

DETECTING FRAUD: MANDATORY DISCLOSURE AND THE FDA DRUG APPROVAL PROCESS

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The valuation of a pharmaceutical company often depends on its ability to bring a drug to market, making information about the likelihood of Food and Drug Administration (FDA) approval critical to investors and a highly sensitive issue for the company. Since the FDA drug approval process is not public, investors must rely on company disclosures to evaluate the likelihood of FDA approval. Currently, the FDA will not disclose the content of action letters sent to sponsor companies, giving company executives dangerous discretion over whether to disclose the information and how to present it. This discretion, coupled with a lack of oversight over the content of the disclosures, has resulted in several recent cases of fraud among pharmaceutical companies. As a way to curb such company discretion and prevent future fraud, this Note proposes mandatory public disclosure of action letters sent by the FDA to sponsor companies.

INTRODUCTION

Most readers will recognize ImClone as the company behind the Sam Waksal and Martha Stewart insider trading scandal,¹ but the fraud at ImClone ran much deeper. On December 28, 2001, ImClone, a rising star in the biotechnology industry, announced that the FDA had refused to consider its application for approval of the much anticipated cancer drug Erbitux.² The announcement caused ImClone's

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¹ Martha Stewart was found guilty of obstruction of justice and of lying to investigators about her sale of ImClone stock the day before the FDA's rejection of the company's flagship drug Erbitux became public. On July 17, 2004, Stewart was sentenced to five months in prison and five months of home confinement. Constance L. Hays, *5 Months in Jail, and Stewart Vows, 'I'll Be Back'*, N.Y. TIMES, July 17, 2004, at A1. ImClone's CEO Sam Waksal was sentenced on June 10, 2003 to seven years and three months in prison, on multiple charges including securities fraud and perjury. Constance L. Hays, *Former Chief of ImClone Is Given 7-Year Term*, N.Y. TIMES, June 11, 2003, at C1; see also *infra* note 6.

² See Press Release, ImClone Sys., Inc., ImClone Systems Incorporated Announces Decision by the FDA Not to Accept for Filing the Erbitux Biologics License Application (Dec. 28, 2001), available at <http://phx.corporate-ir.net/phoenix.zhtml?c=97689&p=irol-newsArticle&ID=568981&highlight=>. The FDA issued ImClone a Refusal to File letter, indicating that the application was insufficient for the Agency to conduct a meaningful

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stock price to drop sixteen percent, from \$55.25 to \$46.46 by the close of the next trading day. By the end of July 2002, the stock had plummeted a total of eighty-seven percent.³ In the year preceding this announcement, ImClone's management had heavily promoted Erbitux, touting the drug's great cancer-fighting potential and leading investors to believe that Erbitux would be quickly approved and launched.⁴ The company continued to promote the drug despite receiving early notification from the FDA that serious problems with Erbitux's application made approval unlikely.⁵

In June 2002, following the FDA's rejection of the Erbitux application, the Securities and Exchange Commission charged ImClone's

review. Amended Complaint at 5–6, *SEC v. Waksal*, No. 02 Civ. 4407 (S.D.N.Y. Mar. 11, 2002), available at <http://www.sec.gov/litigation/complaints/comp18026.htm>. Refusal to File actions are based on “omissions of clearly necessary information” and inadequacies that “should be obvious.” FDA, Manual of Standard Operating Procedures and Policies, <http://www.fda.gov/cber/regsopp/8404.htm> (last visited Aug. 7, 2007) (describing regulatory procedure for Refusal to File actions).

³ Amended Complaint, *supra* note 2, at 2. On July 31, 2002, ImClone stock was valued at \$7.11, down eighty-seven percent from its price before the December 28, 2001 announcement. Yahoo! Finance, IMCL: Historical Prices for ImClone Systems Inc., <http://finance.yahoo.com/q/hp?s=IMCL&d=5&e=16&f=2007&g=d&a=10&b=19&c=1991&z=66&y=3894> (last visited June 19, 2007).

⁴ See Adam Feuerstein, *ImClone Admits It's Got Some 'Splainin' to Do*, THE STREET.COM, Dec. 31, 2001, http://www.thestreet.com/_tscs/tech/adamfeuerstein/10005988.html (reporting CEO Sam Waksal's admission that “his previous boasts about the drug and the ease in which it would be approved have now come back to bite the company”). In an investor conference call on September 19, 2001, Sam Waksal had predicted that Erbitux would be “one of the biggest drugs in the history of oncology.” ImClone Systems Conference Call 14 (Sept. 19, 2001) (transcript available in Tender-Offer Solicitation/Recommendation Statement (Schedule 14D-9C)), available at <http://www.sec.gov/Archives/edgar/data/765258/000095010301501376/0000950103-01-501376.txt>. It has also been reported that the company told “[i]nvestors and hopeful patients alike . . . that the results of ImClone's pivotal clinical trials were, ‘knock-your-socks-off exciting.’” See *An Inquiry into the ImClone Cancer-Drug Story: Hearings Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 2 (2002) [hereinafter *Congressional Hearings*] (statement of Rep. Greenwood, Chairman, Subcomm. on Oversight and Investigations).

⁵ See Andrew Pollack, *S.E.C. Investigates Transkaryotic over Drug Approval*, N.Y. TIMES, May 15, 2003, at C4 (reporting on ImClone's assurances that Erbitux would “easily win approval” despite concerns expressed by FDA for over one year). FDA officials were aware of the Erbitux “hyping” but did not come forward. See *Congressional Hearings*, *supra* note 4, at 223 (statement of Rep. Stearns, Member, Subcomm. on Oversight and Investigations) (“ImClone was hyping Erbitux on 60 Minutes and the cover of Business Week. Meanwhile, the FDA's hands were tied in not correcting any exaggerated claims made by this company.”). The Congressional investigation revealed that FDA officials remained silent due to concerns over trade secrets. *Id.* at 26 (testimony of Dr. Papineau, Detailee, Comm. on Energy and Commerce) (“What we did find from talking to the FDA officials is that they were listening to it and they couldn't talk because of the secrecy—the trade secrets and stuff of drug applications.”).

CEO Sam Waksal with insider trading.⁶ The next day the United States House of Representatives held hearings to examine the ImClone scandal.⁷ The hearings emphasized the great potential for fraud in the pharmaceutical industry. The combination of high monetary stakes and a secretive FDA process creates intense pressures for drug⁸ companies to publicly disclose favorable results while concealing negative information. Though the confidentiality of the FDA approval process ensures that proprietary information is protected, it also creates a convenient veil for companies wishing to suppress unfavorable results.⁹ The ImClone scandal and subsequent pressure from Congress prompted the SEC and the FDA to create a new collaborative process for identifying fraud by public FDA-regulated companies.¹⁰

In this Note, I examine recent cases of securities fraud by FDA-regulated companies and evaluate the consequent SEC-FDA collaborative efforts to identify such fraud. I then propose disclosure requirements that shift the focus from fraud detection to fraud prevention. In Part I, I provide an overview of the current regulatory protections against potential abuses by company insiders. I explain the unique vulnerability of FDA-regulated companies to make misleading disclosures and the uncertainties inherent in current regulatory standards that make it possible for such companies to do so.¹¹ In

⁶ In January 2002, the SEC launched an investigation into Sam Waksal's alleged insider trading. Upon learning that the FDA was about to reject the Erbitux application, but before that information was publicly announced, Waksal attempted to sell his own ImClone shares and also advised his daughter and another family member to do the same. Amended Complaint, *supra* note 2, at 2.

⁷ *Congressional Hearings*, *supra* note 4.

⁸ I will use the terms "drug" and "biologic" interchangeably in this Note, but the terms have different technical meanings depending on the context. A drug refers to any chemical substance used to treat disease, whereas a biologic is a drug derived from living sources. See FDA, Center for Biologics Evaluation and Research, About CBER, <http://www.fda.gov/cber/about.htm> (last visited July 23, 2007) (distinguishing biologics from certain drugs). I will also use the terms "drug company" and "pharmaceutical company" interchangeably to refer to any company that develops a drug that must be approved by the FDA before distribution in the United States.

⁹ See *Congressional Hearings*, *supra* note 4, at 16 (statement of Rep. Stearns, Member, Comm. on Energy and Commerce) ("Is the exchange between necessary confidentiality and public disclosure at an optimum?").

¹⁰ See *infra* Part II.C for further detail on the collaboration between the SEC and the FDA.

¹¹ While other industries also face disclosure challenges, an analysis of these other industries is necessarily beyond the scope of this Note. For a discussion of the materiality of and duty to disclose nonfinancial social and environmental information, see generally David Monsama and Timothy Olson, *Muddling Through Counterfactual Materiality and Divergent Disclosure: The Necessary Search for a Duty to Disclose Material Non-Financial Information*, 26 STAN. ENVTL. L.J. 137 (2007).

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Part II, I detail two case studies of pharmaceutical company fraud. I then examine the recent SEC-FDA collaboration intended to create a more streamlined process for detecting future fraud. Next, in Part III, I explain why this collaboration does not adequately prevent misleading disclosures. Lastly, I propose a more efficient mandatory disclosure mechanism that lessens the opportunity for company executives to misrepresent the nature of private FDA communications. Specifically, I argue that companies should be required to publicly disclose redacted versions of action letters received from the FDA. Such an approach will best balance the protection of trade secrets with the need to deter future fraud.

I

THE CURRENT REGULATORY ENVIRONMENT
INVITES FRAUD

The current regulatory system provides too little oversight of pharmaceutical companies. A secretive FDA process, combined with a lack of clear disclosure standards, has created a uniquely fertile area for fraud. In this Part, I will describe the justifications for the current regulatory system of mandatory disclosure and antifraud regulations that are applicable to all industries. I will also point out the uncertainty inherent in the current standards and the pressures faced by pharmaceutical companies.

A. *Mandatory Disclosure*

In the 1930s, Congress enacted securities legislation in order to protect investors from potential abuses by market insiders.¹² The resulting regulatory system is made up of two interrelated components: mandatory disclosure and antifraud regulations. The Securities Exchange Act of 1934 (Exchange Act)¹³ is the primary source of mandatory disclosure requirements imposed on publicly traded com-

¹² See Joseph A. Franco, *Why Antifraud Prohibitions Are Not Enough: The Significance of Opportunism, Candor and Signaling in the Economic Case for Mandatory Securities Disclosure*, 2002 COLUM. BUS. L. REV. 223, 230 & n.18 (2002) (describing Congressional emphasis on information disclosure and accuracy); Roberta Romano, *Empowering Investors: A Market Approach to Securities Regulation*, 107 YALE L.J. 2359, 2367 (1998) (citing failure to protect investors from fraud and inadequate corporate disclosure as justifications for federal intervention in 1930s).

¹³ 15 U.S.C. §§ 78a–nn (2000 & Supp. IV 2004). The Securities Act of 1933, 15 U.S.C. §§ 77a–aa (2000 & Supp. IV 2004), governs primary market transactions and imposes mandatory disclosure requirements, strict procedures, and heightened antifraud liability for public offerings. This Note, however, will focus on secondary market disclosure and antifraud regulations, primarily imposed by the Exchange Act.

panies.¹⁴ The Exchange Act also created the Securities and Exchange Commission (SEC),¹⁵ charged with the administration of the federal securities laws.¹⁶ Public companies are required to disclose certain information through periodic filings with the SEC. The securities laws ensure the reliability of this information by subjecting public companies to civil liability for fraudulent misstatements and/or omissions.¹⁷

One goal of mandatory securities disclosure is stock price accuracy.¹⁸ Reliable information is therefore critically important to healthy markets;¹⁹ however, the most effective method of achieving

¹⁴ An issuer (a legal entity that offers securities to finance its operations) may also face disclosure requirements imposed by the state of incorporation, the rules of the stock exchange on which the issuer's shares are listed, and the issuer's own articles of incorporation. See Merritt B. Fox, *Required Disclosure and Corporate Governance*, 62 *LAW & CONTEMP. PROBS.*, Summer 1999, at 113, 114 (1999).

