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To Ban or Not to Ban DTC, That is the Question

By **John Mack**

To ban, or not to ban DTC advertising: that is the question:
Whether 'tis nobler for the pharma industry to suffer
The slings and arrows of politicians seeking the office of presidency,
Or to take arms against a sea of troubles, Republican and Democrat
And by opposing end them?

Frist to Industry: Time to Clean Up Your Act

The pharmaceutical industry must be reeling from the blow just recently delivered by Senate Majority Leader Bill Frist (R-TN) who called upon the industry to impose "a two-year moratorium on advertising for new drugs and a government audit to determine how drug ads have affected the way Americans are treated for illness."

Frist declared: "It's time for drug companies to clean up their act. If they don't, Congress will."

Deconstructing Frist's Proposal

It might be useful to take a critical look at Frist's statement and deconstruct what he says to help provide further insight into the issue, establish some balance, and possibly reveal Frist's motives.

Frist leads off by quoting a few DTC taglines:

- "Keep the spark alive;"
- "The healing purple pill;"
- "If a playful moment turns into the right moment, you can be ready;"
- "For everyday victories."

"Those are taglines for some of America's best-selling, most widely advertised prescription drugs in recent years," Frist says. "We all know them because we've heard them over … and over … and over again."

Reach and Frequency

Obviously, Frist is not a marketer. Repetition or "frequency" is one of the most important principles of traditional advertising. In order to drum the message into people these days, advertisers have to be much more repetitious, or so the conventional thinking goes. People are just not paying as much attention to ads as they used to.

Permission-based marketing, on the other hand, may be a better solution that, if used more effectively by the pharma industry, could have saved it from this type of criticism. For more on this topic, see "Out-of-the-Box Marketing: Will It Work for Pharma?"

Frist also acknowledged that DTC ads had broad reach, another important advertising principle: "We've heard them on the television set and our favorite radio programs. We've read them in newspapers and weekly magazines. We've seen them on billboards along the highway and, yes, even on stock cars at our favorite racetracks."

DTC Issue Has Political Wings

One might think it odd that Frist would mention stock cars and racetracks, but it is no doubt a calculated political ploy designed to appeal to "Joe Six Pack" voters who otherwise would have nothing in common with the rich, former heart transplant surgeon.

Frist uses the DTC issue to bash his political opponents and set up battle lines for the 2008 campaign. He tries to blame the Clinton administration, for example, for "opening the door [to DTC advertising] too widely." He was referring to the 1997 "Draft Guidance for Industry and FDA," which clarified how drugs could be advertised on television (Frist says, the rule "liberalized the disclosure rules for televised ads in 1997").

"As a result, direct-to-consumer advertising exploded to levels that many could not have anticipated. And this has driven up prescription drug use and spending and, I believe, led to inappropriate physician prescribing."

One wonders where the Republicans were while all this was going on? The Republican-controlled Congress of the day had no trouble blocking other Clinton initiatives. Could it be that Frist is establishing battle lines between himself and Clinton—Hillary that is—that will inevitably be drawn in 2008?

Framing the issue this way also avoids having the Bush administration take a share of the blame. If anything, the 1997 FDA guidance give the industry an inch and it took a mile. Clearly, if the FDA were

more vigilant during the Bush administration and less cozy with the drug industry, we wouldn't be talking about banning DTC today.

Another indication that Frist has an eye on his political future is his call for "a government study of the costs, consequences and any potential benefits of direct-to-consumer advertising." A government study is always a good way to keep your name in the news or at least revisit the issue again and again during a political campaign.

DTC and Docs

Frist is a physician who believes that through DTC advertising "drug companies market their products…over the heads of doctors." Physicians, however, clearly are divided on the merits of DTC and the AMA is currently studying the effect of marketing drugs directly to consumers. Frist fails to mention that many physicians are well aware of the effectiveness of DTC (see "Results from FDA Physician Survey on DTC Advertising") and that physicians often participate in the ads themselves (see "Survey Results: Straight-Talking DTC").

Frist paints a picture of hapless docs under pressure to prescribe whatever medications their patients ask for. "Patients, seeing the ads,' Frist says, "place new demands on their doctors. My medical colleagues are pressed for time. Driven by the drumbeat of advertising, relentless pressure to contain costs, and the understandable desire to please their patients, some harried physicians write unneeded prescriptions rather than arguing with their patients or explaining why a less expensive drug would be just as effective."

