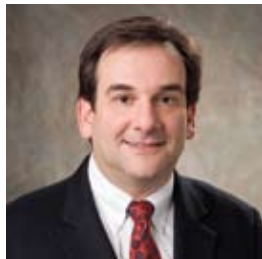


PLACING PATIENTS FIRST

It should come as no surprise that the pharmaceutical industry has an image problem. In just a few short years, we've witnessed a dramatic change in public perception. From being one of the most well-respected industries in existence, our reputation has plummeted. Given the unique role the pharmaceutical industry plays in the healthcare system—manufacturing and marketing products that improve, sustain and even save people's lives—regaining and restoring the public's trust is of utmost importance as we continue to develop new medicines.



DR. OREN COHEN, chief medical and scientific officer at Quintiles Transnational Corp., suggests ethics and education are the key elements in restoring the public's trust in the pharmaceutical industry.

The declining reputation of pharma mostly has to do with several high-profile events that have betrayed the public's trust in some way. These breaches are essentially about transparency and conflict of interest—situations in which people perceive that the interests of patients take a backseat to profits. For both ethical and business reasons, it is incumbent upon us as an industry to take self-initiated actions in an effort to regain the public's trust.

FROM THE TOP

A company that conducts itself in an ethical and transparent manner does so from the top down. Roy Vagelos' tenure at Merck was iconic in this regard, and there are many fine examples of ethical business operations today. The simple premise is that ethical corporate conduct and putting patients first is in fact the best business model. Vagelos proved that when companies do things in an ethical and transparent way, and thereby gain the public's trust, business prospers and shareholder value increases. It's not a guarantee, but there are countless examples now where trust is lost and shareholder value is destroyed when the business does not put patients' interests first. Companies must recognize that making

decisions based on clinical input and patients' interests is absolutely essential. You cannot put marketing and profits above all else. You've got to have a business model with good ethics built into it.

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Companies in this industry must make ethics a central part of their organizations. A good place to start is the development of an internal forum, where people can discuss ethical issues in an open way. At Quintiles, for example, we've established a council on research ethics, and I would encourage other companies in this industry to move in that direction, if they haven't already done so. The council has a broad membership from different functions across the organization, and has a mission to encourage and engage in discussion of ethical issues. There are directives and initiatives that come out of the council on an ad-hoc basis, and when issues arise that require action, they're taken to the business lines for clarification and further action, if necessary.

PUBLIC EDUCATION

Beyond instilling a top-down sense of ethics within an organization, companies also must take an active approach to educating the public. Public education that includes an open, honest, transparent discussion about the risk/benefit analysis of medicines is absolutely critical to our collective, long-term business model.

The general public also bears some responsibility to understand risk and benefit. Everyone wants a magic bullet—a drug that is perfectly safe and efficacious. Obviously, there's no such thing. Education is something that our industry does very well, so we should be making a concentrated effort to educate the public about what risk/benefit analysis really means.

Physicians play a critical role in patient education. It's increasingly necessary for physicians to assume the role of risk manager, rather than that of diagnostician and prescriber. They

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need to take a broader view to digest an abundance of information and data. That might be asking a lot, but it's imperative that they're able to translate a risk/benefit analysis to their patients. It's a lot of work—and somewhat of a departure from the traditional role of physicians—but that's the direction of the future.

SHARED RESPONSIBILITY

The other key players in the equation of responsibility are the regulatory agencies. The U.S. Food and Drug Administration and the European Medicines Agency not only need to find a way to make the process more efficient, they also need to make scientifically driven decisions to determine approval pathways that will actually be meaningful at the healthcare level. These agencies need to work closely with industry so that the approval of drugs is not done in a vacuum where the only questions being answered are to fulfill regulatory science and not clinical science. Certainly, these agencies have a tough mandate, and they're always strapped for resources, but they have a responsibility to the public they serve to stick to their guns and make the right decisions. They also have a responsibility to industry to balance fairness, efficiency and good science, so that we're getting as much bang for our development buck as possible.

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Although there is a certain amount of responsibility to be borne by patients, physicians and regulatory agencies, it is ultimately up to the pharmaceutical industry itself to police its own actions and regain the public's trust. Specific acts of transparency—clinical trial registration, full results reporting, health education and more responsible direct-to-consumer advertising, for example—certainly can be part of the solution; but the overall perception of the industry will change only when biopharmaceutical manufacturers follow the example set by leaders such as Roy Vagelos, and establish a patient-first mentality throughout their organizations.