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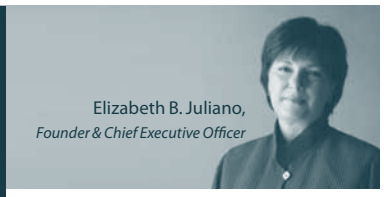

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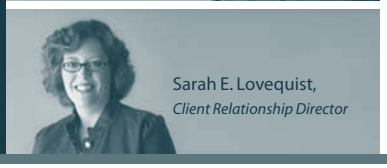

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MIM Reporter

THE REVIEW OF
MEDICAL INFORMATION MANAGEMENT
FOR LITIGATION

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The Social Media Shuffle

Throughout the last decade, marketing and promotion of pharmaceutical products has been affected by direct-to-consumer (DTC) advertising regulations, and most recently by the sudden boom of social networking and various online media tools. Drug makers have been waiting for the U.S. Food and Drug Administration (FDA) to promulgate social media advertising guidelines since 2009 – to date, firm guidelines have not been issued, and drug companies have not been given concrete guidance about what information must be included in social media site communications, or their responsibility for same. Although it is hesitant to promulgate new regulations, the FDA has not wasted any time reprimanding drug companies for inappropriate tweets and Facebook postings.

New or updated regulations are necessary so drug makers understand FDA expectations as companies begin to directly communicate with consumers, and as consumers communicate with one another, about their experiences with various prescription drugs. Without regulatory guidance, what's a drug company to do?

THE FDA'S ARGUMENT

Generally speaking, the FDA is hesitant to disseminate formal social media regulations due to the ever-changing social media landscape, and potential impact on the overall public health and welfare. Part of the delay is attributed to the FDA's belief that Twitter and Facebook will not be around in the future, which in turn will cause any new rules to quickly become outdated and insignificant.[i] Part of the delay may also be attributed to the FDA's belief that sufficient DTC advertising regulations already exist. Existing regulations notwithstanding, one of the main issues that the FDA must address is how to meet the demands of current regulations through online, DTC ads.

DTC prescription drug advertising regulations are codified at Title 21 of the Code of Federal Regulations – the regulations pertain to all prescription drug advertisements transmitted through print media, television, radio or telephone communications.[ii] Existing regulations require prescription drug information to include a "fair balance" of the benefits and risks of an advertised product, both in content and presentation of the information.[iii] The rules further direct that an advertisement must contain a true, brief summary of all side effects, contraindications and effectiveness of the prescription drug.[iv] The advertisement may not mislead consumers, and may only recommend and suggest uses for the drug that are actually contained in the drug's label and have already been deemed "safe" by qualified experts.[v]

MIM Reporter
THE REVIEW OF MEDICAL INFORMATION MANAGEMENT FOR LITIGATION

On April 28, 2011, the FDA posted a Notice in the Federal Register of its intent to conduct three concurrent studies in order to assess how current print, radio and TV advertising rules may be applied to social media advertising; public comment was invited on same.[vi]

Specifically, the studies will evaluate whether the presentation of risk information on drug websites influences consumers' perceptions of a drug's risks and benefits, whether "special features" like personal testimonial videos and interactive visuals on drug websites influence risks and benefits perception and understanding, and whether links to and citations from external organizations referenced on a drug's web site home page influence consumer perceptions.

Participants in the studies will be consumers diagnosed with the medical condition related to the drug in question.

The FDA itself recognizes it is behind when it comes to being prepared to handle the demands and pressures of social media. As stated in its Federal Register notice, "the original regulations that presently determined the FDA's position on DTC promotion were written at a time when the available media for DTC promotion were print and broadcast, and the primary audience was health care professionals. This dynamic is shifting, and evidence is needed to support guidance development."[vii] The Notice's public comment period ended June 27, but to date the FDA has not set forth any additional guidance, or announced any plans to do so.

THE INDUSTRY'S POSITION

Acknowledging that advertising regulations do exist, industry advertisers assert that marketing in cyber space is completely different from traditional television, radio or print advertising; the differences make it impossible for the industry to apply existing rules in cyber space.[viii]

Specifically, companies do not want to be held accountable for content they do not generate: devoting time and money to monitoring and deleting inappropriate comments from every website or internet communication is impossible but necessary as same could lead to questions from governmental regulators, especially if the content relates to an adverse event. The industry is looking for FDA guidance on when a company is responsible for content over which it has no control as opposed to content posted to an online environment over which it may have some control or ability to influence, such as off-label use of a prescription drug.[ix] Along with content control, the industry wants to ensure that consumers are able to distinguish information posted by a company itself versus information posted by a third party.

