Prescription: Washington

Web of Confusion

FDA Tries to Clarify Rules for Internet Advertising

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resure from consumer groups and

drug companies alike has forced

the FDA to consider issuing guid-

ance on how so-called Web 2.0 appli-


cations can be used in advertising drugs

and medical devices. Pharmaceutical and
device manufacturers have increasingly

been using YouTube, Twitter, blogs, pod-
casts, Wikis, and other social media tools
to take advantage of the emergence of

the Internet as a vehicle for advertising.

But the use of these tools, as well as their
concomitant space limitations, some-
times makes it difficult for companies to
comply with the FDA's advertising reg-
ulations, which were written for print
media and television.

Michele Sharp, PharmD, Senior Di-
rector of U.S. regulatory affairs at Lilly,
told a two-day FDA meeting in Novem-
ber:

"Frankly, to date, Lilly has avoided sig-
nificant interaction with health care pro-
fessionals and patients about our prod-

cucts in social media forums—largely

because of a lack of clarity in under-
standing [the] FDA's expectations as to
how we could participate and comply
with FDA requirements."

In March 2009, in its first indication of
concern, the FDA sent out warning let-
ters to a number of drug companies re-
questing that they revamp their current
online advertising campaigns. Letters to
Merck & Co., Eli Lilly & Co., Genentech,
Inc., and others cited the “sponsored
links” for their products. These links pop
up when someone types a health term
into a search engine such as Google. The
FDA complained that those banners
were devoid of information on the topic
of risk. The agency also criticized Glaxo-
SmithKline for its visual ads on behalf of
Treximet (sumatriptan/naproxen), an
agent for migraine. The agency said that
the company had communicated the
drug’s serious risks in smaller text, and
they were less prominently displayed,
than the eye-popping visual images ap-
pearing on the computer monitor meant
to highlight the drug’s effectiveness.

A citizen’s petition submitted to the
FDA four months earlier, in December
2008, might have led to those March let-
ters. That petition was filed by the Pre-
scription Project, a coalition of groups
led by Community Catalyst in partner-
ship with the Institute on Medicine as a
Profession. The organization is funded
by the Pew Charitable Trusts. The peti-
tion asked the FDA to enforce its rules
and to require Abbott Laboratories, Stry-
ker Corporation, and Medtronic, Inc., to
withdraw their video ads for medical
devices used in heart, hip, and neck sur-
geries from YouTube.com. In addition to
objecting to those ads, the petition re-
quested that the FDA issue guidelines for
consumer-directed broadcast advertising
of prescription drugs and restricted
devices on the Internet to clarify how
federal and FDA rules apply to online
drug and device promotions.

The September 2009 Federal Register
announcement of the November 2008
meeting raised many of the issues that
the Prescription Project had raised in its
petition. Some of the questions discussed
at that meeting included the following:

- When a company sets up a chat
room for online discussions of
health conditions, should the com-
pany be held responsible for infor-
mation provided by participants in
those sessions?
- How should data on safety and risks
be displayed in the sponsored links
(the subject of the FDA's warning
letters in March 2009)?
- Should there be a “one-click rule” so
that complete information on the
risks of a drug or a device would be
only one mouse click away?
- What is a company’s responsibility
to communicate adverse events that
might be associated with its prod-
ucts reported on the Internet?

The fact that the FDA is asking these
questions, but has no answers, helps to
explain why pharmaceutical companies
have been slow to jump into Web adver-
tising. Most firms seem to be unsure of
how FDA rules apply and are hesitant to
expand their Internet advertising pres-
ence—whether it is aimed at physicians,
pharmacists, or consumers—when those
moves could result in enforcement ac-
tion by the FDA. Most drug companies
are waiting for clarification from the FDA
before committing to aggressive Web
strategies.

“The warning letters sent earlier this
year around paid search ads have only
heightened this uncertainty,” explained
Lilly’s Dr. Sharp.

But Lilly has dipped its toe in the water.
It launched a blog on Medscape, written
by its medical team in the U.S., to share
information with physicians. The blog
allows the usual give-and-take wherein
comments can be posted. However, Lilly
is pre-screening all comments and is
deciding to post any remarks that men-
tion a product for fear of running afoul of
the FDA’s “fair balance” requirement.

Pfizer has done something similar. It
collaborates with Sermo, a physician-only
social network with 111,000 doctors,
about 20% of the nation’s physicians.
Pfizer, in essence, is monitoring the con-
versations. When a topic comes up that
is relevant to its products, the company
can jump in, Web-wise. Pfizer initially
made a relevant Webcast available to
discussion participants; however, physi-
cians rejected that “canned” approach.
Eventually, Pfizer and Sermo developed
tools, called AskRx, which allows a doc-
tor to submit a medical inquiry instanta-
aneously to Pfizer’s medical information
department. Pfizer promises to respond
to that doctor in less than 24 hours with
a scientific answer that is customized and
concise. Pfizer is looking to expand this
service offering to physicians’ “smart”
phones.