9-2015

New DTCA Guidance — Enough to Empower Consumers?

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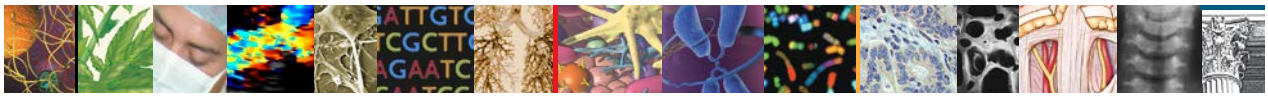

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

SEPTEMBER 17, 2015

New DTCA Guidance — Enough to Empower Consumers?

Christopher T. Robertson, J.D., Ph.D.

As one of only two countries that permit direct-to-consumer advertising (DTCA) of pharmaceuticals, the United States tasks the Food and Drug Administration (FDA) with regulating that advertising to ensure that it doesn't mislead consumers. When a drug maker publishes or broadcasts a claim that its drug has benefits in a particular disease, the FDA requires it to include information on the product's risks as well. Since it's not feasible for companies to include all the important information about their products in a television ad, the FDA requires them to refer viewers to more complete information, such as that in a printed magazine ad. Companies have tended to comply with this requirement by supplementing colorful, persuasive ads with one or two pages of dry text providing the required disclosures, often simply using language that the FDA has approved for other purposes, such as package inserts for prescribers. But research shows that most patients who attempt to read these disclosures find them difficult to understand, and many don't even try to make sense of them.[1] Now, the FDA is in the process of adjusting its DTCA rules, aiming to provide greater assurance that patients receive due warning of the most significant risks — but its tweaks probably don't go far enough to really empower consumers to make smart decisions about the drugs they put into their bodies.

This spring, the FDA revised its guidance for communicating risks in DTCA, which had been in "draft" form since 2004.[1] The agency has long recommended the use of nontechnical language (e.g., "drowsiness" rather than "somnolence") but now also recommends using an evidence-based format for conveying such information. The FDA's research supports the use of a "Drug Facts" box, of the type that has proven successful for over-the-counter products, with familiar headings for "Uses" and "Warnings." Alternatively, companies will be allowed to use a question-and-answer format, as some have already been doing.

The draft guidance gives companies additional discretion about which risks to disclose and how. Though the FDA continues to insist that any "black-box" warnings and contraindications be included, companies will now be able to omit mention of other adverse events. The guidance directs companies to include only the "most serious and the most common" risks posed by a product. The idea that it actually helps to give consumers less of the available information about a product's risks may be counterintuitive, but the FDA is reasonably concerned that the recital of extremely rare risks can distract from, or even

trivialize, the more significant disadvantages of a product.

Still, the guidance raises difficult questions about which risks to exclude, and it's worrisome when discretion is given to marketers who have an interest in downplaying overall risks. For the industry, such discretion is a double-edged sword. If a patient experiences an adverse effect and files a lawsuit, a civil jury may find that the advertising was misleading, and a company's defense may receive little support from the FDA's vague guidance. Some conservative companies may therefore prefer to continue providing comprehensive lists, and the new guidance allows them to do so. If the FDA is serious about streamlining disclosures, it may need to take a stronger approach.

Moreover, the new guidance is not particularly clear or coherent. For example, it states that the "FDA does not intend to object if a firm does not include 'each specific side effect and contraindication,'" but a few pages later, it says that "information addressing the following should be included: . . . All Contraindications."[1] Admittedly, this is only a draft document, and clearer guidance may be provided in the final version. Unfortunately, the FDA often allows draft documents to linger for years — the previous draft guidelines on print advertisements were still not finalized even after a decade. Even final guidance documents are technically not binding, but even in draft form they tend to be very influential in an industry that must work with the FDA on a daily basis. When the guidance remains in draft form perpetually, however, it exacerbates the regulatory ambiguity.

But these concerns are superficial in the context of broader, more fundamental questions about risk disclosure as a regulatory mechanism. From the latter perspective, the guidance represents a relatively modest reform, which retains the basic regulatory structure permitting DTCA but requires accompanying disclosures to mitigate potential harms. The FDA could instead have issued highly restrictive guidelines, perhaps cracking down on industry's use of noncognitive persuasion (think bathtubs in a field of flowers to suggest the romance made possible by an erectile-dysfunction drug), which may undermine rational decision making by patients.[2] (Ironically, when the FDA tried to use its own emotional appeals in the form of graphic cigarette warnings, industry players objected vociferously.) But the Supreme Court's recent First Amendment jurisprudence — granting companies rights to free speech for commercial activities — would probably constrain such an aggressive approach. In recent years, the FDA has sought to avoid litigation for fear that the Court might overreact, further limiting its regulatory ambit.

