Communicating Drug Benefits and Risks Effectively: There Must Be a Better Way

The information that patients receive about the drugs we prescribe for them is in a sorry state. Patients are barraged by direct-to-consumer (DTC) advertising in virtually every medium except cell phone ring-tones. In a health care system that rewards quantity over quality, rushed clinical encounters with physicians and pharmacists leave too little time to review drug risks and benefits, not to mention cost. Yet, public sector oversight of medication information has waned along with other federal regulatory activities, with similar unfortunate results. Occurring on the heels of several high-profile drug risk debacles, this problematic mix of overpromotion, undercommunication, and inadequate regulation has left many patients bewildered and mistrustful of the prescriptions we write, contributing to an unhealthy pattern of medication overuse, misuse, and underuse.

In this issue, Schwartz and colleagues (2) focus on an especially turbid area of medication information: the user-hostile welter of tiny print found in DTC drug advertisements. Federal law requires manufacturers to include this information along with the more compelling and seductive headlines and photos that promote a drug’s benefits. In their current form, these barely legible sections are virtual museums of poor communication: The print is tiny; the prose is usually dull, stiff, and hard to understand; and vital facts are buried in a sea of less relevant data. All in all, these sections seem designed more to satisfy governmental requirements and ward off liability lawyers than to teach patients about the pros and cons of choosing a particular medicine. The format of the information can mask important side effects, as well as—ironically—numb the reader with so many worries that a perfectly worthy treatment may seem too toxic to take. Schwartz and colleagues, who know about far better ways to present complicated facts, designed their own “drug boxes” to replace this microprint overkill. They created new mock-ups of DTC ads for several commonly used drugs: clopidogrel, statins, histamine-2 (H2) antagonists, and proton-pump inhibitors (PPIs). They then performed a randomized, controlled trial to compare the quality of information transfer with conventional DTC ads for these products versus their own more intelligible creations.

The good news was that people assigned to receive the coherently designed drug box ads more accurately understood the benefits and risks of statins and clopidogrel than did those who viewed the information in the current conventional formats. For gastroesophageal reflux disease (GERD), patients who received the drug box ads were more likely to know that PPIs work better than H2-antagonists for severe chronic GERD.

However, the study raises some important concerns. Respondents shown the innovative ads reported that they were less willing to take the statin or platelet inhibitor advertised, even when one was needed—a worrisome outcome. And although it is true that PPIs are more powerful than H2-antagonists for severe GERD, they do not provide immediate relief, and many patients with milder or sporadic symptoms would probably be better off with the older drugs or a swig of liquid antacid as needed. The study did not address the vital cost component of the risk–benefit–cost trial, because most DTC ads do not mention costs at all. But affordability is a key issue for many patients who cannot afford to pay for their prescriptions. We still need a study exploring the presentation of data on the relative expense of competing alternatives and evaluating the effects of providing such cost information.

Despite these important limitations, Schwartz and colleagues have drawn our attention to the need for more creative thinking about how to communicate drug benefits and risks effectively, and the need to study possible solutions in a methodologically rigorous manner. Currently, DTC advertising consumes about $5 billion per year (as the authors point out, this amount is double the entire budget of the U.S. Food and Drug Administration [FDA]), but it is only one of the many fragmented sources of drug risk–benefit information that patients are exposed to. We need to consider Schwartz and colleagues’ study in the context of other data that patients receive (or don’t receive) about prescription drugs.

Neither the package inserts nor the container labels offer as much help as they should. Much discussion about drug information for lay people has focused on the package inserts; however, these documents are primarily written for physicians, not patients, and they are rarely inserted in the packages patients actually receive. Another source is the label affixed to the medication bottle. These communicate the name of the pharmacy in large type but vary greatly in their reporting of warnings (3) and instructions (4). When communicating essential safety information, container labels often use a font too small for many patients to read, and they often emphasize information more relevant to the pharmacist than the patient.

The federal government has attempted, with only limited success, to ensure more reliable sources of medication information. In the late 1970s, the FDA sought to implement a bold plan to ensure that patients would receive with each filled prescription a leaflet containing accurate, intelligible, and complete lay-language information (5). That plan was shelved when the Reagan administration took power, on the grounds that educating patients was not a proper role for government. The Reagan administration preferred the private sector to fill the informational void, with the invisible hand of the marketplace ensuring the

© 2009 American College of Physicians
quality and availability of the content of the leaflets, known as Consumer Medication Information (6).

In this instance, self-regulation appears to have worked no better for drug information than it has for financial instruments. An evaluation in 2003 found that the generally unregulated system of private-sector Consumer Medication Information left many gaps (7); a more recent assessment, which was due in 2006 but not completed until 2008, found that these materials met prespecified quality criteria only about 60% of the time, with legibility and comprehensibility getting the worst scores (8). In 1995, the FDA proposed a plan to ensure that patients receive standardized leaflets, called Medication Guides, for selected drugs believed to have the greatest potential for harm (9). These leaflets also turned out to be difficult for many patients to read (10), and pharmacies often fail to provide them with the prescription, even though it is required by law (3).

With new leadership in Washington, now is a good time to reassess all public sector efforts to ensure accurate, coherent patient drug information so we can maximize the effectiveness and safety of prescription medications. In addition to addressing the various uncoordinated sources of information that patients may or may not receive at the pharmacy, this reappraisal would consider the official “labeling” information document for physicians, the multitude of unregulated privately produced materials handed to patients in drugstores, and—as in the examples studied by Schwartz and colleagues—the flood of DTC information that inundates consumers. Many of us would like to see the end of DTC advertising, which is allowed in nearly no other industrialized country and was not permitted in the United States until 1997. However, for legal reasons, it may be hard to put that genie back in the bottle (11).

If we must live with this torrent of patient-directed drug infomercials, Schwartz and colleagues’ study reminds us that we need to come up with more innovative ways of presenting that complex data and monitoring the cognitive effects of these well-intentioned experiments. This reappraisal should not stop with evaluating patient-directed materials. Physicians need to learn about benefit and safety data through sources that are more useful than the tiny-print overkill that now constitutes these official documents (12–14). But as the work of Schwartz and colleagues points out, more than reformatting will be needed to create educational materials that guide physicians and patients in the right direction. As lay people and physicians increase their demands for coherent, evidence-based, unbiased drug information, we would all be well served by a comprehensive program to replace our current patchwork of bad communication and excessive promotion with a responsible national system of balanced, evidence-based, and user-friendly drug information.
Current Author Addresses: Drs. Avorn and Shrank: Division of Phar-
macroepidemiology and Pharmacoeconomics, Brigham and Women’s
Hospital, 1620 Tremont Street, Suite 3030, Boston, MA 02120.