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

5 to 10 minutes of reading these references than from talking with a drug sales representative or viewing a journal advertisement. Certainly, they would gain a more objective and broader overview of a particular drug class and alternatives.

It is true that individual physicians must buy these references while conversations with pharmaceutical sales representatives or lectures sponsored by pharmaceutical companies are free to the physician. However, the $5000 per physician per year pharmaceutical companies spend[3] on promoting their medications is passed on to the physicians' patients in terms of higher drug costs.

Perhaps the pharmaceutical companies could better use the money spent in marketing communications that "are primarily informational and serve to educate the medical profession"[1] by sending each physician a yearly subscription to *The Medical Letter, Drug Evaluations Annual*, and *Drug Facts and Comparisons*.

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Value and Need for Pharmaceutical Promotion Disputed

Wind[1] and Levy[2] make compelling arguments in their attempt to justify current pharmaceutical company advertising and marketing practices. The essence of their assertions is that the pharmaceutical industry's promotional activities provide drug and therapeutic information superior to other means of physician education, including professional society-sponsored continuing medical education, peer-reviewed medical literature, and other nonbiased sources of drug information.

There exists little doubt as to the effectiveness of the promo-education (or "promeducation") efforts of the industry. Avorn et al[3] demonstrated that the prescribing habits of physicians are more closely allied with the promeducation literature from industry than with the findings from the medical literature regarding certain ineffective drug therapies for pain and senile dementia.

But doubt exists in the assertion made by Levy[2] that market pressures and the FDA effectively force manufacturers to provide accurate promeducation. Wilkes et al[4] found, in a critical review of prescription drug advertisements published in major medical journals, a disturbingly high proportion of advertisements that contained misleading information, thus appearing to violate FDA regulations governing the accuracy and balance of drug advertisements.

The further view submitted by Levy[2] that pharmaceutical sales representatives are needed to assist physicians in "keeping up" is of grave concern to those involved in medical education.[5-8] It is likely that in the absence of industry promeducation, that alternative methods for the dissemination of information on important new drugs would be satisfactorily achieved via the rise of publications similar to *The Medical Letter* and with online databases such as COLLEAGUE, DIALOG, and GRATEFUL MED.

However, it is of interest to note that not all new drugs are important drugs. Indeed, between 1981 and 1988, 348 new drugs were approved for marketing. Of these, 291 (84%) were categorized by the FDA as representing "little or no therapeutic gain"; only 12 (3%), or 1.5 drugs per year, were considered an "important" therapeutic gain.[9] This is consistent with our observation that the vast majority of visits by sales representatives are for promeducating us on "me-too" drugs.

Finally, we have concerns about the stated ideas of a competitive marketplace. Levy[2] contends that competition among calcium channel blockers drove down the cost of newer agents. The issue, however, is not one of which calcium channel blocker or second-generation oral cephalosporin or, as illustrated by Felicetta,[10] which HMG-CoA reductase inhibitor to prescribe, but perhaps why physicians are not being promeducated by industry about hydrochlorothiazide, amoxicillin, or niacin. The answer is of course that no huge profits are generated by the use of these equally safe and effective medications, just cost savings to our patients.

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