup> When Biogen issued its press release announcing Hirulog’s apparent success against the retrospectively defined endpoint and the company’s intention to undertake the additional Phase III trial, Biogen did not mention the FDA Director’s observation. While the plaintiffs in the subsequent securities lawsuit claimed that this was fraud, the court ruled that the company “had no duty to disclose [those] reservations.”<sup>196</sup>

An SEC investigation and administrative proceeding against British Biotech concluded quite differently.<sup>197</sup> British Biotech sought FDA approval to test a new cancer drug. The company told the FDA that the test would record the effect of the drug on cancer antigens, which the test would use as surrogate markers for tumors—thereby assuming that the antigen levels bore some relationship to the growth of the tumors.<sup>198</sup> British Biotech also indicated that it would later conduct definitive trials that would rely on traditional markers for efficacy, such as mortality rates and X-ray or CT scan measurements of tumor size.<sup>199</sup> In March 1995, the FDA told British Biotech that cancer antigens alone could not be used as surrogate markers for tumor progression; that, in order to

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193. *In re* Marion Merrell Dow Se. Litig., [1993 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 97,776, at 97,763 (W.D. Mo. Oct. 4, 1993).

194. *In re* Biogen Sec. Litig., 179 F.R.D. 25, 30 (D. Mass. 1997).

195. *Id.*

196. *Id.* at 37.

197. *In re* British Biotech PLC, et al., SEC Administrative Proceeding File No. 3-9915 (June 10, 1999) (Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings and Order of the Commission)[hereinafter “British Biotech order”], <http://www.sec.gov/litigation/admin/34-41505.htm> (last visited March 21, 2002). Respondents neither admitted nor denied the SEC’s findings in the settlement leading to the order.

198. *Id.* Part II.B.2.

199. *Id.*

obtain marketing approval, the company would have to show a correlation between antigen levels and more conventional endpoints; and that, without that information, an interpretation of antigen data would be “unintelligible.” In May, the FDA repeated its position but permitted the company to proceed with the proposed test.<sup>200</sup>

On December 12, 1995, British Biotech filed a Form 6-K with the SEC, incorporating a November 30 press release saying that its drug had shown “a positive biological effect on blood concentrations of cancer specific antigens which are recognized as surrogate markers of tumor progression or regression.”<sup>201</sup> On May 21, 1996, British Biotech issued a press release saying that the “[p]ositive . . . results presented in November . . . ‘have been confirmed in larger patient numbers.’”<sup>202</sup>

In response to the May 21 release, the FDA issued a Notice of Violation to British Biotech, informing the company that the press release was misleading because, among other things, it did not disclose the FDA’s position on antigen data. The Notice stated that “the relevance of the ‘positive’ cancer antigen data is vastly overstated.”<sup>203</sup> British Biotech repeated the statements made in its May press release in several Form 6-Ks that it filed with the SEC and in a Form 20-F. In none of these filings or the press releases did British Biotech disclose the FDA position on the use of antigen levels to evaluate drug efficacy. The company finally did so in November 1996.<sup>204</sup>

The SEC instituted an administrative proceeding against British Biotech. While the company settled for a cease and desist order, the Commission found that the filings with the SEC had contained:

materially misleading statements concerning the results [the drug] was showing in the clinical trials. In these reports, British Biotech claimed that [the drug] was showing effectiveness . . . primarily based upon the antigen data, but omitted to disclose the FDA’s position that cancer antigens alone could not be used to establish efficacy, that to establish efficacy British Biotech would have to show a correlation between the antigen data and a more conventional endpoint such as the measurement of tumor

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200. *Id.* Part II.B.3.

201. *Id.* Part II.B.4.

202. *Id.*

203. *Id.*

204. *Id.*

size by X-ray, and that the antigen data could not be used to support FDA approval.<sup>205</sup>

There are many differences between *Biogen* and *British Biotech*. First, the comments by the FDA Director to Biogen simply articulated an implication from the Phase II Hirulog test results, which had been published by March 14, 1994, a little over a month after the FDA Director made his comment on February 4. Those publicly reported results revealed that the drug had not demonstrated efficacy as to the Phase II prospectively defined primary endpoint. It is quite arguable that the FDA comment—that Phase II results raised concerns about the drug’s efficacy—would have added little or nothing to the information already public by March 14.<sup>206</sup> In contrast, the FDA position on antigen data in *British Biotech* was no mere articulation of some obvious implication from data that the company published. Instead, the FDA position was, at least as far as sufficiency for licensing, directly contrary to the company’s statement that antigens “are recognized as surrogate markers of tumor progression or regression.”<sup>207</sup>

Second, the FDA Director’s remarks to Biogen were in the context of FDA’s support for Phase III Hirulog trials against Heparin for treatment of unstable angina. While the FDA had permitted British Biotech to go forward with its test (as apparently was required since the test did not pose a safety threat),<sup>208</sup> the FDA never encouraged British Biotech, and the FDA comments were in the context of (1) grudging approval for the test and (2) a Notice of Violation.

Finally, the FDA did not tell Biogen that any of its public announcements were misleading. In the Notice of Violation, the FDA told British Biotech just that.

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205. *Id.* Part II.C. The SEC pursued British Biotech under section 13(a) of the Exchange Act and Rules 13a-1 and 13a-16, requiring foreign private issuers of registered securities to provide reports on Forms 6-K and 20-K, and under Rule 12b-20, requiring that all periodic reports include information as may be necessary to make required statements not misleading.

206. There is a good deal of authority for the proposition that an issuer cannot be liable for failure to repeat facts that are already publicly reported. *See Heliotrope General, Inc. v. Ford Motor Co.*, 189 F.3d 971, 980–81 (9th Cir. 1999) (no duty to disclose relative costs and benefits of maintaining tax strategy where “the market was aware [through the financial press] of the mounting costs associated with the tax strategy, from which the market could have inferred that the strategy might one day be abandoned as too costly”); *In re Sybase, Inc. Sec. Litig.*, 48 F. Supp. 2d 958, 961–62 (N.D. Cal. 1999) (granting summary judgment. “In this case, Sybase’s product issues were amply reported by industry analysts in numerous publications. Thus, the statements concerning Sybase’s alleged product problems are not actionable as a matter of law, because they were known to the market.”).

207. *British Biotech* order, *supra* note 197, Part II.B.4.

208. *Id.* Part II.B.3. (“The FDA cannot stop the commencement of a clinical trial based upon problems in the protocol unless those problems pose a safety issue.”).

When the FDA provides a private, negative comment to a company which then makes a positive public statement about its clinical tests, the significance of the FDA comment goes mostly to the probability that the tests will lead to FDA approval and the speed with which that might happen. If the negative view is merely one expressed by the FDA staff and takes the form of an inquiry, it may not be material (or at least the company may have no scienter in failing to disclose it), even if the question implies staff concern about the tests, provided that the company's view that the criticism is unwarranted falls within the range of scientific reasonableness. This is the *MedImmune* message, tempered by the caution that a life sciences company should be careful, in stating its own scientifically reasonable view, about implying that the FDA does or must agree.