The Court tends to favor an approach whereby regulators allow companies to advertise but require them to append disclosures to add balance and protect consumer welfare. As legal scholars Carl Schneider and Omri Ben-Shahar have argued, however, as a regulatory tool, mandatory "disclosure is a fundamental failure that cannot be fundamentally fixed."[3] They cite examples from myriad domains in which policymakers have reflexively turned to disclosure as a regulatory tool — and it has failed. Tweaking the disclosure regime, as the FDA is doing here, has proven ineffectual. The regulators of the mortgage industry, in particular, have tried to simplify its disclosures to home buyers, but they've had little success in changing the behavior of consumers or of the brokers who stand between them and lenders. Disclosures are no substitute for regulation of the products themselves to ensure that they provide net benefits to those who consume them, and they are no substitute for having well-trained and unconflicted advisors (e.g., prescribers) ensuring that the product is a good match for the consumer (e.g., the patient).

If disclosure is to work, as others have argued, it must be done right, in a format that's designed to be usable. As an example of success, Fung et al. cite the simple, salient, and familiar "A, B, C" system used to rate restaurants on the basis of public health inspections, with the results posted prominently by the door.[4] The new FDA guidance is a move in this direction, at least if it gives companies more liberty to construct readable disclosures. However, even revised disclosures written by the companies themselves are unlikely to be simple and candid enough to steer patients away from drugs that are inappropriate for them. One can imagine a system that would grant drugs an "A" rating if they proved a substantial advance over the previous standard of care in treating a serious medical condition, with minimal risks or side effects. Regrettably, many of the most widely advertised drugs would not secure that golden ring.

Unfortunately, the FDA's guidance will do nothing to help consumers understand whether drugs really have substantial benefits. Research has shown that a more expansive Drug Facts box could comprehensibly convey data on the proportion of patients who actually benefited from the drug

in key trials and how many had adverse events.[5] If patients and prescribers used such information to make intelligent choices about one drug versus another — or about forgoing medication altogether — it could drive genuine competition and innovation in the pharmaceutical market. That would reflect the sort of "consumer empowerment" that free-speech advocates have used to justify DTCA in the first place. But such an advance awaits bolder action by the FDA and the pharmaceutical industry.

An audio interview with Dr. Robertson is available at NEJM.org

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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This article was published on August 19, 2015, at NEJM.org.

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DOI: 10.1056/NEJMp1508548

HISTORY OF MEDICINE

The Vernacular of Risk — Rethinking Direct-to-Consumer Advertising of Pharmaceuticals

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Aside from New Zealand, the United States is the only country with a strong pharmaceutical regulatory infrastructure that allows direct-to-consumer advertising (DTCA) of prescription drugs in print, broadcast, and electronic media. U.S. consumers are accustomed to full-page ads in newspapers and magazines detailing a drug's benefits — followed by another page of fine print in which its contraindications, risks, and side effects are spelled out in minute detail and equally minute print.

That may soon change, however, as the Food and Drug Administration (FDA) moves to enact new regulations regarding risk communication in DTCA. Earlier this year, the FDA sought public comments on new guidance for pharmaceutical marketers on communicating risks to consumers in print advertisements. This proposal, which the FDA has kicked around in one form or another since 2004, responds to mounting research showing that reprinting highly technical package inserts in print ads does very little to communicate risks to consumers. The goal is to communicate those risks in a new vernacular.

Instead of reproducing the fine print meant for physicians and pharmacists, the FDA proposes that drug marketers use a new "consumer brief summary" focused "on the most important risk information . . . in a way most likely to be understood by consumers." A summary written in everyday language might take the form of a Q&A list, for example, or a Drug Facts box like those on packaging for over-the-counter medicines. Drug marketers are being asked to use popular idiom to communicate with people with a wide range of literacy levels; to use larger fonts and more readable formats; and to use visual elements such as white space, logos, and color schemes to highlight the most relevant risks.[1]

Public comments on the proposal have focused on the challenges of implementation. How many risks are too many to print? How will a manufacturer — or the FDA — know when language is too simple, too technical, or pitched "just right" for average Americans? Missing from this conversation is a broader perspective on the vernacular of risk in pharmaceutical promotion — as something that is not a new DTCA-related duty for the FDA but fundamental to the origins of the category of prescription drugs and their regulation over the past half-century.

After passage of the 1938 Food, Drug, and Cosmetic Act, which established the distinction between prescription-only and over-the-counter drugs, consumers received most information about the latter through ads and most about the former from their physician or pharmacist. Indeed, the category of "prescription-only" medications enabled industry to