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Drug Misbranding Redefined

By Janice G. Inman

The cornerstone of many U.S. Food and Drug Administration (FDA) enforcement actions against pharmaceuticals manufacturers in recent years has been the charge that they and their represetatives have "misbranded" their pharmaceutical products by promoting them for uses not approved by the FDA. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 331(a), prohibits misbranding of a drug product, yet does not define promotion of off-label drug prescription or use as such "misbranding." It is federal enforcement agents who came up with the argument that off-label promotion of a pharmaceutical product equaled "misbranding," and that argument has been very successful.

Although doctors have always been permitted to prescribe medications for uses not officially endorsed by the FDA, manufacturers and their salespeople who actively encouraged such conduct could find themselves the subjects of federal civil and criminal actions. And the consequences are not insignificant. Huge fines have been imposed and settlements obtained, including the October 2012 fine assessed against Abbott Laboratories for marketing Depakote as a treatment for schizophrenics and dementia patients, even though those uses are not FDA-approved. Abbot was ordered to

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FCPA Anti-Bribery Liability for a Subsidiary's Conduct

Recent Developments Suggest Apparent Split Between DOJ and SEC

By Laurence A. Urgenson, William J. Stuckwisch, and Brigham Q. Cannon

In their recently issued joint guidance on the Foreign Corrupt Practices Act (FCPA), the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) explained that a parent company may be liable under the FCPA's anti-bribery provisions for the actions of a subsidiary not only when the parent directly participated in the subsidiary's misconduct, but also "under traditional agency principles." FCPA: A Resource Guide to the U.S. Foreign Corrupt Practices Act, at 27 (Nov. 14, 2012) (Guidance). To determine whether a subsidiary is an agent of its parent such that its knowledge and conduct are imputed to the parent, the DOJ and the SEC said that they evaluate "the parent's control — including the parent's knowledge and direction of the subsidiary's actions, *both generally and in the context of the specific transaction*." *Id*. (emphasis added). Although in previously settled cases the SEC occasionally had employed an expansive agency theory to hold a parent liable under the FCPA's anti-bribery provisions for its subsidiary's conduct, the DOJ's previous public guidance, the "Lay Person's Guide to the FCPA," espoused a narrower theory of parent-company liability, explaining that "U.S. parent companies may be held liable for the acts of foreign subsidiaries where they authorized, directed, or controlled *the activity in question*." Foreign Corrupt Practices Act: Antibribery Provisions, at 3 (emphasis added) (available at www.justice.gov/criminal/fraud/fcpa/docs/lay-persons-guide.pdf).

The new Guidance thus raises the question of how much, if any, knowledge and control of a subsidiary's bribery, as opposed to its actions generally, the government believes is necessary for a parent to be held liable under the FCPA's anti-bribery provisions — and whether the answer is different for the DOJ than for the SEC. The Guidance's one illustration of the agency theory, the SEC's 2009 settled

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administrative action against United Industrial Corporation (UIC), provides little insight. The Guidance's description seems to suggest that the parent must have some level of knowledge and control over the improper payment, noting that in the UIC case: 1) "[T]he parent's legal department approved the retention of the third-party agent through whom the bribes were arranged despite a lack of documented due diligence and an agency agreement that violated corporate policy"; and 2) "[A]n official of the parent approved one of the payments to the third-party agent." Guidance at 28.

The SEC's Expansive Agency Theory

In a few more recently settled cases, however, the SEC appears to have taken the position that a parent may face anti-bribery liability for a subsidiary's bribery even if the parent had no knowledge of it and parental "control" of the subsidiary consisted only of relatively common connections between a parent and a subsidiary. In *Securities and Exchange Commission v. Smith & Nephew plc* (D.D.C. Feb. 6, 2012), the SEC alleged that the parent company was liable for bribery through two of its wholly owned subsidiaries without any allegation that a parent company employee knew of the bribery. Other than indicating that the subsidiaries were agents, the SEC complaint does not explain why they were agents, or otherwise why the parent was liable under the anti-bribery provisions for the subsidiaries' bribery. *Smith & Nephew Complaint*, at ¶¶ 1, 27, 33. Similarly, in *Securities and Exchange Commission v. Johnson & Johnson* (D.D.C. April 8, 2011), the SEC appears to have alleged that the parent was liable under the anti-bribery provisions for its Polish subsidiary's bribery of doctors through the use of trips, without alleging that any employee of the parent knew of the conduct. *Johnson & Johnson Complaint*, at ¶¶ 61-62.

While there may have been more evidence of parental knowledge or control in those cases than was publicly alleged, a more recent settled SEC action clearly imposes anti-bribery liability on the parent in the absence of knowledge of or control over the subsidiary's bribery. In *Securities and Exchange Commission v. Tyco Int'l Ltd.* (D.D.C Sept. 24, 2012), the SEC alleged (among other things) that Tyco, the parent company, was liable for payments made by its indirect, wholly owned subsidiary to a third-party sales agent that paid government officials in Turkey to obtain business. The SEC's complaint alleged that the parent:

> exerted control over [the subsidiary] in part by utilizing dual roles for its officers. At the time of the [bribery], four high-level Tyco officers were also officers of [the subsidiary], including one who was [its] president. Additionally, one of those Tyco officers served as one of five members of the [subsidiary's] board of directors. While there is no indication that any of these individuals knew of the illegal conduct described herein, through the corporate structure used to hold [the subsidiary] and through the dual roles of these officers, Tyco controlled [the subsidiary]. As a result, [it] was Tyco's agent for purposes

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> of the September 2006 transaction, and the transaction was squarely within the scope of [the subsidiary's] agency.
>
> *Tyco Complaint*, at ¶ 25.

