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2020 Life Sciences Securities Litigation Roundup

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2020 Filings

While there was a more than 20 percent decline in the number of securities class actions filed in 2020 (approximately 330 cases) as compared to 2019 (approximately 430 cases), the percentage of cases filed against life sciences companies remained steady at more than 20 percent of the total.[1] Only a half dozen of the new 2020 filings related to COVID-19.

These statistics illustrate that life sciences companies remain attractive targets for securities class action plaintiffs. This is so for several reasons. The uncertainties facing drug and medical device companies are often binary—success or failure of a clinical trial or approval or rejection of a new drug application by the U.S. Food and Drug Administration (FDA). If the clinical hypothesis being tested is not proven or even if a demonstrated clinical benefit is not seen as sufficiently meaningful or if safety and tolerability profiles are not acceptable, life sciences companies' stock prices often immediately drop precipitously. The loss of market value may be particularly severe for clinical stage companies with a single product candidate nearing approval. Moreover, because clinical trials are expensive and revenue is delayed for years in the lengthy FDA testing and approval process, many life sciences companies are required to tap the public markets to fund ongoing studies. Companies that conduct public offerings after announcing positive interim clinical trial results that are followed by less favorable results may also find themselves facing claims under the Securities Act—which do not require a showing of fraud and are subject to concurrent jurisdiction in less experienced state courts.

In addition, drugs and devices may turn out to have troubling side effects that can result in trials being stopped, products being withdrawn, "black box" warnings being required, or enhanced post-market surveillance being mandated. Such matters may adversely affect a life sciences company's stock price, often triggering securities class action litigation.

Finally, beyond the vicissitudes of clinical trials, FDA approval, and post-market surveillance processes, the intense regulation of life sciences companies by the FDA, Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services (HHS), and other agencies —as well as civil and criminal investigations relating to the opioid epidemic, the COVID-19 pandemic, and allegedly anticompetitive conduct—can result in related securities litigation. Last year, a half-dozen cases asserted claims relating to pre- and post-approval inspections for compliance with current good manufacturing practices (cGMP).

As discussed more fully below, the decisions in 2020's crop of life sciences securities class action decisions provide useful guidance as to how companies can minimize the prospect of such suits and maximize their defenses if such claims are filed.

2020 Decisions

Clinical Trials

Successful Trials Where FDA Approval Is Limited or Conditioned

Companies with successful clinical trials are not immune to securities litigation. Even where a study achieves its primary efficacy endpoint, the FDA may nonetheless reject an application for a new drug or device or limit or condition its approval. Such cases often involve circumstances where an efficacious drug presents safety concerns, where the trial's design is deemed deficient, or where data related to important secondary endpoints are inconclusive, problematic, and/or still accruing.

In three cases decided in 2020, the FDA *approved* new drug applications (NDAs) based on successful trial results but either denied approval for a secondary indication afflicting a subgroup of patients (*Alnylam Pharmaceuticals*), required safety warnings to be included in the products' labeling after originally denying an initial NDA (*Antares Pharma*), or mandated that additional post-market safety studies be conducted (*Intercept*). All three cases were dismissed, finding the defendants' optimistic opinions about the trial results to be inactionable as a matter of law.

Thus, in *Alnylam*, the court held that interpretations of trial results are opinions which are not ordinarily actionable even if the FDA ultimately takes a different view. The court also held that opinions about the likelihood of FDA approval "are classically forward-looking" statements which, if accompanied by warnings that the FDA might disagree and deny approval, are sufficient to invoke the protections of the PSLRA's Safe Harbor. Similarly, in *Antares* the court held that the company's characterization of safety data as "positive" was both immaterial "puffing" and—like any interpretation of clinical trial data—an opinion, actionable only if it is "not honestly believed and lacks a reasonable basis."

The courts in *Antares* and *Intercept* also held that the defendants' optimistic statements about safety were not misleading where the fact (but not the details) of adverse events and their potential implications were disclosed. Indeed, in *Intercept*, where the company disclosed the fact and risk of recurrence of hepatoxic side effects in its pivotal trial, the court refused to infer materiality or causality with respect to serious adverse events (SAEs) in the Phase 4 aftermarket study, because 1) the numbers were very small, 2) "hepatoxicity is a known complication of most prescribed drugs," and 3) "[s]ome adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill."

