Pharmaceutical Advertising: The FDA Does Not Protect Us

The recent triptych of viewpoints[1-3] on the presumed usefulness of pharmaceutical marketing seems to signal that the pendulum of opinion is swinging back in the direction of "it's really not so bad after all." The assertions contained therein have been rebutted by others,[4-7] but we will not reiterate the arguments here. We would, however, like to address a commonly held misconception again presented in these articles.

Two[1,3] of the three authors point to the Food and Drug Administration (FDA) and find comfort in the fact that this agency is tasked with regulating drug advertising. Levy[3] points out that "only" 8% of advertisements are in violation of regulations. Translated, this means that at least one of the 11 advertisements in the April issue of the ARCHIVES is likely to be misleading and, thus, provide potentially harmful information.

In fact, the FDA, according to David A. Kessler, MD, commissioner, spends most of its time developing the package insert and not, as asserted by Levy, preapproving advertising. According to Kessler, "Except under very special circumstances, the agency does *not* review or approve advertising and promotional materials before their dissemination by a drug firm" (italics in the original).[8] Furthermore, Kessler states that an " . . . enormous potential exists for misleading advertisements to reach the physician and influence prescribing decisions."

Despite the comforting words of business analysts and apologists for the industry, advertising can be harmful as well as helpful. We advocate a more assertive position and have highlighted the potential pitfalls present in pharmaceutical promotion efforts.[9] We encourage family physicians interested in providing the best care for their patients to become educated in the advertising techniques used by the pharmaceutical industry.

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Pharmaceutical Marketing

I enjoyed the triad of essentially pro-pharmaceutical articles[1-3] in the April 1994 issue of the ARCHIVES and would like to expand on a few points. The World Health Organization, the American Medical Association, the American College of Physicians, and the Pharmaceuticals Manufacturers' Association have also published guidelines on perks to physicians from the drug industry. The bottom line is that all these guidelines are voluntary, and physicians have continued to vote "with their feet."[1] I prefer the succinct opinion of The Royal College of Physicians of the United Kingdom who asked, "would you be willing to have these arrangements generally known?,"[4] referring to any benefits a physician derived from a particular drug company.

Wind[2] and Levy[3] question the effect of cutting promotional costs on the price of pharmaceuticals. Schwartzman estimated that if all marketing expenditures were eliminated, the amount of savings that would eventually be passed on to consumers would amount to only 5% of their drug bill.[5(pp447-452)] This small savings does not include the cost of any alternate system that would be needed to replace the information previously delivered by the drug companies.

Even more convincing of the "marketing therapeutic equilibrium" that exists between physicians and the drug industry is a classic study by Peltzman, which looked at the effects of the controversial 1962 FDA amendments.[5(pp452-458)]

Just before 1962, congress studied and concluded that because of patent protection, heavy promotion by the drug companies, consumer ignorance, and minimal incentives for physicians to be concerned with cost, drugs of dubious quality and unnecessarily high expense were being prescribed by physicians, criticisms that sound remarkably familiar even today. Up to that point, the FDA had only required "proof of safety," which dated back to the origins of the modern drug era and the 1938 Food, Drug, and Cosmetic Act.

With the passage of the 1962 FDA amendment, a proof of efficacy was added to the proof of safety, double-blind experiments were required, generic names were added to the labels, and advertised claims were restricted to those approved by the FDA.

Peltzman attempted to compare the change in demand curves of new drugs introduced before and after 1962.[5(452-458)] If ineffective drugs were being falsely but successfully promoted before 1962, their demand curves should have declined over time as physicians discovered they were ineffective drugs. Demand curves of drugs introduced after 1962 would have been expected to increase since they passed much more rigorous standards of efficacy and advertising claims.

Peltzman found that there were no significant differences between drugs that were introduced before and after the 1962 amendment with respect to their market shares or prices.[5(452-458)] He concluded that the natural forces in the marketplace and the physicians' abilities to distinguish efficacy among drug choices left little room for improvement by a regulatory agency.

Drug companies are not charitable organizations. They are in business to make a profit. Fortunately for society, their products happen to save lives.

In the 1980s, pharmaceutical companies showed the highest rates of profit in big business, with returns on equity 50% higher than the median for Fortune 500 industrial companies (*Fortune*. July 1991:48-54). The profit grabbing of the 1980s has been tempered by the competitive market forces of the 1990s, mainly influenced by the burgeoning growth of managed care.

The current managed care movement means that third-party payment will cover roughly 75% of all prescriptions by 1996, up from 25% in 1986 (*Business and Health*. January 1993:24-30). This will have more influence on which medications physicians order than marketing. Physicians will be prescribing from limited formularies or will at least need to justify to their patients' payers the cost of therapeutic choices, based on ultimate outcomes.

In fact, pharmaceutical companies are becoming "sellers of outcomes." The federal Agency for Health Care Policy and Research has stated it will focus on outcomes in its clinical effectiveness trials beginning in 1994 (*Business and Health*. January 1993:24-30).

Levy[3] gave several excellent examples of the huge potential savings from improved outcomes for medical treatments of congestive heart failure, myocardial infarction, asthma, and depression. Medicaid expenditures for patients taking H_2 receptor antagonists may be 70% less than for patients with ulcer who do not because of avoided hospitalizations and surgeries. The cost of treating preventable diseases of childhood is more than 10 times greater than the cost of vaccination.[6]

The basic principles of a free enterprise system forcing fair prices through unrestrained competition is more applicable to the pharmaceutical industry now than ever before because of the advent of managed care. Pharmaceutical marketing and advertising will remain a crucial element, with an increased emphasis on demonstrating improved outcomes for cohorts of treated patients. The utilization front for drug companies remains the physician's prescription pad, but there will be newer marketing efforts aimed directly at managed care providers. Physicians' choices will be under increasing scrutiny and pressure from third-party payers to justify the costs of medications based on ultimate outcome.

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Is Pharmaceutical Marketing Valuable?

In his recent article, Levy[1] greatly overestimates the informational value of pharmaceutical marketing. He also overestimates the difficulty that physicians have in obtaining drug information from nonpharmaceutical sources.

He states that "direct access to the medical literature is difficult and time-consuming for practicing physicians." He also asserts that information other than pharmaceutical marketing "must be measured against the present system in terms of scope, objectivity, timeliness of information, effectiveness of communication, and cost."

I would argue that commonly available, familiar nonpharmaceutical drug references such as *The Medical Letter*, *Drug Facts and Comparisons*, and *Drug Evaluations Annual*[2] are much better resources than pharmaceutical marketing information. In terms of scope, these resources give physicians access to much more information than do pharmaceutical advertisements or sales representatives, especially about medications not actively being promoted by pharmaceutical companies. These resources are certainly more objective than pharmaceutical marketing sources about the relative value and safety of drugs.

In terms of ready access to information, when I have a drug question while examining a patient, it is much quicker for me to look for the answer in one of these references than to try to contact a pharmaceutical sales representative. In terms of up-to-date information, *The Medical Letter* publishes current reviews of new medications biweekly. These thorough, objective reviews by leading authorities usually appear within a few months of the release of new medications.

As for effectiveness of communication, I believe that most physicians can gain more useful knowledge from