Asking for Guidance

The underlying message from the roughly 70 people who testified at an FDA hearing in mid-November was pretty clear: give us guidance. This is what speaker after speaker seemed to be asking representatives of the agency. These marketers – whether on the pharma or agency side of the business – want to know how they can use the Internet and social media channels to better communicate with patients, caregivers and other health-information seeking individuals.

As Eli Lilly senior director of U.S. regulatory affairs Michele Sharp told the FDA panel:

"There are still important unanswered questions around Internet promotion, and we believe FDA action on those issues would benefit the public health. And [we also] believe it's important for you to hear from companies like us about what has kept us from more active engagement in social media." Sharp called on FDA to address online promotion and social media tools either through "guidance or executive channels" so pharma has "the detail and clarity" it needs to effectively use new media.

The big question for consumer marketers and agency executives as we head into 2010 is how and when the FDA will respond. Tom Abrams, director of the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC), acknowledged that it will be challenging for the agency to address the new-media channels. He didn't provide a timetable for FDA's next steps, other than to note the docket for the hearing will remain open until Feb. 28, 2010, for additional comments. "We will do this carefully so we get this right," he said. "It's too important of an area not to do it right, as we want the best information about medical products [to be available] for consumers and healthcare professionals."

Pfizer chief medical officer Dr. Freda Lewis-Hall noted in her second-day testimony that she believes "social media is a different animal. It does not operate in the same way as other traditional communication channels." Her sentiments were echoed by a majority of the speakers, and even FDA acknowledged that it received the message that the Internet is "different."

The FDA will take its time to evaluate the data, the testimony and the technology. As some of the speakers advocated, perhaps what the agency also needs is a "working group" to provide advice and to answer questions about new technology and social media tools. This would allow FDA to maintain an ongoing review of media and promotion changes and provide an important sounding board for regulatory policy. It also might be a welcome first step to those who are seeking direction from regulators.

Happy holidays and best wishes for the New Year.

Mark Tosh, Editor in Chief

DTC PERSPECTIVES

Robert Ehrlich
Chairman and CEO
DTC Perspectives, Inc.

Mark Tosh
Editor-in-Chief/VP of Analytics

Christine Franklin
Director of Marketing

Jennifer Haug
Associate Editor / Research

Amanda Ehrlich
Associate Editor / Content

Brooke Kobren
Marketing and Production Associate

Stacey Hagenbush
Sales and Marketing Associate

Scott Ehrlich
Director, Business Development

Todd Lawhorne
Public Relations Manager

Debra Rennert
Creative Director

Debra Sander
Office Coordinator

James Ticchio
Art Director
Direct Media Advertising

DTC Perspectives is Published Quarterly By:
DTC Perspectives, Inc.
30 Columbia Turnpike Suite 205
Florham Park, NJ 07932
Phone # 1-973-377-2106
Postmaster: Please send address changes to the above.

Free to Qualified Industry Subscribers in the U.S.
Apply online at www.dtcperspectives.com.

Rates for International and Non-Industry Subscribers:
$72 Per (1 Year) in the U.S.
$96 (1 Year) Outside of U.S.
Back Issues $10 in U.S.
$30 in All Other Countries