These cases affirm that reasonable, caveated, opinions concerning trial results, overall safety, or the prospects for approval will not ordinarily support a securities claim. These cases also demonstrate that while detailed quantitative data is not required, candid disclosure about known side effects and adverse events, as well as the risk that such safety-related issues may recur and affect approval, can counter claims that investors were misled if the FDA ultimately imposes safety-related limitations or, as discussed below, denies approval.

Non-Approval Due to Safety Concerns/Adverse Events

Several cases involved trials which achieved their primary endpoints but approval was nonetheless denied, typically due to safety issues.

In *Endologix*, the plaintiff challenged the company's cautiously optimistic statements that it expected FDA approval of its device based on its successful clinical trial, an opinion the company reiterated when the FDA requested further data about a safety issue that had manifested over time for some patients in an earlier European study. Ultimately, Endologix announced that rather than seeking FDA approval, it would develop a second-generation device addressing the issues encountered in Europe. The U.S. Court of Appeals rejected as "implausible" the plaintiffs' theory of fraud, deeming it "improbable that [a company] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure."

Courts were particularly dismissive of cases where the drug being tested had known and disclosed side effects which the company warned might recur. *See also Intercept, supra.* In *Cempra*, the U.S. Court of Appeals for the Fourth Circuit affirmed the dismissal of claims challenging the company's opinions that adverse events experienced in a trial of its drug, which was in a class of pharmaceuticals with known toxicity issues, were "less severe" than those experienced with similar drugs. Cempra also disclosed that adverse events had occurred and warned that the FDA might not agree with interpretation of the safety data, which could (and ultimately did) lead to non-approval. The court concluded that these candid disclosures were inconsistent with any inference of an intent

to deceive investors. Similarly, the court in *Zogenix* rejected claims challenging optimistic statements that despite known toxicity issues, the company expected its drug, previously approved for other indications, would be authorized by the FDA. Instead, the FDA issued a "refusal to file" indicating that the company would be required to include pre-existing toxicity data related to other similar drugs. The court dismissed the case, noting that 1) the company warned investors about, and made no affirmative statements at odds with, the drug's overall safety data, and 2) there were no allegations that the FDA had previously alerted the company that it would require toxicity data for other similar products to be included in the NDA.

However, in a case involving a trial of a new molecule, *Array Biopharma*, the court held that the company's positive statements—most of which were limited to the accurate disclosure that the trial achieved its primary endpoint—were materially misleading because the company failed to disclose negative data related to the secondary endpoints of tolerability, patient-reported quality of life, and overall survival. The court held that "the fact that Defendants may not have made affirmative misrepresentations [referencing the secondary data] does not excuse the alleged material omissions made about the negative study data," apparently swayed by the fact that *after* Array withdrew its NDA, European regulators issued a "non-conclusive" report that the adverse secondary data "all but eliminated the clinical benefit of the treatment."

The reasoning in *Array* is difficult to square with the U.S. Supreme Court's controlling decision in *Matrixx* (not cited by the court), which held that even material data related to clinical trials is not ordinarily required to be disclosed unless its omission renders an affirmative statement materially misleading. Applying this principle, most courts (including *Aveo, infra*) hold that accurate reporting of topline results concerning a primary endpoint does not imply anything about other data in the trial and, thus, does not require such information to be disclosed.

The *Array* court also held that the Private Securities Litigation Reform Act of 1995's (PSLRA's) Safe Harbor was not applicable because 1) the company's forward-looking statements about approvability were intermixed with statements of existing facts and 2) the accompanying cautionary disclosures omitted material facts about the negative secondary data. Again, these conclusions are not easily reconciled with the language of the Safe Harbor and the majority of decisions (including *Alnylam*) applying the provision. Finally, the court found that the company's decision to limit its NDA to patients with greater progression-free survival (PFS) benefit suggested it knew the adverse secondary data would imperil broader approval. *Cf. Endologix*. This inference, together with facts suggesting motive, i.e., that 1) the drug was Array's first and "most important" product, and 2) the company conducted a public offering before the adverse secondary data was disclosed, were deemed sufficient to give rise to a strong inference that the company intentionally or recklessly concealed that data from investors.