¹⁵ Securities Exchange Act of 1934, Pub. L. No. 73-291, § 4, 48 Stat. 881 (codified as amended at 15 U.S.C. § 78d (2000 & Supp. IV 2004)).

¹⁶ 15 U.S.C. §§ 78l-m, o(d) (2000 & Supp. IV 2004).

¹⁷ Under section 10(b), 15 U.S.C. § 78j(b) (2000), of the Exchange Act and Rule 10b-5 of the Exchange Act, 17 C.F.R. § 240.10b-5 (2007), companies may be liable for making material misstatements or omissions in public disclosures. Rule 10b-5 makes it unlawful to make any "untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." *Id.* For a discussion of materiality, see *infra* notes 77-80 and accompanying text.

¹⁸ Many academics have linked share price accuracy to market efficiency. Accurate share prices are said to achieve a more efficient allocation of capital by improving the quality of choice among investments. See, e.g., Allen Ferrell, *Measuring the Effects of Mandated Disclosure*, 1 *BERKELEY BUS. L.J.* 369, 372-73 (2004) (arguing that stock price accuracy is "important test for whether mandated disclosure 'works'"); Merritt B. Fox, *Measuring Share Price Accuracy*, 1 *BERKELEY BUS. L.J.* 113, 113 (2004) (advocating for share price accuracy as worthy goal of public policy); Marcel Kahan, *Securities Laws and the Social Costs of "Inaccurate" Stock Prices*, 41 *DUKE L.J.* 977, 1005-12 (1992) (arguing that accurate stock prices influence capital allocation despite existence of alternative sources of capital for companies). *But see* Edmund W. Kitch, *The Theory and Practice of Securities Disclosure*, 61 *BROOK. L. REV.* 763, 764-65, 770-73 (1995) (stating dominant view that goal of mandatory securities disclosure is price "accuracy enhancement," but arguing that this goal ultimately cannot be achieved due to both regulatory and market-based constraints); Lynn A. Stout, *The Unimportance of Being Efficient: An Economic Analysis of Stock Market Pricing and Securities Regulation*, 87 *MICH. L. REV.* 613, 640-68 (1988) (arguing that importance of stock price accuracy to market resource allocation is overstated).

¹⁹ See, e.g., Bernard Black, *The Core Institutions that Support Strong Securities Markets*, 55 *BUS. LAW.* 1565, 1565-66 (2000) (listing good information as one of two essential elements of viable securities market); Merritt B. Fox, *Retaining Mandatory Securities Disclosure: Why Issuer Choice Is Not Investment Empowerment*, 85 *VA. L. REV.* 1335, 1355 (1999) ("If there is meaningful new information in the market, share prices become more accurate."); Edward Rock, *Securities Regulation as Lobster Trap: A Credible Commitment Theory of Mandatory Disclosure*, 23 *CARDOZO L. REV.* 675, 684-86 (2002) (noting importance of "high quality information" for development of secondary market).

optimal information disclosure has been hotly debated.²⁰ Although the mandatory disclosure regime's merits were fiercely challenged in the 1960s and 1970s,²¹ by the 1980s economists and legal academics had reached a rough consensus that mandatory disclosure laws should be retained.²² Since then, new proposals for deregulating the securities markets have revived the debate. The strongest criticism against mandatory disclosure has come from the proponents of regulatory competition models, who argue that the issuers' freedom to choose their jurisdiction will best achieve optimal disclosure levels. These proposals allow companies to choose among the regulatory regimes of states,²³ nations,²⁴ or stock exchanges.²⁵

²⁰ See Ferrell, *supra* note 18, at 371 (introducing "recurring debate" about necessity of mandatory disclosure system to achievement of optimal disclosure levels); Merritt B. Fox et al., *Law, Share Price Accuracy, and Economic Performance: The New Evidence*, 102 MICH. L. REV. 331, 336 (2003) ("Mandatory disclosure's effect on efficiency has also been a matter of intense debate among the economics-oriented members of the legal academy."); Franco, *supra* note 12, at 229-30 (noting debate over need to regulate disclosure and arguing that "popular perception" favors greater regulation).

²¹ See, e.g., George J. Benston, *Required Disclosure and the Stock Market: An Evaluation of the Securities Exchange Act of 1934*, 63 AM. ECON. REV. 132, 153 (1973) ("The conclusion of this study . . . must be that the disclosure requirements of the Securities Exchange Act of 1934 had no measurable positive effect on the securities traded on the NYSE."); Stephen A. Ross, *Disclosure Regulation in Financial Markets: Implications of Modern Finance Theory and Signaling Theory*, in ISSUES IN FINANCIAL REGULATION 177, 183-93 (Franklin R. Edwards ed., 1979) (using incentive-signaling model to show that, under certain conditions, disclosure legislation is unnecessary because market forces will lead to adequate disclosure); George J. Stigler, *Public Regulation of the Securities Markets*, 37 J. BUS. 117, 124 (1964) (concluding that SEC regulations "had no important effect on the quality of new securities sold to the public").

²² See, e.g., John C. Coffee, Jr., *Market Failure and the Economic Case for a Mandatory Disclosure System*, 70 VA. L. REV. 717, 721-23 (1984) (arguing that mandatory disclosure is justified because information is public good, disclosure minimizes social waste, and management can profit from giving false signals to market); Frank H. Easterbrook & Daniel R. Fischel, *Mandatory Disclosure and the Protection of Investors*, 70 VA. L. REV. 669, 672-73, 714 (1984) (arguing that current SEC regulation is preferable to regulation "in hands of states and judges" and conceding that there is "a case for mandatory disclosure"); see also Franco, *supra* note 12, at 233-35 & n.25 (citing key articles to show historical approval of mandatory disclosure regime). Mandatory disclosure laws have also been supported politically for almost seventy years. See *id.* at 233 & n.25.

²³ A company may choose to incorporate in any of the fifty states and the District of Columbia, thereby binding itself to the corporate laws of the state of its choosing. For a discussion of the value of this model and why it should be extended to securities regulation, see Romano, *supra* note 12, at 2367. Romano proposes a system of "competitive federalism," allowing firms the choice of federal or any state law regulatory scheme. *Id.*

²⁴ See, e.g., Stephen J. Choi & Andrew T. Guzman, *Portable Reciprocity: Rethinking the International Reach of Securities Regulation*, 71 S. CAL. L. REV. 903, 907-08, 921-24 (1998) (proposing system of "portable reciprocity," allowing firms to choose securities law regime of any nation to govern their securities offerings, regardless of physical location of transaction).

²⁵ See, e.g., Paul G. Mahoney, *The Exchange as Regulator*, 83 VA. L. REV. 1453, 1455 (1997) (arguing that securities exchanges should be primary regulators); A.C. Pritchard,

Despite these criticisms, there are many benefits to a mandatory disclosure regime. Mandatory disclosure has been justified as a necessary correction for market failures caused by the “public good” nature of information.²⁶ Absent mandatory disclosure, company insiders, who control the information needed to assess stock value, will naturally disclose less than what would be optimal for investors and the market.²⁷ Furthermore, information disclosure often benefits competitors, which makes it even less likely that companies will voluntarily disclose such information.²⁸

Mandatory disclosure also alleviates duplicative and wasteful research. Since investors value information on public companies, they have an incentive to use considerable resources to try to obtain an informational advantage over other investors. Mandating standardized disclosure of corporate financials reduces duplicative efforts by competing investors to seek out this information individually, thereby limiting socially wasteful expenditures.²⁹

For information disclosure to be effective, however, the information’s users must internalize it.³⁰ In other words, information must affect investment choices in order to justify a mandatory disclosure

Markets as Monitors: A Proposal to Replace Class Actions with Exchanges as Securities Fraud Enforcers, 85 VA. L. REV. 925, 983–1000 (1999) (advocating for system of antifraud enforcement by securities exchanges). Stephen Choi has also proposed a regulatory regime based on the different informational needs of specific types of investors. See Stephen Choi, *Regulating Investors Not Issuers: A Market-Based Proposal*, 88 CAL. L. REV. 279, 282–83 (2000) (proposing regulatory system classifying investors by information resources and focusing regulatory resources on investors that need protection).

²⁶ See, e.g., Fox, *supra* note 19, at 1346 (“[A]t all levels of disclosure, an issuer’s private marginal costs will exceed its social marginal cost by an amount equal to these interfirm costs. Even managers who completely identify with existing shareholders . . . would therefore choose a regime with a disclosure level below the social optimum.”).

²⁷ See Black, *supra* note 19, at 1567–68 (describing “market for lemons” as consequence of insider control of company information and incentive to exaggerate company’s future prospects); see also Easterbrook & Fischel, *supra* note 22, at 685–87 (describing free-rider and appropriation problems of information as public good).

²⁸ See Easterbrook & Fischel, *supra* note 22, at 685–86 (describing information underproduction due to benefits to third parties, both competitive and noncompetitive); see also Fox, *supra* note 19, at 1353–54 (arguing that almost all corporate disclosures have interfirm costs).

²⁹ See Dale Arthur Oesterle, *The Inexorable March Toward a Continuous Disclosure Requirement for Publicly Traded Corporations: “Are We There Yet?”*, 20 CARDOZO L. REV. 135, 201–02 (1998) (arguing that government intervention may mitigate socially wasteful expenditures caused by duplicative research). The mandatory disclosure regime can thus be characterized as increasing the quantity and quality of available information through public subsidization of the search costs. See Coffee, *supra* note 22, at 722 (arguing that mandatory disclosure system can be viewed as societal cost-reduction strategy).

³⁰ For a summary of concerns about information overload resulting from increased disclosure, see Troy A. Paredes, *Blinded by the Light: Information Overload and Its Consequences for Securities Regulation*, 81 WASH. U. L.Q. 417, 419–21, 444–72 (2003).

system. In practice, however, individual investors do not directly read or digest most of the information disclosed to the public.³¹ Nevertheless, investors who personally do not read a company's disclosure might still learn of it from market intermediaries, such as brokers or analysts.³² Those investors who do learn the disclosed information will make investment decisions based on that information, and these decisions will affect the stock price. Other investors will make decisions based on the market price movement until the price eventually stabilizes at a level that accurately reflects the information disclosed.³³

Although academics have debated the merits of the current SEC approach to regulating securities,³⁴ advocates on both sides of the debate agree that information disclosure is a critical component of an efficient market.³⁵ Stock prices move in response to new information.³⁶ Securing the accuracy of that information is therefore important to both market reliability and investor confidence. A mandatory disclosure system coupled with an antifraud regime reduces information search and verification costs for professional investors and analysts,³⁷ enhancing stock price accuracy for all investors. These benefits accrue regardless of which specific regulatory structure imposed the

³¹ See STEPHEN J. CHOI & A.C. PRITCHARD, *SECURITIES REGULATION: CASES AND ANALYSIS* 32 (2005) (noting that most individual investors do not read annual reports and other corporate disclosures).

³² See Homer Kripke, *The SEC, the Accountants, Some Myths and Some Realities*, 45 N.Y.U. L. REV. 1151, 1165 (1970) (“[T]he intelligent investor . . . who tries to act in any informed way does so by getting at least part of his information second hand, filtered through professionals.”).

³³ This follows the semi-strong version of the efficient market hypothesis, which argues that stock prices incorporate all publicly available information even if that information does not reach the individual investor. See generally Ronald J. Gilson & Reinier H. Kraakman, *The Mechanisms of Market Efficiency*, 70 VA. L. REV. 549, 554–65 (1984) (tracing origins and history of efficient capital market theory).

³⁴ Proponents of regulatory competition models argue that the supposed benefits of mandatory disclosure are inadequate justifications for the current monopolistic SEC system. See *supra* notes 23–25 and accompanying text. If an unregulated market would yield suboptimal disclosure, then investors would push companies to opt into a system that does provide the desired disclosure level. See, e.g., Stephen J. Choi & A.C. Pritchard, *Behavioral Economics and the SEC*, 56 STAN. L. REV. 1, 3–4 (2003) (summarizing argument that investors will demand risk premium for lack of disclosure); Romano, *supra* note 12, at 2367 (“[A] theoretical need for government regulation to prevent a market failure is not equivalent to a need for a monopolist regulator.”).