If the company has already published the hard data on which the FDA's comment is based and if the securities market is likely to know how the FDA views such data (as in *Biogen*), then the FDA's comment itself adds little to the market's calculation of license probability and timing. In that event, the FDA communication should be immaterial. If, however, the FDA view is based on data that the company is not disclosing or if (as alleged in *British Biotech*) the market is likely to be unaware of the FDA's view of the data or if (as alleged in *Marion Merrell Dow*) the company has disclosed neither the data nor the FDA comment, then the marginal importance of the FDA's views may be greater. If the FDA flatly states that a company's public statement is misleading (as alleged in *British Biotech*), the company should think long and hard before publicizing positive test results without also airing its dispute with the agency. Similarly, if FDA staff have actually delivered a draft report directly contrary to the company's position (as alleged in *Zila*), then the company should think carefully about reiterating its view without also disclosing the fact and substance of the FDA report.

Assuming that the analysis just suggested shows that the FDA's comments are important, there is at least one additional consideration. The company may believe that the FDA is mistaken and that it can convince the agency of its error. If the company reasonably concludes that it can persuade the FDA on the issue in a time period that is modest in comparison to the then-projected schedule for FDA approval, the FDA comment should not be material while the company attempts to convince the FDA of its error. A company employing this strategy, however, should periodically reevaluate its judgment that the FDA comment is immaterial for this reason. As time passes, the probability that the FDA's yet-unchanged position may significantly delay or altogether scuttle ap-

proval may increase to such a level that the agency's comment or question becomes "material" under the securities laws.

### B. *Company Characterization of Interim FDA Action*

Life sciences companies face a somewhat different problem when the FDA takes action while clinical tests are underway. In that event, the market may expect the company to explain the significance of the action and, in particular, what the action portends for licensure. Companies may be tempted to provide their opinions on that portent. But doing so may create serious problems.

One court refused to dismiss a claim that a company had violated 10b-5 by publicly suggesting that the FDA had approved a request to end patient randomization *because* the FDA had favorably reviewed interim clinical data. The company argued there was "no basis . . . for inferring that . . . [it] was not justified in assuming that permission had been granted based on the test results it submitted together with the request."<sup>209</sup> The court responded that if the company "merely assumed the significance of the FDA's permission . . . then it was reckless to make the factual assertion that the presentation of the data and the FDA's action were causally connected."<sup>210</sup> Another court refused to dismiss a claim against a company that had attributed a delay in Advisory Committee action to the Committee's need to absorb test information, when the subsequent adverse Committee decision suggested that the delay might arguably have been due to concern over whether the clinical trial demonstrated efficacy.<sup>211</sup>

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209. *In re PLC Systems, Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 119 (D. Mass. 1999).

210. *Id.* The court held that:

so much of [one release] stating that "[d]ue to the dramatic differences in the clinical outcomes between the TMR group and the medical therapy group the FDA has allowed PLC Systems to stop randomizing patients," and so much of [a second release] claiming that "[a]s a result [of reviewing the data], the FDA allowed the Company to stop randomizing patients to medical therapy," are actionable . . . . Presented as assertions of fact, the capacity of the statements to mislead is apparent. A reasonable investor would have concluded from these statements that the FDA had made a preliminary endorsement of The Heart Laser's therapeutic efficacy.

*Id.*

211. *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 963 (D. Md. 1995). One defendant in *MedImmune* had said that "[u]ntil they . . . reach a comfort level of having gone through everything, they don't feel comfortable going through the Advisory Committee" and was reported as saying that "the FDA has been unable to complete all of its necessary work on the application." *Id.* at 963. The court viewed this as at least potentially misleading:

Arguably both of these statements were attempts to reassure the public that FDA's postponement of the drug review was not a cause for concern and simply a matter of routine. But the comments of Dorothy Scott, staff fellow at FDA's Office of

These decisions suggest that companies do well to simply report FDA interim actions without public comment attributing those actions to some inferred FDA view that a drug or device works or is likely to receive FDA sanction in some speedy way, or at all. In many cases, such comments may be only an educated guess. A court could later conclude that publicizing such speculation is reckless in a 10b-5 sense. If a company does make a public interpretive comment on FDA action, it may wish to state clearly that only the FDA knows for certain why it took the interim action, that the FDA has not stated a reason to the company (if indeed this is the case), and that the company is providing only its own opinion.

### *C. Disclosing Application Denials*

While it might seem at first blush to be straightforward, even reporting licensing denials can prove surprisingly tricky. Of course, if the FDA has disapproved applications, it is improper to continue to state simply that “preliminary FDA action . . . is expected shortly.”<sup>212</sup> But what may appear to be a final denial may, in the end, simply comprise a turn in a winding road that leads to a licensed, viable product. What can a company say when it believes that to be true?

The SEC’s pending action against ICN presents this case. The SEC alleges that: ICN sought approval of ribavirin (trade name Virazole) as a monotherapy treatment for chronic hepatitis C. On November 25, 1994, the FDA informed ICN by letter that the application was “not approvable” because the data in the application failed to show safe and efficacious treatment. On November 29, representatives of the FDA told ICN in a phone conversation that the application was “not fixable.” On December 5, ICN issued a press release which did not say that the FDA had denied the drug application but indicated that the company was amending its application to seek approval for the drug as a component of a combination therapy:

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Blood Research and Review . . . suggest that, by the time of the statements, FDA may have taken a harder line and MedImmune may in fact have been aware of considerably more serious reasons for the postponement. . . . If FDA had indeed communicated such concern to MedImmune and did so in such a way as to indicate that ultimate approval of Respivir looked problematic, then Hockmeyer’s statements could possibly have misled an investor into thinking that the review process remained totally problem-free.

*Id.* at 968.

212. SEC v. Schiffer, [1998 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 90,247, at 91,082–83 (S.D.N.Y. June 11, 1998) (granting preliminary injunction); *see also* SEC v. Schiffer, [Current Binder] Fed. Sec. L. Rep. ¶ 91,426 (S.D.N.Y. May 10, 2001) (granting SEC’s unopposed motion for summary judgment against estates of defendants who did not settle).

We are pleased the FDA has reviewed our application so quickly, and we will respond promptly as well. Amendment of applications are [sic] a common component of an often lengthy regulatory review process . . . We see this as another step in the process . . . We believe that Virazole has an important therapeutic role to play in the treatment of chronic hepatitis C. In order to expedite the review process and make Virazole available to patients as soon as possible, our amended application probably will include a request for approval of Virazole as a treatment of hepatitis C in combination with other drug therapies.<sup>213</sup>

The SEC sued ICN, claiming that the press release violated 10b-5 because it failed to reveal that the FDA had sent ICN a “not approvable” letter and had concluded that the data in ICN’s application failed to show that Virazole safely and effectively treated hepatitis C.<sup>214</sup> The company responded that, although the release failed to use the words “not approvable,” (1) the company’s statement that it would probably submit an amended application for Virazole’s use in combination with other drugs was a clear signal that the FDA had not licensed Virazole as a monotherapy; (2) the release correctly forecasted that ICN would pursue approval for the drug’s use in a combination therapy; (3) the company did indeed proceed with combination therapy studies with FDA sanction; and (4) the FDA ultimately licensed Virazole to treat hepatitis C in combination with interferon.<sup>215</sup> The court denied ICN’s motion to dismiss the Commission’s complaint.<sup>216</sup>

The Commission’s view reflects a continuing tension in its analysis. On the one hand, the SEC recognizes the power of the efficient market analysis, which assumes that financial professionals set the price after conducting sophisticated analysis often based on industry-specific expertise. Securities analysts specializing in life sciences stocks may well realize that a company files an amended application only when the FDA has effectively denied the original application. On the other hand, the SEC is also concerned about the unsophisticated investor and, therefore, may require companies to phrase disclosures in a way that even the naïf may understand.

