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The Sitting Ducks of Securities Class Action Litigation: Bio-Pharmas and the Need for Improved Evaluation of Scientific Data

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THE SITTING DUCKS OF SECURITIES CLASS ACTION
LITIGATION: BIO-PHARMAS AND THE NEED FOR IMPROVED
EVALUATION OF SCIENTIFIC DATA

BY STUART R. COHN* & ERIN M. SWICK**

ABSTRACT

Rule 10b-5, a powerful weapon against any publicly-listed company whose share price drops on adverse news, is particularly skewed against pharmaceutical and other bio-technology companies (bio-pharmas). It is not a coincidence that there is a disproportionate number of class actions filed against bio-pharmas. The volume and complexity of data underlying most bio-pharma cases create enormous outcome uncertainties, settlement pressures, and potentially huge contingent liabilities over substantial periods of time. The vulnerability and risks that bio-pharmas face in Rule 10b-5 class actions are unique among all publicly-traded industries, yet many cases proceed along traditional grounds without courts employing either their statutory or inherent powers to obtain objective expert assessment of the data underlying plaintiffs' claims. Most judges have neither the training nor the capacity to differentiate between the positions of opposing experts or to reach their own independent assessment of the research data.

The unstated premise of the Supreme Court's Daubert v. Merrell Dow Pharmaceuticals opinion is that courts have an obligation to fully understand the evidence prior to any decision-making, and that the use of court-appointed experts will allow judges to decide motions to dismiss with greater confidence and accuracy. The early appointment of such experts may also have the salutary effect of causing plaintiffs to pause and consider whether the claims are sufficient to warrant the up-front imposition of court-appointed expert costs. If courts begin to recognize in greater numbers the importance of obtaining objective expert testimony, we believe that a more level playing field will evolve to reduce the disproportionate vulnerability of bio-pharmas to securities law class actions.

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I. INTRODUCTION

More than 2000 patients with renal cell carcinoma, or kidney cancer, participated in a clinical trial of the GlaxoSmithKline drug pazopanib.¹ The Food and Drug Administration (FDA) reported that the three deaths

¹See Press Release, GlaxoSmithKline PLC, GlaxoSmithKline Receives Unanimous FDA Panel Approval Recommendation for Votrient (Oct. 5, 2009), available at http://www.gsk.com/media/pressreleases/2009/2009_pressrelease_10103.htm.

observed were "from liver injury that [was] related to or associated with pazopanib."² However, members of the FDA Oncologic Drugs Advisory Committee, including experts in liver injury, said it wasn't clear if the three deaths were from drug induced liver injury.³ Despite their doubts, the panel unanimously recommended that the FDA approve pazopanib for the treatment of patients with kidney cancer.⁴ On October 19, 2009, the FDA acted upon the panel's recommendation and approved pazopanib to be marketed and sold under the name Votrient.⁵

Pazopanib is just one example where scientists, experts, and the FDA are unsure whether a pharmaceutical or biotechnology product has an acceptable benefit-to-risk profile for human treatment. Experts may disagree or be uncertain as to conclusions to be drawn from the data. Uncertainty in the scientific world is mirrored in the investment world, as investors in publicly-traded pharmaceuticals and biotech companies (herein collectively referred to as "bio-pharmas") are similarly situated in trying to determine whether a pharmaceutical or biotech product has an acceptable investment benefit-to-risk profile. Investors are eager to embrace companies developing the next blockbuster drug or device, but litigation history suggests that investors are not as willing to accept the downside losses when promising developments fail. Bio-pharmas are susceptible to broad swings in stock prices given the enormous cost-benefit scales involved in product development and revenue potentials. When high prices based on future prospects turn into disappointing losses, class action lawsuits are often not far behind.

The paradigmatic securities fraud case against bio-pharmas, as noted by one court of appeals, begins "where a promising drug or medical device is approved by the FDA and then later proves to have health risks which affect the market for the drug."⁶ The benefit-to-risk profile in both the scientific and investment realm are closely linked, but despite the high risks and

²Jennifer Corbett Dooren, *Kidney-Cancer Drug Gets Panel's Backing*, WALL ST. J., Oct. 6, 2009, at D3.

³*Id.*

⁴*Id.*

⁵Press Release, GlaxoSmithKline PLC, FDA Approves GlaxoSmithKline's Votrient for Advanced Renal Cell Cancer (Oct. 19, 2009).

⁶*N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 47 (1st Cir. 2008). Recent class action litigation includes: *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000) (holding that defendant corporation's statements regarding the inconclusiveness of the relationship between its weight-loss drugs Pondimin and Redux and heart-valve disorders did not constitute an actionable material misrepresentation or omission), and *In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187 (S.D.N.Y. 2008) (holding that investors did not sufficiently allege facts supporting an inference of scienter against the makers of MS drug, Tysabri).

uncertainties, investors are wont to cry foul when health concerns pop up during or after the FDA approval process. Responding to one such class action, a district court compared investing in an untested pharmaceutical product to investing in "an airplane company before Orville and Wilber Wright figured out how to make them fly: there was a huge upside potential but also a pretty good chance of losing everything."⁷ The court dismissed the plaintiff's securities fraud class action mindful of the fact that "securities laws do not exist to provide down-side investment insurance."⁸

Investment risks in bio-pharmas are different than all others because of the combination of (i) the enormous costs of product development, (ii) the magnitude of potential rewards, (iii) the complex, imprecise, and scientific nature in the products offered, and (iv) the active and often unpredictable role of the FDA in determining product marketability. These factors lead to uncertainty in forecasted results for a product before and, if FDA approved, after marketing has begun. As researchers are processing data, company executives are making disclosures to an interested investing public, disclosures often compelled by SEC reporting requirements or by the insatiable appetites of investment analysts. As noted in one survey of securities litigation:

Because life sciences companies are in the business of venturing into the unknown, their stock price is inherently volatile. Moreover, it is an unmistakable fact that only a small number of new drugs survive the FDA approval process, often leading sciences companies to face bad news concerning adverse events, patient harm, or unexpected results. . . . Thus, the volatility of a life sciences company's stock, the various challenges that these companies face in the life cycle of a drug, and the required disclosure of information are all factors that make life sciences companies particularly vulnerable to securities fraud class actions.⁹

⁷*In re Northfield Labs., Inc. Sec. Litig.*, 527 F. Supp. 2d 769, 784 (N.D. Ill. 2007). Coincidentally, one of the authors of this article also used the Wright Brothers history to analyze the securities laws. See Stuart R. Cohn, *The Impact of Securities Laws on Developing Companies: Would the Wright Brothers Have Gotten Off the Ground?*, 3 J. SMALL & EMERGING BUS. L. 315 (1999).

⁸*In re Northfield Labs.*, 527 F. Supp. 2d at 784.

⁹MICHAEL L. KICHLIN & DAVID A. KOTLER, DECHERT SURVEY OF SECURITIES FRAUD CLASS ACTIONS BROUGHT AGAINST LIFE SCIENCES COMPANIES I (2008), http://www.dechert.com/library/Survey_of_Securities_Fraud_CA_06-08.pdf. Accounting firm PricewaterhouseCoopers presents similar figures, suggesting that pharmaceutical industry class actions represented 9%, 13%, and 10% of federal securities class actions in 2006, 2007, and 2008,

Although investor disappointments abound, bio-pharmas often avoid securities liability because the Rule 10b-5 scienter requirement presents a high burden of proof for plaintiffs in most securities fraud class actions.¹⁰ However, the scienter requirement is far from an absolute safeguard for bio-pharmas. Scienter has been held to include "recklessness," a concept not far from gross negligence. One judge or jury's concept of gross negligence (which is not actionable under Rule 10b-5) may be another judge or jury's concept of recklessness.¹¹ Moreover, the complexities surrounding analysis of clinical trials, coupled with a company's natural inclination to trumpet early favorable test results, may provide enticing fodder for plaintiffs' counsel when later studies discount the earlier prognostications. Even if a bio-pharma succeeds at the motion to dismiss stage, substantial time, energy, and costs have been incurred in defending a securities fraud action, and the constant threat of litigation may adversely affect the free flow of information regarding product development.

The complex nature of pharmaceutical and biotech products and the high risks and rewards that attract investors have made this industry unusually susceptible to securities fraud litigation. According to Dechert's Survey of Securities Fraud Class Actions, litigation against "life sciences companies" represented approximately 13% of the class actions in 2006, 14% in 2007, and 10% in 2008, figures that are well above the proportionate number of bio-pharmas relative to all listed companies.¹² Part II of this article looks at the process of product development by pharmaceutical and biotech companies, including the FDA approval process and the uncertainty of the FDA response to clinical trial data provided by the company. Part III considers the difficulty in applying securities laws to pharmaceutical and biotech companies, in particular the lack of congruence between FDA and SEC standards, the interpretation of test and adverse reaction results, and the lack of judicial expertise in heavily scientific matters. It also considers the competing needs of companies to disclose information to investors with the need to avoid statements that could later be used as Plaintiff's Exhibit A if projections based on early clinical data prove to be incorrect. Part IV suggests reform through the increased use of court-appointed experts under

respectively. For 2009, the percentage increased to 14% of total filings, or 22 cases. PRICEWATERHOUSECOOPERS, 2009 SECURITIES LITIGATION STUDY 10-11 (2010), http://10b5.pwc.com/PDF/NY-10-0559%20SEC%20LIT%20STUDY_V7%20PRINT.PDF.

¹⁰ 17 C.F.R. § 240.10b-5 (2009).

¹¹ See generally *infra* note 125 and accompanying text.

¹² KOTLER, DECHERT LLP, DECHERT SURVEY OF SECURITIES FRAUD CLASS ACTIONS BROUGHT AGAINST LIFE SCIENCES COMPANIES 1, 2 (2009), http://www.dechert.com/library/Survey_of_Securities_Fraud_CA_4-09.pdf.

the Federal Rules of Evidence, inherent judicial authority, and Federal Rules of Civil Procedure. These reforms will assist in ameliorating the costs and risks imposed on bio-pharmas by securities fraud class actions.

II. THE PROCESS OF PRODUCT DEVELOPMENT AND RECALL

A review of the extended and complex processes underlying drug and product approvals is necessary in order to appreciate the disclosure demands imposed on publicly-traded bio-pharmas during the application and marketing periods. This Part II is a brief description of the application and continuing review processes, bearing in mind that at every stage there are highly sensitive disclosure concerns.

A. *Regulation of Pharmaceuticals and Medical Devices Prior to FDA Approval*¹³

Modern day pharmaceuticals are both a treatment to prevent or cure disease and a revenue generating product subject to strict regulation during their costly development, testing, production, marketing, and distribution processes. For each new pharmaceutical approved by the FDA, a company will spend, on average, between \$1.2 and \$1.3 billion dollars on research and development (R&D).¹⁴ This number has skyrocketed in recent years, representing an increase of \$500 million dollars since 2000.¹⁵ With the exception of a few blockbuster drugs, the commercial success rate of pharmaceuticals remains low. In fact, just two out of ten medicines ever produce revenues that match or exceed average R&D costs.¹⁶ In the United States, the average pharmaceutical firm will invest as much as five times more in R&D than the average manufacturing firm.¹⁷

The FDA was created under the Federal Food, Drug and Cosmetic Act of 1938 (FDCA). The FDCA requires that manufacturers, rather than

¹³The process described in this section is specific to pharmaceuticals. Medical devices that support or sustain human life undergo a similar approval process by the FDA. The process requires a Premarket Approval (PMA) application which includes data on safety and effectiveness, including required pre-clinical and clinical trial data. Information concerning medical device approval is found in 21 C.F.R. § 814.20-47 (2009).

¹⁴Pharm. Research and Mfrs. Of Am., *Pharmaceutical Industry Profile 2009*, 38-39 (2009), available at <http://phrma.org/files/attachments/PhRMA%202009%20Profile%20FINAL.pdf>.

¹⁵*Id.* at 39.

¹⁶*Id.*

¹⁷Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, 1, 9 (2006), available at <http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf>.

the FDA, prove the safety of a drug before it can be marketed.¹⁸ The FDCA also authorizes factory inspections and established penalties for fraudulent claims and misleading labels.¹⁹ Beginning in 1962, under the Kefauver-Harris Amendment, manufacturers were required to show not only a drug's safety for human use, but also a drug's efficacy through clinical investigations by qualified researchers.²⁰ Drug safety, quality, and efficacy remain the three key tenets in FDA drug approval today.

The FDA approval process is divided into three stages – a pre-clinical stage, a clinical stage, and a post-clinical stage. The pre-clinical stage begins when a pharmaceutical company identifies a promising molecule or compound that could be useful in treating a certain disease.²¹ For example, a researcher may identify an enzyme or protein that appears to be a critical link in the disease process and focus on inhibiting that enzyme or protein to create a treatment benefit.²² Once a particular molecule has been identified, it is tested in laboratory studies with animal subjects.²³ If promising data is found in animal subjects, the company files an Investigational New Drug application (IND)²⁴ with the Center for Drug Evaluation and Research (CDER) at the FDA. The IND application contains information in three broad areas: Animal Pharmacology and Toxicology Studies, Manufacturing Information, and Clinical Protocols which explain proposed human trials.²⁵ Once the IND is submitted, the company must wait thirty calendar days before initiating any clinical trials while the FDA reviews the application.²⁶

If the FDA does not object, the manufacturer may commence clinical trials. The trials occur in three phases. Phase I trials are aimed primarily at establishing drug safety and pharmacology.²⁷ Typically, between twenty and one-hundred healthy volunteers receive very low dosages of the investigational treatment.²⁸ On average, about two thirds of Phase I

¹⁸Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BD. OF FAMILY PRACT. 362, 363 (2001).

¹⁹*Id.*

²⁰*Id.* at 364.

²¹FDA, *How Drugs are Developed and Approved* (2009), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm>.

²²Lipsky & Sharp, *supra* note 18, at 364.

²³*See How Drugs are Developed and Approved, supra* note 21.

²⁴21 C.F.R. § 312 (2009); *see also* FDA, *Investigational New Drug (IND) Application* (2009), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>.

²⁵*IND Application, supra* note 24, at 2.

²⁶*Id.*

²⁷21 C.F.R. § 312.21(a) (2009); *see also* Lipsky & Sharp, *supra* note 18, at 365.