Array serves as a cautionary tale for small clinical-stage companies dependent on the approval of a previously untested product and also dependent on the capital markets to raise capital to continue their studies. As discussed further below, even where there is no duty to disclose confounding or problematic underlying trial data, the failure to do so has risks. *Array* is also one of several 2020 cases counseling in favor of carefully crafting forward-looking statements and against relying on boilerplate, unchanging risk factors. *See Apyx, Trevana* and *Innocoll, infra*.

Limited or Non-Approval Due to Data Insufficiencies

Courts also dismissed cases where a trial achieved its primary efficacy endpoint but concerns about the sufficiency of still-accruing data resulted in the FDA limiting approval (*Alnylam, supra*) or advising that an application be delayed. (*Aveo Pharmaceuticals*). In *Aveo*, the FDA advised the company to delay filing its Biologics License Application (BLA), even though the trial met its primary PFS endpoint of because of concerns that secondary overall survival (OS) data was still accruing, not trending favorably, and patients were being "lost to follow up." The *Aveo* court held the company's disclosure of the study's topline PFS results and that the interim OS data had not yet shown a benefit, as well as the disclosure that patients were dropping out of the continuing OS aspect of the trial, did not give rise to any duty to provide further details or require the company to speculate that the FDA would recommend delaying the filing of a BLA, particularly because the company had warned of the risk and potential impact of delays as well as the uncertainties related to OS outcomes. Again, *Aveo* demonstrates the utility of well-crafted risk disclosures.

Failed Clinical Trials

Surprisingly, only three decisions last year involved cases where pivotal trials failed to achieve their primary efficacy endpoints. One such decision, *Tokai Pharmaceuticals*, affirms that even a failed clinical trial ordinarily will not support a securities fraud claim where the company candidly

discloses critical information about its trial's design limitations and uncertainties about the underlying clinical hypothesis, as well as the consequent risks that the trial will not succeed. Two other cases, however, sustained claims where challenged statements concerning trials that later failed were both categorical and contradicted by contemporaneously available information.

In i, a device manufacturer rejected as "unsubstantiated" and a "blatant mischaracterization" a short seller's speculation that a delay in announcing trial results likely indicated that the study had failed to meet its primary endpoint. That speculation turned out to be accurate, as the company announced several weeks later. The court held that the categorical denial of the short seller report misled investors to believe that the trial had demonstrated the efficacy of the device. In the court's view, the defendants' knowledge that the trial had failed, coupled with the fact that the company was dependent on the success of the device, provided a strong inference that its affirmative denial of the short seller's report and its delayed disclosure of the trial results was reckless or intentional and meant to deceive investors. Moreover, like the court in *Array*, the *Apyx* court determined that the company's forward-looking statements about its prospects for FDA approval were not entitled to protection under the PSLRA's Safe Harbor, because 1) they mixed matters of ascertainable fact with future projections and/or 2) the accompanying risk disclosures were "boilerplate" and "not narrowly-tailored to the existing known risk," which had already materialized.

Apyx is instructive because it demonstrates that comments on negative third-party reports may be deemed to be affirmative representations to the contrary. Although speculative short seller reports are often biased, move the market (particularly for small, thinly traded companies), and infuriate management, it may be better to bite one's tongue or, at least, carefully script any response. *Apyx* also suggests that it may be better to bite the bullet and promptly disclose disappointing news rather than to delay its inevitable disclosure, perhaps by third parties whose interests are not necessarily aligned with the company's. *Apyx* is also one of several 2020 cases that counsel in favor of carefully crafting forward-looking statements and against relying on boilerplate, unchanging risk factors in order to assure safe harbor protections. *See also Array, supra* and *Trevana* and *Innocoll, infra.*

In another case involving a failed clinical trial, *NewLink*, the U.S. Court of Appeals for the Second Circuit largely reversed the district court's prior dismissal. In *NewLink*, the company stated that its Phase 3 trial design and its interpretation of topline interim OS results were premised upon life expectancy assumptions it claimed were supported by "all the major studies." However, the plaintiffs cited an equal and equally credible number of studies suggesting that the company's life expectancy assumptions were too low. When topline interim results, which were not broken out by treatment and control groups, showed that, overall, study participants were living longer than the company's life expectancy assumptions, the company rejected suggestions that those assumptions might be incorrect, implying that the drug was efficacious. When the final data was unblinded, however, it turned out that the seemingly positive interim topline results reflected that patients in the control group not only lived longer than expected (but within the timelines predicted by scientific literature not considered by the company), they also outlived patients in the treatment group.

