American Enterprise Institute for Public Policy Research

March 2007

The Truth about the Drug Ads

By John E. Calfee

Looming on the horizon is a political battle over direct-to-consumer advertising (DTCA) of prescription drugs. The Prescription Drug User Fee Act (PDUFA) is up for renewal, as it has been every five years since 1997. First passed in 1992, PDUFA authorizes the Food and Drug Administration (FDA) to collect fees from pharmaceutical companies submitting new drugs for approval, as well as a separate annual fee for each prescription drug on the market. (Before PDUFA, taxpayers alone funded FDA product reviews.) Because user fees cover most salaries of FDA drug regulators, the pharmaceutical industry, Congressional leaders, and the FDA itself all support renewal. But this time around, Congress is expected to tack on provisions dealing with drug safety and other matters, especially DTCA.

Congress should seek a little perspective on DTCA before trying to fix it. Most consumers think that direct-to-consumer ads provide useful information—especially about newer drugs—and help them prepare to talk to their doctors. At the same time, many are skeptical about pharmaceutical advertising and wonder whether regulation is tough enough. This is unsurprising. Polls dating back to the 1930s consistently show that roughly two-thirds of consumers think advertising is useful, but are skeptical about the truthfulness of advertising and think more regulation is needed regardless of the actual state of regulation. Thus, consumers confront DTCA with suspicion, but also with the intention to make use of information that seems valuable.

What about doctors? You might think they hate drug ads, but that is not quite true. They want to see more regulation for DTCA and they wish there were fewer ads. But according to a 2002 FDA survey, on the whole, physicians do not see the ads as disruptive or harmful to patient visits.

The real question is how DTCA affects patient care. Here, a key point is that a lot of DTCA focuses exactly on what you would expect: underused drugs for undertreated or even underdiagnosed conditions. This creates the potential for DTCA to accomplish a lot of good. In the only published experiment on the effects of DTCA, Richard Kravitz and several coauthors found that seriously depressed patients were much more likely to receive recommended treatments (drugs, therapy, and follow-up visits) if they asked about advertised drugs.

Despite its prominence, DTCA may exert its greatest effects indirectly. DTCA is a natural tool for battling drug therapy noncompliance, one of the most intractable problems in medicine. No one knows how many lives are saved by those cholesterol drug ads that rouse wives to pester their husbands to stick with the program. Another DTCA effect is completely invisible. As of now there is no DTCA at all for some of the most important new drugs for cancer and other devastating illnesses like age-related macular degeneration, the leading cause of blindness in the elderly. But there could be, and this is something that health-care payers have to bear in mind when deciding whether to cover breakthrough drugs. In Europe, where DTCA is prohibited partly to save costs, uptake of the most innovative new drugs is

John E. Calfee is a resident scholar at AEI. A version of this article appeared on American.com on February 2, 2007.

typically slower than it is in the United States. The prohibition also hurts research and development by severing the natural link between aggressive marketing and the payoffs of costly innovation.

Getting Medical Breakthroughs Safely to Market

What about the advertising of brand new drugs? A recent report on drug safety from the Institute of Medicine recommended a two-year moratorium for new drugs. Although this recommendation appears to have strong support on Capitol Hill, it does not make much sense. Almost all new drugs do more good than harm. Some of them provide unique benefits, such as more effective treatment for cancer or age-related macular degeneration, high cholesterol, and that depressing standby—depression itself. A DTCA moratorium would keep such benefits from some patients and would, paradoxically, delay the accumulation of safety data. Even Vioxx and its maligned competitors like Celebrex have proved to be, at most, only marginally riskier than the older and much less studied drugs with which they competed. The quick uptake of Vioxx and Celebrex plus an avalanche of research on new ways to use them (they help prevent colon cancer, for one thing) accelerated the collection of safety data, too.

Almost all new drugs do more good than harm. Some of them provide unique benefits, such as more effective treatment for cancer or age-related macular degeneration, high cholesterol, and that depressing standby—depression itself.

And how big of a deal is DTCA, anyway? Notwithstanding its in-your-face approach, DTCA is a small force in a large market. Total DTCA budgets are on the order of $5 billion annually, but that is small change in the $250 billion pharmaceutical market. Dozens of econometric studies of DTCA's market impact reveal a mere shadow of the presumed colossus that has transfixed politicians, journalists, and medical academics. Estimated effects are invariably small; in my own analysis of the cholesterol drug market, we found no effect at all beyond a modest boost for drug compliance. The effects that emerge are usually limited to a modest expansion of the total drug category (antidepressants or anticholesterols, for example), with little impact on brand shares. No one can reasonably blame DTCA for recent growth in health-care spending.

Even the most infamous example of DTCA—the torrent of advertising for Vioxx and its competitors—had remarkably little effect. What guaranteed a tumultuous reception for Vioxx and Celebrex was not advertising, but rather the enthusiasm with which specialists in treating arthritis and ulcers welcomed the arrival of an entirely new type of anti-inflammatory that could prevent some of the tens of thousands of deaths widely thought to be caused every year by traditional pain relievers.

DTCA and First Amendment Rights

Like nearly all advertising, DTCA evokes deeply mixed feelings among firms. It quickens competition by exploiting comparative advantages in efficacy, side effects, and convenience. Its tendency to turn the spotlight on drug safety and costs can exhaust the patience of firms that market only to doctors. On the whole, DTCA can undermine the interests of individual firms almost as often as it reinforces them, although PhRMA, the industry trade organization, strongly supports DTCA. These muddy circumstances leave DTCA ripe for political attacks and draconian regulation.

But DTCA, like most commercial speech, has First Amendment protection. The continuing political battle over DTCA is an excellent example of why constitutional protection for advertising and other commercial speech is a very good thing. DTCA is already overregulated because the industry dares not dispute FDA rules in court. For pharmaceutical companies, maintaining good relations with the agency that approves new drugs, new indications, and manufacturing facilities is far too important to be recklessly endangered through legal challenges to ad regulations. DTCA's supporters are diffuse, partly because its benefits are themselves diffuse and poorly measured. DTCA's opponents, however, are well organized on Capitol Hill and elsewhere. PDUFA renewal provides the perfect opportunity to tighten regulation even more—though, fortunately, regulation remains subject to First Amendment limits.

The bottom line: Congress is headed in the wrong direction if it intends to rein in prescription drug advertising to consumers. Those ads do a lot of good. If we get new regulation, let us hope that the First Amendment trumps the law of unintended consequences.