Michael A. Santoro, PhD, JD

Corporate Governance Reform at Merck

A Pharmaceutical Industry Standard for the 21st Century?

This article assesses the rationale for, and the potential impact on medical and scientific ethics of, the corporate governance reforms adopted by Merck as part of the legal settlement of the *Fagin* case.

In 2004, Merck shareholders filed a shareholder derivative lawsuit, *Fagin v. Scolnick et al.* (New Jersey Superior Court Docket No. ATL-L-3406-07-MT), contending that current and former company officers and directors breached their fiduciary duties in the marketing of the painkiller Vioxx, causing investors to lose billions. *The New York Times* called the *Fagin* case a potentially "pivotal moment in the corporate governance arena."[1] This article assesses the rationale for, and the potential impact on medical and scientific ethics of, the corporate governance reforms adopted by Merck as part of the legal settlement of the *Fagin* case,[2] and argues that the court-mandated reforms constitute an industry ethical standard for the 21st century that other pharmaceutical companies should proactively and voluntarily adopt.

Background to *Fagin* Litigation

Merck voluntarily took Vioxx off the market in 2004 when a study reported that people taking the drug had an increased risk of cardiovascular problems. Merck has never acknowledged wrongdoing in connection with lawsuits filed by thousands of patients alleging that they suffered health problems after taking Vioxx, even though the company agreed in 2007 to a $4.85 billion settlement of these claims, including claims by families of more than 3,100 people who died of heart attacks or strokes.[3] Moreover, the company did not acknowledge any wrongdoing in the *Fagin* settlement terms. Despite Merck's unwillingness to take public responsibility for the Vioxx tragedy, the very fact that the company has had to pay out such large settlement amounts to plaintiffs, and that it has had to radically change its ethics program, its committee structures, and its most basic corporate governance policies to settle the *Fagin* case, amply demonstrate that the ethical lapses leading to Merck's Vioxx problems were deep-rooted and systemic.

We are accustomed to thinking of ethical lapses by companies as being solely due to the personal failings of individuals. However, corporate wrongdoing can also be attributed to failures in the systems, policies, and practices employed to prevent and detect ethical lapses. During the events leading up to the Vioxx tragedy, Merck simply did not have adequate corporate governance systems and procedures in place to safeguard patient safety, ethical communications with physicians, and scientific integrity

issues. One study found, for example, that published scientific papers misrepresented mortality findings associated with Vioxx in clinical trials of patients with Alzheimer's disease or cognitive impairment.[4]

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Perhaps the most glaring shortcoming, however—and the shortcoming most forcefully addressed by the court in the *Fagin* settlement terms—was the failure of Merck's Board of Directors to assume responsibility for key ethical challenges facing the company. The three most crucial issues in the Vioxx case—patient safety, scientific integrity, and ethical marketing practices—were either completely omitted or treated in a vague and cursory manner, both in Merck's corporate governance policies and in its various ethics codes and compliance systems.[2] In short, Merck employees had inadequate corporate guidance for how to deal with the real-world challenges of assuring patient safety, scientific integrity, and ethical marketing practices. The *Fagin* settlement terms were designed to remedy these shortcomings in effect during the Vioxx tragedy.

The *Fagin* settlement terms set forth five broad areas of commitment by Merck:

1. engagement of an independent auditor to review the company's compliance with legally mandated adherence to the Food and Drug Administration Amendments Acts of 2007 (FDAAA)[5];
2. creation of the Office of Chief Medical Officer;
3. creation of a new Risk Committee and Product Safety Committee;
4. governance changes for the company's Board of Directors; and
5. amendments to the company's Code of Conduct.

Independent Audit of FDAAA Compliance

Pursuant to the FDAAA and regulations promulgated thereunder, Merck, like any other pharmaceutical research company, is required to register its clinical trials and submit results to a public registry. Pursuant to the *Fagin* settlement terms, Merck also has agreed to appoint an independent auditor who will review and report on the company's compliance with the internal procedures adopted to comply with its FDAAA requirements.