The district court in *NewLink* had dismissed claims challenging the company's statements about expected survival rates as reflecting a mere difference of scientific opinion, agreeing with the majority of courts (including the U.S. Supreme Court in *Omnicare* and the courts in *Antares* and *Alnylam, supra*) that opinions about clinical trial design and the interpretation of data are generally not actionable so long as those opinions have a reasonable basis and are genuinely believed. However, the Second Circuit concluded that the company's representations about life-expectancy did not qualify as opinions, noting the "specificity of the representation and the authority with which it was made"—asserting that *all* the major studies were in accord—together with the fact that the statement was not framed by language such as "we think" or "we believe." Finding that investors would consequently not be alerted to the fact that the statements about life expectancies were merely opinions, the Court of Appeals determined that "a reasonable person [might] think that a more detailed investigation [of the scientific literature] lay behind the ... statement" and that "no meaningful evidence existed to rebut" the company's life expectancy assumptions. In this regard, the court also considered the context in which the statement was made—i.e., it was part of a well-prepared professional presentation at an important conference for biotech investors, in contrast to an off-the-cuff statement in response to an impromptu question during an investor call that might arguably be entitled to more leeway.

The Second Circuit also noted that even if the statements about life expectancy assumptions were considered as opinions, a statement of opinion can be actionable where it implies the absence of contrary facts—i.e., that there were not studies suggesting a longer life span for afflicted patients. Although the Supreme Court in *Omnicare* held that an opinion is not misleading simply because of "some fact cutting the other way," the *NewLink* Court determined that "the sheer volume of

competing facts [i.e., the numerous contrary studies referenced by plaintiffs] required the company either to speak less confidently about the control group's [expected] survival rate or to disclose the existence of studies showing [longer] survival rates."

In the same vein, the U.S. Court of Appeals disagreed with the lower court concerning NewLink's discussion of the interim top line survival data, specifically its statement that it did not have "any reason" to believe that the control group could live longer than it had assumed. The court held that in making this statement the company again misleadingly "implied that there were no competing facts on survival rates, not that [it] had merely deemed [any such] competing facts less persuasive."

NewLink suggests that when referencing scientific literature in support of clinical trial assumptions or interpretations, a company should consider 1) refraining from using definitive phrases like "all" studies, 2) conducting a reasonably complete survey of studies on the subject, 3) acknowledging the existence of credible competing points of view and explaining why the company believes them to be less persuasive, 4) prefacing its statements with phrases such as "we think" or "we believe" so they are clearly understood to be opinions, and 5) providing caveats explaining *specific* ways that results could differ from expectations, e.g., that the assumptions about life expectancy or other relevant design parameters could turn out to be incorrect. Another 2020 case, *Recro Pharma*, held that where experts' views are at odds with a company's more optimistic statements and opinions, such statements may be materially misleading, although the court dismissed the claims because the evidence was insufficient to demonstrate that these contrary views were known to senior executives.

These cases demonstrate that companies should always consider whether their own positive opinions should be caveated to at least acknowledge in a general way that competing scientific perspectives exist. *NewLink* also teaches that comments concerning the interpretation of topline interim trial results should always be approached with caution. *NewLink* is not the only case in recent memory where unblinding revealed that the control group performed better than the treatment group and explained the seemingly positive topline results.

Communications with the FDA

Lack of Prior FDA Warnings

Several of the decisions discussed above held that the absence of prior FDA warnings about deficiencies that ultimately lead to non-approval undermined an inference of scienter. *See Aveo, Zogenix,* and *Antares, supra*. Similarly, in *Ampio*, the court rejected claims that the defendants knew or were deliberately reckless in ignoring the risk that deficiencies in the design of its successful trial would be questioned and lead to non-approval where the FDA had not previously expressed concerns in that regard. The *Ampio* court also rejected the plaintiff's suggestion that the company was reckless in failing to seek input from the FDA with respect to its trial design prior to its final pivotal trial. As in *Endologix*, the court rejected the plaintiffs' theory of fraud as illogical. The court held that "[t]he idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly carry on a defective trial ... virtually defies reason[.]" Again, the decision *Array*, where the company did not receive negative feedback from European regulators until *after* the company withdrew its NDA, is an outlier.