²⁸Lipsky & Sharp, *supra* note 18, at 365.

compounds will be found safe enough to progress to Phase II.²⁹ Phase II clinical trials are used to determine whether a new drug is effective in treating a particular ailment.³⁰ This phase also tests the appropriate dosage, method of drug delivery, and determines common short-term side effects.³¹ Phase II trials enroll between 100 and 300 patients with the disease the drug is intended to treat. If a drug is ineffective or produces extreme side effects it will not move forward to Phase III testing.³²

Phase III clinical trials aim to confirm previous findings in a larger population, establish efficacy for a particular condition, provide data on long-term side-effects, and consider additional population subsets.³³ The overall length of a Phase III trial is between two and ten years, depending on the nature of the drug or treatment.³⁴ The FDA has recognized that a lengthy clinical trial period may be inappropriate for certain high-priority medications, such as advanced HIV or cancer treatments. Where an unmet need and serious disease exists the FDA may permit an expedited review under the fast track, accelerated approval, or a priority review system.³⁵

If a drug remains promising after clinical trials, the company may file a New Drug Application (NDA) with the FDA³⁶ asking for FDA approval of a new pharmaceutical for sale and marketing in the U.S.³⁷ The

²⁹*Id.*

³⁰21 C.F.R. § 312.21(b) (2008) ("Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study . . .").

³¹Robert J. Meyer, Director, Office of Drug Evaluation II, FDA's Drug Approval Process (2004), available at <http://www.hhs.gov/asl/testify/t040401.html>.

³²Lipsky & Sharp, *supra* note 18, at 365.

³³21 C.F.R. § 312.21(c) (2009) ("Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained . . ."); see also Lipsky & Sharp, *supra* note 18, at 366.

³⁴Lipsky & Sharp, *supra* note 18, at 366.

³⁵Phase III testing may be significantly abbreviated if the FDA allows accelerated approval by using a surrogate endpoint for the study. A surrogate endpoint is essentially a marker, like a laboratory measurement or physical sign, used in clinical trials as an indirect or substitute measurement representing a clinically meaningful outcome, such as survival or symptom improvement. For example, CD4 cell counts could be used to measure the effectiveness of an antiviral medication in treating HIV-infected patients, or tumor shrinkage could be a physical sign representing the effectiveness of a cancer treatment. FDA, *Fast Track, Accelerated Approval and Priority Review* (2009), <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccessToImportantNewTherapies/ucm128291.htm>; see also Lipsky & Sharp, *supra* note 18, at 366.

³⁶Mary K. Olson, *PDUFA and Initial U.S. Drug Launches*, 15 MICH. TELECOMM. & TECH. L. REV. 393, 396 (2009); see also 21 C.F.R. § 314 (2009).

³⁷Aside from R&D costs the filing of an NDA is costly. Fees for an NDA requiring clinical data in the 2010 fiscal year are \$1,405,500. Prescription Drug User Fee Rates for Fiscal Year 2010, 74 Fed. Reg. 38,451, 38,455 (August 3, 2009).

NDA includes information about human and animal studies and also includes information about drug ingredients, the manufacturing process, packaging, and labeling.³⁸ FDA review teams of medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts use the NDA to determine whether the drug meets safety, quality, and efficacy standards.³⁹ The FDA typically acts to approve or deny the application within 365 days for a standard NDA, and within 180 days for an accelerated NDA.⁴⁰ If an NDA is approved, the drug may then be marketed in the United States.⁴¹

B. Regulation of Pharmaceuticals and Medical Devices After FDA Approval

In the United States, approximately four billion prescriptions are written each year and nearly 500,000 adverse events are reported.⁴² Yet only a fraction of a drug's possible reactions can be identified prior to public marketing.⁴³ This increases the importance of developing effective reporting structures and proper pharmacovigilance after a drug is marketed. The FDA has in place several pharmacovigilance practices including post-market surveillance, risk management plans, post-market studies (also known as Phase IV trials), and as a last resort, requests for product recalls.⁴⁴

1. Post-Market Surveillance and Adverse Event Reporting

Drug sponsors and consumers are the primary sources of post-

³⁸FDA, *New Drug Application (NDA)* (2010), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>.

³⁹Olson, *supra* note 36, at 396.

⁴⁰Drug approval time in the United States has fallen dramatically after introduction of the Prescription Drug User Fee Act (PDUFA) in 1992. PDUFA requires that pharmaceutical manufacturers pay fees to the FDA along with their NDAs. The fees are used to provide employees to process NDAs more rapidly. Olson, *supra* note 36, at 398-99. On September 27, 2007, President George W. Bush signed into law H.R. 3580, the Food and Drug Administration Amendments Act of 2007. This bill reauthorized the fees set forth in PDUFA. See FDA, *Prescription Drug User Fee Act (PDUFA)* (2010), <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>; see also 21 C.F.R. § 314.100 (2009).

⁴¹Lipsky & Sharp, *supra* note 18, at 366.

⁴²Laura B. Faden & Christopher-Paul Milne, *Pharmacovigilance Activities in the United States, European Union and Japan: Harmonic Convergence or Convergent Evolution?*, 63 FOOD DRUG L.J. 683, 683-84 (2008).

⁴³LARS NOAH & BARBARA A. NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS 267 (Foundation Press 2002).

⁴⁴See Lipsky & Sharp, *supra* note 18, at 366.

market surveillance. Currently, drug sponsors are required to report adverse drug experiences that occur after the drug is on the market.⁴⁵ Within fifteen days after receiving a report of a serious and unexpected adverse experience, the drug sponsor must submit a "15-day Alert Report" to the FDA.⁴⁶ Additional periodic reporting is also required every quarter for the first three years after approval and annually after the third year.⁴⁷ In addition to mandatory reporting, the FDA has provided guidance to drug sponsors in three risk management documents,⁴⁸ including the FDA Good Pharmacovigilance Practice and Pharmacoepidemiological Assessment.⁴⁹ This document provides nonbinding recommendations on how to identify and evaluate safety signals that are being received from the market and recommends that drug sponsors conduct pharmacoepidemiological studies, patient registries, and surveys of patients and providers.⁵⁰

In addition to sponsor reporting, the FDA's Office of Surveillance and Epidemiology (OSE) collects information from health care professionals and consumers using the MedWatch program, which is entered into the Adverse Event Reporting System database (AERS).⁵¹ The FDA is responsible for bi-weekly screenings of AERS and must post quarterly

⁴⁵21 C.F.R. § 314.80 (2010); *see also* Faden & Milne, *supra* note 42, at 686 (2008).

⁴⁶Serious adverse drug experiences are considered to be any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. This list is not exclusive and the FDA allows other events to be considered serious adverse drug experiences upon appropriate medical judgment. Unexpected adverse drug experiences are any adverse drug experience that is not listed in the current labeling for the drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity. "Unexpected," as used in this definition, refers to an adverse drug experience that has not been previously observed (i.e., included in the labeling) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product. 21 C.F.R. § 314.80(a) (2009); *see also* 21 C.F.R. § 314.80(c).

⁴⁷21 C.F.R. § 314.80(c)(2).

⁴⁸*See* U.S. DEP'T. OF HEALTH AND HUMAN SERVICES, GUIDANCE FOR INDUSTRY: PREMARKETING RISK ASSESSMENT 2 (2005), *available at* http://www.fda.gov/ohrms/dockets/ac/05/briefing/20054136b1_01_Premarket%20Risk%20Assessment.pdf; U.S. DEP'T OF HEALTH AND HUMAN SERVICES, GUIDANCE FOR INDUSTRY: DEVELOPMENT AND USE OF RISK MINIMIZATION ACTION PLANS 1 (2005), *available at* http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-136b1_03_Risk%20Minimization%20Action%20Plans.pdf [hereinafter RISKMAPS]; U.S. DEP'T. OF HEALTH AND HUMAN SERVICES, GUIDANCE FOR INDUSTRY: GOOD PHARMACOVIGILANCE PRACTICES AND PHARMACOEPIDEMIOLOGICAL ASSESSMENT 1 (2005), *available at* <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf> [hereinafter GOOD PRACTICES].

⁴⁹GOOD PRACTICES, *supra* note 48, at 1.

⁵⁰*Id.* at 12-17.

⁵¹FDA, *Adverse Event Reporting System (AERS)* (2009), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

reports of safety risks identified in the last quarter.⁵² If a potential safety concern is identified in the AERS, further evaluation might include epidemiological studies or regulatory action to improve product safety and protect the public health.⁵³ Possible actions include updating a product's labeling information, restricting the use of the drug, communicating new safety information to the public, or, in rare cases, removing a product from the market.⁵⁴

2. Risk Management

The FDA can require a company to submit a Risk Evaluation and Mitigation Strategy (REMS) plan for a drug if there is a need to ensure that the benefits of a drug outweigh the risks associated with use of that drug.⁵⁵ The REMS includes mechanisms to limit known or potential risks like use of a medication guide or a patient package insert. To assure safe use of products, the REMS may "require health care providers that prescribe the drug, and pharmacies, practitioners or healthcare settings that dispense the drug to undergo special training or certification," and to provide for patient enrollment in drug registry.⁵⁶ The FDA is presently using this strategy to increase preemptive safety. According to one drug safety expert, "[t]he FDA has, during the past eight years of risk management and REMS programs, moved beyond reacting to drug safety crises with new regulations to trying to prevent crises before they happen."⁵⁷ In lieu of a full REMS, the FDA may recommend a voluntary Risk Management Action Plan (RiskMAP) for products with increased risk benefit profiles.⁵⁸ The elements of a REMS and RiskMAP are similar, but the RiskMAP is entirely voluntary and is used primarily to "meet specific *goals* and *objectives* in minimizing known risks of a product while preserving its benefits."⁵⁹

⁵²See Food and Drug Administration Amendments Act, H.R. 3580, 110th Cong. § 921 (2007).

⁵³*AERS*, *supra* note 51, at 1.

⁵⁴*Id.*

⁵⁵See 21 U.S.C. § 355-1(a)(1) (2006) (describing the Secretary's ability to require a company to submit a risk evaluation and mitigation strategy).

⁵⁶Faden & Milne, *supra* note 42, at 687.

⁵⁷*FDA Shifts to Pre-Emptying Drug Risks as REMS Program Reaches 'Terrible 2'*, PRNEWswire, Nov. 11, 2009, http://www.briart.com/artcile.php?id=prnw.20091111.PH09487&show_article=1.

⁵⁸See RISKMAPS, *supra* note 48, at 3-12 (explaining the role of RiskMAPs in risk management and reasons for implementation).

⁵⁹*Id.* at 5.

3. Phase IV Trials

Phase IV trials, or post-marketing commitments, are primarily conducted to study long-term effects of the product, to determine additional risks, benefits, or optimal usages of the medication, or to study populations that were underrepresented in clinical trials.⁶⁰ These studies may be voluntary or, under certain circumstances, mandated by the FDA.⁶¹ Phase IV trials are often used as a condition for approval by the FDA and are agreed to by the drug sponsor in order to get the drug to market.⁶² Other instances of mandatory Phase IV trials include drugs that obtained accelerated approval,⁶³ drugs approved only on the basis of animal efficacy data,⁶⁴ or drugs approved for adults before pediatric studies could be conducted.⁶⁵

4. Product Recall

The FDA recognizes two methods of recall—voluntary recall and recall at the request of the FDA.⁶⁶ Most drug recalls are voluntary and initiated by the manufacturer or distributor after discovery of a serious danger posed by the product.⁶⁷ The FDA's principal role in a voluntary recall "is to oversee a company's strategy and assess the adequacy of the recall,"

⁶⁰See U.S. DEP'T. OF HEALTH AND HUMAN SERVICES, GUIDANCE FOR INDUSTRY: REPORTS ON STATUS OF POSTMARKETING STUDY COMMITMENTS IMPLEMENTATION OF SECTION 130 OF THE FOOD AND DRUG MODERNIZATION ACT OF 1997, 1-6 (2006), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080569.pdf> (providing background information on postmarket studies).

⁶¹See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(a), 121 Stat. 922, 926 (2007) (codified at 21 U.S.C. § 355-k (2008)) (expanding the FDA's authority to require Phase IV trials by adding §505(o) to the Food, Drug, and Cosmetic Act); see also 21 U.S.C. § 356b (2006) (permitting the FDA to monitor postmarketing study commitments).

⁶²See 21 U.S.C. § 355(k) (2006), amended by 21 U.S.C. § 355(k)(3)-(5) (Supp. II 2008) (describing post-market requirements).

⁶³See, e.g., 21 C.F.R § 314.510 (2010) (setting forth the regulation that the FDA may approve marketing for a new drug based on surrogate endpoint); see also 21 C.F.R § 314.530 (2009) (setting forth the safety standards to which accelerated approval drugs must comply).

⁶⁴See 21 C.F.R § 314.610 (2010) (stating that if clinical studies in humans cannot be conducted ethically, FDA may approve a drug solely on animal studies and require the sponsor to conduct postmarket studies to verify safety and efficacy in humans).

⁶⁵See *id.* § 314.55 (2010) (requiring applicants of all new drugs likely to be used in pediatric patients to demonstrate safety and efficacy in pediatric populations prior to approval, in some cases, the FDA will grant deferral of this requirement and require the sponsor to conduct post-market studies).

⁶⁶See *id.* § 7.40(b) (2010). See generally *id.* §§ 7.40-7.59 (explaining the FDA drug recall policy and procedures).

⁶⁷See FDA 101: Product Recalls- From First Alert to Effectiveness Checks (2009), available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm>.

rather than to initiate the recall.⁶⁸ The FDA generally requests a product recall only in urgent situations.⁶⁹ For example, on March 30, 2007, the FDA requested that Novartis Pharmaceuticals Corporation voluntarily cease the marketing of Zelnorm, a drug used to treat Irritable Bowel Syndrome, because of serious cardiovascular adverse events (e.g., angina, heart attacks, and strokes) associated with the drug.⁷⁰

Throughout February and March 2007, Novartis reported to the FDA the results of a new analysis of 29 short-term (1 - 3 months) randomized, controlled clinical trials of Zelnorm. . . . Thirteen Zelnorm-treated patients (or 0.1%) had confirmed cardiovascular ischemic events, and only 1 placebo-treated patient (or 0.01%) with an event.⁷¹

The FDA concluded that for most patients the benefits of the drug no longer outweighed the risks.⁷²

C. *The Pressure to Disclose During Product Development*

At each stage of product development, bio-pharmas are faced with sensitive and often difficult disclosure decisions. When an IND application has been filed and clinical trials are ongoing, companies face pressure for early and frequent releases of information regarding the results of clinical trials.⁷³ Mandatory disclosures may be required under the SEC periodic reporting requirements or exchange disclosure requirements in addition to voluntary disclosures in the form of press releases or publication of information about what is in the product "pipeline."⁷⁴ Investors, like

⁶⁸*Id.*

⁶⁹See 21 C.F.R. § 7.40(b) (describing Food and Drug Administration requested recall).