Frist cited a study from the University of California-Davis in which "researchers sent actors in good health to 152 doctors' offices in three cities to find out if they could get prescriptions for simulated symptoms."

"The study found that if an actor requested Paxil, a heavily promoted antidepressant, he was five times as likely to walk out of the doctor's office with a prescription for the drug.," Frist said. "The research suggested that direct-to-consumer advertising increases patient demand for specific medications, even in situations where the prescriptions aren't needed."

Contrary to the way this study was reported in the media and summarized by Frist, the research does NOT prove that marketing of prescription medications for depression may exert significant influence on treatment decisions. Rather it proves that physicians, more often than not, will prescribe a drug if his or her patients ask for it.

That says more about the practice of medicine than it odes about DTC advertising. "Prescribing antidepressants for adjustment disorder, as presented in the study, is at the margin of clinical appropriateness," said Dr. Richard L. Kravitz, lead investigator on the study.

Shame on the physician, therefore, who caves in to the whim of patients and inappropriately prescribes antidepressants. For more on this, see "Blame the Doc, Not DTC!"

Education vs. Promotion

"America needs a patient-centered health care system," said Frist. "Timely, accurate, complete, and balanced information must be a pillar of any such system. And advertising can help provide this information. But right now it simply is not."

It is clear that the FDA would like to see DTC ads play a larger role in educating consumers. It believes consumer-directed promotion of prescription drugs "can convey useful health information to patients." The February, 2004 draft guidance on disease awareness communications especially talks about this (see "FDA Draft Guidance for Print DTCA: Less than Feared").

"In its proper place," Frist suggests, "direct-to consumer drug advertising can empower consumers. It can give them information they need to make informed, smart decisions about their health. It can inform them about new therapies. These are good things."

But is branded DTC advertising the right vehicle to accomplish these "good things"?

The Coalition for Healthcare Communication (an organization representing several ad agencies and health communications companies) doesn't think so. It asserts that "the primary goal of direct to consumer advertising is and should be to convince a consumer to discuss a medical condition with his or her doctor. To ask advertising to educate is to ask it something it is not capable of doing." (See "Is DTC Educational or Motivational?")

On the other hand, non-branded DTC disease-awareness advertising can be equally effective at driving consumers to seek medical attention.

"In markets where DTC (on a brand named basis) is not permissible," said Brian Towell, head of Doghouse Communications, a healthcare communications agency in the UK, "companies are allowed in many cases to promote by therapeutic concern/area, and tell customers that if they have this or that problem, a solution can be discussed with their primary care physician. I have worked on a number of these myself, and would agree that

information encouraging individuals to present with symptoms and signs that they may have chosen to ignore."

On June 13, 2005, Bristol-Myers Squibb released its "Direct-to-Consumer Communications Code" that promised—among other things—to put more emphasis on non-branded disease-awareness advertising. For all newly launched products, BMS promises to "Develop disease state awareness advertising, as appropriate, for diseases that may be potentially treated by our newly launched medications in order to further educate consumers and healthcare professionals." For more on this code, see "Emrging DTC Principles" below.

ED Drug Ads: Bad Boys of DTC

Frist references erectile dysfunction (ED) drug ads at several points in his statement. He laments that you cannot escape DTC, even at Nascar races where Viagra sponsors Mark Martin's Viagra Taurus.

Frist explicitly mentions ED drug ads several times in his statement. The following is just two examples of what he had to say:

"Today's advertising leaves parents more often having to explain to their 10-year old children what erectile dysfunction is than how to prevent and treat high blood pressure."

"Just think, how many parents have found themselves watching a sporting event with their son or daughter only to be assaulted by an ad for an erectile dysfunction drug? Advertising during last year's Superbowl comes to mind."

From these statements and proposals to limit ED ads by other politicians, it is obvious that ED drug ad campaigns have greatly damaged the image of the drug industry and have become the "bad boys" of DTC advertising. They are easy targets for critics.

Several articles and opinion pieces in this newsletter have warned that these ads "push the envelope" of DTC advertising and tarnish the industry's reputation (see "Are ED Ads Too Sexually Explicit?", "Super Bowl DTC Debut: Was It Good for You?" and "Marketing Drugs Like Packaged Goods at the Super Bowl").