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213. Complaint for Permanent Injunction and Other Relief ¶ 35, *SEC v. ICN Pharmaceuticals, et al.*, Civil Action No. SACV 99-1016 DOC (ANx) [hereinafter “ICN Case”] (C.D. Cal. filed Aug. 11, 1999).

214. *Id.* ¶ 36.

215. Defendants’ Memorandum In Support of Motion to Dismiss or for Summary Judgment at 22-24, 32-33, ICN Case (C.D. Cal. filed Oct. 8, 1999).

216. *See* Civil Minutes, ICN Case (Dec. 7, 1999) (also declining to address defendants’ motion for summary judgment as premature).

*ICN* is still pending, and the company may ultimately prevail or the case may settle. It illustrates, however, that when the FDA tells a company it will not approve a pending application, the company may find itself in securities litigation if it reports that news in a way that avoids the pejorative the FDA used to describe its action.<sup>217</sup> A company facing *ICN* facts may find it is safer to expressly state that the FDA has not approved an application, then go on to discuss any further steps the company plans.

#### IV. DISCLOSING AND COMMENTING ON GOVERNMENT INSPECTIONS, INVESTIGATIONS AND PROSECUTIONS

The government pervasively regulates biotechnology companies. Aside from licensing products, the government inspects those companies, requires remedial action where inspectors find compliance failures, investigates suspected wrongdoing (including the submission of false data), and in extreme cases, even criminally prosecutes company employees and executives. As regulatory actions pass along the continuum from the routine to the disturbing and even to the corporate life-threatening, life sciences companies can find it difficult to discern the difference between events that must be disclosed and those that need not be published. Since these regulatory actions frequently appear to be “bad news,” which the companies would prefer not to announce, they are akin to negative test results and raise the same two disclosure questions: (1) when is the regulatory event “material” and (2) when does the company have a duty to disclose it.

##### A. Materiality

The mere fact that the FDA conducts an inspection is not by itself material. Inspections are routine events in the industry,<sup>218</sup> and the invest-

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217. See also *In re Zila, Inc. Sec. Litig.*, No. 99-0115 PHX EHC (CP), 2000 U.S. Dist. LEXIS 15800 (D. Or. Oct. 13, 2000) (denying motion to dismiss where the company allegedly stated that it expected FDA approval in three to four months, after the FDA had refused an application as inadequate on its face but before the company submitted an amended application; stated, again before submitting an amended application, that everything requested by the FDA had been provided and that the company was simply waiting to hear from the agency; submitted a second application that the FDA summarily refused, then submitted a third; and stated, after an FDA advisory panel unanimously recommended against approval on the basis of insufficient data, that the panel had recommended “a refinement of data” and that there was “confusion over some of the data.” *Id.* at \*5. After the company issued the press release with these last comments, the FDA warned the company that the release was not accurate because the FDA panel had recommended a study with a different design).

218. See *Robbins v. Moore Medical Corp.*, 894 F. Supp. 661, 674 (S.D.N.Y. 1995).

ment professionals who follow biotechnology companies presumably know this. The case becomes harder when, after an inspection, the FDA notifies a company of problems the company must correct. At that point, the company must determine whether it should disclose *now* an event the importance of which will be determined in the *future*, when the company learns to a certainty whether it has satisfactorily corrected the difficulties, and, if so, at what cost.

One frequently useful tool to evaluate the “materiality” of events with future implications is a test developed in the merger context. In *Basic Inc. v. Levinson*,<sup>219</sup> the Supreme Court rejected a bright line test that merger discussions were only “material” if they progressed to the point of an “agreement-in-principle.” Instead, the Court held that “materiality ‘will depend at any given time upon a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity.’”<sup>220</sup>

In the life sciences context, this means the results of an FDA inspection are not material, even when the FDA demands corrective action, if the company reasonably estimates that it can accomplish that corrective action<sup>221</sup> by spending an amount of money that is modest in comparison to the company’s overall finances and if taking the corrective action will not have some other important effect, such as delaying the introduction of a company’s only product past a critical market window.<sup>222</sup>

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219. 485 U.S. 224 (1988).

220. *Id.* at 238, quoting *SEC v. Texas Gulf Sulfur Co.*, 401 F.2d 833, 849 (2d Cir. 1968) (en banc), cert. denied, 394 U.S. 976 (1969).

221. In *Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 50 (2d Cir. 1995), the FDA inspected the defendant’s Kansas City plant three times. The first inspection revealed 34 deficiencies; the second, 14 deficiencies. But the third inspection found 85 manufacturing deficiencies and led to suspension of production. In holding that the first two inspections, and their results, were not material, the court observed that between the two inspections the number of deficiencies had been cut by more than half, “indicating that the plant was improving,” and that the FDA had not imposed any sanctions on the subsidiary. *Id.* at 52.

222. *Robbins*, 894 F. Supp. at 674 (“Because . . . Defendants reasonably believed that compliance costs resulting from the inspection were minimal, it was neither false nor materially misleading to state on March 30, 1990, that Moore believed it was in material compliance with the relevant regulations.”); see also *Acito*, 47 F.3d at 52–53 (affirming dismissal of complaint and stating, in a case where the defendant produced over 1,000 products in over 30 countries, that it “would be unduly burdensome and impractical to publicly disseminate the results of every inspection of every plant”).

If it were possible to tell in advance how its stock price would react, that information might help a company considerably in evaluating materiality. See *Employer-Teamsters v. America West*, [2001–02 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 91,606, at 97,550 (D. Or. May 31, 2001) (“The information about America West’s maintenance issues, the FAA investigation and the FAA settlement agreement [including a \$5 million fine] . . . was obviously not material to the reasonable investor because the market did not react when this

Nevertheless, some government actions may lead to very serious results for a company. In *Morse v. Abbott Laboratories*,<sup>223</sup> plaintiffs alleged these facts: the FDA began an inspection of the defendant's pharmaceutical facilities in North Chicago on July 5, 1989. The inspection lasted until November 3, when the FDA issued a report noting 56 deficiencies. After the FDA found Abbott's response insufficient, the agency imposed sanctions. The sanctions included the prohibition against Abbott's selling affected products to any federal agency and a hold on FDA approvals for New Drug Applications and Abbreviated New Drug Applications until Abbott took action that the FDA deemed adequate. Plaintiffs alleged that Abbott did not disclose any of this during a class period running from February 21, 1989, through March 20, 1990.<sup>224</sup> In denying a motion to dismiss, the court found that plaintiffs' allegations described "material" events. "The complaint describes a situation in which a corporation and its 'insiders' realized the significance of FDA sanctions, know about FDA inspections of their facilities, the violations uncovered and the sanctions imposed, and do not thereafter disclose this material information on SEC filings."<sup>225</sup>

Stated differently, and assuming for purposes of analysis that the plaintiffs' allegations were true, there was a point when Abbott knew that the probability of sanctions was sufficiently high and the consequences of the possible sanctions sufficiently harmful that the regulatory action was "material." The court unfortunately does not identify that point by date or particular event.