³⁵ See *supra* note 19 and accompanying text.

³⁶ For example, each of the disclosures described in this Note had a dramatic effect on stock prices. See *supra* note 3 and accompanying text (Imclone); *infra* notes 124, 130 and accompanying text (Biopure); *infra* note 149 and accompanying text (TKT).

³⁷ See Zohar Goshen & Gideon Parchomovsky, *The Essential Role of Securities Regulation*, 55 DUKE L.J. 711, 737–38 (2006) (discussing cost-saving effects of mandatory disclosure for information traders).

disclosure.³⁸ The next section highlights how disclosure regulations uniquely affect pharmaceutical companies.

B. *Pharmaceutical Companies Face Unique Pressures*

Pharmaceutical companies face tremendous market pressures to disclose information. Drug companies confronting substantial development costs often seek to raise funds through the public markets.³⁹ The cost of developing a single prescription drug (from initial research to final FDA approval) has been estimated to range from \$800 million to \$1.7 billion, and the time to market for a single pharmaceutical product may take as long as fifteen years.⁴⁰ As a small drug company often focuses on one or two products, the company's market value depends on the public's perception of the company's ability to bring the products to market.⁴¹ Even large pharmaceutical companies are under intense pressure to maintain a pipeline of profitable drugs.⁴²

³⁸ This Note recommends mandatory disclosure of specific material information for FDA-regulated companies. This proposal necessitates a mandatory disclosure regime. The proposed disclosure of FDA communications could be achieved under the current SEC model or an alternate regulatory competition model. *See supra* notes 23–25 and accompanying text. It is beyond the scope of this Note, however, to evaluate whether the optimal level of information disclosure would be achieved more effectively under a regulatory competition model or the current SEC model.

³⁹ Healthcare companies represented twenty-one of the forty-one initial public offerings during 2005, raising over one billion in capital. *See* Sergio Garcia, *United States: Life Sciences Companies Face Special Disclosure Challenges*, MONDAQ.COM, Mar. 15, 2006, <http://www.mondaq.com/article.asp?articleid=38388&searchresults=1&print=1> (citing 2006 VentureWire report).

⁴⁰ *Id.*; Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 164, 166 (2003) (estimating total cost of bringing drug to market at \$802 million and time between start of clinical testing to marketing approval at 90.3 months); Jim Gilbert et al., *Rebuilding Big Pharma's Business Model*, 21 IN VIVO: BUS. & MED. REP., Nov. 2003, at 1, 1, available at http://www.bain.com/bainweb/PDFs/cms/Marketing/rebuilding_big_pharma.pdf (estimating cost of discovering, developing, and launching new drug at \$1.7 billion by factoring in costs of failed prospective drugs); Tufts Center for the Study of Drug Development, *Background: How New Drugs Move Through the Development and Approval Process* (Nov. 1, 2001), <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=4> (estimating that to develop new medicine, "a drug company typically spends \$802 million over the course of 10 to 15 years").

⁴¹ *See* Carolyne R. Hathaway et al., *Increased Scrutiny of Investor Communications by Federal Regulators*, UPDATE, Jan./Feb. 2006, at 17, 17, available at http://www.lw.com/upload/pubContent/_pdf/pub1470_1.pdf; Jeanne Whalen, *Scavenger Hunt: Small Firms Seek to Profit From Drug Giants' Castoffs*, WALL ST. J., Feb. 7, 2007, at A1 (reporting that smaller drug companies' "entire business is riding on just a handful of potential drugs").

⁴² *See* Gilbert et al., *supra* note 40, at 3 (summarizing big pharmaceutical companies' reliance on "blockbuster" model to yield high returns and noting importance of developing drugs that will ultimately be marketable after FDA approval); Whalen, *supra* note 41 (describing "intense pressure to make hefty profits" for big companies in "\$600 billion drug industry").

Gaining FDA approval for a drug is therefore highly likely to affect the stock prices of all publicly traded drug companies.⁴³

Since a pharmaceutical company must await FDA approval before it can market and sell its product, it relies on its potential for obtaining FDA approval to attract investors. This potential is most frequently exhibited through promising preliminary clinical trial results.⁴⁴ Information about the product's clinical development and likelihood of FDA approval is extremely valuable to investors and a highly sensitive issue for the company.⁴⁵ Since the FDA approval process is not public,⁴⁶ the market must rely on information the company itself discloses in order to assess the likelihood of FDA approval.⁴⁷ The company thus faces great pressures to cloak the progress of its clinical trials as well as the nature of its communications with the FDA in terms that are, at times, overly optimistic.⁴⁸

Before a pharmaceutical company can bring a drug to market, it must obtain FDA approval—a process that can take many years.⁴⁹ A drug company must first file an Investigational New Drug Application (IND), a request for FDA authorization to conduct clinical trials of an investigational drug or biological product on humans.⁵⁰ This applica-

⁴³ See David D. Miller, President, Biotech Monthly, *Are FDA Delays Hurting Biotech Stock Valuations?* (Aug. 17, 2001), <http://www.biotechmonthly.com/briefings/fda-delay.htm> (noting that biotech stocks “tend to be driven almost exclusively by news events” and that analysts base stock-price targets on projected timelines for FDA approvals).

⁴⁴ See Hathaway et al., *supra* note 41, at 17 (noting that clinical trial results are “key drivers of the firms’ financial prospects”).

⁴⁵ See *id.* (describing importance of information to company and investors); Susan Warner, *SEC and FDA Join Forces Against Biotech*, SCIENTIST, July 19, 2004, at 48, 49 (“For many biotech companies without revenue or profits, information is about all that they have to sell.”); Garcia, *supra* note 39 (noting that product’s value can “rise or fall rapidly” depending on investor perceptions of company’s ability to develop product and bring it to market).

⁴⁶ See *infra* note 61 and accompanying text.

⁴⁷ See Pollack, *supra* note 5 (reporting that FDA secrecy causes “dilemma for biotechnology investors” who are “almost totally dependent on the company’s version of what is happening”).

⁴⁸ See Hathaway et al., *supra* note 41, at 17 (describing executives’ inclination to “overstate favorable—and minimize unfavorable—clinical or regulatory information”); Bernadette Tansey, *Rise in Biotech Lawsuits*, S.F. CHRON., Jan. 26, 2004, at E1 (hypothesizing that increased shareholder suits against biotechnology companies are attributable to allegations that biotech executives “can be sorely tempted to downplay regulatory setbacks”); Jonathan Kotler, *Aggressive Fraud Enforcement Remains in Play*, http://www.nutter.com/publications_events.php?section=7&MediaID=17 (last visited Aug. 7, 2007) (describing “[t]he temptation to ‘puff’ the prospects of a new drug” among biotech executives).

⁴⁹ See generally BLANCHARD RANDALL IV, CONG. RESEARCH SERV., THE U.S. DRUG APPROVAL PROCESS: A PRIMER (2001), available at <http://www.thememoryhole.org/crs/more-reports/RL30989.pdf>.

⁵⁰ See FDA, Biological Product: Information on Submitting an Investigational New Drug Application, <http://www.fda.gov/cber/ind/ind.htm> (last visited June 14, 2007).

tion requires the company to submit the results of preclinical testing performed on laboratory animals, along with a description of the proposed human testing.⁵¹ The sponsor⁵² may not begin clinical trials on human subjects until the IND has been approved.⁵³ If approval is received, the sponsor must conduct three phases of clinical trials before it can file a New Drug Application (NDA), the formal request for FDA approval to market the drug in the United States.⁵⁴

Once the FDA review team completes its evaluation of the NDA, the FDA sends the sponsor an action letter.⁵⁵ This action letter comes in three forms: approved, not approvable, and approvable.⁵⁶ An approved letter notifies the sponsor that the drug has been approved and details labeling and other postmarket requirements.⁵⁷ A not approvable letter details why a drug cannot be approved based on the information submitted in the application.⁵⁸ Not approvable letters are fairly unusual,⁵⁹ as problems with the application are generally detailed in an approvable letter. An approvable letter signifies to the sponsor that certain actions must be taken before the drug will be approved.⁶⁰ Approvable letters can therefore signify that approval is imminent (listing a few minor concerns that can be easily corrected),

(explaining that IND must be secured prior to interstate shipment of any new drug or administration of such drug to humans); *see also* RANDALL, *supra* note 49, at 7–9 (describing IND application requirements and process).

⁵¹ For an overview of the FDA's approval process, *see* FDA, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA CONSUMER (SPECIAL REPORT), Jan. 2006, www.fda.gov/fdac/special/testtubetopatient/drugreview.html [hereinafter *FDA's Drug Review Process*].

⁵² A sponsor is any entity that develops a drug and then applies for FDA approval of that product. *Id.*

⁵³ *Id.*

⁵⁴ *See id.* (describing clinical trial and NDA process); RANDALL, *supra* note 49, at 10–11 (describing FDA's review process of NDAs). For biologics, the equivalent of an NDA is called a Biologics License Application (BLA). *See infra* note 100. This Note uses the terms “drug” and “biologic” interchangeably. *See supra* note 8.

⁵⁵ For a description of the NDA review process and the makeup of the review team, *see* INST. OF MED., *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* 40–46 (Alina Baciú et al. eds., 2006), *available at* http://books.nap.edu/catalog.php?record_id=11750 [hereinafter *FUTURE OF DRUG SAFETY*].

⁵⁶ *FDA's Drug Review Process*, *supra* note 51. These action letters are also called complete response letters. Press Release, FDA, FDA Proposes Changes to Provide Clearer Information to Drug Sponsors Concerning Reviews of Their New Drug Applications (July 19, 2004), *available at* <http://www.fda.gov/bbs/topics/news/2004/NEW01092.html>.

⁵⁷ *FUTURE OF DRUG SAFETY*, *supra* note 55, at 51.

⁵⁸ *Id.*; *FDA's Drug Review Process*, *supra* note 51.

⁵⁹ RANDALL, *supra* note 49, at 11 (“At this point in the review process, refusing to approve an application is fairly unusual.”).

⁶⁰ *FUTURE OF DRUG SAFETY*, *supra* note 55, at 51. According to the FDA, “[a] designation of approvable means that the drug can probably be approved, provided that some issues are resolved first.” *FDA's Drug Review Process*, *supra* note 51.

or they can list hundreds of significant problems that can only be corrected with additional clinical trials.

The FDA approval process is not public.⁶¹ Not only will the FDA not discuss ongoing clinical trials, the agency will not even confirm the existence of an application for a given drug.⁶² The FDA has defended its lack of disclosure as necessary to protect trade secrets and other commercially protected information.⁶³ The FDA's culture of secrecy, however, goes far beyond protection of proprietary information.⁶⁴ The agency views its commitment of confidentiality to the sponsor as superseding any responsibility to provide public information. Exemplifying this point, acting FDA Commissioner Lester Crawford told the *Wall Street Journal*, following the ImClone scandal, that the FDA's job "is not to alert the investor community, or to pre-alert the consumer and patient community. . . . The time-honored way, the policy of the FDA, is not to reveal anything."⁶⁵

Although companies may and do disclose the nature of some FDA communications to investors,⁶⁶ the FDA itself will not publicly disclose the content of those communications. Action letters, therefore, only become public upon the approval of a drug.⁶⁷ Consequently,

⁶¹ See William G. Childs, *The Implementation of FDA Determinations in Litigation: Why Do We Defer to the PTO but Not to the FDA?*, 5 MINN. INTELL. PROP. REV. 155, 166–67 (2004) (describing private *ex parte* FDA review process).

⁶² See 21 C.F.R. § 314.430(b) (2006) ("FDA will not publicly disclose the existence of an application or abbreviated application before an approvable letter is sent to the applicant."); see also Tom , *FDA Rules Need Tweaking*, S.F. CHRON., July 1, 2002, at E1 (reporting on FDA nondisclosure policy).