⁷⁰See Press Release, U.S. Food and Drug Admin., FDA Announces Discontinued Marketing of GU Drug, Selnorm, for Safety Reasons (March 30, 2007), available at <http://fda.gov/newsevents/newsroom/pressannouncements/2007/ucm108879.htm>.

⁷¹*Id.*

⁷²See *id.*; see also Matthew Herper, *FDA to Novartis: Stop Selling Zelnorm*, FORBES.COM, Mar. 30, 2007, http://forbes.com/2007/03/30/novartis-fda-drug-biz-cx_mh_0330novartis_print.html.

⁷³See Liora Sukhatme, *Deterring Fraud: Mandatory Disclosure and the FDA Drug Approval Process*, 82 N.Y.U. L. REV. 1210, 1218-22 (2007) (discussing pressures faced by pharmaceutical companies).

⁷⁴See generally 21 C.F.R. § 314.430 (2010) (discussing availability of public disclosure). A survey of major drug company's websites including: Merck, Pfizer, GlaxoSmithKline, Eli Lilly, AstraZeneca, and Bristol-Myers Squibb revealed that each company has a section devoted to listing what drugs are in its product development portfolio. The drugs are often categorized by stage in

investment analysts, also have an insatiable appetite for information on the next big breakthrough, causing persistent pressure upon bio-pharmas for their latest evaluation of the accumulating data.⁷⁵

Disclosure concerns persist during the FDA evaluation process. The FDA regularly communicates with applicants concerning scientific, medical, and procedural issues that arise during the review process.⁷⁶ Communications from the FDA may generate disclosure requirements because NDA deficiencies or inquiries may be considered material to investors.⁷⁷ Even if a product is approved by the FDA, disclosure hazards will continue to surface as adverse events are reported or post-marketing commitments, like Phase IV trials, demonstrate unforeseen health risks. As evidenced by such notorious post-FDA approved recalls as Vioxx or Celebrex, a bio-pharma's exposure to significant securities laws claims is never eliminated.⁷⁸

III. FACTORS AFFECTING BIO-PHARMA SUSCEPTIBILITY TO SECURITIES CLASS ACTIONS

There is no publicly-traded industry comparable to bio-pharmas with regard to the uncertainties of risk-reward potentials.⁷⁹ During the course of product development there will be numerous ups and downs, testing successes, interpreted and reinterpreted calculations, retesting projects, product re-configurations, and usage reformulations prior to an NDA filing. By this time the company has spent millions, and test results have been

development and type of indication (i.e., anemia, depression, pain, COPD), as well as what phase certain drugs are in the product development pipeline.

⁷⁵See Sukhatme, *supra* note 73, at 1216 (explaining investor interest).

⁷⁶21 C.F.R. § 314.102(a) (2010) (describing the general principles of communication between the FDA and applicants).

⁷⁷Communication between the FDA and drug sponsors is not public information. Communication in a response letter, for example that a drug is approvable or not approvable, may give rise to disclosure obligations under the securities laws. *See id.* § 314.430 (2010) (covering availability for public disclosure of data and information in an application or abbreviated application); *see also* Sukhatme, *supra* note 73, at 1219-21 (recommending public disclosure of FDA communications).

⁷⁸See Jonathan V. O'Steen & Van O'Steen, *The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries Resulting From Defective Drugs*, 48 ARIZ. L. REV. 67, 67-70 (2006) (discussing the trend towards preemption of state claims when an FDA-approved drug is the subject of the claim).

⁷⁹The development of a new line of automobiles, for example, may be comparable in terms of costs and time-lines, but once the automobile has been developed it is not subject to termination based on agency suspension or unforeseen adverse health reactions. Even the exploding Pinto was not withdrawn from the market, despite numerous tort actions. If manufacturers ultimately engage in recalls, the automobiles remain in the market. On the contrary, product recalls for bio-pharmas generally result in at least an extended, if not permanent, elimination of the product from the market.

sufficient to move forward but not conclusive as to eventual success.⁸⁰ The bio-pharma may think that it is onto a major new product, but the company knows that there are numerous hurdles to clear before fruition. Disclosure concerns become even more sensitive once the company files an NDA. The FDA review process can take anywhere from months to years. The company has no control over FDA timing, yet the investing public is eager to learn every bit of progress.⁸¹ The bio-pharma is also in a state of uncertainty. FDA communications with the company, which are confidential, may be pointed and sometimes negative, but do not necessarily indicate an end result.⁸² The bio-pharma is caught between wanting to express confidence in its research capacities and not wanting to overly-excite potential investors. Yet disclosure is demanded. If, in hindsight, the company's initial announcements are too negative, the *SEC v. Texas Gulf Sulphur* scenario might arise for disappointed stock sellers.⁸³ If the company was too positive, disappointed buyers will constitute the class.⁸⁴

FDA product or device approval is a major milestone, yet it is simply one step along the continuum of disclosure risks and concerns. FDA and company monitoring of potential adverse reactions and unintended effects is a never-ending process that could lead to swift and surprising market recalls. The FDA may recommend recalls without evidence of actual harmful effects in order to further evaluate a product.⁸⁵ If even a temporary recall occurs, stock prices may be affected and it will be difficult to resuscitate a product's market position, leaving the company once again vulnerable to litigation by disappointed investors.⁸⁶

⁸⁰See Sukhatme, *supra* note 73, at 1218 ("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.").

⁸¹See *id.* at 1217 (describing investor's behavior).

⁸²See *id.* at 1221 (quoting acting FDA Commissioner as saying "the policy of the FDA is to reveal nothing").

⁸³See *SEC v. Texas Gulf Sulphur*, 401 F.2d 833, 863-64 (2d Cir. 1968) (holding that an injunction may be issued if a company releases misleading statements which are meant to affect the company's market price).

⁸⁴See *supra* notes 8-9 and accompanying text.

⁸⁵E.g., Jennifer Corbett Dooren & Jared A. Favole, *FDA Calls for Temporary Halt in Use of Glaxo's Rotavirus Vaccine*, WALL ST. J., Mar. 23, 2010, at D6 ("The Food and Drug Administration recommended Monday that doctors temporarily stop using GlaxoSmithKline PLC's Rotarix child vaccine after parts of an extraneous virus were found in the product. . . . The FDA said that while there is currently no evidence of a safety risk associated with the vaccine, it needed to learn more.").

⁸⁶See, e.g., *GlaxoSmithKline Profit Plunges After Avandia, Paxil Legal Costs*, THE FINANCIAL, July 10, 2010, available at http://finchannel.com/news_flash/Pharmacy/67833_Glaxo_SmithKline_Profit_Plunges_After_Avandia,_Paxil_Legal_Costs/ (noting that Rotarix stock was

A. *Disclosure Pressures and Obligations*

Pressure for early and frequent release of information regarding product development comes from several sources:

(1) SEC Periodic Reporting Requirements

The Form 10-Q and Form 10-K both require 1934 Act reporting companies to include Management's Discussion and Analysis of Financial Condition and Results of Operations.⁸⁷ Although much of that information is explanatory as to past results, Instruction 3 to Item 303(a) requires the discussion to "focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition."⁸⁸ This is a call for soft, forward-looking information, exactly the type of information that might be suitable for products in the development stage with high potential revenue-generating capacities.

(2) Exchange Disclosure Requirements

Publicly-listed companies are expected to provide to the investing public a continuous disclosure of material information. The New York Stock Exchange Manual, for example, states that, "[a] listed company is expected to release quickly to the public any news or information which might reasonably be expected to materially affect the market for its securities."⁸⁹ Early test results for bio-pharma products may well be material, given the enormous costs sunk into research and the high market interest in potential outcomes. Bio-pharmas may justifiably conclude that securities laws concerns obligate them to make early and ongoing public announcements well before additional and more definitive clinical trials are completed.

(3) Regulation FD

Market analysts and others involved in the securities industry put enormous pressure on publicly-traded

significantly impacted by the FDA recall).

⁸⁷See 17 C.F.R. § 229.303 (2010) (describing the Management's Discussion and Analysis of Financial Condition and Results of Operations inclusion of forward-looking statements).

⁸⁸*Id.* at instruction 3.

⁸⁹New York Stock Exchange Manual, § 202.5, available at <http://www.nysemanual.nyse.com>.

companies to disclose pending developments, projections, and other information that may not have yet been publicly disclosed. That is their job and they do it well. So well, in fact, that the SEC felt compelled to issue Regulation FD to assure that market-sensitive information is not selectively disclosed.⁹⁰ With bio-pharmas, the inquiries can be particularly intense as potential products move from early to later clinical trials and then to potential formal marketing approval by the FDA. Company press releases, which may have been carefully couched in cautionary language, may generate a flood of inquiries regarding the facts behind the release, company projections, and current testing programs.⁹¹ Bio-pharma executives cannot readily shut off such inquiries, as the companies need to maintain solid relationships with Wall Street for capital resource purposes. Answers to inquiries however may inadvertently reveal material information that must, pursuant to Regulation FD, be disclosed to the public.⁹² The result may be an even more heated market than is merited or intended.

The disclosure obligations noted above raise uniquely sensitive concerns for bio-pharmas by reason of market pressures, factual uncertainties, potential government intervention, and length of time during which all of these factors exist. Exacerbating these factors is the fact that clinical trial results and evaluations often run into the thousands of pages and

⁹⁰See Selective Disclosure and Insider Trading, Exchange Act Release No. 43,154, [2000 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 86,319, at 83,676 (Aug. 15, 2000). Regulation FD is set forth at 17 C.F.R. §§ 243.100-103 (2009).

⁹¹See William O. Fisher, *Key Disclosure Issues for Life Sciences Companies: FDA Product Approval, Clinical Test Results, and Government Inspections*, 8 MICH. TELECOMM. & TECH. L. REV. 115, 117 (2001-2002) ("The recent adoption of Regulation FD emphasizes that life sciences companies must communicate information on . . . key subjects directly, often making announcements in these critical areas to a market that has not been alerted by analysts who have anticipated the news. All of this increases the pressure on biotech executives who address the investment community.").

⁹²Regulation FD requires that if there is an intentional disclosure of material information to securities professionals, meaning that the person making the disclosure either knew, or was reckless in not knowing, that the information is both material and nonpublic, the company must make a simultaneous public disclosure. If the disclosure is unintentional, meaning that the person making the disclosure did not know or was not reckless in not knowing, that the information was material and nonpublic, the company must make public disclosure promptly, meaning within 24 hours after initial disclosure or commencement of the next day's trading. 17 C.F.R. §§ 243.100(a), 243.101(a), (d).

contain scientific and research data readily subject to alternative interpretations. Yet the bio-pharma must distill this voluminous and multi-faceted information into short, comprehensible press releases and statements for the investment community. Inherent within this process is that not all information will be disclosed, as judgments are made as to current interpretations and potential materiality.

The bio-pharma's disclosure dilemma is illustrated by a class action brought against a pharmaceutical that, having announced favorable Phase II results, subsequently announced that preliminary Phase III results were not favorable.⁹³ Plaintiffs argued that the Phase II announcement was misleading because it failed to reveal numerous allegedly material factors and results.⁹⁴ The court dismissed plaintiffs' charges in an opinion that was perceptive yet somewhat troubling:

The securities laws do not impose a requirement that companies . . . who report information from imperfect studies include exhaustive disclosures of procedures used, including alternatives that were not utilized and various opinions with respect to the effects of these choices on the interpretation of the outcome data. . . . *Reasonable minds could differ with respect to the value of the Colorado [Phase II] study in determining the therapeutic effects of Auriculin. Reasonable minds cannot conclude, however, that defendants' failure to exhaustively catalogue those possibilities was fraudulent.*⁹⁵

Although the defendant bio-pharma won, the court's reference to reasonable minds differing provides cold comfort, as a different judge may have reasonably concluded that the value of the Phase II study was so affected by the omitted information that the defendant's motion to dismiss could not be granted. The latter conclusion is precisely what occurred in *In*

⁹³Padnes v. Scios Nova Inc., No. C 95-1693 MHP, 1996 WL 539711, at *1 (N.D. Cal. Sept. 18, 1996).

⁹⁴Scios Nova was testing a drug to treat acute renal failure. A press release issued after a Phase II study stated that the drug had demonstrated a statistically significant reduction in the need for dialysis. The preliminary Phase III results failed to confirm that the drug reduced the need for dialysis. Plaintiffs argued that the company failed to reveal Phase II results showing that (a) the drug did not increase urine flow rates, (b) it had no substantial effect on glomerular filtration or changes in serum creatinine, (c) different dosages and routes of administration were used, (d) a higher percentage of control-group patients received vasopressors, and (e) diuretics were not administered to control-group patients after the first 24 hours. Plaintiffs also challenged that the dialysis results were statistically significant. *Id.* at *2.

⁹⁵*Id.* at *5 (emphasis added).

re Biogen Securities Litigation,⁹⁶ in which plaintiffs sued on the basis of a press release following preliminary Phase II trials stating that the test results looked "very good" and that "we have a very large potential market for the drug."⁹⁷ The statements were not based on the endpoint results as initially conceived for the study, which had not been met, but rather were based on a post-study conclusion that the drug provided other unanticipated favorable results.⁹⁸ It was on this basis that the company issued its optimistic statements. Plaintiffs' challenge could well have been dismissed by some judges, as in the *Scios Nova* case,⁹⁹ on the ground that reasonable minds might have differed as to the value of the Phase II study but that the optimistic evaluation based on a post-study change in direction was not fraudulent. That was not the court's conclusion, however, as it denied defendants' motion for summary judgment based upon the failure to disclose that the study's primary endpoint as initially conceived was not realized.¹⁰⁰ These fine distinctions are forced upon courts by the complexities of the multiple analyses processes inherent in the bio-pharma industry.

B. *The Disclosure Trigger: Materiality or Statistically Significant?*

Complicating the analysis paradigm for bio-pharmas is the issue of materiality. Whether a particular event is material can often be a borderline call for any company, but the question is especially difficult for bio-pharmas. Two factors exacerbate the difficulty. One is the serious health concerns that are at issue. Given the public's sensitivity to health concerns, when do adverse health results become material? Is one death sufficient to raise concerns? The materiality concerns when health is at stake are in a much different class than claims that financial statements are misleading or that facts regarding merger negotiations have been improperly withheld. Death and drug-related illness have low levels of public tolerance. If materiality is judged by what the reasonable person would consider important in making an investment decision, the public intolerance to adverse health reports may create a materiality issue even though, from the bio-pharma's more scientific-oriented perspective, there is still much more data to be collected.