DTC and Drug Prices

"… let there be no mistake: drug advertisements fuel America's skyrocketing prescription drug costs," Frisk vehemently states. "They cause more people to take prescription drugs. They create an artificial demand. And they drive up our nation's overall health care costs. They needlessly and wastefully rive up your health costs."

Frist cited a 2002 Government Accountability Office (GAO) study to back up his claim that "increased direct-to-consumer advertising has helped fuel escalating drug costs."

PhRMA, in its "Statement on the Value of Direct to Consumer Advertising," states that "Evidence does not link advertising and drug prices." PhRMA doesn't cite the source of this evidence, however it could be the same GAO report that Frist referred to.

The Summary of the GAO report contends that there is a link between heavily advertised drugs and sales of those drugs. It certainly doesn't provide evidence for a cause and effect link that proves that DTC helps "fuel" escalating drug costs.

Drug company shareholders and Wall Street analysts are the real high-octane fuel behind rising drug costs. Pfizer CEO Henry McKinnell suggests "investors' confidence in the risk and rewards" drives prices (see the review of his book in this issue). Eliminating this "fuel" would go a long way toward keeping drug prices down. Although Frist points out that "patient safety should be paramount, not the bottom line," no one would expect him to ban selling drug company shares for 2 years!

DTC and Communicating Risk

Frist criticized the 1997 guidance for requiring "only that drug companies disclose the most significant risks" to consumers and not "a full picture of a drug's risks and benefits."

However, drug risk communication experts and the FDA agree that "less is more" when it comes to educating consumers about risks in drug ads. On February 4, 2004, the FDA issued long-awaited draft guidance documents designed to improve communications to consumers and health care practitioners about health conditions and medical products. The draft guidance "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" encourages manufacturers to use clearer, less cluttered formats for presenting risk information and encourages them to focus their risk disclosures on the most important and the most common risks and to do so in language easily understood by the average consumer. (See "FDA Draft Guidance for Print DTCA: Less than Feared," Pharma Marketing News, Vol 3, #2).

Frist cited a 2002 FDA survey in which "nearly 60 percent of patients reported that drug advertisements don't provide enough risk information. And 58 percent of patients felt that ads portray products as better than they are."

Continued on next page…

He also quoted from a separate FDA survey of physicians in which"75 percent of physicians said that ads led patients to overestimate the efficacy of the drugs. And 65 percent of physicians noted that patients confuse the risks and benefits of drugs advertised to consumers."

The FDA survey also showed that DTC advertising, when done correctly, can serve positive public health functions such as increasing patient awareness of diseases that can be treated, and prompting thoughtful discussions with physicians that result in needed treatments being prescribed - often not the treatment in the DTC advertisement. This study also demonstrates that most physicians view DTC advertisements as one of many factors that affect their practice and their interactions with patients, both positively and, in some respects, negatively. See "Results from FDA Physician Survey on DTC Advertising."

Communicating risk in DTC ads is not easy and some pharma executives acknowledge the industry needs to learn more about how to do it effectively. Hank McKinnell, CEO of Pfizer, for example, in his book "A Call to Action," says "We're doing research with patient and consumer groups on the subject of risk communications that I hope will give the industry and regulators some valuable guidance on how people interpret messages about risk." (See a review of Mckinnell's book in this issue.)

To make sense of trial data and risk information, consumers need to look at and understand numbers. As pointed out in a recent Washington Post article, however, "many people don't demand the same kinds of numbers [as they do with money matters] when judging medical findings."

For more information on this topic, please see "Numbers, Math and Communicating Risk" and "Can Drug Ads Communicate Risk?"

FDA Weakness

"Right now," said Frist, "the FDA has neither the resources to scrutinize direct-to-consumer drug advertisements nor the power to review them for accuracy before they are viewed by the American public."

Frist accurately depicts the FDA's lack of resources, but does not accept any responsibility on behalf of the Bush administration for "defanging" the agency.