Undisclosed FDA Communications

Where the FDA did express concerns about safety or trial design that were neither heeded nor disclosed, courts split as to whether the failure to disclose the regulators' negative feedback stated a securities fraud claim. In such cases, courts assessed whether the omitted information 1) was material and 2) rendered optimistic statements about a company's product obtaining or retaining approval materially misleading, as *Matrixx* instructs.

In *ReWalk Robotics*, the U.S. Court of Appeals for the First Circuit reaffirmed the general rule that life sciences companies do not ordinarily have an affirmative obligation to disclose "each detail of every communication with the FDA." Instead, the Court of Appeals held that "a failure to divulge the details of interim 'regulatory back-and-forth' with the FDA ... when the defendants do provide warnings in broader terms does not generate a strong inference of scienter." Accordingly, although the FDA repeatedly expressed concerns about ReWalk's delayed and allegedly deficient post-market surveillance compliance—a condition of its device's approval—the court held that the company did not violate the securities laws by not disclosing the FDA's informal complaints prior to the issuance of a formal warning letter. The U.S. Court of Appeals also noted that ReWalk did regularly warn investors about the consequences of non-compliance, including the potential for the product's

withdrawal from the market—which did not occur—and that such disclosures undermined any inference of scienter.

In contrast, in *Trevena*, the court denied a motion to dismiss where the company failed to disclose that the FDA had raised objections and concerns prior to the start of the company's Phase 3 study, questioning the trial's design, including its primary endpoints. Ultimately, Trevana's NDA was rejected on an advisory committees' recommendation which referenced the failure to address the FDA's concerns. The *Trevana* court held that the company's positive statements about its trial and its drug's prospects for approval were materially misleading in light of the company's failure to disclose the FDA's unheeded objections. The court also held that the company's precarious financial situation and its dependence on the product for which it was seeking approval supported an inference that the company had a motive to conceal the FDA's objections from investors—again, a common theme.

In denying the motion to dismiss, the *Trevana* court also rejected the argument that the *ReWalk* court found persuasive, i.e., that risk disclosures that the drug might never be approved refuted any claim that investors were misled or that defendants acted with an intent to deceive. The *Trevana* court determined that such "boilerplate," unchanging risk disclosures were ineffective where specific risks —i.e., the FDA's *stated* disagreement with the trial's design—had already materialized but were not disclosed.

These cases demonstrate that companies ignore FDA informal guidance at their peril—both with respect to the regulatory consequences for their products and securities law exposure for the company and its senior executives. While there is no duty to disclose regulatory back-and-forth or interim, non-official guidance (*ReWalk*), optimistic statements about a product's prospects that might otherwise be protected may be deemed actionable where negative feedback from the FDA is not disclosed. The decision in *Trevana*, like those in *Array* and *Apyx, supra*, and *Innocoll, infra*, also cautions that companies should regularly review their risk factors, making certain to update and tailor cautionary statements to address new developments and changing circumstances. This is particularly true where, as in *Trevana*, the company has received less-than-positive regulatory feedback. In such cases, warning of merely possible risks may be ineffective because the risk may be viewed as having manifested. But *cf. ReWalk, supra*.

Mischaracterized FDA Communications

Unlike *Trevana* and *ReWalk*, where the companies failed to disclose negative FDA feedback, a number of cases involved overly optimistic characterizations of companies' communications with regulators. Again, while a company is not ordinarily required to disclose informal or interim FDA communications, once a company chooses to speak about the FDA's comments, its characterizations of such feedback must be accurate and not misleading by omission.

In *Acer Therapeutics*, the defendants' offering documents represented that "the FDA agreed that additional clinical development [was] not needed and stated that we may submit a 505(b)(2) NDA." In a subsequent SEC filing, this representation was amended to state that the FDA had agreed that "an additional clinical trial is not *likely* needed." While the FDA did not refuse to file the NDA, it determined that the data (licensed from a European observational trial) was deficient. The court held that the company's changed its characterization of the FDA's "agreement" suggested that the less equivocal version in its offering documents was false. In the court's view, this also supported an inference of scienter. In contrast to the courts in *Endlogix* and *Ampio*, the notion that a company, highly dependent on a single product, would "bet the farm" and seek FDA approval despite knowing that its data was deficient did not strike the *Acer* court as implausible. Rather, the court found that the more plausible inference was that the company simply took "a gamble" on approval despite known deficiencies in the data submitted in its NDA.