⁶³ See Abate, *supra* note 62 (discussing FDA's fear that competitors would use FDA documents to find faster ways to receive approval for rival drugs); see also Jeanne Lenzer, *Drug Secrets: What the FDA Isn't Telling*, SLATE, Sept. 27, 2005, www.slate.com/toolbar.aspx?action=print&id=2126918 (discussing FDA's classification of clinical trial data as trade secrets).

⁶⁴ During Senate hearings evaluating the FDA's Drug Approval Process, Abbey Meyers, the president of the National Organization for Rare Disorders, described the FDA as "one of the most secretive government agencies that any consumer will ever have to deal with. Virtually everything about a drug is considered proprietary." *FDA's Drug Approval Process: Up to the Challenge? Hearing Before the Sub. Comm. on Health, Education, Labor and Pensions*, 109th Cong. 58 (2005) (statement of Abbey Meyers).

⁶⁵ Peter Landers and Chris Adams, *Potent Mix: Drug News, Stock Trading – ImClone Case Puts the Spotlight on FDA, as Legislators Wonder If More Data Should Get Out*, WALL ST. J., June 14, 2002, at C1 (quoting Commissioner Crawford).

⁶⁶ Public companies generally disclose the filing of an IND or an NDA because the potential approval of a new drug is deemed highly material to the company's financial future. See Peter Lurie & Allison Zieve, *Sometimes the Silence Can Be Like the Thunder: Access to Pharmaceutical Data at the FDA*, 69 LAW & CONTEMP. PROBS., Summer 2006, at 85, 89 (noting that companies generally report such information in SEC filings).

⁶⁷ Although the FDA publicizes approval correspondence upon a drug's final approval, there is usually a delay of weeks or months and the documents are typically heavily redacted. To view a list of approved drugs and available correspondence regarding those

if a drug is never approved, the letters remain confidential. If a public company does choose to disclose information contained in these action letters, it must ensure that its public statements are not materially misleading.⁶⁸ An uncertain materiality standard and lack of guidance from the SEC, however, have made that determination difficult and nuanced.⁶⁹ The next section will discuss the materiality determination of voluntary disclosures and the need for increased standardization of such disclosures.

C. *Uncertainty About What to Disclose Under the SEC's Materiality Standard*

Public companies face three principal disclosure requirements: an annual Form 10-K,⁷⁰ a quarterly Form 10-Q,⁷¹ and a current Form 8-K,⁷² filed for specified events that the SEC has deemed particularly important to investors. Companies are not required to make public disclosures outside of these SEC filing documents.⁷³ If a company chooses to disclose information, however, that information cannot be materially misleading.⁷⁴ Since pharmaceutical companies face unique pressures to disclose information regarding clinical trials and the FDA approval process,⁷⁵ they must make nuanced decisions as to which information is material and what is and is not misleading.⁷⁶

drugs, see Drugs@FDA, FDA Approved Drug Products, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm> (last visited May 15, 2007).

⁶⁸ See *supra* note 17 and accompanying text.

⁶⁹ See Kotlier, *supra* note 48 (“The biotechnology field is unique in that a company must make nuanced decisions about its expectations for the success of a particular product and how to accurately describe the status of FDA clinical trials.”).

⁷⁰ Section 13a of the Exchange Act authorizes the SEC to require public companies to file annual Form 10-K reports disclosing certain specified information. Exchange Act Rule 13a-1, 17 C.F.R. § 240.13a-1 (2006).

⁷¹ Exchange Act Rule 13a-13 requires quarterly reports on a Form 10-Q. Exchange Act Rule 13a-13, 17 C.F.R. § 240.13a-13 (2006). This form is less extensive than the Form 10-K and does not require that financial statements be audited (as does the 10-K). CHOI & PRITCHARD, *supra* note 31, at 167.

⁷² Exchange Act Rule 13a-11 requires current reports on Form 8-K. Exchange Act Rule 13a-11, 17 C.F.R. § 240.13a-11 (2006). See *infra* note 171 for an overview of Form 8-K.

⁷³ See *Gallagher v. Abbott Labs.*, 269 F.3d 806, 808 (7th Cir. 2001) (“We do not have a system of continuous disclosure. Instead firms are entitled to keep silent (about good news as well as bad news) unless positive law creates a duty to disclose.”).

⁷⁴ See *supra* notes 17, 68 and accompanying text.

⁷⁵ See *supra* Part I.B.

⁷⁶ A company may find it difficult to evaluate the significance of FDA communications. See Warner, *supra* note 45, at 48 (“[B]iotech executives often find it hard to judge the importance of an FDA decision, much less communicate it quickly to shareholders. ‘Often the information that companies receive from the FDA is, at best, inscrutable.’”).

Information is deemed material if there is a “substantial likelihood that the disclosure . . . would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.”⁷⁷ This standard has produced much uncertainty: Who is a “reasonable investor,” and what qualifies as “significant”? Courts have considerable leeway in evaluating materiality, leaving company executives with few reliable guidelines for determining the materiality of company disclosures.⁷⁸ Liability becomes particularly uncertain and problematic for forward-looking information.⁷⁹ A determination of the materiality of forward-looking information requires a balancing of the probability that the event will occur and the magnitude of the event.⁸⁰

The uncertainty inherent in the materiality standard can be particularly problematic for pharmaceutical companies. Public statements predicting the odds of FDA approval are likely to be viewed as material because the company’s valuation often depends on its ability to bring its drugs to market.⁸¹ Nevertheless, the decision of when and how to disclose FDA communication is complicated. Investors’ increasing demand for information may conflict with a company’s fears of investors’ overreaction. Company executives might genuinely

⁷⁷ TSC Indus. v. Northway, Inc., 426 U.S. 438, 449 (1976).

⁷⁸ See Joan MacLeod Heminway, *Materiality Guidance in the Context of Insider Trading: A Call for Action*, 52 AM. U. L. REV. 1131, 1148–56 (2003) (discussing lack of guidance for materiality standard in securities litigation); David A. Hoffman, *The “Duty” to Be a Rational Shareholder*, 90 MINN. L. REV. 537, 542–43 (criticizing courts’ use of economic rationality as proxy for reasonableness in materiality determinations because “[s]hareholders’ behavior deviates from economic rationality in both predictable and unpredictable ways”); Pritchard, *supra* note 25, at 936 (“Corporate managers and their counsel assessing the ‘materiality’ of a given fact receive little guidance from the courts.”).

⁷⁹ Forward-looking information refers to predictions about events that may occur in the future. The Private Securities Litigation Reform Act of 1995 added a safe harbor in private litigation for forward-looking statements (the safe harbor only applies to private actions and does not protect issuers from SEC litigation). Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, sec. 102, §§ 27A, 21E, 109 Stat. 737, 749–53 (amending Securities Exchange Act of 1934 and Securities Act of 1933 and providing safe harbor so long as forward-looking statement is “accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement”). It is important to note that boilerplate cautionary language will not generally protect the issuer from liability. See, e.g., *Asher v. Baxter Int’l, Inc.*, 377 F.3d 727, 732 (7th Cir. 2004) (“[B]oilerplate[] warnings . . . won’t do; cautions must be tailored to the risks that accompany the particular precautions.”).

⁸⁰ *Basic, Inc. v. Levinson*, 485 U.S. 224, 238 (1988) (adopting approach taken in *SEC v. Texas Gulf Sulphur Co.*, 401 F.2d 833, 849 (2d Cir. 1968) (en banc), 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”).

⁸¹ See *supra* note 41 and accompanying text (noting importance of FDA approval to valuation of small firms).

believe that the FDA has misinterpreted a drug's merit and that further discussion will change agency officials' minds. The firm might therefore decide that certain information is immaterial and choose not to disclose it, fearing negative and unwarranted investor reactions to setbacks that company executives feel they can overcome.⁸²

As recent scandals⁸³ have increased public scrutiny over pharmaceutical industry disclosures, many legal advisors to drug companies have noted the heightened risks of liability for public disclosures.⁸⁴ Consequently, industry and practitioner publications have advised companies to take the following proactive steps to avoid liability: (1) set up internal review procedures for public disclosures, (2) ensure that public disclosures are consistent and balanced,⁸⁵ and (3) obtain SEC and FDA review of public statements before they are issued.⁸⁶

Recent scandals have also sparked growing investor distrust of pharmaceutical firms. For example, biotechnology companies⁸⁷ were served with seventeen percent of all U.S. shareholder suits in 2003

⁸² See *supra* notes 75–76 and accompanying text (discussing difficulty of determining significance of certain FDA communications).

⁸³ See *infra* Part II.

⁸⁴ See, e.g., David Filmore, *SEC and FDA: Tag-team Regulating*, MOD. DRUG DISCOVERY, Nov. 2004, at 33, 34 (noting advisors believe that potential FDA involvement “is enough to raise companies’ alert levels when it comes to making public disclosures”); Elizabeth Gray, *SEC and FDA Team Up to Monitor Disclosures*, NAT’L L.J., May 31, 2004, available at http://www.foley.com/files/tbl_s31Publications/FileUpload137/2066/00506040006Foley.pdf (discussing coordinated SEC and FDA efforts to “tak[e] enforcement action when they have reason to suspect” that public disclosures are “false and misleading”); Hathaway et al., *supra* note 41, at 19–20 (noting that SEC-FDA collaboration has facilitated heightened scrutiny of investor communications and offering guidelines that pharmaceutical companies can follow to withstand such scrutiny); Nixon LLP, *SEC-FDA Collaborate on New Road Rules*, SEC. L. ALERT, Nov. 9, 2004, at 1, 1, available at http://www.nixonpeabody.com/linked_media/publications/SLA_11092004.pdf (“[The SEC-FDA initiative] also sends a strong message to the industry that the rules of the road have changed and preapproval promotional statements will be subject to heightened scrutiny from here on out.”); Paul D. Rubin & Anne D. Spiggle, *Compliance with SEC Disclosure Requirements: Practical Pointers for Publicly Traded, FDA-Regulated Companies*, REG. AFF. FOCUS, May 2004, at 1, 1 (“As a result [of the cooperation between the SEC and the FDA], companies now need to be particularly cautious in disclosing FDA-related information to the public.”).

⁸⁵ See Hathaway et al., *supra* note 41, at 19–20 (suggesting that internal review process include “individuals who are not directly involved in the clinical trials or regulatory proceedings” and that investor communications be consistent with those made to FDA).

⁸⁶ See Rubin & Spiggle, *supra* note 84, at 4 (arguing that review by both SEC and FDA is “essential to ensur[ing] compliance with both agencies’ legal standards”). My proposal, detailed in Part III, would require public disclosure of FDA action letters, relieving some of the uncertainty involved in the current system.

⁸⁷ Biotechnology companies are a subset of pharmaceutical companies that use living organisms or other biological systems to manufacture drugs.

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despite making up only two percent of publicly traded firms.⁸⁸ Drug companies have consequently increased their levels of public disclosure in response to market demands for greater information about drug development and clinical trial results.⁸⁹ The increased levels of disclosure, coupled with a company's natural enthusiasm for its product, create fertile ground for overly optimistic public statements.⁹⁰

The secrecy of the FDA approval process allows sponsor companies to determine when and how to disclose information regarding FDA applications. Part II tells the stories of two drug companies that chose to delay disclosure of their drug approval problems. By misrepresenting communications they received from the FDA, these companies were able to maintain artificially high stock prices. In both cases, mandatory disclosure of FDA action letters would have prevented the fraud.

II

CASE STUDIES: FRAUD AND THE SEC-FDA RESPONSE

Company executives face increasing pressure to disclose information about the likelihood of FDA approval of flagship drugs. There are, of course, reputational incentives for rational executives to disclose honestly. A reputation for disclosing accurate and complete information to investors will increase investor trust and benefit a company in the long term.⁹¹ Company executives, however, have historically been willing to risk their personal reputations as well as the company's public image in exchange for short-term profits.⁹² The

⁸⁸ See Tansey, *supra* note 48 (quoting results of Pricewaterhouse Coopers's Securities Litigation Study of 2003).