The bio-pharma's perspective leads to the second difficulty in assessing materiality. The entire process of drug or product development is

⁹⁶*In re Biogen Sec. Litig.*, 179 F.R.D. 25 (D. Mass. 1997).

⁹⁷*Id.* at 30-31.

⁹⁸*Id.*

⁹⁹*See generally* *Padnes v. Scios Nova Inc.*, 1996 WL 539711, (N.D. Cal. Sept. 18, 1996).

¹⁰⁰*In re Biogen Sec. Litig.*, 179 F.R.D. at 39.

founded on tests and trials that provide "statistically significant"¹⁰¹ evidence that it is not chance but rather the drug or product that is causing the desired results. Moreover, and here is where substantial litigation arises, once the drug or product is in the market and unexpected adverse health events begin to appear, the bio-pharma must determine whether those results are "statistically significant" to warrant public disclosure, recall, or suspension.¹⁰² This is an especially difficult task, as the adverse event numbers are generally in low fractions of total usage. Moreover, the users of the drugs or products are often in a weakened condition to begin with and it may not be clear whether the apparent adverse results are due to the drug or are "opportunistic" consequences of pre-existing conditions.¹⁰³ Bio-pharmas make their determinations based on statistically significant results following analysis of substantial scientific data. Yet, statistical significance is not the same as the securities' law standard of materiality.

The lack of congruence between the securities' law standard of "materiality" and the bio-pharmas' "statistically significant" testing standards was illustrated in *In re Pfizer, Inc. Securities Litigation*,¹⁰⁴ a class action brought by Pfizer shareholders based on allegedly misleading statements by

¹⁰¹Tests of statistical significance are used to determine whether a relationship exists between two variables. A statistical analysis proceeds by testing a "null hypothesis" that there is no relationship between two variables against an "alternative hypothesis" that some specified relationship exists. The generally accepted confidence interval in scientific studies is ninety-five percent, meaning that a study is not statistically significant unless the "null hypothesis" of no relationship can be excluded with ninety-five-percent confidence. This means that the probability the observed finding occurring by chance is not greater than 5 times out of 100 (a p-level of 0.05). See generally LEE BURCHINAL, METHODS FOR SOCIAL RESEARCHERS IN DEVELOPING COUNTRIES 1, 511 (2008), http://srmdc.net/srmdc_022208.pdf.

¹⁰²Medical device and drug manufacturers need not disclose isolated reports of harm suffered by users of their products until those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the products and are sufficiently serious and frequent to affect future earnings.

Plumbers & Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc., 673 F. Supp. 2d 718, 741 (S.D. Ind. 2009) (quoting *In re Medtronic Inc., Sec. Litig.*, 618 F.Supp.2d 1016, 1023 (D. Minn. 2009)).

¹⁰³Attempting to determine whether adverse events were caused by the administered drug or by the already weakened physical condition of the patients (the latter being so-called "opportunistic" results) is one of the most difficult and challenging problems facing bio-pharmas and the FDA. In a class action against Biogen, Idec, Inc. based on the drug Tysabri that was pulled from the market after some adverse event reports, including deaths by multiple sclerosis users, the FDA's Deputy Director of Neurology Products stated "[w]e were not impressed that the overall mortality rate was markedly different than [what] we might expect in MS studies." *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 50 (1st Cir. 2008). In other words, the FDA's conclusion was that the totality of the adverse events was more likely based on opportunistic results rather than caused by the administered drug. This, however, is an area rife with difficult line-drawing.

¹⁰⁴*In re Pfizer, Inc. Sec. Litig.*, 584 F. Supp. 2d 621 (S.D.N.Y. 2008).

Pfizer over a five-year period regarding its Bextra and Celebrex drug products.¹⁰⁵ Three studies conducted by Pfizer during the five-year period had each indicated adverse cardiovascular events associated with the drugs.¹⁰⁶ When the negative results were finally revealed, the FDA directed that Bextra be removed from the market and a "black box" warning be put on Celebrex's label.¹⁰⁷ A drop in Pfizer's share price immediately followed.¹⁰⁸ In the ensuing Rule 10b-5 litigation, Pfizer's motion to dismiss asserted that the withheld information regarding the test results was not material because the results were not statistically significant.¹⁰⁹ Pfizer cited *In re Carter-Wallace Inc. Securities Litigation*, in which the Second Circuit Court of Appeals stated: "[d]rug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings."¹¹⁰

Having based its argument on the lack of statistical significance, Pfizer asked the court to take judicial notice that 5% is the commonly regarded threshold for the statistically significant standard.¹¹¹ The court refused, noting that: "[i]t is one thing to take notice of the fact that an author has written that 5% is the threshold for statistical significance. It is quite another thing entirely to use that 5% figure as a basis for rejecting the significance of complicated medical studies."¹¹²

Having rejected the dominance of the statistically significant standard, the court needed to emphasize that *In re Carter-Wallace* and similar decisions cited by Pfizer did not substitute a statistically significance standard for the more abstract materiality standard: "[a]lthough the *Carter-*

¹⁰⁵*Id.* at 629-30.

¹⁰⁶*Id.*

¹⁰⁷"A black box warning is the most negative warning the FDA uses, and is the last step before a drug is pulled from the market." *Id.* at 631.

¹⁰⁸"During the Class Period, Pfizer's stock rose to a high of \$47.44 per share before falling to \$21.09." *In re Pfizer*, 584 F. Supp. 2d at 631.

¹⁰⁹"Defendants . . . contend that they had no duty to disclose the results of the three studies at the core of Plaintiffs' complaint because the results were not statistically significant and thus were immaterial." *Id.* at 633; *accord* *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1178 (9th Cir. 2009) (concluding that "the district court erred in relying on the statistical significance standard to conclude that Appellants failed adequately to allege materiality").

¹¹⁰*In re Pfizer Inc., Sec. Litig.*, 584 F. Supp. 2d at 633 (quoting *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998)). Pfizer also relied upon *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000), holding that undisclosed adverse reports had not provided statistically significant information.

¹¹¹*In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d at 634.

¹¹²*Id.*

Wallace and *Oran* decisions stand for the proposition that isolated adverse event reports, lacking statistical significance, do not prove that a drug is unsafe, . . . the decisions 'do not hold that adverse event reports are always immaterial.'¹¹³

Other courts have similarly noted that omitted information may be material for securities law purposes even in the absence of statistically significant evidence.¹¹⁴ If statistical significance, the measuring rod for fundamental decisions in the bio-pharma industry, is not the equivalent of materiality, the disclosure standard for securities law purposes, case law has created a liability trap for bio-pharmas who rely upon statistical evidence. If test results or adverse reports can be characterized, contemporaneously or in hindsight, as statistically significant, using industry measures, materiality is proven. But if such results or reports cannot be so characterized, materiality may nevertheless be present depending upon a court's judgment as to severity and impact. The clear clash between the ostensibly objective, numerically based standard of the bio-pharma industry and the amorphous standard of the securities laws presents an enormous liability risk to the bio-pharmas.¹¹⁵

The statistical significance-materiality dichotomy may be heading towards resolution. In *Siracusano v. Matrixx Initiatives, Inc.*,¹¹⁶ plaintiffs alleged that the defendant pharmaceutical company engaged in misrepresentations and withheld accumulating adverse event reports. The company was well aware of the reports but, during the critical period, publicly denied their statistical significance.¹¹⁷ The District Court, choosing

¹¹³*Id.* at 636 (quoting *In re Bayer AG Sec. Litig.*, No. 03 Civ.1546 WHP, 2004 WL 2190357, at *8 (S.D.N.Y. Sept. 30, 2004)).

¹¹⁴*In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 210 (S.D.N.Y. 2008) (holding that omitted information "may become material even in the absence of statistically significant evidence in light of other indications that the risk associated with adverse . . . events is legitimate and serious enough to threaten . . . sales").

¹¹⁵The facts in *In re Carter-Wallace, Inc. Securities Litigation*, illustrate the disclosure dilemma caused by adverse event reports. Carter-Wallace had received reports of six deaths during a five month period related to the use of its drug, Felbatol. Only when four more deaths occurred in a single month did the company advise the FDA. In the ensuing litigation, the court noted that the four deaths occurring in a single month prompted the disclosure and that "the earlier reports are not by themselves sufficient to support inferences of either actual knowledge or recklessness." *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998). By what standard did the court make its conclusion? Six deaths over five months were not material until there was added four deaths within a month. Other courts might well have found that the prior six deaths were material. If there is no numerical standard, how is a company to judge its liability risks while assessing the impact of incoming data?

¹¹⁶*Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167 (9th Cir. 2009), *cert. granted*, 130 S. Ct. 3411 (June 14, 2010).

¹¹⁷Following an article in the Dow Jones Newswires referring to FDA concerns and lawsuits

to apply the statistically significant standard adopted by the Second Circuit in *In re Carter Wallace, Inc. Securities Litigation*, dismissed the Rule 10b-5 complaint, finding that there was no materiality because the number of adverse events was not “statistically significant.”¹¹⁸

The 9th Circuit reversed, holding that “the district court erred in relying on the statistical significance standard to conclude that Appellants failed adequately to allege materiality.”¹¹⁹ In rejecting the statistical significance standard, the 9th Circuit focused on what it referred to as a “fact-specific inquiry” to determine materiality, based on what a reasonable investor would have considered significant.¹²⁰ The court then went on to recount nine instances of adverse events reported to Matrixx over a 4 1/2 year period, concluding that these reports were sufficient to meet pleading standards for materiality. In June, 2010, the Supreme Court granted certiorari. The split among the circuits regarding the appropriate materiality standard is the apparent basis for the Court’s acceptance of the case.

If the Supreme Court sides with Matrixx and bio-pharma advocates for the statistical significant standard,¹²¹ a major uncertainty in Rule 10b-5 litigation may be resolved. It should not be supposed that judicial acceptance of a statistical standard, however, will necessarily relieve bio-pharmas of litigation concerns. Experts will continue to argue over statistics, whether they are reliable, whether they represent proper subsets of data, and whether the so-called adverse events are in fact the result of the particular drug or device instead of other factors. Courts will continue to be faced with a plethora of data and conflicting expert interpretations. Our concern regarding judicial competence in this arena, discussed more fully in Part IV, is not likely to be substantially alleviated regardless of which way the statistical significant-materiality dichotomy is resolved.

C. *The Scierter Defense: Not Always What It's Cracked Up To Be*

Rule 10b-5's scienter requirement is plaintiff's principal burden and the main reason for dismissal of class action litigation. In Dechert's survey of 25 securities fraud class actions filed against bio-pharmas in 2007, as of

filed against Matrixx, the company issued a press release stating that “[t]he overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.” 585 F. 3d at 1173.

¹¹⁸*Id.* at 1178.

¹¹⁹*Id.*

¹²⁰*Id.* The “fact-specific inquiry” phrase was taken from *Basic Inc. v. Levinson*, 485 U.S. 224, 240 (1988).

¹²¹At least four pharmaceutical industry groups have filed *amicus curiae* briefs in support of the statistical significant standard for purposes of Rule 10b-5 materiality determination. See 42 Sec. Reg. L. Rep. 1675 (BNA) (Sept. 3, 2010).

April 2009, motions to dismiss for lack of sufficiently pled scienter had succeeded in 11 cases, and such motions were pending in eight other cases.¹²²

If the motions are granted in only half of the eight cases, that would result in 15 of the 25 cases, 60%, being dismissed for lack of well-pled scienter. Plaintiff's burden is heightened by the pleading requirements of the Private Securities Litigation Reform Act of 1995, which imposed on plaintiffs suing under Rule 10b-5, the requirement that the complaint "shall, with respect to each act or omission alleged . . . , state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."¹²³ The double whammy of scienter and rigorous pleading standards provides a substantial barrier to plaintiffs' actions surviving the motion to dismiss stage.¹²⁴

Despite the formidable obstacles that plaintiffs face in adequately pleading scienter, a chink in defendants' armor exists because of the unanimous circuit court adoption of recklessness as a substitute for the more demanding intent requirement of scienter.¹²⁵ Recklessness is a difficult allegation to plead and prove, but it has one enormous advantage over strict scienter, namely that it is not dependent on the actor's state of mind.¹²⁶ There is a universe of difference between proving intent to deceive and proving that the materiality of the facts was so obvious that defendants *must have*

¹²²KOTLER, *supra* note 12, at 4.

¹²³Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737, (codified as amended in scattered sections of 15 and 18 U.S.C.). 15 U.S.C. § 78u-4(b)(2) (2006).

¹²⁴The heightened pleading standards do not apply to enforcement actions by the SEC. *See SEC v. Lucent Techs., Inc.*, 363 F. Supp. 2d 708, 717 (D.N.J. 2005) ("[T]he heightened requirements for pleading scienter under PSLRA do not apply to actions brought by the SEC."), *accord SEC v. ICN Pharms., Inc.*, 84 F. Supp. 2d 1097, 1099 (C.D. Cal. 2000).

¹²⁵When the Supreme Court adopted scienter as the culpability standard for Rule 10b-5, it left the door open to whether recklessness could qualify within the scienter standard. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976) ("In this opinion the term 'scienter' refers to a mental state embracing intent to deceive, manipulate, or defraud. In certain areas of the law recklessness is considered to be a form of intentional conduct for purposes of imposing liability for some act. We need not address here the question whether, in some circumstances, reckless behavior is sufficient for civil liability under Section 10(b) and Rule 10b-5."). There is now unanimous acceptance among district and circuit courts that recklessness meets the scienter standard. *See, e.g.*, cases discussed in Kurtis A. Kemper, Annotation, *What Constitutes Recklessness Sufficient to Show Necessary Element of Scienter in Civil Action for Damages Under 10(b) of Securities Exchange Act of 1934 (15 USCS § 78j(b)) and Rule 10b-5 of the Securities and Exchange Commission*, 49 A.L.R. FED.392 (1980).

¹²⁶An oft-quoted definition of recklessness sets forth the following elements: (1) a highly unreasonable omission, (2) involving not merely simple, or even excusable negligence, but an extreme departure from standards of ordinary care, (3) which presents a danger of misleading buyers or sellers, and (4) that is either known to defendant or is so obvious that defendant must have been aware of it. *Sundstrand Corp. v. Sun Chemical Corp.*, 553 F.2d 1033, 1045 (7th Cir. 1977) (citing *Midwestern Okla. Dev. Auth.*, 428 F. Supp. 719 (W.D. Okla. 1976)).