The defendants in *Innocoll* also suffered the consequences of overstating supposed "agreements" by the FDA with respect to its clinical trials. In *Innocoll*, the company stated that the FDA had agreed to the use of an integrated endpoint, rather than requiring separate testing of the drug and device components of the product. Instead, it appeared the FDA had only agreed to allow the integrated trial to proceed without providing any agreement that such a trial would be sufficient for approval. Subsequently, in its "refusal to file" letter, the FDA indicated that separate trials of the device component of the product were required. In holding that the plaintiff adequately alleged that the company's overstated representations about the FDA's "agreement" were made with scienter, the *Innocoll* court, like the court in *Acer*, noted that the defendants were "strapped for cash" and, thus, it was plausible that they decided to forgo the expensive separate device testing. The court also held that the generic warning that the FDA might not accept the NDA did not counter any such inference or refute allegations that investors were misled, because the risk factor was "boilerplate," did not change over time, and was not tailored to the risk that the FDA might require that the device

be tested in a separate study. Accordingly, the *Innocoll* court, like the courts in *Trevana, Array,* and *Apyx*, held that the company's general warnings were insufficient 1) to render the company's statements not misleading or 2) to insulate forward-looking statements under the PSLRA's Safe Harbor.

These cases illustrate the need for caution in characterizing FDA communications and suggest consideration of policies limiting comments on interim feedback. The risks of inadequate risk factors, and the increased likelihood that perceived short cuts by small companies strapped for cash will support an inference of scienter, heightens the risks posed by even inadvertent mischaracterization of FDA feedback.

Post-Approval Issues

In addition to *ReWalk*, which involved post-market surveillance compliance, a number of cases addressed adverse events and safety issues arising with respect to products already on the market. In *Intercept*, where the risk and potential consequences of post-approval adverse events were accurately disclosed, the court rejected claims that investors were misled because specific details of such occurrences were not provided. In so holding, the *Intercept* court also noted that the number of SAEs during a Phase 4 post-market surveillance trial were small and arguments that defendants were "motivated to conceal the very safety issues that their company was reporting to the FDA in order to prevent a negative [market or] regulatory response" were implausible.

In a case against Avanos Medical, the U.S. Court of Appeals for the First Circuit affirmed the dismissal of claims that the defendants intentionally concealed defects in their surgical gowns, agreeing with the district court that the plaintiff failed adequately to plead that the executive defendants were aware of the alleged product defects. Moreover, the First Circuit also held that a single statement that the gown was a "key product" was insufficient to support an inference of scienter under the "core operations" theory—a "must have known" inference which the Second and Ninth Circuits have endorsed in very limited circumstances. *See, e.g., Align* and *Immunomedics, infra*.

FDA Compliance

Current Good Manufacturing Practices

Six cases decided in 2020 involved an alleged failure to comply with FDA current good manufacturing practices (cGMP), premised on a failure to disclose inspectional observations of possible cGMP violations noted by the FDA on Form 483s. Such inspections occur both in connection the pre-approval process and also to assure continued compliance by established manufacturers. A 2020 decision in *Nabriva Therapeutics* undertook an exhaustive review of decisions concerning non-disclosure of Form 483s, adducing key principles from past cases that also help in understanding the Form 483 cases decided in the past year.

As an initial matter, *Nabriva* confirmed the generally accepted rule that because a Form 483 constitutes interim FDA feedback, Form 483s are not necessarily material. *See also PolarityTE* and *Ocular Therapeutix infra; accord ReWalk, supra*. As the Nabriva court explained, the "advisory language that accompanies all Forms 483, to the effect that the circumstances noted therein are merely observational in nature" make plain that they "do not represent a final agency determination regarding ... compliance."

The *Nabriva* court then surveyed prior cases and determined that courts require disclosure of a Form 483 only in very specific circumstances, i.e., 1) where the consequences of the Form 483 are qualitatively and quantitatively material, e.g., where the Form 483 relates to inspections required for FDA approval and commercial launch of a small company's sole or significant new product (*Nabriva; Immunomedics; Ocular; Teligent; PolarityTE*) and 2) where its omission renders an affirmative statement materially misleading, e.g., a) where the company made *an affirmative statement* that it was cGMP compliant (*Teligent*); or b) where the company warned only that FDA citations *might* be issued, when, in fact, a Form 483 had already been received (*Nabriva; Immunomedics*).