⁸⁹ See Filmore, *supra* note 84, at 34 ("The increased disclosure of early-stage drug development information, in fact, is the primary reason for the SEC's growing interest in this sector . . ."); Hathaway et al., *supra* note 41, at 18 (pointing out trend towards "more extensive and detailed disclosures in investor communications" among drug companies).

⁹⁰ See *supra* note 48 and accompanying text.

⁹¹ See Donald C. Langevoort, *Organized Illusions: A Behavioral Theory of Why Corporations Misdemean Stock Market Investors (and Cause Other Social Harms)*, 146 U. PA. L. REV. 101, 112 (1997) ("Senior management's group interests are contractually aligned with the long-term success of the firm as reflected in its share price, and the firm benefits from a reputation for honesty.").

⁹² See Patricia M. Dechow et al., *Causes and Consequences of Earnings Manipulation: An Analysis of Firms Subject to Enforcement Actions by the SEC*, 13 CONTEMP. ACCT. RES. 1, 31 (1996) (arguing that firms in study "chose to risk (and ultimately lose)" benefits of reliable reputations "for the prospect of short-term gain"); see also Frank B. Cross & Robert A. Prentice, *The Economic Value of Securities Regulation*, 28 CARDOZO L. REV. 333, 340 (2006) (describing acknowledgement by economists that managers will risk reputation for immediate gain).

slew of cases of corporate fraud during the Enron era⁹³ show that company insiders may be unable to resist pressure to conceal negative information in the short term despite the likely long-term reputational damage to the company.⁹⁴ The same pattern of behavior can be seen in the case studies described in this Part.

A. *Biopure*

Biopure is a public biotechnology company engaged in the development and manufacture of blood substitutes.⁹⁵ By 2002, the company had developed two products: Oxyglobin and Hemopure.⁹⁶ Oxyglobin is a canine blood substitute that has been approved by the FDA for veterinary use to treat canine anemia.⁹⁷ Hemopure is Biopure's attempt to apply this oxygen-delivering technology to human use.⁹⁸ As of this writing, Hemopure has not yet received FDA approval for human use.⁹⁹

⁹³ For a discussion of Enron, WorldCom, and other corporate fraud cases, see generally Kathleen F. Brickey, *From Enron to WorldCom and Beyond: Life and Crime After Sarbanes-Oxley*, 81 WASH. U. L.Q. 35 (2003); Marleen A. O'Connor, *The Enron Board: The Perils of Groupthink*, 71 U. CIN. L. REV. 1233 (2003); Linda O. Smiddy and Melissa Ihnat, *Introduction: Conference on Enron, Worldcom, and Their Aftermath*, 27 VT. L. REV. 817 (2003). In reaction to this wave of corporate scandals, Congress passed the Sarbanes-Oxley Act in 2002 "[t]o protect investors by improving the accuracy and reliability of corporate disclosures made pursuant to the securities laws." Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745 (codified as amended at scattered sections of 15 U.S.C.). Under this mandate, the SEC subsequently implemented new mandatory disclosure requirements. See Press Release, SEC, SEC Proposes Rules to Implement Sarbanes-Oxley Reforms (Oct. 30, 2002), available at <http://www.sec.gov/news/press/2002-155.htm> (prohibiting misleading statements in company disclosures and implementing new mandatory disclosure requirements).

⁹⁴ See Robert A. Prentice, *The Inevitability of a Strong SEC*, 91 CORNELL L. REV. 775, 781-82 (2006) (discussing how reputational benefits have proven inadequate in encouraging companies to provide timely and accurate disclosures (citing Dechow et al., *supra* note 92, at 31)); see also Robert A. Prentice, *Regulatory Competition in Securities Law: A Dream (that Should Be) Deferred*, 66 OHIO ST. L.J. 1155, 1202-04 (2005) (describing managers' bias towards serving own personal interests at expense of shareholders' interests).

⁹⁵ Biopure, Overview, <http://www.biopure.com/shared/home.cfm?CDID=1&CPgID=5> (last visited May 28, 2007).

⁹⁶ *Id.* Biopure introduced Oxyglobin in the United States in 1998. Biopure, Oxyglobin, <http://www.biopure.com/shared/home.cfm?CDID=2&CPgID=54> (last visited May 28, 2007). The company then sought FDA approval to market Hemopure in 2002. Biopure, Hemopure, <http://www.biopure.com/shared/home.cfm?CDID=2&CPgID=53> (last visited May 28, 2007).

⁹⁷ Oxyglobin consists of stabilized hemoglobin, the protein that carries oxygen, and is designed to transport oxygen to tissues upon infusion of the drug. Biopure, Oxyglobin, *supra* note 96.

⁹⁸ Biopure describes Hemopure as a chemically-stabilized bovine hemoglobin solution intended to carry oxygen to areas of the body that larger, regular red blood cells cannot reach in certain trauma situations. Biopure, Hemopure, *supra* note 96.

⁹⁹ See *id.* (emphasizing that Biopure has been approved for veterinary use); see also Complaint at ¶ 1, SEC v. Biopure Corp., Civ. A. No. 05-CA-11853-WGY (D. Mass. Sept.

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On July 31, 2002, Biopure submitted a Biologics License Application (BLA)¹⁰⁰ to the FDA, requesting approval for Hemopure's use as a substitute for red blood cell transfusions in acutely anemic adult patients undergoing orthopedic surgery.¹⁰¹ While the BLA was pending, Biopure also submitted an IND¹⁰² in March 2003, seeking FDA approval to begin human clinical trials of Hemopure on in-hospital trauma victims. The new application was necessary because, unlike trials involving scheduled orthopedic surgeries, clinical trials in a trauma setting necessarily involve using the blood substitute on patients without their consent.¹⁰³ The application relied on data from the clinical trials previously conducted in support of the pending BLA for use in anemic orthopedic patients.¹⁰⁴ A month after this trauma IND application, Biopure received a phone call from the FDA notifying the company that a clinical hold¹⁰⁵ had been placed on the trauma trials due to "safety concerns" arising out of the previous orthopedic BLA clinical trial data.¹⁰⁶

14, 2005), available at <http://www.sec.gov/litigation/complaints/comp19376.pdf> (noting that "Hemopure has not been approved by the FDA for use in humans").

¹⁰⁰ The Biologics License Application (BLA) is the NDA equivalent for a biologic drug. FDA approval to market a biologic is granted by issuance of a biologics license. The BLA is submitted following the completion of initial laboratory and animal testing showing that investigational use in humans is reasonably safe. FDA, Frequently Asked Questions About Therapeutic Biological Products, <http://www.fda.gov/cder/biologics/qa.htm> (last visited May 28, 2007).

¹⁰¹ See Complaint, *supra* note 99, at ¶ 2; Press Release, Biopure Corp., Biopure Receives FDA Response to Hemopure® Marketing Application (Aug. 1, 2003), available at http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=bpur&script=417&layout=0&item_id=437651.

¹⁰² For a description of INDs, see *supra* note 50 and accompanying text.

¹⁰³ When applying for FDA approval, a sponsor company must specify the indication (symptoms or disease that the drug is intended to relieve) for which its product is to be used. Investigational New Drug Application, FDA, available at www.fda.gov/opacom/morechoices/fdaforms/FDA-1571.pdf. The original Biopure BLA was for use of its blood substitute during voluntary surgeries. The subsequent IND application was for approval to use the blood substitute for *trauma* patients, who most likely cannot consent to trial participation due to their emergency status. This type of trial is therefore inherently more complicated. See Thomas M. Burton, *FDA to Weigh Using Fake Blood in Trauma Trial*, WALL ST. J., July 6, 2006, at B1 (explaining rarity of nonconsent studies).

¹⁰⁴ See *supra* note 101 and accompanying text.

¹⁰⁵ The FDA may order a clinical hold if it determines that a proposed study of an investigational drug or biologic poses significant risks for human subjects. A clinical hold is a rare action; it suspends the investigation and bars the administration of the investigational drug or biologic to human subjects. FDA, Clinical Hold/Refusal to File Meetings, <http://www.fda.gov/cber/oversite/oversite.htm> (last visited May 28, 2007); see also CTR. FOR DRUG EVALUATION & RESEARCH, IND PROCESS AND REVIEW PROCEDURES (INCLUDING CLINICAL HOLDS) 5-12 (1998), available at <http://www.fda.gov/cder/mapp/6030-1.pdf> (discussing policies and procedures for issuing and overseeing clinical holds).

¹⁰⁶ See Complaint, *supra* note 99, at ¶ 29.

A week after being informed of the clinical hold, Biopure filed a registration statement with the SEC¹⁰⁷ offering an additional one million shares of common stock for sale.¹⁰⁸ In these offering documents, Biopure stated that it had applied for FDA approval for Hemopure only for perioperative use for patients undergoing orthopedic surgery.¹⁰⁹ Although the company stated plans to expand Hemopure's indications (symptoms or disease that the drug is intended to relieve) by designing and submitting additional clinical trials for FDA approval,¹¹⁰ it did not mention that it had already filed an IND with the FDA to conduct trials for the trauma indication. The offering documents discussed the potential use of Hemopure for trauma victims without disclosing that a clinical hold had in fact already been placed on such use due to safety concerns.¹¹¹

Biopure received a letter from the FDA dated April 25, 2003, confirming that the agency had imposed a clinical hold on the trauma trials because "subjects would be exposed to an unreasonable and significant risk of injury."¹¹² After receiving this letter, however, Biopure continued to raise money from investors throughout May 2003 without disclosing either the FDA's concerns regarding the BLA data or the clinical hold placed on the trauma trials.¹¹³ In late May, a month after receiving the clinical hold letter, Biopure issued a press release describing planned clinical trials for trauma patients and again failed to disclose the clinical hold.¹¹⁴ That same day, Thomas Moore, Biopure's president and CEO, participated in an investor conference

¹⁰⁷ Biopure Corp., Post-Effective Amendment No. 1 to Registration Statement (Form S-3) (Apr. 16, 2003).

¹⁰⁸ Biopure Corp., Current Report (Form 8-K), at 1 (Apr. 17, 2003).

¹⁰⁹ Biopure Corp., *supra* note 107, at 4.

¹¹⁰ *Id.*

¹¹¹ See Complaint, *supra* note 99, at ¶ 32 ("We are also developing Hemopure for potential use in trauma and other medical applications.").

¹¹² *Id.* at ¶ 34. The FDA letter stated that "results of a pivotal human trial, used in support of the Hemopure BLA, and referred to in the IND, indicated that use of Hemopure, compared to human blood was associated with a higher incidence of life-threatening [Serious Adverse Events], including death and cardiac arrest." *Id.*

¹¹³ Biopure filed additional registration statements with the SEC in May 2003, providing for the sale of up to 1,715,687 shares of common stock and warrants to purchase up to 343,138 shares of common stock. *Id.* at ¶ 35; Biopure Corp., Prospectus Supplement dated May 2, 2003 (Form 424B5), at S-1 (May 6, 2003) (providing for up to 882,353 shares of common stock and warrants to purchase up to 176,471 shares); Biopure Corp., Prospectus Supplement dated May 5, 2003 (Form 424B5), at S-1 (May 6, 2003) (providing for up to 833,334 shares of common stock and warrants for up to 166,667 shares). These prospectus supplements incorporated by reference the misstatements and omissions in Biopure's April offering documents and again failed to disclose that the FDA had placed a clinical hold on the trauma trials for safety reasons. See Complaint, *supra* note 99, at ¶ 36.

¹¹⁴ See Press Release, Biopure Corp., Biopure Announces 2003 Second Quarter Financial Results (May 22, 2003), available at http://www.corporate-ir.net/ireye/ir_site.zhtml?

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call and assured listeners that the company was unaware of any problems with the BLA.¹¹⁵ Moore also stated that Biopure was planning the in-hospital trauma trials.¹¹⁶ Moore again made no reference to any concerns raised by the FDA or the clinical hold placed on the trauma trials.

