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U.S. v. Novartis: Reaffirming the Importance of Updating and Adhering to Corporate Policies

A recent decision in a false claims act case, *United States ex rel. Bilotta v. Novartis Pharmaceuticals Corporation* (*Novartis*),[1] underscores the importance of policing employee adherence to corporate policies and industry codes, and assessing strategic responses to allegations involving the violation of company policies when engaged in litigation with the federal government over whether the company broke the law.[2]

Although Novartis is a pharmaceutical company, the decision's implications extend far beyond the health care industry and should be considered by corporations in all regulated industries. For such businesses, there typically are three interconnected worlds of governance: federal and state laws and associated regulations, internal corporate policies and industry-specific codes of ethics. Those rules apply across the spectrum of corporate behavior, from employment rules that govern labor practices to laws that police business dealings with customers to antitrust laws that restrict business dealings among competitors. To be sure, there is — and should be — significant overlap between those behavior-governing rules. Internal corporate policies are designed to guide and control employee behavior to reinforce the spirit of and assure compliance with those federal and state laws and regulations. In addition, many corporations operate in industries that have adopted particularized codes of ethics: voluntary "rules" typically designed by an industry association with the self-policing goal of assuring regulators, enforcement officials and the public at large that industry members are cognizant of and have taken steps to assure compliance with certain laws.

In *Novartis*, U.S. District Court Judge Paul Gardephe reasserts the significance of corporate policies within the three spheres of corporate governance. In that case, a former Novartis sales employee filed a federal false claims act (FCA) suit in early 2011, alleging, *inter alia*, that "from January 2002 through at least November 2011, Novartis systematically bribed doctors to induce them to prescribe drugs from Novartis's cardiovascular division for their patients."[3] The United States elected to intervene and filed its own complaint, alleging that Novartis violated the FCA by paying kickbacks to physicians to induce them to write prescriptions for Novartis drugs in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. The government's complaint also contained allegations regarding Novartis company policies, apparent efforts by sales personnel to evade them and the company's response to certain reports of employee misconduct:

- "According to Novartis's internal policies, speaker events were intended to be educational programs; Novartis would pay doctors to educate other doctors and health care professionals about Novartis drugs by presenting slides prepared by Novartis."[4]
- "Although Novartis policies provided for caps on the price per meal for attendees at these events, sales representatives could avoid these caps by attributing costs that exceeded the caps to 'unmet minimums.'"[5]
- "In instructing that speaker programs must be held at venues 'conducive to an exchange of medical information,' Novartis's policies provide that food and beverages should be 'ancillary to meaningful discussion' and modest in quantity and cost."[6]

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- "The policies also require speakers to make a presentation using slides provided by Novartis, and require at least three health care professionals and one sales representative to be present at every speaker program."[7]
- "There was no system in place to prevent sales representatives from repeatedly selecting the same doctors as attendees at speaker programs on the same topics, or to prevent them from arranging for the same doctors to take turns speaking and attending each other's programs repeatedly."[8]
- "When sales representatives were reported for misconduct, Novartis's only punishment was a 'slap on the wrist,' such as placing a 'conduct memo' in the employee's file."[9]
- "In some circumstances, sales representatives who were reported for non-compliance were even later promoted."[10]

During the pre-motion conference for Novartis's motion to dismiss, the court "questioned whether the Government's Complaint-in-Intervention satisfied the pleading requirements of Fed. R. Civ. P. 9(b) because [it] did not 'contain any allegations about who submitted'" the claims, among other missing details.[11] The court allowed the government to amend, which it did by tapping into the various government databases used to administer Medicare, Medicaid and TRICARE to add "316 pages of spreadsheets that list allegedly false or fraudulent claims for reimbursement."[12]

In order to survive a motion to dismiss under Rule 9(b), the moving government had to sufficiently allege that Novartis knowingly submitted, or caused to be submitted, a false claim along with the necessary intent to violate the AKS. To prove the falsity of the claim, the government will be required to show that a company "ha[d] actual knowledge of the information," "act[ed] in deliberate ignorance of the truth or falsity of the information" or "act[ed] in reckless disregard of the truth or falsity of the information."[13] In the majority of FCA cases that get litigated, the government has declined to intervene and the relator is pursuing the action. In those circumstances, counsel should expect that a relator — without the government's access to the federal health care program claims databases — is not likely to plead fraudulent claims with sufficient particularity: what doctor, day, service or payment. Because the relator (more often than not) cannot plead with sufficient particularity, the court does not need to reach the issue of whether the pleading standards for any scienter allegations have been satisfied.

When the government intervenes, however, counsel should expect that the government will satisfy the particularity requirement for claim allegations and the focus will shift to the remaining allegations in the complaint, including any scienter requirements. The *Novartis* decision illustrates the potential negative consequences that could flow as a result of that shift.

