Curtis C. Verschoor, CMA, Editor

Pharma Industry Has Many Ethics Issues

For many years, the U.S. pharmaceutical drug industry has enjoyed the confidence of all aspects of society, including those most affected by it—the physicians who prescribe the use of specific drugs and patients who are the objects of their intended benefits. Many years ago, these companies were even called "ethical drug companies" by some to differentiate them from the over-the-counter, mass-market pill manufacturer.

In recent years, the rising cost of developing and testing new drugs has resulted in strategic emphasis on creating high-priced "blockbuster" drugs that have the potential for wide usage in treatment of a major disease. Socio-political trends toward smaller government and more widespread industry self-regulation have resulted in more reliance on corporate compliance efforts. Significant advertising directly to the patient about expensive new drugs that may have only limited demonstrated benefit over existing ones could tend to marginalize the impact of the patient's own busy physician. Income tax laws continue to favor employer assumption of the cost of medical care, limiting consumer pressure for lower prices.

An aging population and potential changes in the current lack of financial statement recognition of post-retirement health benefits has led to the realization that managing the constant increases in healthcare costs represents one of the greatest challenges now facing all of American businesses. As part of its review of post-retirement accounting, the Financial Accounting Standards Board (FASB) is considering putting retiree healthcare on the balance sheet. Standard & Poor's estimates that the underfunding of post-retirement benefits other than pensions amounts to nearly double the pension shortfall. Management accountants and financial managers need to give increased attention to minimizing this considerable cost.

Perhaps the major cause of criticism of the pharmaceutical industry is the high—and increasing—cost of drugs. In the U.S., attempts to import drugs or generic equivalents have been thwarted by the industry. Pharma contributions to organizations that help lower-income families pay for their drugs help keep prices high for others and highest for those least able to pay because they don't have an insurance company to negotiate a lower price. The pharma "high price" strategy has led to U.S. consumers paying the highest prices for drugs in the world.

A most disturbing trend affecting drug development noted by a December 20, 2005, *New York Times* story is the increasing level of fraud in scientific research. Research sponsored by drug companies is the backbone of marketing as well as necessary for gaining FDA approval to put a new drug on the market. Members of the Pharmaceutical Research and Manufacturing Association (PhRMA) spent $38.8 billion for research and development in 2004.

Although *The Times* reported that much of the uncovered research fraud has been in studies performed in other countries, Merck & Co. has been severely chastised for its admitted failure to include adverse outcomes in the Vioxx study it used to

market the drug. In the first Vioxx trial, plaintiff lawyers accused Merck of trading its mission of healing and treating sickness for relentless marketing and pursuit of profits.

Merck was unsuccessful in its bid to convince the Texas jury that it didn't rush a lucrative drug to market and slip shoddy science past the Food and Drug Administration to inflate profits. The jury awarded $229 million in punitive damages (out of the $253 million total) and stated it wanted to punish perceived unethical behavior. The fact that Merck had fought hard for the drug's approval and later withdrew it from the market was apparently sufficient to incriminate it.

Rep. Henry Waxman (D.-Calif.) wrote a description of Merck's marketing of Vioxx, "The Lessons of Vioxx—Drug Safety and Sales," for the June 23, 2005, *New England Journal of Medicine* (*NEJM*). The prestigious *NEJM* was also where the results of the Vioxx VIGOR study were published in 2000. This trial had favorable results—fewer gastrointestinal complications than naproxen—but also had unexpected unfavorable findings—significantly more side effects in the form of heart attacks and strokes. Before the drug was withdrawn from the market in September 2004, other studies reported that more than 100 million Vioxx prescriptions had been filled in the United States, many for persons who had a low risk of gastrointestinal problems. This was a tribute to the effectiveness of Merck's marketing but not necessarily cost effective to businesses that paid the bill.

Waxman notes that the pharmaceutical industry spends more than $5.5 billion to promote drugs to doctors each year—more than what all U.S. medical schools spend to educate medical students—and that major drug companies employ about 90,000 sales representatives, one for every 4.7 doctors in the U.S. He refers to the educational objectives served by these efforts and quotes the website of the Pharmaceutical Manufacturers and Research Association: "Many physicians learn about new drugs—indeed, about ongoing research in their areas of specialization—largely through information provided by the companies that market new products." Waxman concludes that if the primary goal is sales and not education and if the information provided to physicians is slanted or misleading, the health consequences for patients can be serious.

In his article, Waxman also reports on the May 5, 2005, public hearings of the Government Reform Committee of the U.S. House. The hearings found evidence of "a broad disparity between the evidence-based perspective provided by scientific journals and expert committees, on the one hand, and the sales pitch used by the company's field staff, on the other….Merck instructed its sales representatives, for example, to provide only certain approved study results to doctors….By contrast, those studies that raised safety questions about drugs were considered background studies….Distributing the results of a background study was 'a clear violation of Company Policy.'"

The May 2005 Congressional hearings also found that "Merck trained its representatives to identify speakers for educational events who were 'opinion leaders' who could provide 'favorable' views of the company's products to other doctors…. Underlining the promotional nature of these events, Merck instructed its sales representatives to track whether the physicians who attended them subsequently prescribed more Merck drugs." Also, "in addition to providing selective evidence and biased presentations, Merck counseled its representatives to use an array of subliminal selling techniques to affect prescribing—potentially undermining the ability of physicians to choose drugs strictly on the basis of the risks, benefits, and costs for a particular patient."

On December 9, 2005, *The Wall Street Journal* reported that the *NEJM* had announced that "data about three Vioxx patients who suffered heart attacks were excised from a crucial study sponsored by Merck [and thus not published in the *NEJM*] that made the painkiller look safer than it should have." Only days later, *The Wall Street Journal* ran a story titled, "At Medical Journals, Writers Paid by Industry Play Big Role." This story quotes the vice chancellor of clinical research at Duke University Medical Center, who said, "Scientific research is not public relations," and "if you're a firm hired by a company trying to sell a product, it's an entirely different thing than having an open mind for scientific inquiry."

In addition to assuring the reliability and transparency of the scientific research used to determine the efficacy and safety of new drugs, what may be needed is a more economics-oriented yet consumer-friendly approach to drug marketing. Questions that should be answered include: Does a new drug perform significantly better than what is already out there, not just better than a placebo? Is the protocol that the drug industry pays researchers to follow designed to make appropriate safety comparisons and is not "gamed" to put a new drug in the best light? Do patients receive adequate information about adverse

side effects? Should an independent body take control of FDA registration trials and require economic justification before approval?

Although the ethics of Merck, a company long considered one of the best corporate citizens in the U.S., are now caught in the headlights of public disapproval, perhaps the practices of the industry as a whole require greater scrutiny. This subject deserves additional commentary. ■

Curtis C. Verschoor is the Ledger & Quill Research Professor, School of Accountancy and MIS, DePaul University, Chicago, and Research Scholar in the Center for Business Ethics at Bentley College, Waltham, Mass. His e-mail address is cverscho@condor.depaul.edu.