A more recent case, also involving Abbott Laboratories, resulted in a different outcome. That case shows that courts are sometimes reluctant to second-guess a company conclusion that an adverse post-inspection write-up is not material because, under the circumstances and taking into account the company's experience with the agency, the company believes the FDA is unlikely to impose significant sanctions. In this later Abbott case, the court recounted these allegations: The FDA inspected Abbott's Diagnostic Division ("ADD") several times after 1993, each time noting shortcomings in quality-control policies and practices. Abbott operated under a compliance plan from July 1995 through February 1998, and the agency noted its continuing concerns at the end of that plan. The FDA conducted another inspection in September and November 1998, and informed Abbott of regulatory violations in

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information was disclosed."'). The problem, of course, is that the company must make its materiality judgment before this market test occurs.

223. 756 F. Supp. 1108 (N.D. Ill. 1991).

224. *Id.* at 1109.

225. *Id.* at 1111.

November 1998 and January 1999. Abbott did not disclose any of this in its 10-K filed March 9, 1999.<sup>226</sup>

On March 17, 1999, the FDA issued a warning letter to Abbott identifying several continuing violations and advising that the agency would take enforcement measures without further warning if the company did not immediately resolve its compliance issues. While Abbott did not disclose this letter, *Bloomberg News* reported it on June 15. After the FDA concluded an additional inspection in July, it issued another Form 483 noting further violations. The company then acknowledged in a September 29 press release both the FDA's allegations and the threat of enforcement action. The company said that it was attempting to negotiate a consent decree but contested the charges against it.<sup>227</sup>

On November 2, 1999, Abbott entered into a consent decree agreeing to pay a \$100 million civil fine and withdraw 125 products from the market. This was reportedly the largest fine ever imposed by the FDA. The company announced a \$168 million pretax charge related to the fine and an inventory write-down. Its stock fell. Shareholders sued, starting their class period on March 17,<sup>228</sup> and focusing on Abbott's failure to promptly disclose the warning letter of that date and the last Form 483.

In granting Abbott's motion to dismiss, the district court acknowledged that the company omitted facts about its ongoing problems with the FDA. However, it found the omitted facts immaterial.

The history between Abbott and the FDA makes all the undisclosed information, viewed in context, seem fairly inconsequential. An investor with full information would see a series of inspections, Forms 483, negotiations, re-inspections, more Forms 483 and more negotiations. Abbott had also been in, and out, of an FDA monitoring plan. Plaintiffs appear to concede that events prior to March 17 did not require disclosure to that point. Given the repeating cycle of inspections, findings and negotiations, without any FDA sanctions, plaintiffs must give us a reason to believe this time was different—something that shows Abbott's prospects had genuinely changed or something from the FDA that said, "This time we're serious." Plaintiffs have failed to do [so].

There is nothing magical about the warning letter. Although the language sounds ominous, it really is rather boilerplate. [Citation

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226. *Anderson v. Abbott Lab.*, 140 F. Supp. 2d 894, 900 (N.D. Ill. 2001).

227. *Id.* at 900–01.

228. *Id.* at 901.

omitted.] This is affirmed by the market's reaction. . . . The *Bloomberg News* report prompted no substantial movement [in Abbott's stock price]. If reasonable investors believed the letter altered the total mix of information, the market would have reacted, at least a little bit.

The May–July 1999 inspection also undermines plaintiffs' claims. Clearly, if the FDA were planning another audit, the agency had not yet decided to sanction Abbott, certainly so far as defendants could tell. Abbott had no reason to say anything, at least until after the new inspection. . . . Even after the inspection and the resulting Form 483, plaintiffs have not alleged facts suggesting this was any different from the many prior inspections and Form 483 findings.<sup>229</sup>

Stated another way, taking into account the history of Abbott's relationship with the FDA, the omitted facts did not suggest a sufficiently high probability of the unprecedented sanctions ultimately imposed to make the inspections or the FDA forms and letters material under the probability/magnitude analysis.

When the Seventh Circuit affirmed *Abbott*, it expressed skepticism about this approach to the extent the trial court employed it to dismiss under Rule 12(b)(6), but nevertheless acknowledged that it might be correct under the Reform Act.<sup>230</sup> Therefore, companies facing similar circumstances should maintain silence only with caution. But, putting aside the specifics of the *Abbott* case, the greater point is that the FDA is an aggressive regulator, not shy of confrontational tactics. A company should be able to use its history with the agency as at least one guide in deciding just what sanctions a threatening letter is likely to bring.

While disclosure questions raised by FDA inspections can be difficult, biotechnology companies have faced even more traumatic issues accompanying serious suspicion of, investigation of, and even criminal prosecution for, submitting false data to the agency. If a company deliberately falsifies data, the government will withdraw permission to market the medical device or drug that the company obtained by an application containing material falsehoods.<sup>231</sup> It may “disqualify” a testing facility

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229. *Id.* at 902.

230. *Gallagher v. Abbott Lab.*, 269 F.3d 806, 808 (7th Cir. 2001) (affirming on the ground that plaintiffs failed to identify any false statement by the company that was misleading because it omitted the FDA's demands. The court rejected the argument that Abbott had a duty to update its March 9 10-k by disclosing the March 17 letter).

231. The Secretary of Health and Human Services “shall” withdraw premarket approval for a medical device if the Secretary finds “that the application [for approval] contained or was accompanied by an untrue statement of a material fact.” 21 U.S.C. § 360e(e)(1)(C) (1994).

for failure to comply with regulations, thereby effectively preventing the use of any studies performed at that facility in applications for new approvals.<sup>232</sup> If a company is convicted of a crime committed in the course of seeking approval for a generic drug, the law requires the government to debar the company from submitting any further applications for such drugs.<sup>233</sup> The FDA may also place a company on an Alert List, which may diminish its prospects for obtaining new approvals.<sup>234</sup>

Where senior executives are not involved in the compilation of the data under investigation, management may only come to a full understanding of the facts and their consequences over time. At first, management may have only a sketchy report of irregularity. An internal investigation, an FDA investigation, or both, may follow. As inquiry proceeds, more facts may come to light, including whether there was indeed falsification and, if so, how extensive it might have been. After the facts are fully developed, the FDA must determine which of its panoply of remedies to invoke.

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The Secretary “shall” also withdraw approval of any new drug application upon such a finding. 21 U.S.C. § 355(e) (1994).

232. The Commissioner of Food and Drugs can disqualify a testing facility which has failed to comply with regulations, if the noncompliance adversely affected the validity of nonclinical laboratory studies and other lesser regulatory actions (e.g., warnings or rejections of individual studies) have not been or probably will not be adequate to achieve compliance. 21 C.F.R. § 58.202 (2001). Disqualification permits the FDA to exclude from its consideration completed studies that the facility performed in the past “until it can be adequately demonstrated that . . . noncompliance did not occur during, or did not affect the validity or acceptability of data generated by, a particular study.” 21 C.F.R. § 58.200. Any study that the facility performed “before or after disqualification may be presumed to be unacceptable . . . . No nonclinical laboratory study begun by a testing facility after the date of the facility’s disqualification shall be considered in support of any application for a research or marketing permit, unless the facility has been reinstated . . . .” 21 C.F.R. § 58.210.