Even where nondisclosure of a Form 483 arguably renders an affirmative statement materially misleading, the omission does not give rise to a securities law claim absent additional facts giving rise to a strong inference that the defendants acted with scienter, i.e., that the defendants not only knew about the Form 483 but intentionally or recklessly misled investors by failing to disclose it. Because there were no facts supporting a strong inference of scienter in *Nabriva*, and the court determined the more plausible inference was the defendants believed they could resolve the cited issues, the court dismissed the case. However, the same court later reached the opposite result

in *Teligent*, finding that the fact that the CEO denied receipt of a Form 483 which was specifically addressed to him gave rise to a strong inference of intentional or reckless conduct. The court in *Immunomedics* found scienter was sufficiently alleged where 1) the Form 483 concerned "core matters of central importance to a company," i.e., the approval of a new drug that was critical to the financially struggling company's success, 2) the citations related to a serious data integrity breach, 3) the company conducted a public offering, and 4) the defendants downplayed the FDA's concerns when they were publicized by third parties.

The courts in *Nabriva, Teligent, PolarityTE*, and *Akorn*, also determined that the companies' more general statements, conveying a commitment to, or outlining risk factors concerning, compliance (*Teligent; Akorn*), the likelihood of FDA approval (*Nabriva*), or statements that were mere "puffing" (*PolarityTE*), were not rendered misleading by non-disclosure of the Form 483s, particularly where the FDA's inspectional observations were not shown to be irremediable, pervasive and persistent, or ignored. In *Akorn*, the court also rejected allegations that the announcement that the issues cited in a Form 483 had been resolved to the FDA's satisfaction somehow misleadingly implied that no potential compliance issues remained.

While most of last year's cases challenged the non-disclosure of Form 483s, Ocular Therapeutix was sued even though it immediately advised investors that it had received a Form 483 in connection with a pre-approval inspection. The First Circuit held that the company's prompt disclosure of the Form 483, along with its warnings about the nature and consequences of any failure to resolve the cited issues—including delay or denial of approval of its new treatment—undercut any inference that the defendants intentionally or recklessly misled investors. The U.S. Court of Appeals also affirmed the dismissal of claims challenging statements of optimism about the company's ability to remediate the cGMP issues cited in the Form 483.

In sum, 2020's Form 483 cases (as well as the earlier cases summarized in *Nabriva*) suggest that even though such citations are not ordinarily required to be disclosed, small companies whose future success depends on approval of a new product, which, in turn, depends on the resolution of cited cGMP issues, should, like Ocular, consider prompt disclosure. All companies should take care not to overstate their level of cGMP compliance and instead describe compliance as an aspirational goal which may not be achieved in a complex and changing regulatory environment. Once a company receives a Form 483 (or even before that time) it should modify risk factors as necessary to indicate that cGMP citations are more than merely possible but are, in fact, sometimes received—language which should obviate any duty to disclose subsequent Form 483s. Once and if observational citations result in official FDA correspondence or actions, of course, disclosure is more likely to be required.

Off-Label Marketing

Two cases involved claims that pharmaceutical companies improperly promoted their products for "off-label" uses not approved by the FDA and allegedly misled investors by not disclosing this practice. Both cases were dismissed. In *Corcept Therapeutics*, the court held that the fact that sales personnel engaged in off-label selling efforts failed to support a securities law claim because there was no showing that they were acting at the behest of management. In a case against Depomed, the plaintiff sufficiently alleged that regional sales directors instructed salespeople to pitch off-label dosages, i.e., opioid dosages higher than the FDA approved, but failed to show that these instructions were actually ever followed, much less that they were widespread. Accordingly, the court held that the plaintiff failed to establish 1) that any statement was rendered misleading by any non-disclosure or 2) that the defendants acted with scienter.