Further, companies are concerned with space constraints imposed by some social media sites that limit the amount of information contained in a post. In this environment, a company is unable to fully describe the efficacy and risks associated with a product in order to comply with existing DTC regulations. The industry needs adaptable guidelines that are applicable to multiple social media outlets.[x]

Finally, the industry would like FDA guidance on how best to participate in interactive discussions via social media, and permission for companies to determine when and whether to participate in discussions or to correct information posted on third party sites.[xi]

In early 2011, the drug and healthcare industries banned together to form a non-profit to aid the healthcare community in defining and advancing the conversation on the "digital landscape." The Digital Health Coalition was created "to serve as the collective voice and national forum for the discussion of current and future issues relevant to digital and electronic marketing of healthcare products and services."[xii] Digital Health engages multiple and diverse stakeholders from all aspects of the healthcare industry, including pharmaceutical and biotech manufacturers, medical technology companies such as AstraZeneca, Roche, Lilly, Merck and Sanofi, as well as representatives from Google and Everyday Health. Digital Health itself has a presence on both Twitter and LinkedIn.[xiii]

Rather than idly wait for the FDA's regulations while continuing to be exposed to risk, Digital Health's stakeholders have started drafting proposed "best practices" based on existing DTC regulations and guidance gleaned from FDA communications.[xiv] Proposed best practices will be circulated for public comment by the end of 2011, with a goal of finalizing and implementing the voluntary guidelines by the end of 2012.[xv]

SOCIAL MEDIA SNAFUS

While the social media debate between the FDA and pharma industry will surely continue beyond 2011, The FDA continues to swiftly issue to pharma companies notifications of potential online DTC advertising violations. Since social media has such an expansive reach, what follows are examples of pharma companies' recent FDA-deemed errors in the U.S. and abroad. If nothing else, the FDA's interpretation and application of existing regulations to each company's use of various social media outlets offers a glimpse of what future regulations may impose.

PRODUCT-SPECIFIC PUBLIC WEBSITES

On June 21, 2011, the FDA sent a warning letter to Cephalon regarding its Trisenox public web site. Trisenox is an FDA-approved drug for treating acute promyelocytic leukemia (APL). On the site, Cephalon prominently "overstated" Trisenox's use in large, bold, colorful font at the top of the page, a no-no per FDA advertising guidelines. Although Trisenox's risks were included at the bottom of the page, the FDA indicated that Cephalon minimized these risks by placing them at the bottom of the page in "small gray font and in single-spaced paragraph format," almost as if to conceal the risks. The FDA's warning letter states that this display, combined with a failure to include the drug's limitations, could potentially mislead patients into believing that Trisenox is approved to treat patients with any kind of APL when same is not true.[xvi] Basically, the FDA determined that critical risk information was not presented on the Trisenox web page and, therefore, not emphasized in the same manner as the effectiveness claims: "the overall effect of this presentation greatly undermines the communication of important risk information, minimizes the risks associated with Trisenox, and misleadingly suggests that the drug is safer than has been demonstrated."[xvii]

Similarly, the FDA reprimanded AMAG Pharmaceuticals, Inc., on October 10, 2010, for its failure to overtly supply consumers with drug risk information directly on the drug's webpage. In reviewing AMAG's GastroMARK® site the FDA noted that a link to download the package insert was available at the bottom of the webpage; in reviewing AMAG's Feraheme page, the FDA found the package insert link "buried in the second sentence" of the page.[xviii] Neither drug's page specifically or clearly set out the risks associated with each drug, and the FDA indicated that links to package inserts "do not mitigate the complete omission of risk information" from the drugs' pages.[xix] The FDA further found that both pages "misleadingly suggest unapproved new uses for the drugs."[xx]

Through issuing these letters, the FDA seems satisfied that existing print and television direct-to-consumer advertising rules may be easily applied to on-line advertising.

YOUTUBE

September 25, 2008 marked what is believed to be the first FDA warning letter specifically targeting online video advertising. Shire Development, Inc. was reprimanded for both product website content and YouTube video testimonial content featuring celebrity Ty Pennington that promoted Adderall XR Capsules.[xxi] The FDA found that the webpage overstated the efficacy of Adderall in the treatment of ADHD, and expand the indications for Adderall beyond

its approved use. Similarly, the YouTube video also overstated the efficacy of the drug through the use of celebrity endorsement claiming that Adderall will "transform" users' lives and improve their "confidence to achieve [their] goals."[xxii] Per the FDA, the video cited no clinical data in support of these claims, and entirely failed to present any drug risk information such as warnings, precautions and common adverse events associated with Adderall as required by DTC advertising regulations.[xxiii]

Shire immediately removed the video from YouTube upon receipt of the warning letter. To be sure, the FDA's letter does not specifically prohibit promotion of pharmaceuticals via YouTube; rather, the letter focuses on the actual content of the video in light of existing advertising regulations.