The purpose of having a public registry for clinical trials is to increase transparency and help to prevent selective reporting of adverse results. Having an independent auditor review internal procedures for FDAAA compliance seems like a sensible step, because it provides the public with another level of credibility and assurance that publicly reported clinical data are accurate. Assuring that the Board of Directors reads the independent auditor's report also helps to protect both patients and investors by alerting the board about potential shortcomings in its FDAAA compliance efforts. Putting the report on the company's website also increases the transparency of the company's efforts and helps to alert the press, government officials, and the public of any shortcomings in a company's FDAAA compliance.

In sum, the appointment of the independent auditor and the dissemination of the resulting reports to the board and to the public will help to assure that Merck remains in full compliance with FDAAA. Every pharmaceutical company should consider adopting this procedure as a best practice.

Appointment of Chief Medical Officer

Perhaps the most significant reform undertaken by Merck pursuant to the *Fagin* settlement terms was to create the office of Chief Medical Officer (CMO). In December 2009, the company appointed Dr. Michael Rosenblatt, a distinguished physician who had been dean of Tufts University School of Medicine since 2003. The CMO position fills a crucial gap in Merck's ethical compliance systems.

Prior to the *Fagin* settlement, Merck had in place an elaborate ethics violation–reporting system that included, among other things, a Chief Ethics and Compliance Officer, Divisional Compliance Officers, and an Ethics Hotline. The General Counsel's office is also a part of the compliance reporting system. The responsibilities of these channels are overlapping, and the redundancy is intended to give employees multiple channels for expressing concerns about practices that might violate the law or Merck's own Code of Conduct. However, none of these systems worked to prevent the Vioxx tragedy from occurring.

One could only speculate whether, if doctors and research scientists within the organization had a clear and credible channel within which to report medical and scientific ethics concerns, it would have made a difference in the way top management and the board would have handled the marketing of Vioxx. However, it is clear that for all the channels that did exist for reporting wrongdoing within

the company, there was no channel dedicated specifically to medical and scientific ethics. The accountants within the company had a clear and well-understood process for reporting financial fraud, but for doctors and scientists, it was unclear where they could go with their concerns.

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The CMO's most important duties, as specified in the settlement terms, are (a) to have "meaningful input" (a phrase that is not further specified in the settlement terms) on product safety issues and (b) to oversee the accuracy and truthfulness of promotion, labeling, and advertising. The CMO is also authorized to receive complaints from any scientific and medical employees or others in the company raising issues of patient safety and scientific integrity. In implementing these reforms, Merck has also agreed to launch an internal publicity campaign to make all of its employees worldwide aware of the new channels available to them for reporting safety and scientific integrity issues to the CMO.

The CMO office reports directly to the CEO of Merck, and also has a direct reporting channel open to the board and the independent directors. By virtue of having a physician in such a high profile position, the medical and scientific personnel within the company will now have a person to whom they can meaningfully communicate their scientific and medical concerns.

The creation of such a strong CMO office may represent a new best practice in medical and scientific ethics for the entire pharmaceutical industry. However, much will depend upon how Merck implements this reform. How strong and independent will the CMO actually be? Which Merck units will report to him? What kind of resources will the CMO get? What kind of access to the board will he have? How will his power be perceived within the company, relative to the power wielded by marketing executives and research directors? The *Fagin* settlement terms give the Merck CMO a constitutional basis to assert great influence within Merck and provide a bulwark against the kinds of inappropriate pressures that led to the Vioxx tragedy.

Risks Committee and Product Safety Committee

The settlement terms also call for the creation of two new committees—one to be chaired by the CMO and to include the General Counsel, CEO, and Chief Compliance Officer, will address "risks that require immediate action and that could affect the Company, its products, or its customers." The other, the Product Safety Committee, will draft and implement procedures to monitor drug safety. `This latter committee will constitute yet another avenue through which employees can communicate regarding drug safety issues.