Non-FDA Issues

Scientific Conference Presentations

Immunomedics had the dubious distinction of litigating (and, unfortunately, losing) motions to dismiss in two distinct securities class actions last year. One of those cases involved the company's failure to abide by the confidentiality rules of the prestigious American Society of Clinical Oncologists (ASCO) which resulted in the company being disqualified from ASCO's conference. Both acceptance to and disqualification from ASCO were a big deal: While the company benefited from the so-called "ASCO bounce" when it announced that its abstract had been accepted for presentation, news that ASCO subsequently disqualified the company because it had already discussed the data at another scientific meeting caused Immunomedics' stock to lose 60 percent of its value. The court held that the company's statement that its abstract had been accepted by ASCO was materially misleading because it necessarily implied that the company had complied with ASCO's requirement that its presentation provide new, not-previously-disclosed data while the defendants were aware of the fact and consequences of their earlier presentation of the same information at a competing scientific

meeting. The fact that certain insiders sold some of their personal holdings after assuring investors that they believed they could reverse ASCO's decision did not help the defendants' cause.

While Immunomedics' troubles arose from trying to "date around" in the scientific community, many biotech companies face the dilemma of trying simultaneously to satisfy the SEC disclosure rules and the exclusivity requirements of medical conferences and journals. Although most conferences' and journals' rules provide for "SEC exceptions," they are generally narrow and can be difficult to navigate. For example, ASCO's rules suggest that only topline qualitative data be disclosed—i.e., that the trial met its primary endpoint, or that interim data is "encouraging"—while more quantitative details must await presentation at the conference. Particularly where data is not entirely positive, the plaintiffs often claim that delayed disclosure in advance of a scientific presentation violates the securities laws. In negotiating these disparate disclosure dictates, companies announcing topline results are well advised to avoid any discussion of a trial's underlying quantitative data prior to its publication or presentation, heeding the *Basic* maxim that in the context of the securities laws, "silence absent a duty to disclose is not misleading." Where the underlying data is clearly material and/or decidedly negative, however, the better course may be early disclosure, particularly where a scientific presentation of the trial's full results would likely disappoint investors and medical experts alike.

Discounts, Rebates, and Anticompetitive Conduct

In *Align Technology*, the court denied a motion to dismiss claims related to alleged discounting, applying the "core operations" theory where the device at issue contributed more than 85 percent of the company's revenues. In a case against AbbVie, statements about the reasons for the success of the company's principal drug were held to be materially misleading where the company failed to disclose an alleged kickback scheme that supposedly spurred sales. Finally, in *Mylan*, the court further narrowed claims related to alleged CMS reimbursement classifications, rebates, and alleged anticompetitive conduct in the generics industry.

2020 Life Sciences Offerings

According to Wilson Sonsini's *Technology and Life Science 2020 IPO Report*,[2] 89 life sciences companies priced IPOs during 2020. 65 percent of the IPOs (58) were for biotech companies. All but 15 of the life sciences IPOs had a total deal value of less than $250 million, suggesting that some of these companies may need to raise additional capital if they are unable to obtain approval of and revenue from products currently in clinical development. While it is good news that investors are eager to fund biotech companies including those without products or even near-term prospects,[3] the number of newly public, relatively small life sciences companies suggests that securities litigation in this particularly vulnerable sector is unlikely to abate.

About the Authors

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Wilson Sonsini has more than 200 litigators in 16 offices around the world, including securities and governance litigators in California, New York, Washington, D.C., Delaware, and Seattle. According to Lex Machina, in 2020 Wilson Sonsini was one of the top firms retained to handle securities litigation cases nationwide, a distinction the firm has maintained for several decades, and is "considered the first port of call for technology and life sciences companies and their executives in defending high-stakes securities litigation claims" by *Chambers USA*. The firm represents public companies, private entities, and their officers and directors in securities and derivative actions in federal and state trial and appellate courts and Securities and Exchange Commission (SEC) and regulatory proceedings as well as in connection with government and internal investigations and corporate governance matters.

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[1] https://www.nera.com/publications/archive/2021/recent-trends-in-securities-class-action-litigation--2020-full-y.html; https://www.cornerstone.com/Publications/Reports/Securities-Class-Action-Filings-2020-Year-in-Review.

[2] https://www.wsgr.com/a/web/39303/Wilson-Sonsini-2020-IPO-Report.pdf.

[3]https://www.wsj.com/articles/biotech-startups-gain-leverage-as-ipos-spacs-beckon-11614249001?page=1.

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