233. If the Secretary of Health and Human Services finds that a company has been convicted of a federal felony for conduct relating to the development or approval of an abbreviated drug application for a generic drug, the Secretary “shall debar such [company] from submitting, or assisting in the submission of, any such application.” 21 U.S.C. § 335a(a)(1) (1994). The Secretary shall also withdraw approval of any abbreviated drug application obtained, expedited or facilitated through bribery, illegal gratuity, fraud, or material false statement. 21 U.S.C. § 335c(a)(1).

234. One commentator described the Alert List and its effect in these words:

The FDA has at various times maintained lists of those whom FDA enforcement officials suspected of cheating. The secret and controversial “Alert List” warned FDA drug reviewers to be wary of submissions made by certain named suspects.

The withdrawal of a new drug application (NDA) that had been “erroneously” granted to a company on the FDA’s Alert List because of flaws in factory good manufacturing practices has been upheld in court.

1 JAMES T. O’REILLY, FOOD AND DRUG ADMINISTRATION § 6.06, at 6–12 to 6–13 (2d ed. 1995).

In deciding when and what to disclose under these circumstances, it can be helpful to recall the materiality test that considers both the probability of adverse consequences and their magnitude. The SEC itself has suggested that this analysis is appropriate when a government investigation is underway. In 1988, the Commission released a statement to guide defense contractors in satisfying their disclosure obligations during ongoing government investigations into illegal or unethical activity. The SEC recognized that, during an investigation, “the exact subjects and scope of the government’s inquiry are still unknown.”<sup>235</sup> Calling expressly on the probability/magnitude test, the Commission wrote:

The potential effects of the government’s inquiry must be discussed in the Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”) in a company’s annual and quarterly reports as well as transactional filings, *if, in light of the associated probabilities and magnitudes, the effects may be material*. Such a discussion should be included where the registrant reasonably expects that the government’s inquiry will have a material adverse effect on a company’s financial condition, liquidity, capital resources, net sales, revenues or income from continuing operations, or such inquiry otherwise would cause a material change in the relationship between costs and revenues. Disclosure also should be provided where, in light of the uncertainty regarding the government’s inquiry, reported financial information would not necessarily be indicative of the company’s future operating results or financial condition.<sup>236</sup>

The law on this subject has multiple, and at first confusing, levels. In determining whether the facts are “material” as of the date the company is considering disclosure, the company must peer into what can be a murky future to try to assess the probability of such events as 1) whether witness interviews and document review will prove that employees falsified data, 2) the extent of the falsification, 3) the resulting FDA action and the consequences of that action to the company, and 4) the effect on the company’s future of discontinuing an illegal practice that may have contributed to past success. However, even though the company has made its own estimate of what action the government may take in applying the probability/magnitude test, the company *need not disclose that*

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235. 53 Fed. Reg. 29226, 29227 (Aug. 3, 1988).

236. *Id.* (emphasis added).

*predicted government action.*<sup>237</sup> In most cases where the probability/magnitude test suggests materiality, the *currently known facts* constituting the existing “material” information will simply be the fact of the government investigation.<sup>238</sup> The company should be able to satisfy any disclosure obligation by saying only that the investigation exists and say that it could lead to government action that could materially and adversely affect the company and its operations and results. The disclosure need not predict what the government will do nor quantify the impact of government action on the company.

Known but unfiled government legal proceedings can also be material.<sup>239</sup> When a company *actually knows* the government’s next legal move, it is not speculation to disclose it. To determine whether the known future proceeding is currently “material,” the SEC has—at least in a pronouncement aimed at the defense industry—again suggested using the probability/magnitude test:

Disclosure also is required of *material* pending legal proceedings involving a company or its subsidiaries. Legal proceedings

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237. *In re Par Pharm., Inc. Sec. Litig.*, 733 F. Supp. 668, 678 (S.D.N.Y. 1990) (“Plaintiffs’ contention that the documents Par disseminated to the public or filed with the SEC should have predicted the consequences of discovery of the bribery scheme and its cessation cannot be the basis of Rule 10b-5 liability”; “[T]he company was not obligated to speculate as to the myriad of consequences, ranging from minor setbacks to complete ruin, that might have befallen the company if the bribery scheme was discovered, disclosed or terminated.”); *see also Ballan v. Wilfred Am. Educ. Corp.*, 720 F. Supp. 241 (E.D.N.Y. 1989),

Wilfred was not obligated to disclose information of which it had no knowledge or about which it could only speculate. Indeed, it would be misleading for it to do so. . . . [D]efendants were not bound to predict as the ‘imminent’ or ‘likely’ outcome of the investigations that indictments of Wilfred and its chief officer would follow, with financial disaster in their train.

*Id.* at 248(citations omitted).

238. The failure to disclose the fact of a serious investigation can be actionable. *See, e.g., In re Independent Energy Holdings PLC Sec. Litig.*, 154 F. Supp. 2d 741, 760 (S.D.N.Y. 2001) (failure to disclose “formal investigation” by regulatory agency, which was the highest level of investigation, was actionable where investigation was not routine and where agency had right to impose a license condition prohibiting company from accepting certain new business).

239. 17 C.F.R. § 229.103 (2000) is applicable to filings under both the Securities Act and the Exchange Act, and requires that issuers:

Describe briefly any *material* pending legal proceedings, other than ordinary routine litigation incidental to the business, to which the registrant or any of its subsidiaries is a party or of which any of their property is the subject. Include the name of the court or agency in which the proceedings are pending, the date instituted, the principal parties thereto, a description of the factual basis alleged to underlie the proceeding and the relief sought. *Include similar information as to any such proceedings known to be contemplated by governmental authorities.*

*Id.* (emphasis added).

*known to be contemplated* by government agencies similarly should be disclosed *where management reasonably believes that such government action will have a material effect upon the company and its business*. In this regard, disclosure of *known contemplated government proceedings* may be required where the result may be the cancellation of a government contract, suspension of payments under a contract, termination of further business with the government, or alteration of the registrant's procedures for obtaining government contracts.<sup>240</sup>

Assuming that application of the probability/magnitude test suggests that an investigation is material, the question remains whether the underlying circumstances being investigated are also material facts that should be disclosed.<sup>241</sup> Where those facts are clear and the relationship of the facts to the investigation or to the company's success are easily understood—e.g., where a company has talked up the high rate of FDA approvals for company drug applications, the authorities are investigating bribery of FDA officials who could influence approvals, and the company has verified that the bribery took place and very likely influenced drug approvals—the underlying facts could themselves be material. However, where the facts are unclear or are extremely technical

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240. 53 Fed. Reg. 29226, at 29227 (Aug. 3, 1988) (emphasis added).