Biopure continued to mislead investors with optimistic press releases¹¹⁷ despite receiving additional letters from the FDA informing the company that the clinical hold would not be lifted and that its “conclusions about product safety remain unchanged.”¹¹⁸ The company also continued to offer stock over the summer of 2003 without disclosing any of the negative FDA communications.¹¹⁹

On July 30, 2003, Biopure received a complete response letter¹²⁰ from the FDA informing the company that its orthopedic BLA would not be approved and listing over 220 deficiencies and questions about Hemopure’s safety and efficacy.¹²¹ In a subsequent press release, Biopure disclosed that the company received a letter from the FDA “requesting additional information” but did not disclose that the letter was a complete response letter or the true nature of the FDA’s concerns.¹²² The press release mischaracterized the major setback

ticker=bpur&script=417&layout=0&item_id=415830 (“Biopure is preparing for a Phase IIa in-hospital trauma trial . . .”).

¹¹⁵ According to the Complaint, Moore stated:

[W]e continue to be very hopeful of an [FDA] response on our [biologics] license application by mid-year or sooner, and we continue to not be aware of any major issues with that application at this time.

Our aim will be to have the product, again, assuming we get approved, on or about June 1st to the end business [sic] and moving product no later than October 1st.

Complaint, *supra* note 99, at ¶ 44 (quoting CEO Moore) (alteration in original).

¹¹⁶ *Id.* (“Parkman Hospital is going to be our initial clinical center to conduct the already announced in-hospital trauma trials that will set us up for subsequent pre-Hospital trials to establish an additional trauma indication for Hemopure.” (quoting CEO Moore)).

¹¹⁷ See, e.g., Press Release, Biopure Corp., U.S. FDA Finalizes Response Date for Biopure’s Marketing Application of Hemopure® (May 30, 2003), available at http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=bpur&script=417&layout=0&item_id=417475 (“We’re very pleased with the FDA’s progress in reviewing our application” (quoting Biopure CEO Thomas A. Moore)).

¹¹⁸ Complaint, *supra* note 99, at ¶ 46.

¹¹⁹ Biopure filed additional registration statements and amendments with the SEC that incorporated by reference previous filings containing false and misleading statements. See Biopure Corp., Registration Statement (Form S-3), at 14–15 (June 19, 2003); Biopure Corp., Amendment No. 1 to Form S-3 Registration Statement (Form S-3/A), at 14 (July 2, 2003); Biopure Corp., Prospectus (Form 424B3), at 14 (July 3, 2003); Biopure Corp., Current Report (Form 8-K), at 3 (July 18, 2003); Biopure Corp., Prospectus Supplement (Form 424B5), at S-3 to S-4 (July 18, 2003).

¹²⁰ Action letters are also referred to as complete response letters. See *supra* note 56.

¹²¹ Complaint, *supra* note 99, at ¶ 70.

¹²² Press Release, Biopure Corp., *supra* note 101.

imposed by the FDA's letter as "encouraging" Biopure "to complete the approval process as quickly as possible."¹²³ Following this positive disclosure, Biopure's stock price increased by more than twenty percent.¹²⁴

Biopure continued to raise money from investors and to file misleading registration statements with the SEC until December 2003.¹²⁵ During that time, the company raised over \$35 million from investors.¹²⁶ On December 11, 2003, four months after the fact, Biopure finally disclosed that the FDA's July 30 letter was a complete response letter.¹²⁷ The company waited until Christmas Eve, 2003, to finally reveal for the first time the clinical hold imposed on the trauma trials more than eight months earlier.¹²⁸ The company also disclosed that the SEC was preparing to file a civil injunctive action against Biopure.¹²⁹ As information about Hemopure's true status in the FDA approval process became public, Biopure's stock price plummeted almost sixty-six percent.¹³⁰

¹²³ *Id.*

¹²⁴ Litigation SEC Release No. 19825, SEC Settles Civil Injunctive Action Against Biopure Corporation and Its General Counsel (Sept. 12, 2006), *available at* <http://www.sec.gov/litigation/litreleases/2006/lr19825.htm> [hereinafter Litigation SEC Release No. 19825].

¹²⁵ *See id.* ("The Complaint alleges that Biopure continued to make misleading statements until December 2003."); *see, e.g.*, Biopure Corp., Registration Statement (Form S-3), at 11-12 (Aug. 22, 2003) (conceding that trading price of Biopure stock "has been and is likely to continue to be extremely volatile" yet listing as explanatory factor "FDA approval of Biopure," not FDA rejection); Biopure Corp., Prospectus (Form 424B3) (Sept. 12, 2003); Biopure Corp., Prospectus (Form 424B3), at 4-5 (Sept. 15, 2003) (stating that FDA had sent Biopure letter in July 2003 "requesting additional information" and discussing Biopure's plans to use Hemopure "in patients undergoing orthopedic surgery"); Biopure Corp., Quarterly Report (Form 10-Q), at 11 (Sept. 15, 2003) (stating that FDA had sent Biopure letter in July 2003 "requesting additional information" and saying Biopure planned "to develop Hemopure for potential use in trauma and other medical applications").

¹²⁶ Litigation SEC Release No. 19825, *supra* note 124.

¹²⁷ Press Release, Biopure Corp., Biopure Announces 2003 Fourth Quarter and Year-End Financial Results (Dec. 11, 2003), *available at* http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=bpur&script=417&layout=0&item_id=477240.

¹²⁸ Press Release, Biopure Corp., Biopure Receives 'Wells Notice' From Securities and Exchange Commission (Dec. 24, 2003), *available at* http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=bpur&script=417&layout=0&item_id=480387.

¹²⁹ Final judgment by consent was finally entered against Biopure and its general counsel, Jane Kober, in September 2006. Litigation SEC Release No. 19825, *supra* note 124. The company was enjoined from "violating antifraud provisions of the federal securities laws" and was required to retain an "independent consultant" to review its disclosure and compliance policies. *Id.* Kober was ordered to pay a \$40,000 civil penalty. *Id.* The company also faced several shareholder actions. *E.g.*, *In re Biopure Corp. Derivative Litig.*, 424 F. Supp. 2d 305 (D. Mass. 2006); *Meyer v. Biopure Corp.*, 221 F. Supp. 2d 195 (D. Mass. 2002).

¹³⁰ Litigation SEC Release No. 19825, *supra* note 124.

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The SEC's Biopure investigation was based on a tip from the FDA¹³¹—an example of the increasing collaboration between the SEC and the FDA to identify fraud among FDA-regulated companies.¹³² While fraud detection and the prosecution of company executives are important deterrents, the securities fraud in this case was easily preventable. Had Biopure been required to publicly disclose the contents of the FDA action letters it received, market professionals would have learned of the problems with the BLA and its clinical hold status, alerting investors to the likelihood that the drug would not be approved by the FDA.

B. TKT

Transkaryotic Therapies (TKT) was a biotechnology company based in Cambridge, Massachusetts.¹³³ In June 2000, TKT filed a BLA seeking FDA approval for its flagship product, Replagal, a drug intended to relieve the painful symptoms of a genetic disorder called Fabry's disease.¹³⁴ Fabry's disease is rare, and treatment for the disease is extremely costly—approximately \$160,000 per patient annually.¹³⁵

On January 2, 2001, in response to TKT's BLA, the FDA sent TKT a complete response letter¹³⁶ indicating that the company's submitted data for the drug failed to show that Replagal was an effective treatment for Fabry's disease.¹³⁷ The letter criticized the study's methodology as "inappropriate and unacceptable" and noted that the trial failed to show a statistically significant effect on pain relief.¹³⁸ The letter also stated that TKT could cure this deficiency only by con-

¹³¹ Ross Kerber, *A Tip from FDA Led to SEC's Suit Against Biopure*, BOSTON GLOBE, Oct. 10, 2005, at F1.

¹³² See Hathaway et al., *supra* note 41, at 17 ("Indeed the SEC's suit is one more manifestation of a broader effort by the SEC and FDA to monitor investment communications by FDA-regulated companies."). A formal collaboration was announced in 2004. See *infra* Part II.C.

¹³³ Andrew Pollack, *British Company to Buy U.S. Maker of Anemia Treatment*, N.Y. TIMES, Apr. 22, 2005, at C2. Transkaryotic Therapies (TKT) was purchased by Shire Pharmaceuticals Group in 2005. *Id.*

¹³⁴ Fabry's disease is a lipid storage disorder that causes extreme pain (particularly in the hands and feet), eye manifestations, and increased risk of heart attack or stroke. See National Institute of Neurological Disorders and Stroke, NINDS Fabry's Disease Information Page, <http://www.ninds.nih.gov/disorders/fabrys/fabrys.htm> (last visited May 28, 2007).

¹³⁵ See Complaint at 5, SEC v. Selden, Civ. A. No. 0511805 (NMG) (D. Mass. Sept. 1, 2005).

¹³⁶ See *supra* note 56.

¹³⁷ See Complaint, *supra* note 135, at 9. ("The clinical study data you have provided do not provide substantial evidence of efficacy for [Replagal].").

¹³⁸ *Id.*

ducting additional clinical trials.¹³⁹ The next day, TKT issued a press release stating only that TKT had received a complete response letter in which the “FDA [had] asked for further explanation in several areas and requested additional data.”¹⁴⁰ TKT made no mention of the FDA’s warning that only additional clinical trials could cure the methodological and efficacy deficiencies of the submitted data.

On April 26, 2001, several months after receiving the complete response letter, TKT executives informed the FDA that the company would no longer seek approval for Replagal as a pain treatment.¹⁴¹ Instead, TKT discussed the possibility of applying for FDA approval based on the drug’s ability to improve kidney function.¹⁴² The FDA staff explained that a different basis for approval would be possible but that such approval would require the submission of data from new clinical trials.¹⁴³ In its SEC filings, TKT made no mention of its decision to seek approval of Replagal on different grounds or of Replagal’s lack of progress in the FDA approval process.¹⁴⁴ Rather, it continued to assert that the FDA simply “requested further explanation in several areas and additional data.”¹⁴⁵ TKT thereby perpetuated the impression that the company was continuing to pursue FDA approval for Replagal on the basis of pain relief and that this process was on track.¹⁴⁶

¹³⁹ *Id.* (“[A]dditional analyses or otherwise revised analyses of the clinical data you have submitted will be unable to address this deficiency. In order to provide substantial evidence of efficacy, we recommend that you conduct additional clinical studies and submit the results to [the FDA].”).

¹⁴⁰ Press Release, TKT, TKT Receives FDA Complete Review Letter on Replagal™ (Jan. 3, 2001), available at <http://www.shire.com/shire/NewsAndMedia/PressReleases/showtktshirepress.jsp?ref=76&tn=3&m1=8&m2=36>.

¹⁴¹ See Complaint, *supra* note 135, at 12.

¹⁴² *Id.*

¹⁴³ See *id.*

¹⁴⁴ See, e.g., Transkaryotic Therapies, Inc., Annual Report (Form 10-K), at 6–7 (Apr. 2, 2001) (identifying Replagal as treatment for pain associated with Fabry disease and stating simply that “[i]n January 2001, the FDA issued a complete review letter which requested additional data and asked for further explanation in several areas”); Transkaryotic Therapies, Inc., Quarterly Report (Form 10-Q), at 12 (May 14, 2001) (disclosing that FDA issued complete response letter for Replagal requesting additional information without mention of alternate grounds for approval or further detail on nature of additional information that FDA required).

¹⁴⁵ Transkaryotic Therapies, Inc., Quarterly Report (Form 10-Q), at 12 (May 14, 2001).

¹⁴⁶ See Press Release, TKT, TKT Announces Meeting of FDA Advisory Committee to Review Replagal™ BLA for Fabry Disease (July 8, 2002), available at <http://www.shire.com/shire/NewsAndMedia/PressReleases/showtktshirepress.jsp?ref=158&tn=&m1=&m2=> (quoting TKT President and CEO Richard Selden as “pleased that the FDA is taking this next, important step in the review of our BLA,” while not disclosing FDA assertions that clinical data did not show drug’s effect on pain or that company decided to seek approval based on improvements in kidney function rather than pain relief).

