

Physician

The Independent Medical Business Newspaper

In the early days of *The Medical Letter*, which was first published in 1959, information about drugs was practically unavailable to non-professionals. There was no drug advertising to the general public, there were no patient package inserts, and newspapers and magazines seldom wrote about medication (or some other things that they seem to be obsessed with now). The *New York Times* could go for months without a single story on a prescription drug that it considered fit to print. The *Wall Street Journal*, which covered the pharmaceutical industry as part of its routine, was more likely to say something about drugs once in a while, but the emphasis was usually on the profits they generated, rather than their effects on health.

As late as the 1970s, when *The Medical Letter* considered issuing press releases to trumpet some of its articles, the consensus was that we shouldn't do it because doctors wouldn't like it if patients came into their offices waving our press releases in their faces. Well, that was heaven, but no one knew it then.

The Medical Letter

A reliable source in the age of "instant information"

By Mark Abramowicz, MD

The explosion in drug information from the Internet, direct-to-consumer advertising, television, newspapers, etc., has had some obvious consequences, and some not so obvious. For one thing, there is a new obsession with safety that may not always benefit patients, however earnestly the media believes otherwise. I doubt, for instance, that either penicillin or aspirin would have survived if they had been introduced in the current regulatory atmosphere. Aspirin causes bleeding and increases the risk of cerebral hemorrhage, by more than Vioxx increases the risk of myocardial infarction. And penicillin injections can kill patients in seconds; that would go from the front pages of the tabloids right into congressional hearings.

Another consequence of the new fascination with drugs and the information overload has been that the

FDA and the pharmaceutical industry have somehow become co-villains. The FDA is faulted for not detecting adverse effects of new drugs more promptly, as though any fool could do that if he hadn't been bribed by user fees from the drug companies. But aspirin was probably the most widely used drug in the world for 50 years or more before anyone realized that it had an anti-platelet effect that could cause bleeding. And tetracyclines were around for 25 years before anyone realized that they caused children's teeth to become hypoplastic and discolored. Dark teeth—how hard to see is that? But none of us saw it, or, if we did, realized that tetracyclines were responsible.

The pharmaceutical industry, for all its power and wealth, has also been taking some unfair abuse in the new information age. These companies are in business to make money.

That is what their shareholders want, and their first obligation, other than to obey the law, is to their shareholders. If the law permits them to advertise to consumers, they do so vigorously. Whether the law should permit that is another question. And whether the same companies that make a profit from a drug should control, in one way or another, the clinical trials that test the drug's efficacy and safety is still another question.

Beginnings

So where does *The Medical Letter* fit into all this? Well, we are clean. *The Medical Letter* is a nonprofit publication that does not accept advertisements. Sales of subscriptions, books, software, continuing education materials, and licenses are our sole source of support. We do not accept grants, gifts, or donations. We do not sell large numbers of reprints of our articles to the pharmaceutical companies. (I don't know of any other publication that places this restriction on reprint sales.) No one takes us to lunch, flies us anywhere, or plays golf with us.

The Medical Letter was started by two unusual men, Arthur Kallet and Harold

Aaron, MD. Kallet was an engineer who co-wrote the book *100,000,000 Guinea Pigs*, which was a best-seller in the 1920s. Some say it played an important part in the Food and Drug Act of 1938, which required for the first time that drugs must be shown to be safe before they can be marketed. Kallet also was a co-founder of Consumer Research, which became Consumers Union, and he started the publication of *Consumer Reports*. Aaron was an internist who was on the advisory board of Consumers Union. He suggested to Kallet that doctors could use something like *Consumer Reports* to help them judge the worth of new drugs coming on the market. They borrowed \$25,000 from a psychiatrist with a wealthy wife, and *The Medical Letter* was born.

In the early years, some pharmaceutical companies objected to the frank assessments of their products, and a few threatened lawsuits. But the suits never materialized, and gradually the companies became used to a sometime antagonist that at least had the courtesy to permit them to comment on the preliminary drafts of its publications. Since 1969, when I first began working at *The Medical Letter*, the only threat of a lawsuit came from Linus Pauling,

There is a new obsession with safety that may not always benefit patients, however earnestly the media believes otherwise.

who had already won a Nobel Prize in Chemistry and was later to win the Nobel Peace Prize. He sent us a ten-page lawyer's letter outlining the royalties he would not earn and the prizes he would not win because we had published an article saying there was no acceptable evidence that vitamin C prevents colds. Arthur Kallet responded to that by quickly publishing another article on the same subject, saying we felt a need to consider the issue again; and we concluded once more, perhaps a little more emphatically, that there was no evidence that vitamin C prevents colds. We never heard from Dr. Pauling again.

The evaluation process

The Medical Letter evaluates almost all new drugs, and in its younger sister publication, *Treatment Guidelines from The Medical Letter*, recommends the drugs of choice among various categories of drugs.

The process works as follows. We ask a physician or pharmacist who has had

some experience with the drug to write the first draft of an article, following our format. If no one suitable is available, someone in our office writes the first draft. Then we edit the first draft and send it for comments or corrections to *The Medical Letter's* Advisory Board, the first authors of all the articles cited in the text, eight to 12 consultants from panels we have developed in every specialty, the manufacturer of the drug being evaluated, the manufacturers of competing drugs, the FDA, and, if appropriate, the Centers for Disease Control and Prevention. After judiciously incorporating the comments of our reviewers, we check all the facts, edit extensively through several more drafts, check back with reviewers or other experts to clarify difficult issues, and go to press—every two weeks with *The Medical Letter* and once a month with *Treatment Guidelines from The Medical Letter*. The whole process, from assigning the draft to publication, typically takes

about two months.

The Medical Letter is evidence based but recognizes that all evidence is not created equal, and so we are consensus-based as well. I could offer many examples of conclusions from *The Medical Letter* that were unpopular with somebody but proved to be correct, and some that were off the mark. We steadfastly maintained, for example, that SSRI antidepressants used appropriately in children and adolescents were much more likely to prevent suicide than to cause it, in the face of withering opinions to the contrary in the popular press and some medical journals. On the other hand, we probably were overconcerned, in the early years of their use, with the side effects of HMG-CoA reductase inhibitors (statins). When we realize we made a mistake, we print corrections, addenda, and, sometimes, re-evaluations.

We do everything we can to get it right and make it clear. *The Medical Letter* is not anti-industry. It is pro-practitioner. ◼

Mark Abramowicz, MD, is the editor of *The Medical Letter*.