*been aware of it.*¹²⁷ Once materiality is sufficiently alleged to get past the motion to dismiss stage, it might not be an arduous path to prove that defendant must have been aware of the danger and thus acted beyond excusable negligence. Even a good faith belief that the results of clinical trials or adverse event reports are not material may not preclude a finding of recklessness where a court concludes that the belief is not sufficiently justified by the totality of facts.¹²⁸

Moreover, as recklessness edges away from intent, one court's view of excusable negligence may be another's perception of inexcusable recklessness.¹²⁹ While this blurring of standards is applicable to all Rule 10b-5 defendants, it is particularly sensitive for bio-pharmas whose public statements can never be more than a mere fraction of the mountainous, detailed results and analyses that precede such announcements.¹³⁰ Once a class action is commenced, press releases and other public statements are subjected to scrutiny based upon such voluminous background material. Discrepancies, overly optimistic projections, allegedly material omissions, and even internal interpretive disagreements¹³¹ may be readily found when the thousands of pages of underlying materials are reviewed; especially as

¹²⁷See, e.g., *In re PLC Sy., Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 115 (D. Mass. 1999) ("Moreover, plaintiffs allege that defendants knowingly or recklessly made reassuring statements about The Heart Laser's approval track at the FDA when in the absence of complete data, *they knew or should have known* that FDA approval, at least in the projected time frame, was highly improbable.") (emphasis added).

¹²⁸*SEC v. Infinity Group Co.*, 212 F.3d 180, 192 (3d Cir. 2000) ("good faith, without more, does not necessarily preclude a finding of recklessness").

¹²⁹E.g., *Rolf v. Blyth, Eastman Dillon & Co., Inc.*, 570 F.2d 38 (2d Cir. 1978), *amended*, Nos. 77-7104, 77-7124, 1978 WL 4098, at *1 (2d Cir. 1978) (Rule 10b-5 liability found, contrary to dissenting opinion that defendants engaged only in negligent conduct).

¹³⁰In at least one bio-pharma case the volume of records was the principal factor in transferring the case from New York to the defendant's home state of Georgia. *In re AtheroGenics Sec. Litig.*, No. 05 Civ. 00061, 2006 WL 851708, at *5 (S.D.N.Y. Mar. 31, 2006) ("... the 'voluminous documentation' surrounding the AGI-1067 clinical trials, among other documentation, are available in defendant's sole office in Alpharetta.").

¹³¹Fisher, *supra* note 91, at 152.

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

Id. Fisher cited *In re Synergen Securities Litigation*, 863 F. Supp. 1409 (D. Colo. 1994) as an example where conflicting internal reports resulted in a court's denial of the defendant company's motion to dismiss.

such review is done in hindsight with the benefit of knowing that the seemingly insignificant risk has now materialized. What should have been said becomes controlling, and the volumes of test results and analyses conducted over an extended period provide ample opportunity for plaintiffs to find nuggets that arguably should have been disclosed.¹³²

The disclosure dilemmas facing bio-pharmas, particularly the dangers of early press releases when measured by hindsight scrutiny, is illustrated by the *PLC Systems* litigation.¹³³ PLC had developed a laser device for use in heart operations on patients with end-stage coronary artery disease¹³⁴. An initial press release following a clinical trial lauded the device for having reduced the mortality rate for treatment of such patients. The press release was silent, however, as to whether there was any improvement in patient perfusion,¹³⁵ a major goal of the device, as PLC did not regard the early test results on this matter as statistically significant. A subsequent press release did reveal a statistically significant increase in perfusion. However, the failure to have included any reference to perfusion in the initial release was held to be actionable under Rule 10b-5.¹³⁶ The court's conclusion reflects the exquisite line-drawing forced upon courts by uncertain standards and upon defendants in the bio-pharma industry:

The failure to disclose the fact that the six month data showed no significant improvement in perfusion, the study's primary endpoint, is more troubling, as the absence of any such improvement might signify to a sophisticated investor that TMR offered no long term benefit to end-stage patients generally. The Amended Complaint does not allege that PLC concealed negative data, but that it failed to disclose that the six month data did not, at least yet, show a statistically meaningful increase in perfusion. One might fairly, without a fuller explanation of the study's protocol, regard the absence of a positive result in perfusion to be an adverse finding. . . . While the issue is close, . . . I conclude that the failure to

¹³²*In re Pfizer, Inc. Sec. Litig.*, 584 F. Supp. 2d 621, 635 (S.D.N.Y. 2008) ("... the significance the parties perceive in the report turns on whether the relevant data set of clinically relevant adverse events is to be broken down by sub-group or assessed in the aggregate.").

¹³³*In re PLC Systems, Inc. Sec. Litig.*, 41 F. Supp. 2d 106 (D. Mass. 1999).

¹³⁴*Id.* at 108.

¹³⁵"Perfusion is the act of 'forcing blood or other fluid to flow from the artery through the vascular bed of tissue.'" *Id.* at 111 n.1 (citing *Stedman's Medical Dictionary* 1325 (26th ed. 1995)).

¹³⁶*Id.* at 120.

disclose the perfusion results . . . is actionable.¹³⁷

One might wonder whether into the potential liability equation there should be added the investment judgments made and foreseeable risks accepted by plaintiff class members. During the pre-FDA approval process, investors are making a bet on the future, just as are the companies who continue to pour millions of dollars into the ensuing trials and FDA applications. Both investors and companies are hoping for favorable outcomes for which neither can be sure, yet the risk of continuing investment and continuing research costs is worth the enormous rewards, should there be eventual success.¹³⁸ We should not suppose that investors in bio-pharmas who are motivated by the potential of new medical devices and new drugs are unaware of the risks or are so naive as to think that early favorable results, indeed even early favorable prognostications, are anything more than hopeful signs.¹³⁹ And when those hopeful signs fail to materialize, to the great disappointment of both the investors and the company, is it appropriate that the company alone suffers economic loss while investors, who are well aware of the high risk-benefit paradigm for bio-pharmas, seek recovery

¹³⁷*In re PLC Systems*, 41 F. Supp.2d at 120. One might also wonder how realistic the court was in believing that investors who purchased PLC shares after the press release were in fact misled by the absence of any reference to perfusion. The conclusion that the omission was material and misleading assumes investors who were aware of the perfusion concept, acted upon the absence of reference to it.

¹³⁸*See, e.g.,* Thomas Gryta, *Drug Firm Seeks Alzheimer's Breakthrough --- Late Stage Data for Medivation's Dimebon Awaited; Treatment Could Yield Billions of Dollars, New Option for Patients*, WALL ST. J., Feb. 17, 2010, at B4B.

Medivation Inc. is expected to report late-stage data for its experimental Alzheimer's disease treatment, Dimebon, by mid-year . . . in what will be the second test of the drug's effectiveness. . . . Success in the trial could lift shares to \$80, . . . while its failure could send them down to \$15. Shares of Medivation closed at \$32.27 on Tuesday.

Id. The risk-reward paradigm of bio-pharma securities may be contrasted with other industries where unexpected announcements do not result in similar stock price volatility. *See, e.g.,* Vanessa Fuhrmans & Christoph Rauwald, *Daimler Posts Loss, Cancels Dividend*, WALL ST. J., Feb. 19, 2010, at B2 (Daimler reported a "surprise fourth-quarter net loss and cancelled its dividend for the first time in 14 years, . . . [catching] investors off guard," yet its share price dropped only 5% on the day.); *see also In re Nuvelo, Inc. Sec. Litig.*, 668 F. Supp. 2d 1217, 1225 (N.D. Cal. 2009) (disclosing a drug failed phase 3 trials, caused Nuvelo's stock price to fall from the previous day's close of \$19.55 to \$4.05 per share).

¹³⁹For example, the offending press release in the *In re PLC Systems Securities Litigation*, 41 F. Supp. 2d 106, 113 (D. Mass. 1999), contained the following disclaimer: "Note: Certain of the above statements may be forward-looking statements that involve risks and uncertainties. In such instances, actual results could differ materially as a result of a variety of factors including competitive developments and risk factors listed from time to time in the Company's SEC reports." The release also stated that "PLC Systems *hopes* TMR will one day be utilized as a treatment for the various stages of coronary artery disease." *Id.* at 109 (emphasis added).

through monetary damages?¹⁴⁰ Sometimes, some degree of monetary recovery is appropriate. In Part IV, we address various forms of bio-pharma litigation and suggest reforms that may at least cause a pause in the race to the courthouse where there is a substantial accumulation of scientific evidence.¹⁴¹

D. *Safe Harbor for Projections: Important But Limited Protection*

Rule 10b-5 actions against bio-pharmas have frequently been based on forward-looking statements, such as predictions of the value of potential products or the timing or potential approval by the FDA. Inasmuch as stock market movements are largely influenced by predictions, forward-looking statements by bio-pharmas are especially sensitive given the enormous risk-benefit potentials. To the extent that bio-pharma company public statements can be characterized as projections, additional protection from class action litigation is provided by the safe harbor provision inserted into the 1934 Act by the Private Securities Litigation Reform Act.¹⁴² The provisions went beyond the protections afforded by the judicially developed "bespeaks caution" doctrine.¹⁴³ Forward-looking statements, defined to include financial projections and plans regarding products, enjoy a safe harbor from Rule 10b-5 liability if either (i) "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement,"¹⁴⁴ or (ii) plaintiff fails to prove that the person making the statement had "actual knowledge" of its false or misleading nature.¹⁴⁵ The cautionary statement defense is similar to the "bespeaks caution" doctrine, but, in the absence of such cautionary language, the requirement that plaintiff prove actual

¹⁴⁰A distinction could appropriately be made for company disclosures in a capital-raising endeavor, such as an IPO or private offering. In those instances, the company is seeking the assistance of investors to fund the device or product and all conceivable risks should be fully disclosed. When share purchases of bio-pharmas are made in the secondary market, both the company and investors are using their own funds and companies have much less to gain by misstatements or omissions. This distinction may be one of the bases for the culpability differences between section 11 (strict liability for issuers) and Rule 10b-5 (scienter).

¹⁴¹See *infra* Part IV.C.

¹⁴²15 U.S.C. § 78u-5.

¹⁴³"[W]hen an offering document's forecasts, opinions or projections are accompanied by meaningful cautionary statements, the forward-looking statements will not form the basis for a securities fraud claim. . . . In other words, cautionary language, if sufficient, renders the alleged omissions or misrepresentations immaterial as a matter of law." *In re Westinghouse Sec. Litig.*, 90 F.3d 696, 707 (3d Cir. 1996).

¹⁴⁴15 U.S.C. § 78u-5(c)(1).

¹⁴⁵15 U.S.C. § 78u-5(c)(1)(B)(i).

knowledge goes beyond the judicial scienter requirement by not modifying the intent element through the concept of recklessness.

The protections afforded by statute, however, can be elusive. The condition that forward-looking statements be accompanied by "meaningful cautionary statements" is subject to "eye of the beholder" evaluation. Particularly, when judged with the benefit of hindsight, were the predictions that we now know were inaccurate sufficiently couched in cautionary language to merit the statutory protection? Disclosures by bio-pharmas are necessarily fragmentary, revealing only a small portion of the totality of test results, interpretive studies, sub-grouping data and other scientific and documentary materials. In making its public statements regarding the potential value or efficacy of a product, has the bio-pharma sufficiently revealed the "important factors" that could affect the attainment of the stated projections? Boilerplate statements of non-assurance do not suffice; particularity is the key. Room exists for substantial argument, especially in hindsight, that sufficient particularity was lacking. One commentator has suggested that the requirement for particularity with regard to potential FDA approval might require disclosure that FDA approval is not only contingent on test results, but that in addition, 1) results are based on certain protocols and are subject to human errors, 2) that there may be several ways to interpret test results, 3) that the FDA might not agree that the test protocols were sufficiently enforced, and 4) that the FDA might interpret the test results differently.¹⁴⁶

The same factors that may lead to the denial of the first defense, i.e. meaningful cautionary statements, will also affect the second defense, lack of actual knowledge of falsity. When a statement is made by a business entity, plaintiff must prove that the statement was made with the approval of an executive officer who had actual knowledge that the statement was false or misleading.¹⁴⁷ Given the voluminous nature of the information shared within the company's executive offices, proof of knowledge of non-disclosed information that could affect the likelihood of the projected outcome may be readily attainable.¹⁴⁸ The importance of hindsight cannot be underestimated, as the chances are high that somewhere in the massive materials underlying the projections there are interpretations and results that can now be seen to

¹⁴⁶Fisher, *supra* note 91, at 123.

¹⁴⁷15 U.S.C. § 78u-5(c)(1).

¹⁴⁸*See, In re Equimed, Inc. Sec. Litig.*, No. 98-CV-5374 NS, 2000 WL 562909, at *5-6 (E.D. Pa. 2000) (explaining a letter sent to every director was used to support scienter allegations); *see also In re Aetna, Inc. Sec. Litig.*, 34 F. Supp. 2d 935, 953 (E.D. Pa. 1999) (noting because individual defendants were in high management positions, there was "strong circumstantial evidence" that defendants had knowledge of the undisclosed facts).

have a significance not earlier considered or recognized.

Perhaps the greatest problem with reliance on the statutory protection is that projections are nearly always accompanied by hard, factual information on which the projections are based. It is extremely difficult for a publicly-traded bio-pharma to limit its disclosures within the statutory safe harbor of the 1934 Act.¹⁴⁹ Hard information is not within the statutory protection and is subject to the standard objections of being misleading or incomplete. Even if a company attempts to limit its disclosure to a pure projection, inevitably the questions from market analysts and others will cause the company to disclose the hard information on which the projections were based. At this point we are back to standard Rule 10b-5 jurisprudence, replete with its ambiguities regarding scienter, materiality, and omissions. For example, the statement that the company expected to file an application with the FDA within a particular time period, itself a projection, was held not to be entitled to either the "bespeaks caution" doctrine or the statutory safe harbor where plaintiffs' case was based on the company's alleged failure to disclose that there were serious flaws in the Phase III testing process.¹⁵⁰

Further complicating the projections issue is whether there is a duty to update if the company determines that prior projections are now materially inaccurate. Although the trend in Rule 10b-5 cases appears to disfavor an obligation to update soft information that is clearly set forth as a projection, the issue has not been fully resolved.¹⁵¹ Factors that may affect a court's decision in a particular case may include 1) the timing of the projection relative to the discovery of its inaccuracy, 2) the type of cautionary statements that may have accompanied the projection, 3) the extent of the

¹⁴⁹ See 15 U.S.C. § 78u-5(c).

