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Second Circuit Highlights Difficulty in Pleading Fraud Claims Involving the Interpretation of Clinical Data

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Plaintiffs often file securities fraud claims against pharmaceutical companies alleging that the company misled investors about clinical data, despite the US Food and Drug Administration (FDA) subsequently approving the drug and agreeing with the company's interpretation.

In December 2023, the US Court of Appeals for the Second Circuit **affirmed dismissal of securities fraud claims** arising from this fact pattern. The plaintiffs alleged the defendant company misled investors by stating that its device could be marketed as a healthier alternative to cigarettes. In affirming dismissal, the Second Circuit decided two important issues about statements characterizing clinical trials and the interpretation of data.

First, building upon a line of related Second Circuit precedent, including ***Kleinman v. Elan Corporation*** and ***Tongue v. Sanofi***, the court held that interpretations of scientific data consistent with the FDA's **ultimate** views are per se reasonable and thus inactionable as a matter of law. Such agreement is not required, however – the court also made clear that even where a regulator does not agree with a defendant's interpretation, the defendant's opinion is not misleading as long as the defendant actually held the view and conducted a meaningful inquiry.

Second, the court held that general statements that a trial complies with Good Clinical Practice requirements are inactionable opinions because they are inherently subjective. Such statements are protected even when not prefaced by "we believe" or "we think."

The Second Circuit's opinion provides strong support for pharmaceutical companies that face securities fraud claims based on an alleged misinterpretation of clinical trial data.

Background

The defendant company, Philip Morris International ("PMI" or "the Company"), developed IQOS, a device that it marketed as a safer alternative to cigarettes. IQOS heats, but does not combust, tobacco in single-use cartridges called HeatSticks. PMI first launched IQOS in Japan and sought to market it in the US. Around early 2017, the Company applied for FDA authorization to market IQOS in one of several ways:

1. For general use, without any claims about health benefits.
2. As a "reduced exposure" tobacco product, which reduces exposure to harmful chemicals.
3. As a "reduced risk" tobacco product, which reduces the risk of tobacco-related diseases.

While the FDA application was pending, the Company expressed optimism about continued sales growth in the Japanese market and FDA approval. In the same time frame, Reuters published an article reporting that a former PMI scientist alleged "serious irregularities" with the IQOS clinical studies. About a month later, an FDA advisory committee recommended that the FDA grant the application as a "reduced exposure" tobacco product but deny it as a "reduced risk" product. PMI's stock price dropped after the Reuters article and the FDA committee's announcement.

In April 2018, PMI disclosed that IQOS' share of the tobacco market in Japan was growing, but that HeatSticks sales – a lagging indicator to device sales – were down 39%. That day, the price of PMI stock dropped again.

In September 2018, the plaintiffs filed a securities class action complaint in the US District Court for the Southern District of New York alleging claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. Among other things, the plaintiffs alleged that PMI made false or misleading statements about the IQOS clinical study results and methodology.

In April 2019, while this action was pending in the district court, the FDA authorized PMI to market IQOS. In July 2020, the FDA also authorized marketing it with "reduced exposure" claims, finding that the studies showed that IQOS significantly reduces exposure to harmful chemicals, and that while PMI did not demonstrate IQOS would significantly

reduce harm and risk of tobacco-related diseases, lower exposure would be "reasonably likely" to reduce risk of tobacco-related morbidity and mortality.

The district court dismissed the plaintiffs' complaint in February 2020, and again in September 2021, twice finding that it failed to adequately plead falsity and scienter.

The decision

The Second Circuit affirmed the district court's dismissal, holding that the plaintiffs failed to allege that any statement was false or misleading when made.

Statements about Good Clinical Practice compliance are opinion, not fact

The court held that the Company's statements that certain studies were conducted according to **Good Clinical Practice (GCP)** – **an international quality standard for clinical trials** – were inactionable opinion.

The Second Circuit first rejected the plaintiffs' technical argument that the statements could not be opinions because they did not start with language such as "we think" or "we believe." It instead interpreted the Supreme Court's 2015 decision in ***Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*** as holding that language like 'we believe' or 'we think' is **sufficient** –not **necessary** – to render a statement one of opinion rather than fact." Indeed, the court went on to clarify that where a statement expresses an "inherently subjective … assessment, that is **also** sufficient to render it one of pure opinion."

To that end, the Second Circuit agreed with the defendants that GCP are not a set of hard-and-fast rules such that compliance is objectively verifiable, but rather are general and inherently subjective standards (including, for example, having "scientifically sound" clinical trials and "qualified" researchers"). A statement confirming compliance with GCP is thus an opinion because it requires "inherently subjective" determinations. To further illustrate this, the court pointed out that while the plaintiffs relied on allegations from a former PMI scientist "confirming GCP violations," the FDA itself had identified no GCP violations in its own "extensive" review.