Corporate Governance Reforms

The settlement terms require Merck to institute a number of governance changes with respect to its Board of Directors. The lead (nonexecutive) director is charged to meet regularly with the CMO. This crucial linkage solidifies the reporting channel of scientific and medical integrity issues through to the nonexecutive members of the board. This reporting structure was intended to elevate medical and scientific ethics issues in a pharmaceutical company to the same status that the Sarbanes-Oxley Act gave to accounting issues in the wake of the Enron scandal. The nonexecutive board members now have a direct line of communication about medical and scientific integrity issues in the same way that the Sarbanes-Oxley Act[6] gave directors access to information about potential accounting fraud.

The settlement terms also strengthen the independence of, and critical judgment exercised by, the board. One of the most distressing aspects of the Vioxx episode is that, even when information percolated up to the Board of Directors suggesting that there might be significant concerns about patient safety and scientific integrity, the board failed to investigate these reports and assume responsibility for patient safety and scientific integrity. The board's lack of oversight can, in part, be explained by the fact that it was not specifically charged with the duty of care over medical and scientific issues.

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If one examines the duties entrusted to the board in the publicly available document, "Policies of the Board," one finds that the board is charged specifically with exercising 12 duties, none of which indicates, even in an indirect way, that Merck is a medical and scien-

tific company whose primary business is to discover, manufacture, and sell drugs to patients. There is no mention of science, no mention of medicine, and no mention of patients. The description of corporate duties is so generic that it is impossible to tell what line of business Merck is engaged in.

The *Fagin* settlement terms require that the "Policies of the Board" be amended to include a new Section (1)(m), stating that board members must

> "be at all times in the exercise of their duties cognizant of the fact that the Company is a medical and scientific company whose primary business is to discover, manufacture, and deliver to patients medicines with well-characterized safety profiles; and shall promote high ethical practices in the conduct of the Company's research and the Company's relations with the academic, scientific, and medical community."

In hindsight, the fact that, prior to implementation of the *Fagin* settlement terms, Merck's board was not given any specific responsibility for medical and scientific ethics and integrity goes a long way toward explaining how the Vioxx tragedy came about.

There was previously no board-level committee charged with assuring patient safety and scientific integrity.

Another important reform contained in the settlement terms is the expansion of the duties of the Research Committee to include responsibility for medical and scientific ethics and integrity issues. There was previously no board-level committee charged with assuring patient safety and scientific integrity. To remedy this, the *Fagin* settlement terms revised the duties of the existing Research Committee to state that this committee "considers and makes recommendations on matters related to the Company's strategies and operations for the research and development of pharmaceutical products and vaccines. This Committee shall promote high standards of clinical ethics, and scientific integrity, with respect to the Company's research."

Shareholder and public safety interests are both served by expanding the duties of the Research Committee, which already had responsibility for providing input on the company's research strategies, to include responsibility for research ethics and integrity. Specifically charging the board with responsibility for medical ethics and scientific integrity and expanding the scope of the Research Committee beyond strategic considerations to integrity and ethics are steps that establish a new standard of best practices for the entire pharmaceutical industry.

Amendment of Code of Conduct

The lack of attention to scientific integrity was not just a problem at the board level during the unfolding of the Vioxx tragedy; there were also instances where Merck employees inappropriately attempted to influence the integrity of medical and scientific research.[4] To help assure that such improper influence will not occur in the future, and that marketing personnel at the company will not have undue influence on the decision to conduct research on off-label uses of a drug, the settlement terms provide that Merck will amend its Code of Conduct to include a new provision on scientific and academic integrity that reads as follows:

> "At Merck we understand and respect the role of independent scientific and academic research and debate to medical, scientific, and human progress. Accordingly, in all research endeavors that are sponsored by Merck we will refrain from attempting to influence the results and conclusions of such research. Clinical research at Merck shall be conducted under the direction of qualified medical and scientific personnel and according to high standards of medical and clinical ethics."

The settlement terms provide that Merck will amend its Code of Conduct to include a new provision on scientific and academic integrity.