241. A number of decisions from outside the biotechnology industry hold that illegal conduct posing a real threat to the continuation of a business may be a "material" fact. Its materiality may derive either from the circumstance that disclosure of the illegal conduct could harm the business by, for example, threatening vital licenses, or from the circumstance that discontinuation of an illegal practice might deprive the issuer of an advantage that has been important to its success. *See Decker v. Massey-Ferguson, Ltd.*, 681 F.2d 111, 119 (2d Cir. 1982); *Roeder v. Alpha Industries*, 814 F.2d 22, 26 (1st Cir. 1987); *Greenfield v. Professional Care, Inc.*, 677 F. Supp. 110 (E.D.N.Y. 1987); *SEC v. Jos. Schlitz Brewing Co.*, 452 F. Supp. 824, 830 (E.D. Wis. 1978). It may also be actionable to report financial numbers where the operations generating them are illegal and the illegal conduct is not disclosed. *Levitan v. McCoy*, [Current Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 91,608, at 97,560 (N.D. Ill. Sept. 20, 2001) (denying motion to dismiss claim that earnings were overstated because bank credit card division has been systematically violating Truth in Lending Act); *Gaming Lottery Sec. Litig.*, [2000–01 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 91,339, at 95,939 (S.D.N.Y. Feb. 27, 2001) (granting summary judgment on liability against certain defendants. "For Defendants to include the operating revenues of Specialty Manufacturing together with those of Gaming Lottery in its quarterly financial reports without disclosing the material risk to Gaming Lottery of operating without a license constitutes concealment of a material fact.")

In Staff Accounting Bulletin No. 99, the Commission staff took the position that companies cannot evaluate materiality by quantitative economic effect alone. The staff listed "concealment of an unlawful transaction" among the considerations that could render material a numerically small misstatement on a financial statement. 64 Fed. Reg. 45,150, at 45,152 (1999). While this Bulletin concerned misstatements in financials (and particularly "managed earnings"), the SEC may apply its reasoning to other disclosures. If so, it will make even more difficult the task of determining whether misconduct is material.

and their interpretation is uncertain—as may often be the case in the life sciences context—it should be sufficient to disclose the investigation and not the facts themselves.

Even where the facts are clear, it may be sufficient to disclose the investigation and possible (but not predicted) consequences. In *Ieradi v. Mylan Laboratories, Inc.*,<sup>242</sup> the trial court dismissed a 10(b) case against a drug manufacturer the Federal Trade Commission had sued for restraint of trade. Mylan disclosed the FTC investigation in its SEC filings and asserted that such “governmental inquiries [are] . . . inherently uncertain” and that, “[t]he Company may be unable to realize [its] plans and objectives . . . due to various important factors, including . . . if the FTC concludes, on the basis of its investigation, that the Company has acted improperly.”<sup>243</sup> The shareholder bringing the securities action claimed the company improperly failed to disclose two exclusive supply contracts which allegedly gave the company the market power to impose the price increases that prompted the FTC investigation. The Third Circuit affirmed the dismissal, finding no error in the district court’s conclusion that “the existence and substance of the exclusive supply contracts was immaterial.”<sup>244</sup>

[A]lthough [plaintiff] does allege that the contracts . . . were anticompetitive and in violation of the antitrust laws, we seriously doubt that “the reasonable investor” possesses the depth of antitrust law expertise that would allow him or her to conclude that the contracts were susceptible to successful attack under the antitrust laws. Knowledge that the FTC was engaging in an investigation of Mylan’s extraordinary pricing . . . because of its [allegedly] anticompetitive activities was much more informative to “the reasonable investor” than information pertaining to Mylan’s exclusive contracts for raw materials for two of its drugs.<sup>245</sup>

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242. 230 F.3d 594 (3d Cir. 2000).

243. *Id.* at 597 (alterations in original).

244. *Id.* at 599.

245. *Id.* at 600. Companies should rely on this decision with caution. Other courts could emphasize that the efficient market theory rests on the assumption that experts evaluate public information about companies and make buy and sell recommendations and decisions, influencing a sufficient number of trades to set stock prices. Following that line of analysis, a court might conclude that the information about the contracts was material because these market experts could evaluate the contracts’ antitrust importance.

Flipping the *Ieradi* analysis, where regulatory action follows as a matter of course from underlying facts, it may be sufficient to disclose those facts and not the resulting action. *In re K-tel Int’l, Inc. Sec. Litig.*, 107 F. Supp. 2d 994, 1005 (D. Minn. 2000) (where NASDAQ-listed company published financials showing that its net tangible assets had fallen below the

If this can be said about exclusive contracts and their antitrust implications, it might also be said about investigations of life sciences companies that are, at bottom, scientific disputes.

Moreover, as a practical matter, a company will want to be cautious in disclosing underlying facts relating to a government investigation. The inherent uncertainties in collecting, verifying, and evaluating facts argue against such disclosure except in the clearest cases. Even then, it may be quite difficult to determine whether past conduct is material either because the government might issue sanctions that will significantly hurt the company or because the company's discontinuation of an improper practice which contributed to past success might significantly dim the company's future prospects.

### B. *Duty To Disclose*

Assuming that a company has applied the probability/magnitude test and determined that regulatory events (or misdeeds by employees that will have regulatory consequences) are "material," there remains the question of when the biotechnology company must disclose this information.

Turning back to two principal triggers for disclosure duty—trading in the stock by the company or insiders and statements by the company that are misleading if the company does not also reveal the regulatory action—the most problematic cases will be those involving the latter. Once the company has "material" information about an inspection, notice of noncompliance, or government investigation, the company must determine each time it speaks whether it should disclose the regulatory development to prevent misleading by omission.

General laudatory comments about a company generally do not mislead by a failure to disclose material, adverse regulatory action.<sup>246</sup> Even a statement that the company maintains "comprehensive quality assurance programs" is too general to require disclosure of post-inspection FDA advice that a manufacturing facility is out of compliance with agency

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dollar minimum necessary for continued listing, failure to publicize NASD delisting letter did not create a strong inference of fraudulent intent).

246. *See* *Robbins v. Moore Medical Corp.*, 894 F. Supp. 661, 666, 669–70 (S.D.N.Y. 1995) (statements that newly acquired subsidiary "has established a fine reputation for quality products" and was "highly regarded in the industry for its quality line of products" created no duty to disclose difficulty in obtaining FDA approval of "recipes" for generic drugs it manufactured). *See also* *Anderson v. Abbott Lab.*, 140 F. Supp. 2d 894, 909 (N.D. Ill. 2001) (accurate report of past financial results is not misleading because the reporting company does not simultaneously discuss regulatory problems. The accurate historical figures "do not suggest anything about regulatory compliance that could be misleading.").

rules.<sup>247</sup> The undisclosed facts must bear a more specific relationship to the company's comment before the securities laws require disclosure of those facts to prevent the comment from deceiving investors. For example, self-praise for a high rate of rapid FDA approvals may well create a duty to reveal improprieties in company-FDA relations, such as illegal gratuities paid to FDA personnel.<sup>248</sup>

Not infrequently, biotech companies simply state that they believe they are in material compliance with FDA regulations. If the company is violating those regulations in an important way at the time it makes the statement, the statement may be false and subsequent securities law litigation could be based on that misrepresentation. If the company is not committing a "material violation" at the time it makes the statement, the statement is not "false."<sup>249</sup> But what if the company knows of FDA violations but is uncertain whether they will be prove to be significant?