¹⁵⁰ *In re Cell Pathways Sec. Litig.*, No. 99-725, 2000 WL 805221, at *11 (E.D. Pa. 2000). Defendants argue that each of the challenged statements regarding CPI's plans and expectations for the NDA filing for exisulind is forward-looking because the statements relate to CPI's future plans and use language of futurity. However, allegations based upon omissions of existing facts or circumstances do not constitute forward looking statements protected by the safe harbor of the Securities Act.

Id. (internal quotations omitted).

¹⁵¹ See *Stransky v. Cummins Engine Co., Inc.*, 51 F.3d 1329, 1332 (7th Cir. 1995), (amended April 7, 1995) ("Some have argued that a duty to update arises when a company makes a forward-looking statement — a projection — that because of subsequent events becomes untrue. . . . This court has never embraced such a theory, and we decline to do so now.") *Contra*, *In re Time Warner Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993) ("We agree that a duty to update opinions and projections may arise if the original opinions or projections have become misleading as a result of intervening events."). The safe harbor created in the 1934 Securities Act post-dates much of the litigation in this area. The safe harbor's lack of reference to updating projections suggests that projections initially protected under the safe harbor provisions would not lose their protection by virtue of subsequent events. This issue however has not been judicially resolved.

discrepancy between the projection and the current information, and 4) a court's perceived relationship of the statements to attempted stock market manipulation.¹⁵² This is all in addition to claims that the factors that caused the projection to become inaccurate were known or should have been known at the time the projection was made.¹⁵³

E. *Compounding the Problem: Lack of Judicial Expertise*

The problems of materiality and scienter applied to bio-pharma class actions are exacerbated by a lack of expertise on the bench. There is probably no other publicly-traded industry in which data is so voluminous, so subject to numerous classifications and sub-categories, and so open to contrary opinions by industry and regulatory experts. It is difficult to identify any other product or service offered by publicly-held companies that generates such problems of data evaluation. Now insert a judge who is confronted with legal issues of materiality and scienter, opposing experts dueling over the minutia of clinical trials, disclosures, and scientific evaluations made over extended periods of time, and one must wonder whether any judge can feel comfortable finding or denying Rule 10b-5 liability. Supreme Court Justice Stephen Breyer has commented on this inherent problem:

. . . most judges lack the scientific training that might facilitate the evaluation of scientific claims or the evaluation of expert witnesses who make such claims. . . . Furthermore, science itself may be highly uncertain and controversial with respect to many of the matters that come before the courts. Scientists often express considerable uncertainties about the dangers of a particular substance. . . . What, for example, is the relevance to human cancer of studies showing that a substance causes some cancers, perhaps only a few, in test groups of mice or rats? What is the significance of extrapolations from toxicity studies involving high doses to situations where the doses are much smaller? Can lawyers or

¹⁵²See *Warshaw v. Xoma Corp.*, 74 F.3d 955, 959 (9th Cir. 1996). The defendant company responded immediately to contradict a securities analyst's negative prediction as to the likelihood of FDA approval for a pending drug application, the court noting that "in response to market fears about FDA approval, Xoma's president flatly stated that 'everything [was] going fine.' Such general statements of optimism, when taken in context, may form a basis for a securities fraud claim. . . ." *Id.* (internal citations omitted).

¹⁵³See *supra* note 127 and accompanying text.

judges or anyone else expect scientists always to be certain or always to have uniform views with respect to the extrapolation from a large dose to a small one, when the causes of and mechanisms related to cancer are generally not well known. Many difficult legal cases fall within this area of scientific uncertainty.¹⁵⁴

To be sure, there will be occasions when the evidence allows judges to readily understand the liability issue. Internal memoranda or discussions may reveal serious concerns, as when the executives of a major pharmaceutical concluded that adverse event reports were sufficient to be "putting the brand at risk."¹⁵⁵ An equally clear case exists when public announcements are directly contrary to FDA-expressed concerns. The more likely scenario, however, is a court faced with a series of press releases containing both optimistic statements and cautionary disclaimers, underlying mountains of internal and external reports that fail to be entirely conclusive, and regulatory denials that may have been as surprising to the company as to the investing public. Now enter well-financed class action attorneys, with experts who have spent hundreds of hours sifting through past data, and defendants' experts who refute each of plaintiffs' allegations with equally scientifically-oriented arguments, and we are likely to find a judge longing for the simple case of a good old fashioned fraud. This is not to say that reported decisions are not well thought through and carefully written. Rather, it is to suggest that even the most well-meaning jurists may misunderstand or have uncertainty over the significance of the disputed scientific data. Hence, it is not surprising to see a judicial admission that the decision is a close call,¹⁵⁶ or that the ultimate analysis of the merits will be

¹⁵⁴STEPHEN BREYER, *Introduction to FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 2, 4* (2d ed. 2000), [http://www.fjc.gov/public/pdf.nsf/lookup/sciman00.pdf/\\$file/sciman00.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/sciman00.pdf/$file/sciman00.pdf). Justice Breyer clearly had in mind the evidentiary problems arising in biopharma litigation. Elsewhere in his Introduction he observed that:

. . . a decision wrongly granting compensation, although of immediate benefit to the plaintiff, can improperly force abandonment of the substance. Thus, if the decision is wrong, it will improperly deprive the public of what can be far more important benefits — those surrounding a drug that cures many while subjecting a few to less serious risk, for example. The upshot is that we must search for law that reflects an understanding of the relevant underlying science. . . .

Id. at 3-4.

¹⁵⁵*In re Bayer AG Securities Litig.*, 2004 WL 2190357, at *15 (S.D.N.Y. Sept. 30, 2004) ("The August 2000 safety meeting was a turning point. Various Bayer executives . . . agreed that the confluence of information about the adverse effects of Baycol was 'putting the brand at risk. . . . That knowledge renders defendants' post-August 2000 silence actionable.").

¹⁵⁶*See supra* note 137.

left for another day to the eventual trier of fact.

IV. MEETING THE CHALLENGE OF SUI GENERIS LITIGATION CONCERNS

The most significant bio-pharma litigation problem is the objective assessment of multiple public disclosures in the context of voluminous data collected during the development, testing, trial, and marketing periods. Such data is inevitably subject to varying interpretations, conjectures as to protocols, explanations as to unanticipated results, and uncertainties as to the numbers, types, and causes of adverse reactions. Unlike nearly every other product for which it is the company alone who makes judgments on pre-marketing and marketing data, judgments by bio-pharmas are subjected to critique and possible rejection by a federal agency, rejections that themselves are subject to scientific critique.

The *sui generis* nature of bio-pharmas poses a difficult issue in the context of securities litigation. Rule 10b-5 actions against bio-pharmas are more likely to be based on competing interpretations of scientific data than the manipulation of financial data. Although a majority of such suits are dismissed, principally on the failure to meet strict scienter pleading requirements, there are sufficient difficulties in assessing the voluminous data that courts may justifiably be hesitant to rule at the motion to dismiss stage. Moreover, even when bio-pharmas succeed at the motion stage, they will have incurred substantial litigation costs and financial uncertainties that could affect ongoing and future research programs. It is not enough, in our judgment, to say "such is the result of being a publicly-held company." The extraordinary contingencies affecting bio-pharmas and their investors require, we believe, something other than an ordinary response.

We have considered and rejected some alternative responses. One alternative would be to create a Rule 10b-5 carve-out for bio-pharmas, such as a presumption favoring dismissal of any action against bio-pharmas unless actual intent to deceive is clearly shown. We do not favor such a carve-out as it could lead to less carefully prepared and more insufficiently considered public statements. A second alternative is to consider a limitation on damages. Investors in bio-pharmas are apt to be well aware of the risks and volatilities inherent in bio-pharma securities investments. They are hoping for an investment home run. When matters do not turn out as hoped, perhaps absent actual malice or intentional deceit by the bio-pharma, these investors should not be able to recover their entire out-of-pocket damages, but rather some more limited amount that accounts for their acceptance of risk. While we find some merit in this approach, it would create substantial measurement difficulties and may have the effect of reducing securities laws compliance incentives. Moreover, current jurisprudence does not support a judicial splitting of the baby, thus securities law decisions necessarily result

in an all or nothing approach.

If, as we assert, the principal difficulty lies with data assessment, we believe that the most appropriate reform measure is to assure that the court has an objective evaluation process at the motion stage through the consultation of a neutral court-appointed expert.¹⁵⁷ A court-appointed expert will not usurp the authority of the judge in weighing the evidence and determining an outcome. Judge Richard Posner noted that in a case with a "staggeringly large record . . . that includes so much highly technical statistical material . . . [t]he judge . . . may not understand the neutral expert perfectly but at least [the judge] will know that [the expert] has no ax to grind."¹⁵⁸ As discussed below, procedures are already in place to allow courts to utilize objective evaluations at an early stage in the litigation. Our recommendation does not call for a radical reform, but rather a greater emphasis and willingness at the judicial level to use powers that currently exist.

Court-appointed experts should, in our judgment, be particularly useful in cases involving substantial data evaluation, which is often the case where products have failed to gain FDA approval or have been recalled based on adverse results. More frequent use of court-appointed experts at the motion stage will give courts much-needed assistance in understanding complex material, including the troublesome relationship between the assessment of scientific data using statistical significance and the application of securities laws using the somewhat ambiguous materiality standard.¹⁵⁹ Moreover, the up-front division of costs imposed on the parties may provide a sobering influence on plaintiffs eager to initiate Rule 10b-5 actions.¹⁶⁰

¹⁵⁷One judge has expressed the importance of neutral experts in the following terms: The work of such experts is especially critical in dealing with complex mass tort problems such as the instant case. The dilemma presented here is a typical of these exceptional cases: the epidemiological and other scientific questions are complex and riven with uncertainties and interdependent variables; the number of persons affected runs into the hundreds of thousands; the courts cannot proceed toward a just and equitable result without some reasonably firm data projecting the numbers and volume of claims at issue; and all parties have strong and conflicting interests in the character of that data. These factors, alone and in combination, point to the necessity of neutral, expert assistance under the auspices of the court.

In re Joint E. & S. Dist. Asbestos Litig., 830 F. Supp. 686, 693 (E. & S.D.N.Y. 1993).

¹⁵⁸DEBORAH RUNKLE, *Court-Appointed Scientific Experts: Providing Objective Scientific Advice to the Judiciary*, in SCIENTIFIC EVIDENCE REVIEW CURRENT ISSUES AT THE CROSSROADS OF SCIENCE, TECHNOLOGY AND THE LAW 19, 33 (Cynthia H. Cwik & Helen E. Witt, eds., 2007).

¹⁵⁹See *supra* Part III.B.

¹⁶⁰Litigation in the "nuisance" category that lacks substantial merit but is brought for quick settlement purposes may well be discouraged by the prospect of objective expert reports and up-front costs to cover such reports.

A. Reform Through the Use of Court-Appointed Experts

In the seminal case *Daubert v. Merrell Dow Pharmaceuticals*, the Supreme Court reemphasized the obligation of trial judges to act as gatekeepers admitting only relevant and reliable evidence.¹⁶¹ Preliminarily, a judge must determine whether the expert is proposing to testify to scientific knowledge that will assist the trier of fact to understand or determine a fact in issue.¹⁶² If the evidence would in some way be helpful to the trier of fact, then *Daubert* requires that a judge examine proffered evidence to determine "whether the reasoning or methodology underlying the testimony is scientifically valid."¹⁶³ This means the judge must determine whether the evidence or testimony is grounded in the methods and procedures of science.¹⁶⁴ "Another pertinent [but not dispositive] consideration is whether the theory or technique has been subjected to peer review and publication."¹⁶⁵ Judges may also look to the "known or potential rate of error" and the "general acceptance" of the evidence in the scientific community.¹⁶⁶ The Court emphasized that although this inquiry is a flexible one, the overarching inquiry must focus on scientific validity of the principles underlying the proffered evidence.¹⁶⁷

The Supreme Court recognized in *Daubert* that scientific conclusions are subject to perpetual revision but balanced this uncertainty with the realistic notion that law must resolve disputes quickly and finally.¹⁶⁸ The Court acknowledged that

in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That,

¹⁶¹ *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 589 (1993).

¹⁶² *Id.*

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

FED. R. EVID. 702.

¹⁶³ 509 U.S. at 592-93.

¹⁶⁴ *Id.* at 590.

¹⁶⁵ *Id.* at 593-94.

¹⁶⁶ *Id.* at 594.

¹⁶⁷ *Daubert*, 509 U.S. at 594-95.

¹⁶⁸ *Id.* at 596.

nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.¹⁶⁹

This acknowledgement of practical evidentiary limitations cannot be comforting to bio-pharmas because whether, and what, evidence is admissible can change the viability of a cause of action or render defense nearly impossible. The conflicting perspectives and analyses of scientific data which forms the foundation of materiality or scienter claims may be included or excluded on the basis of the limited scientific knowledge of the judiciary. Furthermore, in *General Electric Co. v. Joiner*, the Supreme Court determined that the appropriate standard of review of a trial court's *Daubert* decision to admit or exclude scientific expert testimony is abuse of discretion.¹⁷⁰ Given the low likelihood of success in proving an abuse of discretion, the importance of getting the decision right the first time is even more apparent.

The perils a judge faces to admit or exclude scientific evidence in a way that resolves disputes expediently will often require experience and knowledge the judge simply does not have.¹⁷¹ However, the Court has offered guidance in *Daubert* by reminding the judiciary of its ability under the Federal Rules of Evidence (FRE), specifically FRE 706, to procure the assistance of an expert of its own choosing.¹⁷² Additionally, in a concurring

¹⁶⁹*Id.* at 597.

¹⁷⁰*Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 139 (1997).

¹⁷¹Judges responding to a Federal Judicial Center study stated, "I was aware of the limits of my knowledge of [biochemistry]" and "I didn't know anything about computer software...." RUNKLE, *supra* note 158, at 21.

¹⁷²FED. R. EVID. 706 states:

(a) APPOINTMENT. The court may on its own motion or on the motion of any party enter an order to show cause why expert witnesses should not be appointed, and may request the parties to submit nominations. The court may appoint any expert witnesses agreed upon by the parties, and may appoint expert witnesses of its own selection. An expert witness shall not be appointed by the court unless the witness consents to act. A witness so appointed shall be informed of the witness' duties by the court in writing, a copy of which shall be filed with the clerk, or at a conference in which the parties shall have opportunity to participate. A witness so appointed shall advise the parties of the witness' findings, if any; the witness' deposition may be taken by any party; and the witness may be called to testify by the court or any party. The witness shall be subject to cross-examination by each party, including a party calling the witness.