For example, Daniel Troy, former chief counsel to the FDA, was Bush's first FDA appointee. "Troy managed to restrict FDA's ability to use its statutes creatively, and this in turn deterred mid-level managers from advocating new approaches to emerging scientific issues, leaving the agency looking - and feeling - weak." For more on this, see "The House(s) That Troy Built" in a recent post to the Pharma Marketing Blog,

Emerging DTC Principles

Frist acknowledged the "leadership and responsibility" demonstrated by Bristol-Myers Squibb's newly announced "Direct-to-Consumer Communications Code" in which it promised to "refrain from any direct-to-consumer branded mass media (television, radio and print) advertising to promote [a] medication" for a minimum of 12 months following a launch of the medication."

He also referred to PhRMA's industry-wide, soon-to-be-announced voluntary code governing direct-to-consumer advertising, which "should, at a minimum," said Frist, "include a voluntary restriction on the direct-to-consumer advertising of prescription drugs in their first two years on the market."

Frist suggested that a one year moratorium on DTC may not be enough time for "scientists get a complete picture of a new drug's effects. Both doctors and patients need time to learn about new treatments, assess their benefits, and find out more about their risks. A full knowledge base of the potential side effects takes time to develop. Education should always come before persuasion. Patient safety should be paramount, not the bottom line."

For more about various industry efforts to develop DTC advertising principles, see "New DTC Principles Emerging."

Additional Steps

Frist suggested three additional steps that may require legislation or that could happen through "voluntary" work by the drug industry, which he "encourages." These are:

1. "We should give the FDA prior review and approval authority for all direct-to-consumer drug advertising." BMS's Code includes this. "Advertising should boldly and responsibly address safety head-on, replacing upbeat, fantasy-land images with a frank discussion of a product's benefits and risks," said Frist. For an idea of how the industry can do this, see "DTC Straight Talk," which discusses a J&J approach.

2. "We should increase resources devoted to reviewing advertising to determine its accuracy and to ensure all standards are met. The FDA—to whom we have given this responsibility—must have the capability and resources to more thoroughly monitor drug advertising and make

absolutely sure that companies comply with advertising guidelines. The American people assume this is being done—and it is not."

3. "We should give doctors and patients greater access to clinical data and post marketing surveillance efforts about drugs after they become available." For more on this topic, see "A Proposal for a Drug Risk Advisory System."

No Carrot, Just a Stick

Frist backs up his suggestions for voluntary restrictions with a warning. "I will be watching this issue closely. And if the pharmaceutical industry's voluntary restrictions aren't strong enough, I'll support Congressional action to make sure consumers get the protection they deserve. If these voluntary restrictions don't do the job, I believe Congress should act."

Reaction from Pharma Marketing Experts

When the question of banning DTC was put before experts on the PHARMA-MKTING online discussion board, several interesting opinions were expressed that are summarized below.

"I am firmly on the side of banning any kind of named brand advertising direct to the potentially sick and willingly misled. Sticking ads for prescription medications in, amongst and alongside ads for butter, breakfast cereal and pantyhose is fundamentally wrong (and ethically and morally corrupt)." -- Brian Towell, head of Doghouse Communications.

"The right path is probably the one being pursued--a voluntary moratorium until enough time has passed for side effects to manifest and more emphasis on disease awareness as opposed to product ads." -- Terry Nugent, VP Marketing, Medical Marketing Service, Inc.

"The question should not really be 'should we ban DTC.' Instead, 'how do we create processes for better safety and efficacy studies' -- better oversight, better dissemination, etc. [To ban DTC] would be something like banning advertising in general because companies don't have proper accounting practices!" -- Sanjay Virmani

"The consumer should not take drug ads any more seriously than any other kind of advertising. In all cases, caveat emptor should prevail. However, by denying consumers access to information about healthcare, including meds, they have LESS power." -- Katherine O'Neill, an independent pharmaceutical industry consultant.

David Reim of Simstar proposed a thought experiment to imagine a world without DTC advertising for prescription drugs. "In that world," said Reim, "Vitamins can advertise. Supplements can advertise. Nutriceuticals can advertise. And here is the capper to this thought experiment: your personal physician probably doesn't know anything of significance about these "alternative" treatments because they are not mainstream. So, in this thought experiment the lack of DTC drives more people to be open to heavily marketing "therapies" not under the jurisdiction of the FDA. The cat is out of the bag. Pandora's box is open. The physician has lost exclusivity."

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