The DOJ, in contrast, does not appear to have pursued anti-bribery charges against a parent company based on the theory that exerting control generally over a subsidiary renders the parent liable for bribery about which the parent has no knowledge. And, in other cases in which it has alleged numerous indicia of parental control over bribery by a subsidiary, the SEC has not pursued anti-bribery charges. In *Securities and Exchange Commission v. Halliburton Co.* (S.D. Tex. Feb. 11, 2009), for example, the SEC did not charge anti-bribery violations, despite allegations that seem to echo those in UIC and Tyco: "Halliburton exercised control and supervision over its business units, including … KBR. During the relevant period, KBR's board of directors consisted solely of senior Halliburton officials. Halliburton senior officers hired and replaced KBR's senior officials, determined salaries and set performance goals." *Halliburton Complaint*, at ¶ 30. The SEC further alleged that Halliburton's policies and procedures governed KBR's use of agents; Halliburton's legal department did due diligence on the agent who paid the bribes; and Halliburton officials approved hiring the agent who paid the bribes. *Id*. at ¶¶ 31-36.

General Principles of Corporate Liability

The SEC's expansive application of agency theory, at least in the Tyco case, appears to be inconsistent with traditional principles of corporate liability. "It is a general principle of corporate law deeply 'ingrained in our economic and legal systems' that a parent corporation … is not liable for the acts of its subsidiaries." *United States v. Bestfoods*, 524 U.S. 51, 61 (1998). In simplified terms, a parent can be liable for the actions of its subsidiary only when: 1) the parent disregards the corporate form to such an extent that the subsidiary is acting as an "alter ego" of the parent; or 2) the subsidiary acts as the agent of the parent for particular purposes. Addressing the "alter ego" question, the Supreme Court has explained: "Thus it is hornbook law that the exercise of the control which stock ownership gives to the stockholders will not create liability beyond the assets of the subsidiary. That control includes the election of directors, the making of by-laws and the doing of all other acts incident to the legal status of stockholders. Nor will a duplication of some or all of the directors or executive officers be fatal." *Id*. at 61-62. If, however, it is determined that the subsidiary is simply an alter ego of the parent, the parent will be liable for all acts that the subsidiary, as if they were its own. *See id*. at 63.

To impose liability as the result of an agency relationship between a parent and subsidiary, courts examine whether "the principal [parent] is to be in control of the undertaking." *Cleveland v. Caplaw Enters.*, 448 F.3d 518, 522 (2d Cir. 2006). The control analysis under an agency theory appears to focus on control over the specific type of actions at issue. *See, e.g., Cellini v. Harcourt Brace & Co.*, 51 F. Supp. 2d 1028, 1034 (S.D. Cal. 1999) (requiring in an employment case evidence that the parent "exercised any control over [the subsidiary's] day-to-day employment decisions"). As with the alter-ego analysis, common corporate interactions between parents and subsidiaries will not create an agency relationship. Indeed, as one of the (two) cases cited in the Guidance's discussion of agency liability explained, "proof of organization of one corporation by another, or ownership by one corporation of all the capital stock of another, or common officers and directors, is insufficient to show liability. We believe that … proof of such facts, without more, is not substantial evidence as to the agency relationship." *Pacific Can Co. v. Hewes*, 95 F.2d 42, 46 (9th Cir. 1938). While there may be more to the Tyco facts than publicly alleged, it is hard to square the SEC's agency theory in that case with these general principles of corporate liability.

Potential Implications

It is not clear whether the Guidance's description of how the government approaches agency liability in the parent-subsidiary context is an indication that the SEC will continue (or the DOJ will begin) to pursue anti-bribery charges against parent companies that have no knowledge of their subsidiaries' bribery. It is also not clear why the SEC has deemed it necessary to pursue such a theory, given its position that a parent that fails to implement adequate internal controls to prevent bribery at its subsidiary, or whose books and records are false as a result of mischaracterized bribes at its subsidiary, may be held civilly liable under the FCPA's accounting provisions without proof that it knew of the bribery. Indeed, in each of the above cases in which it pursued the expansive agency theory, the SEC also brought books and records and internal controls charges against the parent — and presumably would have been able to obtain the same amount of disgorgement without the anti-bribery charges.

As long as the DOJ does not follow in the SEC's footsteps, and the SEC does not seek to impose additional financial penalties by adding an anti-bribery charge, the uncertain risks of civil anti-bribery liability do not seem so great that they would cause many companies to loosen their control over subsidiaries. Some companies, however, may feel the need to structure their operations to avoid having day-to-day control over their subsidiaries, even when such control makes business sense. That would be an unfortunate result, as exercising control is one way through which companies may improve FCPA compliance at their subsidiaries, thus avoiding potential violations in the first place.

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