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247. *Chu v. Sabratek Corp.*, 100 F. Supp. 2d 827, 834 (N.D. Ill. 2000) ("[T]he affirmative statements in the SEC filings (i.e., that Sabratek and its subsidiaries operated an internal quality assurance program) are far too attenuated from the alleged regulatory problems at the flush syringe manufacturing facility to establish fraud.").

248. *See In re Par Pharmaceutical, Inc. Sec. Litig.*, 733 F. Supp. 668 (S.D.N.Y. 1990) (court denied defendants' motion to dismiss, noting plaintiffs' theory that the public statements

touting Par's [and its subsidiary's] competitive advantage in obtaining FDA approvals . . . were false and misleading because defendants failed to disclose (1) that such advantage was obtained through an illegal scheme of bribes rather than through defendants' expertise and business acumen, and (2) that the public disclosure and/or termination of the bribery scheme would have a profound harmful effect on Par's sales, profit margins and earnings.

*Id.* at 675.). *See also SEC v. Shah*, [1994–1995 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 90,586, at 98,374 (S.D.N.Y. July 26, 1993) (further factual background on the *In re Par* case).

*See also In re Halsey Drug Co., Inc.*, Admin. Proceeding File No. 3-9230, 1997 WL 34873 (S.E.C. Jan. 28, 1997) (SEC found 10(b) violation where Halsey stated in 10-Ks that it had to follow Current Good Manufacturing Practices ("CGMP") at all times, that it manufactured an FDA-approved drug, and that, in order to comply with CGMP, it had to "expend time money and effort in the areas of production and quality control to ensure full technical compliance." It failed to disclose that it was not complying with CGMP because it was using unapproved formulas and procedures and that its employees, at the direction of management, were concealing product adulteration from the FDA.).

249. *Robbins v. Moore Medical Corp.*, 894 F. Supp. 661, 674 (S.D.N.Y. 1995) (no 10(b) violation where the company had a reasonable basis for believing that the problems raised by the FDA inspection to which plaintiffs pointed could be solved by spending a modest amount of money. Accordingly, the company could properly say that it believed itself to be in "material" compliance with statutes and regulations). *Contrast Copley Pharm., Inc. Sec. Litig.*, [1995 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 98,695, at 92,256-57 (D. Mass. Mar. 16, 1995) (dismissal denied where defendants were allegedly aware of alterations to a drug coating without FDA approval and preparation of false batch production records, but company stated that it was "in material compliance with CGMP").

The probability/magnitude test may be helpful once more. In *Chan v. Orthologic Corp.*, the company's Director of Regulatory Affairs allegedly told one of the individual defendants in 1995 that the company was improperly marketing its OL 1000 device for unapproved uses.<sup>250</sup> Orthologic filed a 10-K on March 19, 1996, in which it stated, "The Company believes that its operations are in material compliance with applicable law."<sup>251</sup> The company did not mention the Director of Regulatory Affairs' concern and did not mention any FDA interest in possibly improper marketing. Dismissing the subsequent securities case, the court focused on the probability of government action at the time Orthologic filed the 10-K.

[I]f the company was truly aware of an impending FDA investigation that was likely to result in sanctions against the corporation, the 10-K was . . . misleading. On the other hand, if the company was merely aware of the FDA's interest, but truly thought that it was in material compliance with all FDA regulations, the statement seems logically accurate. Thus, Plaintiffs must allege facts establishing that the company knew that the FDA was "intending" or "likely" to actually take action against it. Plaintiffs have not done so.<sup>252</sup>

Even the warning by the in-house compliance director was insufficient to require disclosure because it did "not establish that the company knew that its statements . . . were false. Thomas is not alleged to have warned of an on-going FDA investigation; rather, Plaintiffs allege that he warned the company of illegal promotional activities."<sup>253</sup> *Chan* teaches that the question of "material" compliance implicates (1) the degree of any noncompliance, (2) the likelihood of resulting FDA action, and (3) the projected impact of such action on the life sciences company.

### C. How To Phrase a Disclosure

Once a company has decided to make a disclosure about (for example) an FDA inspection and notification of noncompliance, there remains the question of what the company should say. The company will be tempted to state that the regulatory action has little significance. Where

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250. *Chan v. Orthologic Corp.*, No. Civ. 96-1514 PHX RCV, 1998 WL 1018624, at \*1 (D. Ariz. Feb. 5, 1998).

251. *Id.* at \*18. On April 29, 1996, the FDA wrote Orthologic to express the agency's concern about improper marketing and promoting, and the FDA sent a formal Warning Letter to Orthologic on May 31, 1996. *Id.* at \*6. But these events occurred after the SEC filing.

252. *Id.* at \*19.

253. *Id.* at \*16.

the company believes that to be true, has a reasonable basis for that belief, and knows of no undisclosed fact that seriously undermines that view, the company should be able to express its belief without incurring securities law liability.

Shortly after Syntex signed a consent decree with the FDA requiring the company to spend \$2 million on corrective advertising for Syntex's most important drug, the company stated in its annual report that:

Although the outcome cannot be predicted with certainty, it is the opinion of management, based on advice of counsel, including counsel advising Syntex on FDA matters, and other considerations, that [the decree] should not have a material adverse effect on the results of operations in the current fiscal year ending July 31, 1992.<sup>254</sup>

The court dismissed a later securities lawsuit in which plaintiffs alleged that the consent decree, in fact, negatively affected Syntex's sales. Holding that the Syntex statement had to be evaluated as of the time it was made, the Ninth Circuit noted that the company distributed the annual report less than three weeks after the consent decree was entered and before the company had any way of knowing how that decree would impact sales. The court also observed that plaintiffs had pointed to no "inside knowledge" that contradicted Syntex's public statement.<sup>255</sup>

The carefully phrased, forward-looking Syntex statement contrasts sharply with the more aggressive statements of the *Westwood v. Cohen* defendants.<sup>256</sup> As summarized by the court in deciding a motion to dismiss, Barr commented on FDA action in the following manner:

October 24, 1991: Barr announces that the FDA has recently inspected two facilities and concluded that Barr might be in violation of certain Current Good Manufacturing Practices. Barr responds that many FDA observations were "trivial in nature and could be considered subjective and retaliatory," adding that the inspection "uncovered no incidence of fraud, misrepresentation, deception or other similar acts."<sup>257</sup>

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254. *In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 929 (9th Cir. 1996)(emphasis omitted). Phrasing a statement as an opinion will not necessarily remove it from securities law scrutiny. *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1108–09 (1991) (Scalia, J., concurring) ("As I understand the Court's opinion, the statement 'In the opinion of the Directors, this is a high value for the shares' would produce liability if in fact it was not a high value and the directors knew that.").

255. *Chan*, 1998 WL 1018624 at \*16.

256. *Westwood v. Cohen*, 838 F. Supp. 126 (S.D.N.Y. 1993).

257. *Id.* at 130.