(b) COMPENSATION. Expert witnesses so appointed are entitled to reasonable compensation in whatever sum the court may allow. The compensation thus fixed

opinion to *Joiner*, Justice Breyer urged judges to use all possible techniques that would assist them in making determinations about complex or technical evidence, including the use of court-appointed experts.¹⁷³ Employing the administrative and inherent authority of the court to provide itself with objective analysis, judges in bio-pharma cases involving complex and voluminous scientific data can more accurately understand the nature of scientific evidence through the use of court-appointed experts.

1. Appointment of Experts Under the FRE 706

Under FRE 706, the court may on its own motion enter an order to show cause why an expert witness should not be appointed.¹⁷⁴ The rule guides and informs the process of appointment, compensation of the witness, and disclosure to the trier of fact.¹⁷⁵ Additionally, the rule provides that witnesses will testify to the ultimate fact finder and be subject to deposition and cross-examination by any party.¹⁷⁶

One of the first and most influential uses of FRE 706 to appoint experts was in breast implant litigation. Breast implants are considered Class III medical devices and require FDA approval before marketing.¹⁷⁷ In 1996, Chief Judge Sam Pointer, Jr. of the Northern District of Alabama, who was charged with handling consolidated federal multidistrict litigation in the silicone breast implant cases, appointed four experts under Rule 706 to serve

is payable from funds which may be provided by law in criminal cases and civil actions and proceedings involving just compensation under the fifth amendment. In other civil actions and proceedings the compensation shall be paid by the parties in such proportion and at such time as the court directs, and thereafter charged in like manner as other costs.

(c) DISCLOSURE OF APPOINTMENT. In the exercise of its discretion, the court may authorize disclosure to the jury of the fact that the court appointed the expert witness.

(d) PARTIES' EXPERTS OF OWN SELECTION. Nothing in this rule limits the parties in calling expert witnesses of their own selection.

¹⁷³522 U.S. at 147-50.

¹⁷⁴The order would likely be entered at the pretrial conference held pursuant to FED. R. CIV.

P. 16. Section 16(c)(12) calls for consideration of the need for "adopting special procedures for managing potentially difficult . . . actions that may involve complex issues . . . or unusual proof problems." FED. R. CIV. P. 16(c)(2)(L). At the pretrial conference according to FED. R. EVID. 104(a) "preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court . . ."

¹⁷⁵FED. R. EVID. 706.

¹⁷⁶FED. R. EVID. 706.

¹⁷⁷FDA, *Learn if a Medical Device Has Been Cleared by FDA for Marketing* (2009), <http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm> (listing breast implants as Class III devices); see also *supra* Part II.

as a National Science Panel in determining the relationship between silicone gel breast implants and connective-tissue diseases and autoimmune dysfunction.¹⁷⁸ Judge Pointer instructed the panel "to review, critique, and evaluate existing scientific literature, research, and publications" to determine whether silicone breast implants could have caused a number of diseases or symptoms.¹⁷⁹ The panel heard from plaintiff's and defendant's experts and reviewed voluminous materials consisting of more than 2000 documents submitted by counsel.¹⁸⁰ After completing its report, the panel was subject to discovery through deposition by counsel. The report largely concluded that scientific evidence could not demonstrate a causal link between the implants and any systemic disease.¹⁸¹ Other similar panels have been used in asbestos litigation,¹⁸² Dalkon Shield contraceptive device litigation,¹⁸³ and environmental toxic tort litigation.¹⁸⁴

2. Appointment of Experts Under Inherent Judicial Authority

Supplementing Rule 706 is the inherent authority of the court to carry out its duties by employing necessary resources including "technical advisors."¹⁸⁵ Technical advisors, unlike experts appointed under Rule 706,

¹⁷⁸*In re Silicone Gel Breast Implant Prod.Liab.Litig.*, No. CV 92-P-10000-S, 1996 WL 34401813, at *1 (N.D. Ala. May 31, 1996); *see also* Barbara S. Hulka et al., *Experience of a Scientific Panel Formed to Advise the Federal Judiciary on Silicone Breast Implants*, 342 NEW ENG. J. MED. 812, 812 (2000) (providing insight by members of the Pointer panel).

¹⁷⁹*In re Silicone Gel Breast Implants*, 1996 WL 34401813, at *3.

¹⁸⁰*See* Hulka, *supra* note 178, at 813.

¹⁸¹*See* Peter Tugwell, Report of National Science Panel, Chapter IV 41 (1998), <http://www.fjc.gov/BREIMLIT/SCIENCE/chap4.pdf>. (After the panel's report was complete several defendants, including Dow Corning, settled the case. Cases that remained were remanded back to their respective districts with the ability to use the panel's report and testimony at trial.)

¹⁸²*See In re Joint E. & S. Dist. Asbestos Litig.*, 830 F. Supp 686, 693 (E. & S.D.N.Y. 1993) (using scientific experts under Federal Rules of Evidence Rule 706 to estimate future asbestos claims).

¹⁸³*Glasser v. A.H. Robbins Co.*, 950 F.2d 147, 147 (4th Cir. 1991) (appointing an expert "to advise the court on estimation of Dalkon Shield Claims").

¹⁸⁴*See Renaud v. Martin Marietta Corp.*, 749 F. Supp. 1545, 1548 (D. Colo. 1990), *aff'd*, 972 F.2d 304 (10th Cir. 1992) (granting summary judgment for defendant on testimony of three court-appointed experts including a physician, geologist, and toxicologist).

¹⁸⁵*See generally In re Peterson*, 253 U.S. 300, 312 (1920) ("Courts have (at least in the absence of legislation to the contrary) inherent power to provide themselves with appropriate instruments required for the performance of their duties."); *Reilly v. United States*, 863 F.2d 149, 154 n.4 (1st Cir. 1988) (noting "[s]uch power inheres generally in a district court"); *Scott v. Spanjer Bros.*, 298 F.2d 928, 930-31 (2d Cir. 1962) ("[w]e believe that the appointment of an impartial medical expert by the court in the exercise of its sound discretion is an equitable and forward-looking technique for promoting the fair trial of a lawsuit."); *see also* FED. R. EVID. 706 advisory committee's note ("[t]he inherent power of a trial judge to appoint an expert of his own choosing is

do not testify nor give evidence, but rather consult with the judge on matters requiring specific expertise.¹⁸⁶ In *Reilly v. United States*, the First Circuit Court of Appeals suggested general factors that might justify appointment of a technical advisor, including "problems of unusual difficulty, sophistication, and complexity, involving something well beyond the regular questions of fact and law with which judges must routinely grapple."¹⁸⁷

In *Hall v. Baxter Healthcare Corp.*, Judge Robert E. Jones of the District of Oregon appointed a panel of scientific experts to assist him in ruling on motions to exclude plaintiff's expert testimony on a link between silicone implants and autoimmune disorders and connective tissue disease.¹⁸⁸

Judge Jones noted that "[i]n view of the complicated scientific and medical issues involved and in an effort to effectively discharge my role as 'gatekeeper' under *Daubert I*, I invoke my inherent authority as a federal district court judge to appoint independent advisors to the court."¹⁸⁹ The technical advisors, including an epidemiologist, rheumatologist, immunologist-toxicologist, and polymer chemist,¹⁹⁰ provided reports that assisted Judge Jones in excluding evidence that did not meet acceptable standards of scientific validity.¹⁹¹

3. Appointment of Special Masters Under FRCP 53

Judges may also appoint special masters under Rule 53 of the Federal Rules of Civil Procedure (FRCP) in order to facilitate discovery, resolve disputes, and manage other parts of the pretrial phase of complex scientific litigation.¹⁹² Special masters may not decide motions or make other dispositive rulings; they perform nonadjudicative functions such as "preliminary assessments of technical or scientific evidence offered by the parties [or] to identify and [manage] court-appointed experts."¹⁹³ For example, Judge Jones in *Baxter Healthcare* used a special master to identify candidates to serve on a panel of court-appointed experts.¹⁹⁴

Appointment of a special master is reserved for special

virtually unquestioned.").

¹⁸⁶WILLIAM W SCHWARZER & JOE S. CECIL, *Management of Expert Evidence*, in FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 39, 59 (2d ed. 2000), [http://www.fjc.gov/public/pdf.nsf/lookup/sciman00.pdf/\\$file/sciman00.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/sciman00.pdf/$file/sciman00.pdf).

¹⁸⁷*Reilly*, 863 F.2d at 157.

¹⁸⁸947 F. Supp. 1387, 1393-94 (D. Or. 1996).

¹⁸⁹*Id.* at 1392.

¹⁹⁰*See id.* at 1393.

¹⁹¹*See id.* at 1394.

¹⁹²*See* SCHWARZER & CECIL, *supra* note 186, at 63; *see also* FED. R. CIV. P. 53.

¹⁹³*See* SCHWARZER & CECIL, *supra* note 186, at 63-65.

¹⁹⁴947 F. Supp. 1387, 1392-93 (D. Or. 1996).

circumstances. The Advisory Committee Notes to FRCP 53 indicate that district judges "bear the primary responsibility for the work of their courts" and "appointment of a master must be the exception and not the rule."¹⁹⁵ Significantly, however, Justice Breyer has recommended the appointment of special masters in matters involving complex scientific or technical evidence.¹⁹⁶ Bio-pharma litigation, with its complex scientific or technical evidence, thus presents the perfect opportunity to engage special masters to assist the judiciary.

B. *Judicial Concerns in the Appointment of Experts*

Despite the urging of members of the Supreme Court and the clear authority to appoint experts, judges have been reluctant to utilize this methodology.¹⁹⁷ One judge explained his hesitancy by noting that appointment of experts will be outcome-determinative, fearing that the apparent objectivity of the expert would give an inappropriate advantage to one party or the other.¹⁹⁸ Another view is that appointment of experts conflicts with their sense of the judicial role in the adversary system.¹⁹⁹ Judges have also expressed concern about the difficulty of sourcing and compensating experts.²⁰⁰ Additionally, concerns of neutrality exist as it may be very difficult to find experts who have had no prior history with particular bio-pharma companies or their products, particularly because many doctors and academic departments have funding and research relationships with major bio-pharma companies.²⁰¹

¹⁹⁵FED.R. CIV. P. 52, Advisory Committee Notes (2003).

¹⁹⁶See *General Electric Co. v. Joiner*, 522 U.S. 136, 147-50 (1997) (Breyer J., concurring).

¹⁹⁷Joe S. Cecil & Thomas E. Willging, *Accepting Daubert's Invitation: Defining a Role for Court-Appointed Experts in Assessing Scientific Validity*, 43 EMORY L.J. 995, 997 (1994).

¹⁹⁸See, e.g., *Hiem v. Sarpy*, 161 F.R.D. 332, 336 (E.D. La. 1995).

¹⁹⁹Howard M. Erichson, *Mass Tort Litigation and Inquisitorial Justice*, 87 GEO. L.J. 1983, 2015 (1999).

²⁰⁰In response to a Federal Judicial Center study questionnaire, judges "spoke of the difficulty in recruiting unbiased experts with the knowledge demanded in litigation. Some didn't know where to turn to initiate the process." RUNKLE, *supra* note 158, at 25.

Unless and until there is a national register of experts on various subjects and a method by which they can be fairly compensated, the federal amateurs wearing black robes will have to overlook their new gatekeeping function lest they assume the intolerable burden of becoming experts themselves in every discipline known to the physical and social sciences, and some as yet unknown but sure to blossom.

BREYER, *supra* note 154, at 7 (citing Letter from Judge William Acker, Jr. to the Judicial Conference of the United States et al. (Jan.2, 1998)).

²⁰¹See David J. Damiani, *Proposals for Reform in the Evaluation of Expert Testimony in Pharmaceutical Mass Tort Cases*, 13 ALB. L.J. SCI. & TECH. 517, 544 (2003) (discussing expert neutrality as "[p]rofessional societies and university departments may encourage testimony that

Many of these concerns, however, can be alleviated. Neutrality and sourcing costs have been addressed by the formation of bodies which make the sourcing of experts easier and more reliable. The trial judge may appoint a private search firm or a special master to seek experts and to vet qualification and conflict concerns. For example, the American Association for the Advancement of Science (AAAS) Court Appointed Scientific Experts (CASE) project²⁰² can provide services to assist the judiciary in sourcing experts.²⁰³ Upon receiving a request from a judge, CASE conducts searches for experts with requested scientific qualifications.²⁰⁴ A representative of CASE directly contacts potential experts to determine their qualifications to testify on a particular issue and to screen for potential conflicts.²⁰⁵ CASE will then provide one or more recommendations of individual experts or panelists to the court.²⁰⁶ A court-appointed expert or panel would not, of course, opine on matters of law, such as what constitutes scienter, or whether a particular misstatement or omission was material. Those issues remain for the trier of fact. But a court faced with such issues often must first grapple with and discern volumes of complex data and conflicting interpretations. It is in this fact ascertainment arena that neutral experts would be most beneficial.²⁰⁷ Ultimately, it will be the judge's

favors businesses in the industry that fund their respective organizations"); *see also* Linda A. Johnson, *Pfizer paid doctors, hospitals \$35 million in last half of 2009*, USA TODAY, March 31, 2010, available at http://www.usatoday.com/money/industries/health/2010-03-31-pfizer-doctor-payments_N.htm?csp=usat.me#uslPageReturn ("Prizer paid doctors and teaching hospitals a total of \$35 million in the last half of 2009 for services ranging from speaking to other doctors about the company's products to running studies of its experimental drugs.").

²⁰²RUNKLE, *supra* note 158, at 26-38; *see generally* CASE Website, <http://www.aaas.org/spp/case/case.htm>.

²⁰³RUNKLE, *supra* note 158, at 25 ("Judge Acker (mentioned at *supra* note 200) subsequently turned to CASE to identify and recommend an expert to assist him in a pretrial hearing.").

²⁰⁴*See id.* at 29.

²⁰⁵*Id.* at 30.

²⁰⁶*Id.* at 30-31.