The court also rejected the plaintiffs' argument in the alternative that the defendants' opinions regarding GCP compliance were nonetheless actionable because they failed to disclose the alleged GCP violations. The Second Circuit reasoned that it was simply the plaintiffs' **opinion** that there were GCP violations and, under *Omnicare*, the defendants' (and FDA's) opinion that the trials were GCP-compliant is not rendered misleading by failing to disclose "the **possibility** of contrary **opinions**." As the court put it, "uch a holding would violate the fundamental principle that the securities laws do not require the people in charge of an enterprise to take a gloomy, fearful, or defeatist view of the future, and instead allow them to be confident about their stewardship and the prospects of the business that they manage."

Opinions about study results are per se reasonable when consistent with FDA interpretation

In another matter of first impression, the Second Circuit held that opinion statements concerning "an interpretation of scientific data that is ultimately endorsed by the " are inherently reasonable, and thus not actionable.

The plaintiffs claimed that PMI's statements characterizing the study results as supporting the conclusion that IQOS has the potential to reduce the risk of smoking-related diseases were false because the advisory committee did not consider the results sufficient to substantiate such claims – though the FDA itself later approved IQOS and determined it would "significantly reduce" exposure, which was "reasonably likely" to translate to lower morbidity and mortality risk in subsequent studies.

As referenced above, the court harkened back to previous decisions in *Kleinman* and *Tongue,* where the Second Circuit held that "dispute about the proper interpretations of data" cannot support a claim for securities fraud. In the 2013 *Kleinman* case, the court held that where plaintiffs take issue with the defendants' opinion regarding scientific studies, but the "defendants' competing analysis or interpretation of data is itself reasonable, there is no false statement." Three years later, the court in *Tongue* suggested in dicta that a defendant's interpretation is reasonable if the FDA ultimately accepted it. After reviewing those cases, the *PMI* court proceeded to expressly adopt that dicta, holding that "where the FDA eventually accepts a defendant's interpretation of the data, that interpretation is per se reasonable as a matter of law." (The court also made clear that opinion statements are not misleading simply because the FDA later disagreed with them, as long as the defendants conducted a "'meaningful inquiry' and in fact held th view" they expressed.)

The court determined that because the FDA's conclusions "**mirror efendants' carefully measured statements** about

the IQOS studies' implications for long-term health outcomes," any allegation that the defendants' "interpretation of the data was irrational or unreasonable … would have little merit" (emphasis added). Put simply, "he FDA's ultimate endorsement of efendants' interpretation of the clinical-studies data **conclusively** establishes that efendants' statements were reasonable, and therefore not actionable, under *Tongue* and *Omnicare*…. It is immaterial that contrary views were held – and even published – by individuals and entities with no say over the regulatory process that PMI's future depended on."

The court concluded by underscoring that plaintiffs cannot state a securities fraud claim by accusing defendants of engaging in "bad science" or not having enough compelling data where the FDA eventually agreed with the defendants:

> The investors' "**argument boils down to a charge that PMI engaged in bad science:** that the IQOS studies' results were not compelling enough, or their methodology not sound enough, to demonstrate that IQOS is fit to be sold in the United States as a healthier alternative to cigarettes. **Certainly, there are scientists – including some of those who conducted the IQOS studies – who share the nvestors' view. But the FDA scientists who granted PMI's application for a marketing order, granted PMI's application for a reduced-exposure order, and found that PMI was "reasonably likely" to demonstrate eligibility for a reduced risk order 'in subsequent studies' … are not among them**. In a consumer-protection case, a mass tort case, or an administrative-law challenge to the FDA's orders, the views of those FDA scientists might be open to challenge. But in this securities-fraud case, they are conclusive" (emphasis added).

General statements about study methodology are inactionable puffery

The court additionally held that the Company's statements about the IQOS studies' methodology – including that the studies were "rigorous," "the best science" and "very advanced" – were inactionable puffery. The court rejected the plaintiffs' argument that these were "determinate, verifiable statements," because the plaintiffs could not identify "any objective, black-and-white standard by which to verify whether PMI's scientific studies were in fact 'rigorous,' 'very advanced,' or 'the best science.'"

Takeaways

- It is now law in the Second Circuit that opinion statements interpreting data that the FDA ultimately agrees with are per se reasonable and therefore inactionable, but it remains to be seen whether other federal courts of appeal will hold similarly.
- FDA agreement is **not** required for an opinion statement to be inactionable – even if a regulator ultimately disagrees with the defendants' opinion, that opinion is not false or misleading where the defendants conducted a meaningful inquiry and held the view they expressed.
- This case strongly supports that general statements that a study complies with GCP requirements are inherently subjective, and therefore should be analyzed as opinions under *Omnicare*.
- The Second Circuit expressly interpreted *Omnicare* as holding that qualifiers such as "I believe" or "I think" are sufficient, but not necessary, for a statement to be considered an opinion.
- General statements that a study's methodology is "vigorous" or "very advanced" are inactionable corporate puffery.

See 21 U.S.C. § 387k(g)(1)–(2).

Id. at *6 (cleaned up).

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