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Finally, on October 2, 2002—over a year after TKT had received the FDA’s complete response letter and decided not to seek approval based on Replagal’s effectiveness for pain relief—TKT issued a press release announcing that it had withdrawn its application to the FDA for approval of Replagal based on the drug’s effectiveness against pain.¹⁴⁷ In the press release, the company disclosed that the FDA had found its data for Replagal to be “uninterpretable” and thus insufficient for approval.¹⁴⁸ The next day, TKT shares closed at \$12.75 per share, down sixty-one percent from the prior day’s close of \$33.25 per share.¹⁴⁹ On September 1, 2005 the SEC filed a civil fraud action against TKT’s CEO for the company’s public misrepresentations.¹⁵⁰

The TKT story is yet another example of a fraud that could have been avoided had the company been mandated to publicly disclose the FDA action letter.¹⁵¹ The FDA’s refusal to disclose any information about new drug applications, and companies’ withholding of FDA communications from the public, have allowed companies to misrepresent the likelihood of gaining FDA approval for their drugs. Scandals such as Biopure, TKT, and ImClone have prompted a recent collaboration between the SEC and the FDA to better detect such fraud. The next section describes this initiative and its shortcomings.

¹⁴⁷ See Press Release, TKT, TKT Provides Regulatory and Commercial Updates on Fabry Disease Program (Oct. 2, 2002), available at <http://www.shire.com/shire/NewsAndMedia/PressReleases/showtktshirepress.jsp?ref=152&tn=3&m1=8&m2=36> (“TKT believes that these pain data demonstrate an important benefit for patients, but has nonetheless concluded that the best approach to obtain a prompt approval for Replagal in the United States is to seek approval on the basis of its renal and cardiac data.”).

¹⁴⁸ *Id.* (“TKT continues to believe that the FDA will approve Replagal, although the FDA’s review of the Replagal Biologic License Application . . . expressed concerns regarding TKT’s clinical data, particularly with respect to pain. The FDA indicated that methodological issues made the pain data uninterpretable and that data . . . did not support approval.”).

¹⁴⁹ See Complaint, *supra* note 135, at 20.

¹⁵⁰ See Litigation SEC Release No. 19357, SEC Charges Former CEO of Massachusetts Biotechnology Company with Securities Fraud (Sept. 1, 2005), available at <http://www.sec.gov/litigation/litreleases/lr19357.htm>. Richard Selden, TKT’s CEO, resigned from the company following the FDA’s rejection of Replagal. Andrew Pollack, *Chief Executive of Troubled Biotechnology Company Resigns*, N.Y. TIMES, Feb. 12, 2003, at C4. The SEC litigation against him remains unresolved as of this writing. TKT also faced several shareholder suits. *E.g.*, *In re Transkaryotic Therapies, Inc. Sec. Litig.*, No. Civ. A. 03-10165-RWZ, 2005 WL 3178162 (D. Mass. 2005) (granting class certifications to plaintiffs in shareholder suit against two of TKT’s former officers, six TKT directors, and four investment banks that underwrote TKT stock offering; plaintiffs alleged TKT made material misstatements and misrepresentations and that shareholders traded in reliance on this information); *In re Transkaryotic Therapies Sec. Litig.*, 319 F. Supp. 2d 152 (D. Mass. 2004) (granting in part and denying in part TKT defendants’ motion to dismiss).

¹⁵¹ See Pollack, *supra* note 5 (reporting that “angry analysts and investors said that TKT had been assuring them . . . that the drug was on track for approval”).

C. SEC-FDA Collaboration

In February 2004, the FDA and the SEC announced the creation of a formal collaboration between the two agencies intended to reduce the incidence of fraud among FDA-regulated companies.¹⁵² A principal part of this collaboration was the establishment of a centralized process for FDA employees to refer false or misleading statements made by FDA-regulated companies to the SEC.¹⁵³ Specifically, the FDA identified liaison officers to facilitate the flow of communication between the two agencies and authorized certain FDA employees to share non-public information with SEC staff.¹⁵⁴ While FDA personnel are not expected to routinely monitor public statements made by companies the agency regulates, employees might encounter misleading statements during the ordinary course of their work.¹⁵⁵ The new procedures are intended to streamline and simplify the reporting of such concerns.

Although the SEC-FDA collaboration is a step in the right direction, it is not the most efficient or most effective method of preventing fraud. Neither agency has the resources to effectively monitor company disclosures.¹⁵⁶ The SEC does not have the resources to comb through every statement made by public companies. Additionally, SEC officials would not know that a statement was misleading unless the FDA first notified the SEC of a drug application's progress.¹⁵⁷ FDA officials, on the other hand, should recognize a misleading statement if they confront one, but FDA officials do not routinely monitor company disclosures—as the FDA acknowledged when announcing

¹⁵² See Press Release, FDA, FDA and SEC Work to Enhance Public's Protection from False and Misleading Statements (Feb. 5, 2004), available at www.fda.gov/bbs/topics/NEWS/2004/NEW01019.html.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ For years, drug safety advocates have urged additional FDA funding. See, e.g., FUTURE OF DRUG SAFETY, *supra* note 55, at 193 (“The[FDA] lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future. . . . There is little dispute that the FDA in general is . . . severely underfunded.”). The SEC is also highly constrained by a lack of resources. See U.S. GEN. ACCOUNTING OFFICE, GAO-02-302, SEC OPERATIONS: INCREASED WORKLOAD CREATES CHALLENGES 11–13 (2002) (identifying resource constraints at SEC as contributing to delays, bottlenecks, and selectivity in enforcement activity).

¹⁵⁷ See *Congressional Hearings*, *supra* note 4, at 231 (statement of Rep. Greenwood) (“[The] SEC is unlikely to have reason to second-guess a company's claims, unless they get some information from the FDA first. . . . [It] has a lot to do and certainly has limited personnel and isn't going to be able to monitor every press release, every printed statement about a potential product.”).

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the formal SEC-FDA collaboration.¹⁵⁸ Furthermore, FDA staff cannot be expected to understand the securities laws and are unqualified to determine when a statement is a material misrepresentation that should be reported to the SEC.¹⁵⁹

The SEC-FDA collaboration also fails to resolve the uncertainty inherent in the materiality standards of disclosure, as described in Part I.C. Even with the collaboration in place, companies will continue to make discretionary decisions as to what types of information to disclose.¹⁶⁰ Currently, the FDA issues confidential letters to drug sponsors.¹⁶¹ The contents of these letters are often material to the company's stock price.¹⁶² The company then determines what, if any, aspects of this communication it will disclose to the public. Only the FDA knows if statements released by the company are misleading, as no one other than the company and the FDA is privy to the contents of the FDA communications.¹⁶³ If an FDA official happens to notice that a company made a misleading statement,¹⁶⁴ she now has a process for reporting her concerns to the SEC.¹⁶⁵ The SEC then chooses whether or not to initiate an investigation. This process therefore relies on the FDA noticing the fraud and the SEC following up on it. There is little guarantee that this would happen in a timely fashion, and no other party has enough information to deter the fraud from happening or to expose it once it begins.

As the Biopure and TKT examples show,¹⁶⁶ companies have great incentives to misrepresent their progress in obtaining FDA approval for their products. While the new streamlined process of information sharing between the FDA and the SEC should accelerate the SEC's response to potential fraud, it is not the most efficient method of preventing the fraud. There may well be several cases of misrepresentation or outright fraud occurring right now; under the

¹⁵⁸ See *supra* note 155 and accompanying text; see also Filmore, *supra* note 84, at 33 (quoting director of FDA's Office of Enforcement: "The information that needs to be disclosed to the public under the SEC laws is strictly an SEC decision" and FDA staff will only inform SEC if information is discovered "under the normal course of our business").

¹⁵⁹ See Filmore, *supra* note 84, at 33 (quoting lawyer who noted that goals and focuses of FDA and SEC "might not always line up").

¹⁶⁰ See *id.* (quoting lawyer who stated that "there is no guidance" as to what information SEC expects companies to disclose).

¹⁶¹ See *supra* notes 55-61 and accompanying text.

¹⁶² See *supra* notes 43, 45 and accompanying text.

¹⁶³ See *supra* note 61 and accompanying text.

¹⁶⁴ The FDA is not required to monitor company disclosures, but FDA officials might come across such a disclosure during the course of their review of the sponsor's application. See *supra* text accompanying note 155.

¹⁶⁵ See *supra* Part II.C.

¹⁶⁶ See *supra* Parts II.A-B.

current regulatory regime, the public will usually have no way of determining this until months or years later.¹⁶⁷ The mandatory disclosure of FDA action letters would be a more efficient solution because it aims to prevent the fraud rather than to detect it after it has occurred. The next Part will explain in detail why implementing a mandatory disclosure system for FDA action letters is a more efficient and more effective solution than the current SEC-FDA collaboration.

III

PROPOSAL: PUBLIC DISCLOSURE OF FDA ACTION LETTERS

This Part details how mandatory disclosure of FDA action letters will reduce the incidence of fraud. I first outline my proposal and then attack each of the likely criticisms to its implementation. I will show why required disclosure by the companies (while not a cure-all) is the most efficient method currently available for minimizing the likelihood for fraud while mitigating the concerns over trade secrets. By allowing the sponsor company to maintain control over its own proprietary information, this proposal limits the potential for free-riding and anticompetitive behavior.¹⁶⁸

Public disclosure of FDA action letters to drug sponsors would enable industry analysts to more accurately assess the likelihood of FDA approval of the drug. Market professionals, such as analysts and traders, closely scrutinize statements made by the public companies they follow. The public availability of this information would thus create a more accurate valuation of the company, preventing company insiders from misleading investors about action letter content.¹⁶⁹ Shifting the burden of monitoring company statements to market analysts and away from government agencies will also allow those agencies to focus on their many other regulatory duties.¹⁷⁰

A. Proposal

Companies are currently required to file a Form 8-K with the SEC upon the occurrence of certain specified events.¹⁷¹ I propose

¹⁶⁷ See *supra* notes 66–67 and accompanying text.

¹⁶⁸ For a detailed description of the anticompetitive concerns see *infra* Part III.B.1.

¹⁶⁹ For a discussion of the importance of information traders in creating an efficient market, see Goshen and Parchomovsky, *supra* note 37, at 737–38.

¹⁷⁰ See, e.g., U.S. GEN. ACCOUNTING OFFICE, *supra* note 156, at 10–13 (listing new SEC regulatory responsibilities and noting increasing SEC imbalance between workload and resources).

¹⁷¹ The SEC created the Form 8-K in 1936, requiring companies to report events in six categories. Since then, the SEC has expanded the number of categories, most notably as part of the 2002 Sarbanes-Oxley Act. For a history of the evolution of the Form 8-K, see

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that the receipt of an action letter from the FDA should be included in this list of events. Under this proposal, companies will be required to submit a Form 8-K with an attached copy of the FDA action letter within four business days of receipt.¹⁷² Companies may redact the letters to protect any proprietary information included in these correspondences.

This disclosure requirement is preferable to the current market situation—where company insiders can choose whether or not to disclose the receipt of an FDA action letter—because it will reduce company insiders' abilities to misrepresent a drug's progress in the FDA approval process. Additionally, requiring each sponsor company to redact and publicly disclose the FDA action letters it receives should not significantly burden a company's resources. On the other hand, the FDA does not have the resources to publicize and redact all the letters that the agency sends out to sponsors.¹⁷³ Redaction is not a costless enterprise; the agency would need to consult lawyers and scientists to ensure that important information is not unintentionally revealed. Giving the company control over the redaction will also better address concerns about protecting proprietary data.¹⁷⁴

Company disclosure is not only more efficient, but it is also more consistent with FDA policies. The FDA sees its role as protecting the public health, not overseeing company disclosures to investors. During questioning by Congress about the ImClone scandal, FDA Commissioner Lester Crawford testified that “[w]hile [the] FDA has authority to correct false or misleading sponsor statements, in appropriate circumstances, primary responsibility for assuring the truthfulness of company statements aimed at investors resides not with [the] FDA, but with the Securities and Exchange Commission.”¹⁷⁵

If this proposal is implemented, the nature of FDA action letters will likely evolve to best meet the needs of the sponsor companies, the investors, the FDA, and the SEC. Since the FDA will know that the sponsor must disclose a redacted version of the letter, the FDA official will likely write the letter in a style that is more conducive to the

Jennifer B. Lawrence and Jackson W. Prentice, *The SEC Form 8-K: Full Disclosure or Fully Diluted? The Quest for Improved Financial Market Transparency*, 41 WAKE FOREST L. REV. 913, 915–19 (2006).