This addition to the company's Code of Conduct, if vigorously implemented and adhered to by the company's employees with marketing responsibilities, will serve to discourage Merck's employees from influencing medical and scientific research inappropriately. Much will depend upon how marketing employees are trained to understand and implement this provision, and whether breaches of the principle of noninterference in matters of scientific integrity are detected and sanctioned. However, there is no doubt that the *Fagin* settlement terms enunciate a clear and forceful ethical standard to guide the interaction of marketing and medical science. Although some pharmaceutical companies may already have such ethical guidance documents in place, this standard should be a best practice for all companies in the pharmaceutical industry to adopt.

Conclusion

At the end of the day, the effectiveness of the *Fagin* settlement terms will depend on the vigor, diligence, and sincerity with which these reforms are implemented and enforced by Merck. In this regard, the company's steadfast refusal to admit wrongdoing in the Vioxx tragedy is not encouraging. Whereas legal liability considerations sometimes push companies to adopt such positions, in this case, $4.85 billion in settlement payments to patients and wholesale revisions to its corporate governance charters and business ethics programs belie any claims that nothing went wrong. In any event, it was inappropriate for a Merck spokesperson to claim immediately after the *Fagin* settlement that "the company acted appropriately and in the best interests of patients with respect to Vioxx."[7] It was somewhat more encouraging that, a few weeks later, Bruce N. Kuhlik, Merck's general counsel, commented soberly that the settlement "is fair and reflects best practices in corporate governance that benefit Merck and its shareholders."[1]

The changes at Merck might well portend a new standard of best practices for the rest of the pharmaceutical industry. Indeed, shortly after the Merck settlement was announced, Eli Lilly adopted a similar set of corporate governance changes to settle the shareholder derivative claims against it in connection with the marketing of Zyprexa.[8]

The *Fagin* settlement terms were clearly intended to increase the power and influence of scientists and doctors in the company. However, a number of issues regarding the effectiveness of these provisions require further research. For example, it will be interesting to assess ethical performance of companies according to whether they have CMOs, and according to whether such CMOs report to the CEO or to others within a company. Moreover, there are other nongovernance mechanisms for influencing the future progress of clinical trials (e.g., strategies on the payment and bonuses of managers, including "clawback" provisions that require managers to disgorge bonuses based on profits generated by results that turned out to be arrived at unethically).

There are inherent challenges to conducting medical and scientific research within a for-profit company. When the system works well, however, it delivers "miracles" for humankind, as Dr. Roy Vagelos, the legendary head of Merck, once declared.[9]

It is time to bring the values of scientific integrity and medical ethics back squarely into the DNA of the pharmaceutical industry.

To get the right mix of science, medicine, and money so as to continue to deliver miracles, the pharmaceutical industry as whole needs to put more trust and power in its scientists and doctors. For too long, the management and governance of pharmaceutical companies have been overly dominated by marketers. This imbalance has been bad for patients and bad for shareholders, and it has severely damaged the image of the industry. It is time to bring the values of scientific integrity and medical ethics back squarely into the DNA of the pharmaceutical industry, and the most effective way to accomplish that is through the kind of corporate governance reforms adopted by Merck to comply with the *Fagin* settlement terms.

The entire pharmaceutical industry should take note of what Merck learned the hard way through nearly a decade of litigation that tarnished the once splendid reputation of the company and led to billions in liabilities and lost profits suffered by shareholders. The road to assuring scientific integrity in the laboratory and medical ethics in the clinical setting most surely travels through the corporate boardroom.

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Michael A. Santoro, PhD, JD, is professor of management and global business at Rutgers Business School. He is the coeditor of *Ethics in the Pharmaceutical Industry* (Cambridge University Press, 2005) and a globally recognized expert in business ethics. As a paid consultant to the plaintiffs' attorneys, he was the principal architect of the corporate governance reforms adopted by Merck as part of the settlement of the *Fagin* shareholder derivative suit. His website can be found at www.michaelAsantoro.com.