FDA Issues Draft Guidances for Industry on Social Media and Internet Communications About Medical Products: Designed with Patients in Mind

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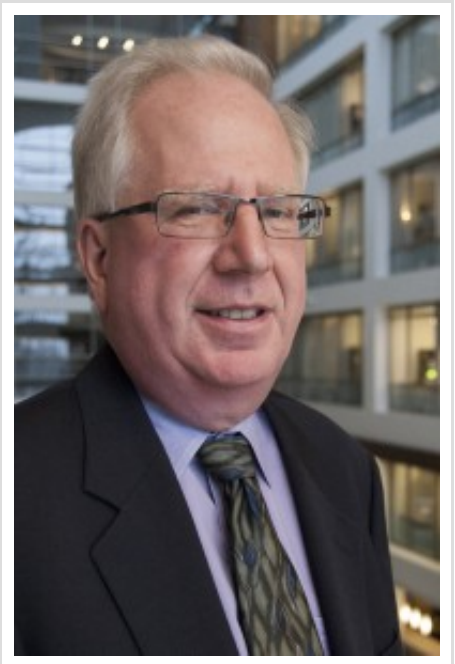
By: Thomas Abrams

Ongoing changes in technology transform medical products – and the ways that both patients and health care providers learn about those products. In today's world, in addition to traditional sources of medical product information, patients and health care providers regularly get information about FDA-regulated medical products through social media and other Internet sources, and those technologies continue to evolve. But regardless of the Internet source used to communicate about medical products, the public health is best served by clear, accurate, truthful and non-misleading information about them.



That's why the agency has proposed two draft guidances for industry with recommendations to help manufacturers and their representatives accurately communicate online about prescription drugs and medical devices.

These documents strive to ensure that the information provided by drug and device companies is

accurate and will help patients to make well-informed decisions in consultation with their health care providers.

Our first guidance provides recommendations for the presentation of risk and benefit information for prescription drugs or medical devices using Internet/social media sources with character space limitations, such as Twitter and the paid search results links on Google and Yahoo. These recommendations address the presentation of both benefit information and risk information in this setting. We understand that communicating on electronic Internet sites with character space limitations can be challenging. But, no matter the Internet source used, benefit claims in product promotions should be balanced with risk information. And companies should provide a way for consumers to gain direct access to a more complete discussion of risks associated with their products.

Our second guidance provides recommendations to companies that choose to correct third-party information related to their own prescription drugs and medical devices. This draft guidance provides FDA's recommendations on the correction of misinformation from independent third parties on the Internet and through social media sites. For example, we recommend that any corrections should address all misinformation in a clearly defined portion of a forum on the Internet or social media, whether the misinformation is positive or negative.

We developed these new guidances, in part, to respond to requests for best practices from companies and other stakeholders. We gave careful thought to our draft recommendations, and we understand technology will continue to evolve. So we worked across FDA Centers and Offices to develop best practices that can be applied to existing online Internet sites — and those that have yet to be developed.

Prescription drugs and medical devices can provide tremendous benefits to patients, but they can also pose certain risks. As a regulatory agency, we are committed to ensuring that the information about these products that their manufacturers and distributors direct at patients and health care providers is accurate and balanced.

These draft guidances are the latest in a series, and the agency is very interested in receiving comments from stakeholders. Please read more about the new draft guidances on our social media guidances webpage, and share your comments and suggestions. The documents represent FDA's current thinking on specific aspects of FDA's evolving consideration of social media sites and other Internet-related matters. FDA continues actively to review, analyze, and develop approaches to a variety of topics related to the labeling and advertising of medical products, including the development of these and other guidances addressing the use of social media platforms and the Internet.

FDA sees social media as an important resource for industry and is committed to developing additional guidance for drug and device manufacturers that outline the agency's current thinking. We do all of this work with the best interest of patients in mind.

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