²⁰⁷We recognize that a court is required at the motion to dismiss stage to accept well-pleaded allegations as true. Nevertheless, plaintiffs' complaints and defendants' motions are replete with exhibits setting forth evaluations, reports, evidence of various studies, and other data that must be understood in order to rule on the motion. Even if the principal basis of a motion to dismiss is the lack of scienter, to reach a conclusion that scienter did not exist requires analysis of substantial reports and data. Legal conclusions are necessarily based on analysis of facts, and in many bio-pharma cases there is no escape from the need to gain an organized, comprehensive understanding of the fundamental facts in light of the alleged offensive disclosures. As noted in *In re Medicis Pharm. Corp. Sec. Litig.*, 689 F. Supp. 2d 1192, 1202 (D. Ariz. 2009), in considering a motion to dismiss regarding scienter "federal courts are required to consider whether 'all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.' (citing *Tellabs, Inc. v. Makoor Issues & Rights, Ltd.*, 551 U.S. 308, 323#(2007) (emphasis removed)). . . . [C]ourts must 'consider the totality of the circumstances.'" (citing *Zucco Partners, LLC v. Digimarc Corp.*, 552 F. 3d 982, 992 (9th Cir. 2009)

determination whether an expert meets scientific qualifications to testify or whether a prior relationship disqualifies a potential expert.²⁰⁸ Another efficient means of sourcing experts is through the appointment of a special master under FRCP 53 to assist in identifying experts.²⁰⁹

Although the concern by judges that the ultimate trier of fact in the case of a jury trial may place undue weight upon the testimony of court-appointed experts is valid, the ultimate determination whether to disclose to a jury that an expert was appointed by the court is left to the judge's discretion.²¹⁰ If a judge determines that a jury should know the nature of the witness's induction into the case, Section 6(e) of the ABA Litigation Section Civil Trial Practice Standards provides guidance on potential jury instructions to minimize the expert's appearance of undue authority because of his association with the court.²¹¹

Additionally, the appointment of experts could have a beneficial externality in the form of settlement negotiations. Neither party may want to wait for the report of court-appointed experts, especially in large class action litigation. The parties in the breast implant litigation overseen by Judge Pointer may have been driven to the negotiating table by the risk of the National Science Panel's findings on causality of silicone gel breast implants.²¹² The fact that a judge is seeking an expert may encourage settlement.²¹³ A CASE search for a court-appointed expert was suspended when parties learned the judge contacted CASE for referral of an expert and settled.²¹⁴ Other suggested benefits of court-appointed experts include

(citation omitted)).

²⁰⁸See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592-93, 595-97 (1993) (recognizing trial judge as gatekeeper for reliability of scientific expert testimony); see also *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 139 (1997) (holding that trial judge's exclusion of proffered expert testimony is reviewed for abuse of discretion).

²⁰⁹*Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1392-93 (D. Or. 1996) (noting the Judge used a special master to identify candidates to serve on a panel of court-appointed experts).

²¹⁰*Monolithic Power Sys. v. O2 Micro Int'l Ltd.*, 558 F.3d 1341, 1347 (Fed. Cir. 2009) (finding no abuse of discretion in district court's disclosure of doctor's independent status to the jury); see also FED. R. EVID. 706(c) ("[I]n the exercise of its discretion, the court may authorize disclosure to the jury of the fact that the court appointed the expert witness.").

²¹¹A.B.A., CIVIL TRIAL PRACTICE STANDARDS 9-10, available at <http://www.abanet.org/litigation/civiltrialstandards/ctps.pdf>.

²¹²David J. Morrow, *Implant Maker Reaches Accord on Damage Suits*, N.Y. TIMES, July 9, 1998, at A1 (reporting that defendant Dow Corning Corporation reached a settlement with plaintiff's lawyers in advance of the final report); see also *supra* note 178 and accompanying text.

²¹³We are not advocating that cases should necessarily be settled based on objective expert reports. Settlements are often driven by the uncertainty surrounding the outcome of a particular motion. If one or the other side is particularly confident in its position and the anticipated result of an objective expert evaluation, settlement may be appropriate and will generally favor the stronger side. Settlement may not always be appropriate, however, especially where contested facts merits more extensive examination of witnesses and data than is possible at a motion stage.

²¹⁴RUNKLE, *supra* note 158, at 24.

increasing the overall quality of testimony from the adversarial experts.²¹⁵

Court-appointed experts are likely to be costly, even more so if the court determines that a panel would be appropriate. Expert fees and expenses could easily range into six figures. Although this may seem a considerable amount for assisting the court in carrying out its duties, the cost of a court-appointed expert seems small in comparison to the magnitude of bio-pharma litigations claims. The use of a court-appointed expert and the associated cost imposed on both parties could also benefit settlement negotiations. Litigation may be diminished, or settlement negotiations may begin sooner, if plaintiffs are likely to incur substantial upfront costs to fund a scientific expert or panel of experts at the motion to dismiss stage.

C. *Recommended Uses of Scientific Experts*

Although the appointment of scientific experts may not be necessary in most types of civil litigation, there is no doubt that the volume and nature of scientific data in bio-pharma litigation requires courts to consider the assistance of scientific experts. Reports, interpretations, and sheer raw data generated by clinical trials and adverse event reports over a period of years can be best understood by scientific practitioners with an eye for statistical interpretation. Judges should utilize this expertise to make more informed decisions about the inclusion or exclusion of evidence. In addition, when the judge is called upon to resolve motions or to be the ultimate trier of fact, a more thorough understanding of the scientific basis of claims may substantially inform decisions of materiality or scienter.

It is likely that one or more of the parties will try to show cause in opposition to the appointment of an objective expert. Either or both of the parties may be fearful of the expert's conclusions, may not want to bear the cost, or may be so confident in their own experts that they would fear the intrusion of another. Yet, examples such as breast implant, asbestos, and Dalkon shield litigation support the use of court-appointed experts.²¹⁶ Whatever the reasons for objections, we believe that the objecting parties should bear a heavy burden in dissuading the trial judge from utilizing FRE 706 or the court's inherent appointment authority.

When considering the use of court-appointed scientific experts, the judiciary should approach the litigation as divided into two categories: (1) Limited Scientific Evidence or Clear Fraud, where no scientific experts

²¹⁵*Id.* (suggesting that knowing their testimony will be scrutinized by a court-appointed expert, partisan experts may adopt more balanced views or modify their testimony).

²¹⁶*See supra* Part IV.A.

would be necessary; and (2) Substantial Accumulation of Scientific Evidence, where scientific experts should be considered.

1. Limited Scientific Evidence or Clear Fraud

Not every bio-pharma case will require the use of court-appointed experts. No expert will be required where a bio-pharma has clearly committed fraud like falsifying data or knowingly making a false statement about a drug's success. The outcome of these types of cases will not hinge upon differing scientific minds and little scientific data will be necessary. Rather, the outcome will depend on proving the actions or mental state of the parties involved in perpetrating the fraud. For example, in *Twinde v. Threshold Pharmaceuticals, Inc.*, a 10b-5 claim survived the motion to dismiss where, after disclosing evidence of liver toxicity associated with its drug to the FDA, the company failed to make mention of the problems in a press release and quarterly report.²¹⁷ The motion turned not upon elaborate interpretation of scientific data but upon establishing actions by defendants in failing to disclose facts that would necessarily prevent or delay FDA approval.²¹⁸

Another case reflecting more traditional notions of securities fraud is *In re Nuvelo, Inc. Securities Litigation*, where the plaintiffs survived a motion to dismiss by alleging that fraudulent statements and omissions concerning the use of a more stringent 0.00125 p-value in a clinical trial adversely affected the stock price.²¹⁹ Plaintiffs may not be able to meet a higher evidentiary standard to show the undisclosed p-value had an effect on the stock price, but the determination will likely not turn on differing scientific minds or intense statistical analysis. Rather, proof of the statements concerning the clinical trial and any actions by Nuvelo that misled investors or concealed known risks of investing will be key in determining the claim. The judiciary is well versed in run-of-the-mill fraud cases and the appointment of experts would be an unnecessary expense thrust upon the parties.

2. Substantial Accumulation of Scientific Evidence

When substantial scientific data is involved, such as multi-phase

²¹⁷*Twinde v. Threshold Pharm., Inc.*, No. C 07-4972 CW, 2009 WL 928132, *11 (N.D. Cal. 2009).

²¹⁸*Id.* at *12.

²¹⁹668 F. Supp. 2d 1217, 1230 (N.D. Cal. 2009).

clinical trial data, pre-clinical animal studies, adverse reaction data, and drug composition or device information, the court should strongly consider appointing scientific experts. Interpretation of the data, viewed in light of a bio-pharma's internal decisions and public disclosures, is likely to be outcome determinative.

Court appointment of experts under FRE 706 should be the preferred course because these experts will not only provide scientific testimony but may also be deposed by each party.²²⁰ Judges have expressed concern for the use of FRE 706 scientific expert appointment because the testimony may be unduly influential to a jury.²²¹ This concern is irrelevant at the motion to dismiss stage because the judge will not be influenced unnecessarily by the testimony of the court-appointed expert. Additionally, each adversarial party maintains the ability to present expert testimony and the judge will weigh it just as he or she weighs the court-appointed expert's testimony.²²²

If the case moves past the motion to dismiss stage, a greater concern is warranted for the appearance of undue authority a court-appointed expert portrays. Although the judge may decline to inform the jury that the expert is court appointed, it is unlikely that this information will remain unknown after questioning by both the plaintiff and defendant. Two possibilities exist for resolving this conflict. The first is to forego appointment under FRE 706 and instead use the inherent powers of the court to appoint technical advisors. These advisors provide no testimony to the ultimate trier of fact, but rather assist the judge in scientific matters. The second resolution is to provide an appropriate jury instruction with the knowledge that the jury must make decisions about the credibility of all witness testimony. In many cases, the influence of a properly sourced neutral expert may cause no harm, as both parties will continue to present a number of experts to proffer testimony that will be considered by the jury. Moreover, it is worth noting that the supposed influence of a court-appointed expert may well be warranted, given the expert's neutrality. Courts should welcome the expert's role rather than avoid it on speculative grounds.

The use of court-appointed experts is especially compelling, we believe, when the bio-pharma litigation involves a drug or device that has been recalled or when the FDA has denied approval of the new drug application. A class action based on product recall or a drug that has been

²²⁰FED. R. EVID. 706(a).

²²¹See *supra* Part IV.B. and accompanying notes.

²²²FED. R. EVID. 706(d) ("Nothing in this rule limits the parties in calling expert witnesses of their own selection.").

denied marketing approval is likely to be accompanied by even more emphasis on the interpretation of scientific data.²²³ Adverse patient reactions may be the subject of substantial debate concerning whether such reactions were caused by the drug or by an opportunistic infection.²²⁴ The parties will argue zealously for or against either proposition with experts, studies, adverse reaction data, and statistics. In the middle will be a judge, likely with limited scientific knowledge.

In the case of an FDA denial, plaintiffs and defendants will proffer voluminous scientific materials relative to the bio-pharma's public disclosures during the application process. For example, the FDA may have provided a Complete Response Letter that "[t]he investigations required under section 505(b) of the [Food, Drug and Cosmetic] act do not include adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling."²²⁵ If this reason was provided, both parties would scrutinize study protocols and the data's scientific reliability to bolster either plaintiff's alleged misrepresentations or the bio-pharma's defense of reasonable belief and lack of scienter. Again, this instance would call for serious and strong consideration of the use of a court-appointed neutral scientific expert to assist the judge in managing the case at the motion to dismiss stage.

V. CONCLUSION

Rule 10b-5, a powerful weapon against any publicly listed company whose share price drops on adverse news, is particularly skewed against bio-pharmas. It is not a coincidence that there are a disproportionate number of class actions filed against bio-pharmas.²²⁶ The volume and complexity of data underlying most bio-pharma cases create enormous outcome uncertainties, settlement pressures, and potentially huge contingent liabilities over substantial periods of time. Erroneous scientific interpretations could mean significant and costly future legal battles for a bio-pharma. The

²²³For example, substantial clinical data and interpretations of "statistical significance" were central to the decision of the court at the motion to dismiss stage in *In re Pfizer, Inc. Securities Litigation*, 584 F. Supp. 2d 621, 629-37 (S.D.N.Y. 2008). The court examined clinical trial data in three studies conducted over a five-year period indicated adverse cardiovascular events associated with the drugs Celebrex and Bextra. *Id.* at 629-30. The FDA had previously requested Pfizer to remove Bextra from the market, and it imposed a "black box" warning on Celebrex. *Id.* at 631.

²²⁴*See supra* note 103 (discussing opportunistic infection associated with Biogen Idec, Inc.'s multiple sclerosis drug Tysabri).

²²⁵21 C.F.R. § 314.125 (2010).

²²⁶KOTLER, *supra* note 12, at 2.

vulnerability and risks faced by bio-pharmas in Rule 10b-5 class actions is unique among all publicly-traded industries, yet many cases proceed along traditional grounds without courts employing either their statutory or inherent powers to obtain objective expert assessment of the data underlying plaintiffs' claims. Most judges have neither the training, nor the capacity, to differentiate between the positions of opposing experts or to reach their own independent assessment of the research data. A judicial reluctance appears to exist regarding the court appointment of experts under FRE 706 or the court's inherent authority to appoint experts or masters for assistance purposes. We do not believe that such reluctance is justified, as evidenced by the occasional successful use of objective experts in highly complex factual litigation.²²⁷

Rule 10b-5 allegations can cover a broad range of perceived misdoing, from run-of-the mill cover ups to misinterpretations of testing or adverse reaction results. These variations suggest that any procedural rule applicable to all Rule 10b-5 actions would be inappropriately broad. We have therefore necessarily limited our reform proposal to the precatory urging that courts be better trained and advised to utilize the powers they possess to obtain expert assistance at the early motion stages. The unstated premise of the *Daubert* opinion is that courts have an obligation to fully understand the evidence prior to any decision-making, and that the use of court-appointed experts will allow courts to decide motions to dismiss with greater confidence and accuracy.²²⁸ Moreover, the early appointment of such experts may have the salutary effect of causing plaintiffs to pause to consider whether the claims are sufficient to warrant the up-front imposition of court-appointed expert costs. Although the identification and qualification of independent experts may be difficult given the extensive inter-relationships between bio-pharmas and academic and research institutions, there are private organizations and judicially-appointed masters that can assist in such searches. Our proposal may result in a slowing of the judicial process and potentially higher litigation costs. Yet, if courts begin to recognize in greater numbers the importance of obtaining objective expert testimony, we believe a more level playing field will evolve to reduce the disproportionate vulnerability of bio-pharmas to securities law class actions.

²²⁷ See *supra* notes 170-76, 180-86, 202-03 and accompanying text.

²²⁸ See *supra* notes 153-64 and accompanying text (discussing *Daubert*).