¹⁷² A Form 8-K must be filed within four business days of the occurrence of a listed event. SEC, Form 8-K, General Instructions 2, available at <http://www.sec.gov/about/forms/form8-k.pdf>.

¹⁷³ See *supra* note 156 and accompanying text.

¹⁷⁴ For a detailed explanation of the need to protect proprietary information and the benefits of relying on company disclosure, see *infra* Part III.B.1.

¹⁷⁵ *Congressional Hearings*, *supra* note 4, at 228 (testimony of Lester M. Crawford, Deputy Comm'r, FDA).

redaction of proprietary information. The FDA official is also likely to organize the letter so as to minimize the likelihood that the company will redact information that should be publicly disclosed. For example, the FDA might summarize important information at the beginning of the letter without including proprietary language so that investors will be able to assess the nature of the letter quickly and accurately.

Although the company might have an incentive to redact more than is necessary, it would be very difficult for the company to hide the letter's basic message. A redacted letter would provide investors with the information necessary to more accurately assess the company's chances of obtaining FDA approval, thereby resulting in more accurate stock prices.¹⁷⁶ If a company chooses to overredact, analysts will still be aware of the action letter and be better equipped to question the company and demand more information.

This proposal will also reduce the uncertainty faced by public drug companies regarding the SEC's current disclosure regime and materiality standard.¹⁷⁷ By requiring FDA action letters to be disclosed, the SEC will relieve some of the uncertainty that companies face when determining if such information is material or not. Sponsor companies will be on notice that failure to disclose an action letter will violate SEC regulations, triggering liability under the securities laws.¹⁷⁸

Before answering specific criticisms of this proposal, it is important to address the claim that market forces, such as general monitoring by analysts, should be sufficient to deter this type of fraud by pharmaceutical companies. The disclosures discussed in this Note require additional monitoring because even the most sophisticated analyst would be unable to detect potential fraud in the context of the FDA approval process. Market intermediaries are generally used to verify financial disclosures made by public companies.¹⁷⁹ Disclosures made by the companies about their drugs' progress in the FDA approval process, however, are not adequately monitored or verified, and investors are forced to rely on the companies to provide accurate

¹⁷⁶ See *supra* note 33 and accompanying text.

¹⁷⁷ See *supra* Part I.C for a discussion of the uncertainty in the current disclosure standards.

¹⁷⁸ See *supra* note 17 and accompanying text (summarizing 10b-5 liability).

¹⁷⁹ For a discussion of why private-market intermediaries sometimes fail to protect investors, see Stephen J. Choi, *A Framework for the Regulation of Securities Market Intermediaries*, 1 BERKELEY BUS. L.J. 45, 48-56 (2004).

information.¹⁸⁰ Even sophisticated institutional investors are unable to detect potential fraud in this area because they do not have access to FDA communications. Relying on market analysts to uncover fraud, therefore, does not solve the problem.¹⁸¹ Without access to the FDA action letters, or knowledge that they exist, market participants will be unable to determine the accuracy of company statements.

B. Criticisms

There are three potential criticisms of this proposal. First, the competitive nature of the pharmaceutical industry urges against forced disclosure of proprietary information. Second, critics might argue that the disclosure will not improve price accuracy because investors will be overwhelmed by too much information disclosure, or because the contents of FDA communications will be too technical for the average investor to understand. Finally, companies might fear that forced disclosure of FDA correspondences may result in market overreaction by investors.

1. Protecting Proprietary Data to Bolster Research Incentives

The FDA and its regulated companies are likely to oppose this proposal because it threatens the strong privacy protections currently afforded to the back-and-forth communications between sponsors and FDA personnel. The FDA and sponsor companies regard confidentiality as sacred.¹⁸² That forced disclosure will diminish research incentives is a legitimate concern. Public disclosure of clinical trial data might encourage freeriding by competitors, hampering the incentive for companies to invest in drug development.¹⁸³ This is particularly problematic in the pharmaceutical industry given the extremely high costs of drug development.¹⁸⁴ Trial protocols and clinical trial results

¹⁸⁰ See Langevoort, *supra* note 91, at 157–58 (noting marketplace dependency on company disclosures in cases where managers have “unique access to certain kinds of risk-related information”).

¹⁸¹ Reliance on analysts and market intermediaries to police fraud has recently come under attack. For an explanation of the deficiencies and opportunistic risks posed by intermediaries and analysts, see Cross and Prentice, *supra* note 92, at 346–49.

¹⁸² See *supra* notes 61–65 and accompanying text.

¹⁸³ See Janene Boyce, *Disclosure of Clinical Trial Data: Why Exemption 4 of the Freedom of Information Act Should be Restored*, 3 DUKE L. & TECH. REV. ¶ 7–8 (2005), <http://www.law.duke.edu/journals/dltr/articles/pdf/2005DLTR0003.pdf> (describing freerider problem); Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 840 (1980) (“Nondisclosure is chiefly supported by the fear that disclosure will diminish research incentives by reducing the profitability of discovery.”).

¹⁸⁴ For estimates of a new drug’s development and marketing costs, see *supra* note 40 and accompanying text.

can be very valuable to competitors looking to reduce these high expenditures.¹⁸⁵ For this reason, drug developers and the FDA have sought to protect clinical trial data from public disclosure.¹⁸⁶

The same concerns may arise in the context of public disclosure of FDA action letters, which inevitably contain protected clinical trial data. Company redaction, however, preserves the confidentiality of proprietary information by empowering the drug sponsor to maintain ultimate control over which information is disclosed. A company is less likely to worry about the release of proprietary information if the company itself makes the final determination as to which data is redacted; that same company would presumably be less comfortable relying on FDA discretion to determine how such information should be released.

Thus, company redaction preserves the confidentiality of proprietary information. Publicly disclosing a redacted letter does not put the company at risk of leaking private data; it only forces the company to disclose the true status of its progress within the FDA approval process. Furthermore, mandated disclosure of redacted documents is not new to securities regulation. For example, companies routinely attach redacted copies of contracts for joint ventures to their SEC filings.¹⁸⁷ The concerns over undermining competition and curtailing research incentives will therefore be less prevalent under this proposal than they would be in cases of direct disclosure by the FDA itself.

2. *Information Overload*

The second concern is that individual investors will not benefit from these disclosures because: (1) there is already too much information for investors to digest, and (2) the technical aspects of the FDA letters will be too difficult for investors to understand. Investors are already inundated with annual reports, quarterly statements, press releases, and analyst reports. Most individual investors do not read the many public disclosures that companies routinely disseminate.¹⁸⁸ Requiring additional disclosures might appear to exacerbate the problem of an already flooded information market. If individual investors do not digest available information, then professional inves-

¹⁸⁵ See Boyce, *supra* note 183, at ¶ 8–9 (noting that escalating clinical trial costs constitute approximately seventy percent of total drug-development costs and that access to data can be helpful in reducing those costs).

¹⁸⁶ *Id.* at ¶ 9.

¹⁸⁷ See, e.g., New River Pharmaceuticals, Inc., Annual Report (Form 10-K), at Exhibit 10.13 (Apr. 1, 2005) (including redacted copy of joint venture contract).

¹⁸⁸ See *supra* notes 30–33 and accompanying text.

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tors who do read company disclosures gain an even greater advantage when more disclosure is mandated.¹⁸⁹

Concerns that there is already both too much information and that the information is too technical are mitigated by the dissemination of that information to all investors. Professional market analysts and brokers who read and evaluate company disclosures also synthesize this information into summary reports and recommendations. Market professionals have the expertise to accurately evaluate technical disclosures, and they will distill the content of FDA action letters into understandable summaries.¹⁹⁰ Market efficiency and stock-price accuracy are therefore enhanced by the incorporation of this public information into the stock price.¹⁹¹

3. *Market Overreaction*

A final concern is the potential for market overreaction. An FDA action letter summarizes concerns about an application for drug approval; it does not determine a drug's merits. An application might be rejected due to concerns about the structure of a clinical trial, even though the drug itself is safe and effective. A drug that is the subject of a rejected FDA application could be approved later through a new application, if the sponsor conducts new clinical trials that satisfy the FDA's specifications. For example, despite the initial rejection of its application, ImClone's Erbitux was eventually approved by the FDA—after additional clinical trials were conducted—and is currently on the market.¹⁹²

Nevertheless, stock price shifts that are retroactively viewed as market overreactions might actually be accurate assessments of the stock's value at the time. Concededly, a company's share price is likely to drop following the disclosure of an FDA action letter requiring additional clinical trials. Although this might be viewed as an overreaction in the long term if the drug is later approved, the low

¹⁸⁹ See CHOI & PRITCHARD, *supra* note 31, at 32 (noting that sophisticated investors gain informational advantage when small investors do not read disclosures).

¹⁹⁰ See Jill E. Fisch & Hillary A. Sale, *The Securities Analyst as Agent: Rethinking the Regulation of Analysts*, 88 IOWA L. REV. 1035, 1040–42 (2003) (explaining that sell-side analysts research, analyze, and synthesize company and industry information into reports that are distributed to investors); John L. Orcutt, *Investor Skepticism v. Investor Confidence: Why the New Research Analyst Reforms Will Harm Investors*, 81 DENV. U. L. REV. 1, 6–8 (2003) (same).

¹⁹¹ For a discussion of the semi-strong version of the efficient market hypothesis, see *supra* note 33 and accompanying text.

¹⁹² See Letter from Karen D. Weiss, Dir., Office of Drug Evaluation, to Lily Lee, Vice President, Regulatory Affairs & Biostatistics, ImClone Sys., Inc. (Feb. 12, 2004), available at <http://www.fda.gov/cder/foi/applletter/2004/125084ltr.pdf> (authorizing ImClone to manufacture Erbitux).

share price is likely to be indicative of the drug's potential for approval at the time of the action letter. If subsequent clinical trials improve the likelihood of approval, then the stock price will rise accordingly.

Absent mandatory disclosure, company executives, believing in the drug's merit and potential for eventual approval, might be tempted to completely withhold any negative FDA communication from the public. As the Biopure, TKT, and ImClone cases show, the decision to withhold information should not be left to company insiders. Requiring the company to disclose the action letter provides an opportunity for company executives to mitigate negative market reactions by presenting evidence of the likelihood of the drug's eventual approval.

CONCLUSION

The high cost of drug development leads many pharmaceutical firms to raise capital through the public markets. Gaining FDA approval determines profitability for many FDA-regulated companies and thereby greatly impacts a company's stock price. The long time-table before a drug can be marketed makes information about the FDA approval process highly sensitive and material to investors.

Pharmaceutical companies face unique disclosure challenges.¹⁹³ Under the current regime, investors must rely on company disclosures to determine the likelihood that the FDA will ultimately approve a drug. The FDA policy of absolute secrecy regarding drug applications has allowed executives of FDA-regulated companies too much discretion in deciding what, if anything, to disclose to the public. Unfortunately, increasing market pressures have proven too strong for some companies. To maintain high stock prices, the companies described in this Note chose to conceal negative FDA communication from the public.¹⁹⁴

To prevent future instances of fraud, this Note recommends a system of mandatory disclosure for FDA action letters.¹⁹⁵ By requiring FDA-regulated companies to file a Form 8-K upon the receipt of an action letter and to attach a redacted version of that letter, the SEC can be assured that important material information will reach investors in a timely manner. Company executives will be deterred from misleading investors about the content of these critical FDA communications without sacrificing important proprietary information about their drugs.

¹⁹³ See *supra* Part I.B.

¹⁹⁴ See *supra* Part II.

¹⁹⁵ See *supra* Part III.