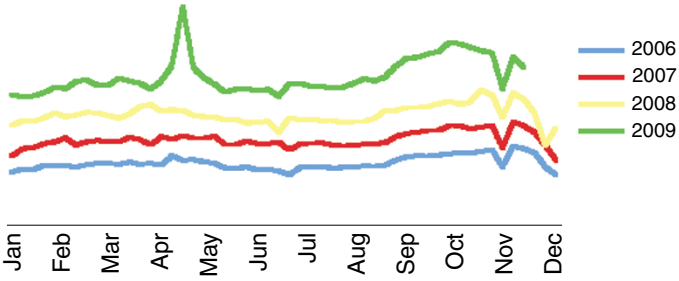
# Drug ads move online, creating a web of regulatory challenges

Not too many months ago, a person who entered "multiple sclerosis medication" into Google would find, at or near the top of the list of retrieved links, the following one, paid for by the drug's maker: "Multiple Sclerosis? Satisfied with your MS Medication or Looking for Something Different? www.Tysabri.com."

Today, entering the same search terms, one would find the following, subtly altered, link: "Multiple Sclerosis-MS. *MyMSTreatment.com* A Multiple Sclerosis Treatment That's Different."




**Health Condition Searches (excluding swine flu);** data from Google

With a single click of the mouse, both links would ultimately deliver the online user to the same place: the company-sponsored website promoting Biogen Idec's Tysabri, a multiple sclerosis drug that in rare cases can cause a life-threatening viral brain infection and is therefore usually reserved for patients who haven't responded to other therapies. But the difference in the links—nowhere in today's version does the brand name 'Tysabri' appear—arises from the latest skirmish in a battle over how drug advertisements are going to be regulated in the fast-changing Internet world.

The US Food and Drug Administration (FDA), which is responsible for policing the online advertising of prescription drugs and devices, last spring sent letters to Biogen Idec and 13 other companies declaring that sponsored links such as the one for Tysabri were "misleading" and in violation of the law. The link suggests that Tysabri is effective, the agency wrote, "but fail[s] to communicate any risk information."

"It was a perfectly responsible form of advertising," says Naomi Aoki, a spokeswoman for the Cambridge, Massachusetts-based Biogen Idec. "The second you clicked on that link, it took you to a page that did have fair balance relating drug risks and benefits." She adds, "Google ads are tricky because there's not much room to say a lot there."

In response to the FDA's actions last spring, drug company–sponsored links now include the name of the disease or the name of the drug used to treat it—but not both—so as to fall in line with existing US regulations, which state that advertisers must present both risk and benefit information evenhandedly. "It can be done right," says Thomas Abrams, who heads the FDA's Division of Drug Marketing, Advertising and Communications, which sent out the letters.

But what constitutes 'right' in the online world—from blogs to Facebook to disease-related chat rooms—is a complicated thing to tease out and, in many senses, is a target moving as fast as the evolution of the Internet and social media itself. That much was evident at a forum the FDA hosted in Washington, DC in November to discuss how to regulate online drug information and promotion. The packed public event sought input on a laundry list of questions posed by the agency, including the following: how can drugmakers disclose required information in forums that are as limiting as Twitter's 140 characters?

## A web of worry

The FDA currently has no regulations tailored specifically to drug and device promotion on the Internet, a fact that concerns many, especially in light of the explosion of medical use of the Internet. On Google alone, health condition queries, excluding swine flu searches, grew threefold between 2006 and 2009.

At the forum, "if there was one point of agreement, it was that the FDA should rapidly adopt a set of guidances specific to the Internet," says Jeffrey Francer, the assistant general counsel at the Pharmaceutical Research and Manufacturers of America, the Washington, DC–based lobby group for the drug industry.

Consumer advocates put a different spin on it: "The industry is not off the hook from making sure that consumers will see the fair balance of information—both benefits and harms—when it promotes its products on the Internet," says Steven Findlay, who testified at the hearing for Consumers Union, an advocacy group with offices in Washington, DC.

But just how to achieve that is in the eye of the beholder. At the meeting, Amy Cowan, Google's Head of Industry for Health, noted that the 'click-through rate' on company-sponsored links—that is, the percentage of users presented with a link who click on it and end up viewing the official product website—fell off dramatically after the FDA moved against the companies last spring. Before the change, the links "were more relevant, transparent and informative to the user's queries," Cowan told the forum.

A public comment period on the FDA's many questions remains open until 28 February. At some point after that—the agency won't say when—the FDA is expected to issue a specific set of rules governing drug promotion on the Internet.

Even then, say agency watchers, a host of problems remain, not least of which is the flourishing universe of offshore criminal operations selling prescription drugs—or counterfeits—in open violation of a 2008 US law that bans Internet sales without a prescription (*BMJ* **339**, b3457; 2009).

There is also the bugbear of where to find resources for the agency to enforce any new rules for law-abiding companies. With 59 full-time employees charged with reviewing all 71,759 industry submissions of promotional material in the 2009 government fiscal year, the FDA staff could cope with only a fraction of them. As a result, many say that the industry itself will need to foot the bill, through user fees.

"If FDA is going to do anything to improve the accuracy of information on the Internet, they need more resources," says Diana Zuckerman, the president of the Washington, DC–based National Research Center for Women and Families. "Some of those resources are going to have to come from the companies whose products are being advertised in social media."

Some watchdog groups are fearful that too much reliance on user fees can lead to the agency's 'capture' by the industry it regulates. But Zuckerman and others are gearing up to demand their use—and, with them, mandatory industry submissions of advertising—when negotiations on the renewal of the current user fee law begin later this year.

*Meredith Wadman, Washington DC*