US aims to tighten rules on direct-to-consumer drug ads

With a new Congress controlled by the Democratic Party, the US biotech industry might be facing tighter restrictions on direct-to-consumer (DTC) advertising. This spring, Congress is set to debate measures that include a two-year moratorium on advertising for newly approved products and higher user fees for extra Food and Drug Administration (FDA) staff to monitor television, print and radio advertisements.

The US and New Zealand are the only countries that allow DTC drug advertising, and such ads pumped $4.5 billion into the US media economy in 2006, up from $2.8 billion in 2002, according to the drug and biotech industries.

However, over the past several years—and after the spectacular safety failure in 2004 of a heavily advertised and top-selling drug, the COX-2 inhibitor Vioxx (rofecoxib)—calls have grown louder for more government control.

"The ads have limited educational value and may oversell the benefits of drugs in ways that might conflict with promoting...health," says Dominick Frosch, assistant professor of medicine at the University of California, Los Angeles (UCLA). In the January/February issue of the *Annals of Family Medicine*, Frosch and colleagues published an analysis of television drug ads, concluding that 95% of analyzed ads appealed to emotion and none mentioned lifestyle changes as an alternative to a pill.

In an editorial accompanying the report, David Kessler, a former FDA commissioner, and Douglas Levy, one of Frosch's colleagues at UCLA, wrote, "There is nothing wrong with pharmaceutical companies communicating directly with consumers, but they should adhere to the standards and ethics of medicine, not the standards and ethics of selling soap or some other consumer product that presents minimal risks." They add that drug advertising does not "effectively or consistently convey important information about product risks and benefits."

Gary Ruskin, executive director of Commercial Alert, a non-profit group out of Washington opposed to DTC advertising feels that the study "confirms the obvious, that the purpose of [drug] ads is to sell drugs irrespective of whether the viewer needs the drug or whether there's a better, safer, cheaper alternative, which includes no drug at all… DTC ads ought to be illegal and [Commercial Alert is] trying to make them illegal," he adds "We hope that our members of Congress get up the courage to do what is right and ban [them]."

Senators Michael Enzi (above) and Ted Kennedy of the Senate Committee on Health, Education, Labor and Pensions are co-sponsoring legislation to give FDA greater authority and resources to oversee direct-to-consumer advertising.

An outright ban, however, is unlikely; none of the proposals Congress is set to debate includes a total ban.

In response to criticism, in January 2006 the Phamarceutical Research and Manufacturers of America (PhRMA), based in Washington, DC, implemented voluntary guidelines for DTC advertising that aim to "improve communications about pharmaceutical risks and benefits, educate the public about prescription medicines and treatment options, enhance health awareness and motivate patients to talk with their healthcare providers about their health," says Karen Katen, president of Pfizer Human Health in New York, who chairs PhRMA's group on affordability and access.

The guidelines call for companies to wait "an appropriate amount of time" after new product approval before advertising to consumers, but does not define that time.

The Biotechnology Industry Organization (BIO), for its part, has not adopted similar guidelines, and a spokeswoman for Washington-based BIO said that "our companies don't advertise nearly as much as the PhRMA members." However, several companies that make biotech products, including Amgen, in Thousand Oaks, California, and New Brunswick, NJ–based Johnson & Johnson, have signed onto PhRMA's guidelines.

But the guidelines don't go far enough for Senators Ted Kennedy (D-MA), chairman of the Senate Committee on Health, Education, Labor and Pensions (HELP), and Michael Enzi (R-WY), the ranking Republican Party member. In February, they introduced a broad FDA safety overhaul bill that would go beyond the voluntary PhRMA advertising guidelines. In a statement, Kennedy said, "An essential part of any drug safety proposal must be to give the FDA the authority and resources it needs to oversee direct-to-consumer advertising, and to allow the FDA to impose conditions or limits on that advertising where needed to protect the public health."

The Enzi-Kennedy bill would add staff to the FDA office that oversees DTC advertising and ban DTC advertising on newly approved products for two years.

Adrian Thomas, vice president of benefit-risk management at Johnson & Johnson, disagrees with such a moratorium, calling it a "troubling change" that "introduces First Amendment issues."

Although the HELP committee has not scheduled a hearing on the bill, a spokeswoman says that the legislation would "likely move forward" this spring.

Also in February, the FDA recommended that Congress pass a new Prescription Drug User Fee Act (PDUFA) that includes separate fees for DTC ads. The current PDUFA bill, which expires in September, does not require user fees for advertising review, only for review of new drug applications. If Congress adopts the FDA's proposal, the agency estimates it would collect $6.2 million in the first year, which it would use to add 27 staff members for DTC ad reviews.

David Beier, senior vice president for global government affairs at Amgen, is "almost certain" companies will end up paying for DTC ad reviews. "It looks like, to the extent that people want to do DTC, they'll be paying for it," he says, adding Amgen has not decided whether it would continue to run DTC ads if such fees were required.

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