In *Novartis*, after determining that the government's additional spreadsheets provided sufficient particularity for the allegedly false claims,[14] the court then turned to scienter and the allegations regarding the failure to adhere to company policies and comply with industry ethics codes. The court rejected Novartis's argument that "violations of internal policies are not sufficient to demonstrate an anti-kickback violation" because plaintiffs had alleged "more than mere violations of internal policies."[15] Instead, the court ruled that violations of internal policies — standing alone — can constitute proof of intent under the Anti-Kickback Statute:

> Novartis's conduct — as alleged in the pleadings — violates each of these policies, raising a strong inference that Novartis acted knowingly and willfully in using the speaker events to induce prescription-writing in violation of the anti-kickback laws.[16]

The court further found that allegations that Novartis's conduct violated "pharmaceutical industry standards" similarly supported "an inference that Novartis acted with the requisite scienter here."[17] The court noted that the complaint's allegations were sufficient "at the pleading stage" to "outweigh" Novartis's "plausible opposing inference" that physicians "may have prescribed Novartis cardiovascular division drugs for proper purposes, rather than in exchange for kickbacks."[18] The court reached these (albeit preliminary) determinations without addressing whether the complaint contained sufficient particularized allegations about which specific employees might be responsible for the alleged conduct, how or whether the witness(es) supporting the government's allegations might credibly be aware of such conduct or, crucially, addressing whether the alleged state of mind of those employees could be imputed to the company.[19]

To the extent other courts adopt the analysis in *Novartis*, the collateral consequence of an employee breach of internal policy or industry code of ethics and a corporate failure to appropriately sanction those employees could yield adverse consequences in the event of follow-on federal FCA litigation. Counsel should expect that when weighing admissibility at trial, the court will look through this prism: If there is admissible evidence that demonstrates that an employee violated a company policy, is the intent that can be inferred from that evidence similar to the intent that would establish a violation of the federal statute at the core of the alleged false claims count? Company counsel should consider the context in which it prefers the court to evaluate the merits of that "evidence" in any action alleging violations of company policies or codes of ethics.

END NOTES

1 *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, No. 11 Civ. 0071 (PGG), slip op. at 2 (S.D.N.Y. Sept. 30, 2014).

2 Other courts have opined that violation of company policy (in each case, accounting policies and practices which affected the company's reported financial results) may be used to support an inference of intent to violate federal law. *See, e.g., Pirraglia v. Novell, Inc.,* 339 F.3d 1182, 1192 (10th Cir. 2003) ("Violation of a corporation's internal policies can support a claim of scienter when coupled with other evidence of intent to defraud, such as motive and opportunity."); *Chalverus v. Pegasystems, Inc.*, 59 F. Supp. 2d 226, 234 (D. Mass. 1999) (holding that investors satisfied PSLRA scienter pleading requirements in part because violation of company's internal policy supported inference that defendants knowingly or recklessly misled investors); *Novak v. Kasaks*, 216 F.3d 300, 311 (2d Cir. 2000) (reversing district court decision to dismiss investors' 10(b) claims because defendants' conscious misstatements — including "knowingly sanction[ing] procedures that violated the Company's own markdown policy" — gave rise to a strong inference of the required state of mind).

3 *Novartis,* at 2.

4 *Id.* at 2.

5 *Id.* at 6.

6 *Id.* at 33.

7 *Id.*

8 *Id.* at 6.

9 *Id.*

10 *Id.* at 7.

11 *Id.* at 10.

12 *Id.* at 11.

13 31 U.S.C. § 3729(b).

14 Novartis also moved to dismiss separate but related claims brought by the State of New York and the relator; that portion of the order is not discussed here.

15 *Novartis*, at 31-32.

16 *Id.* at 33.

17 *Id.* at 34.

18 *Id.* at 34-35.

19 Alleging (and ultimately proving) scienter in the corporate context presents unique challenges and has engendered different outcomes across the various federal Courts of Appeals. The Sixth Circuit is the most recent court to address the issue, and adopted the rule (in a securities case) that the state of mind of any of the following is probative of whether an alleged corporate misdeed was made with the requisite scienter: (i) the individual who engaged in the alleged misconduct; (ii) any individual who authorized, requested, reviewed or approved of the alleged misconduct; and (iii) any senior management individual or board member who "ratified, recklessly disregarded, or tolerated" the alleged misconduct after it purportedly occurred. *In re Omnicare, Inc. Sec. Litig.*, No. 13-5597, 2014 WL 5066826, at * 17 (6th Cir. Oct. 10, 2014) (internal citation omitted).