November 7: *The Wall Street Journal* reports that the FDA presented Barr with a proposed consent decree requesting that Barr cease manufacturing and distribution until certain regulatory issues were resolved and also reports that the company declined to agree to the decree. Barr's vice president for finance and chief financial officer is quoted as saying that there is "no question as to the safety or efficacy of any of our products."<sup>258</sup>

November 11: The vice president/CFO claims that the FDA is trying to close Barr's manufacturing facilities due to "a whole series of very technical issues."<sup>259</sup>

April 27, 1992: Barr announces it has filed suit to stop the FDA from enforcing an "Alert List" against some of the company's products. The president/CEO says he does not think that the FDA inspection raised "serious issues."<sup>260</sup>

April 29: Barr again says that the FDA "uncovered no incidents of fraud, misrepresentation, deception or any similar unlawful acts."<sup>261</sup>

June 12: The FDA announces a lawsuit against Barr, seeking an injunction prohibiting Barr from manufacturing or selling pharmaceuticals.<sup>262</sup>

June 15: Barr issues a press release asserting that the FDA allegations are "consistent with the agency's pattern of retaliation against the company which testified against the agency in Congress in 1989." The company repeats that "no incidents of fraud, misrepresentations, deception or any similar unlawful acts" have been uncovered.<sup>263</sup>

August 24: Barr announces that the FDA is no longer seeking a total shutdown but only asking the court to review issues associated with specific products.<sup>264</sup>

February 4, 1993: A United States district court issues a preliminary injunction against Barr, ordering suspension of

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258. *Id.*

259. *Id.*

260. *Id.* at 131.

261. *Id.*

262. *Id.*

263. *Id.* at 130 n.7, 131.

264. *Id.* at 131.

24 products until completion of validation studies for each and ordering recall of 12 batches of pharmaceuticals that were released on the basis of potentially inaccurate test results or had content uniformity and assay problems.<sup>265</sup>

Plaintiff survived a motion to dismiss in the subsequent securities case “because of Barr’s affirmative comforting statements.”<sup>266</sup> The *Westwood* opinion does not pinpoint what facts the company knew that made its statements misleading. Thus, the case might be decided differently now that the Reform Act explicitly demands that plaintiffs plead such facts. As may have been the case in *Xoma*, the *Westwood* court may have concluded the company went too far in public statements specifically designed to minimize bad news.

Two more recent cases focus on a company’s knowledge and belief about agency action. After the FDA issued warning letters following inspection of syringe manufacturing facilities, Sabratek issued press releases saying that the company had already addressed the FDA’s concerns and that the company had no reservations about the safety of its products. The FDA later denied a 501(k) application for the syringes, and the company suspended production for a time, although ultimately the agency approved a revised application. A securities lawsuit based in part on the press releases failed because “the defendants’ belief that Sabratek had adequately addressed the FDA’s concerns, although obviously mistaken, was not obviously false.”<sup>267</sup> Stated differently, plaintiff failed to allege facts to show that the defendants did not genuinely believe their statements or that the statements lacked any reasonable basis.

Sofamor Danek similarly disclosed an FDA warning letter but allegedly “downplayed” its significance in ways not completely specified by the court deciding the later securities case.<sup>268</sup> Granting the motion to dismiss that case, the court stressed that the company was under no duty to express alarm:

If the company had . . . publicly predicted that the FDA would move against the company, the opinion would have come to look

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265. *Id.*

266. *Id.* at 134.

267. *Chu v. Sabratek Corp.*, 100 F. Supp. 2d 827, 835 (N.D. Ill. 2000).

268. *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 401 (6th Cir. 1997), *cert. denied*, 523 U.S. 1106 (1998) involved alleged improper marketing, including sponsorship of seminars in which the company’s device was promoted for uses that the FDA had not approved. Footnote 2 refers to a “conference call with stock analysts on October 20, 1993, when the company’s president allegedly downplayed the FDA’s August warning letter and ‘stated that SDG would continue to comply with the FDA rules regarding medical education.’” *Id.* at 401 n.2.

increasingly questionable with the passage of time, and the prediction would have proved to be flatly erroneous. This illustrates, we think, why predictions not “substantially certain to hold,” like most matters of opinion, simply do not come within the duty of disclosure.<sup>269</sup>

In these circumstances, a “we will respond to the agency promptly and believe at this time that we can satisfy the FDA” comment should be safe, provided the company does indeed hold this opinion and it is not unreasonable. Of course, the company must, each time it speaks about the FDA concern in the future, reevaluate the then-present circumstances by considering the likelihood of additional government actions and the degree to which those actions could affect the company. If the application of the probability/magnitude test to unfolding events suggests that a comment “downplaying” the government’s actions is no longer justified, the company should not continue to minimize the FDA’s words and deeds.

Four protocols will help biotechnology companies phrase disclosures of negative regulatory action in ways that minimize the chances of a lawsuit and maximize the chances for a successful early motion *if* a lawsuit is filed. First, a company should consult with experienced securities counsel before it makes each disclosure. Second, a company should disclose only the “material” facts of which it is certain. Since this may change as management learns more, the company may want to state expressly that it is speaking “on the basis of the company’s review to date” and may wish to state that the investigation (or inspection or other regulatory action) is continuing. A company should not publicize what it only infers, but has not yet confirmed—whether that be wrongdoing by employees, possible falsification of data, etc. Third, while a company may wish to include in its disclosures a description of current government action and even a description of *possible* further government actions and a statement that such actions *could* have a material adverse economic impact, the company should generally avoid publicly forecasting what the government will do. For example, it is generally wise to abstain from predicting that the government has nearly finished an investigation or that the government will impose no penalties or sanctions. Finally, each company facing such disclosures will be tempted to make statements suggesting that regulatory actions are ill-founded or motivated by some improper animus. As tempting as it is to make such statements, it may prove prudent to avoid saying more than (assuming that the company can

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269. *Id.* at 402.

say this in good faith): “The company is responding to the agency’s actions. While the company cannot predict final agency action or the ultimate impact of such action on the company, the company believes, on the basis of its investigation and analysis to date, that the facts do not warrant a sanction.” Each time the company repeats this belief, it will need to review the then-current facts and apply the probability/magnitude analysis to confirm that the belief is still warranted.

### CONCLUSION

As securities law meets the biotechnology industry, it comes face-to-face with government regulation and science. Life sciences companies and their investors can find FDA regulation frustratingly unpredictable, particularly when it comes to forecasting drug or device approval. How the companies, and the courts, address such forecasts will provide a crucial test of the forward-looking statement provisions of the Reform Act.

Science may not provide the certainty that the layman expects, and reports of clinical trials can require judgment calls. Companies will struggle with those judgments and with how to convey sometimes complicated test results and protocols to an investing public unversed in the intricacies of biotechnology research. The courts, in their turn, must be prepared to seriously address disclosures, even on motions to dismiss without the benefit of discovery and a biostatistical tutorial.

As companies discuss their science with regulators, that very dialogue generates disclosure issues. Companies seeking the right balance between keeping their shareholders informed and avoiding interpretation of FDA action may find that courts later determine the companies have gone too far in publishing inferences drawn from the agency’s actions.

The biotechnology world will continue to be an arena in which issuers must decide when to disclose government inspections (and, on occasion, investigations) and what to say about them. The companies will do so knowing that the SEC, and the courts, may review those decisions months or years later to determine when, if ever, the investigation became material and when, if ever, the company had a duty to disclose it.

There may be no other industry in which these ingredients—disclosure law, science and regulation—overlay each other in quite so challenging a way.