TWITTER

In July 2011, the U.K.'s Prescription Medicines Code of Practice Authority (PMCPA) ruled that Bayer violated the Association of the British Pharmaceutical Industry (ABPI) Code of Practice by tweeting about the launch of its drugs Levitra and Sativex. Promotion of a prescription drug is illegal in the U.K. per Code clauses 22.1 (ban on advertising prescription-only medication to the public) and 22.2 (public information must be factual and balanced).[xxiv] Although both tweets contained a link to a Code-appropriate press release, the PMCPA noted that the tweets themselves had not been approved for Code compliance.[xxv]

In its ruling, the PMCPA acknowledged that U.K. pharma companies may use social media outlets like Twitter to provide information to the public, but that the material must nonetheless comply with the Code in general, and clause 22 specifically.[xxvi] Although the ruling did note that providing information to the public was a legitimate activity for U.K. pharmaceutical companies, the PMCPA nonetheless plans to make an example of Bayer by running advertisements about this case in several medical journals.[xxvii]

Had these tweets been issued in the U.S., it is likely that the FDA would have issued a similar warning letter: the Levitra tweet mentioned that the drug is used to treat erectile dysfunction, and the Sativex tweet indicated it is used to treat "spasticity due to Multiple Sclerosis." Both tweets may be construed by the FDA as claims about the drugs' efficacy. Per FDA regulations, claims of efficacy must be accompanied by product safety and risk info, but including all of this information within a 140-character tweet is next to impossible.[xxviii]

FACEBOOK

At the end of May, Facebook announced to pharma companies that, as of August 15, 2011, they must allow public comments on their company or patient-specific community Facebook pages. Pages relating only to specific products or drugs will remain closed to comment. Previously, companies were able to turn-off the comments functionality on their Facebook page, allowing complete company control over posted content, and rightfully so – many stringent general advertising regulations are already in place, and any negative comments or complaints may trigger a company's Adverse Event reporting duties.

Drug companies must now decide whether to continue using Facebook and accept any comments that may be posted, while continuously monitoring Facebook through either human review or a computer application like PharmaWall, or abandon their Facebook presence. Of course, companies still have the option of paying to advertise on Facebook, which many critics believe is the impetus behind Facebook's sudden "rule change." [xxix]

After Facebook's rule-changing announcement, Pfizer adamantly stated that Facebook is part of its social media strategy and its pages will remain on the site even after same are opened to the public. Prior to pages being opened, though, Pfizer's Facebook page was hacked by the infamous "vigilante" group Script Kiddies, also responsible for hacking, among others, Fox News' Twitter account.

When asked why Pfizer was a target, one of the hackers stated that Pfizer is a "corrupt giant" guilty of harming and killing people; the goal of the hack was to promote awareness by posting material recycled from other media outlets; no company confidential information was leaked.

Since Pfizer was unable to prevent the hack (the security issues were strictly Facebook's), Pfizer maintained that it will continue its Facebook presence, using the hack as a "learning experience" to be shared with other pharma companies.[xxx]

Prior to the August 15 wall opening, Johnson & Johnson and AstraZeneca both removed pages.[xxxi] With the wall opening, several other companies immediately elected to remove their pages from Facebook: Purdue Pharma removed its "In The Face Of Pain" page; Amgen removed its "Breakaway From Cancer" page despite earlier statements that the page would remain online; and Bayer removed its "Strong at Heart" page in favor of only maintaining one page, "I Am ProHeart."[xxxii]

Conversely, one company in particular has embraced the wall opening as an opportunity to engage with the public. Sanofi Pasteur, Inc. has decided to monitor its "Sounds of Pertussis" Facebook page, specifically inviting Facebook users to "join our page, connect with us and share information."[xxxiii] Sanofi's theory is that consumers want to interact with pharma companies, and Facebook has simply forced pharma to "address issues."[xxxiv]

CONCLUSION

The world of social media is ever-changing, and its use by the pharmaceutical industry is largely unregulated. Understandably, drug companies are hesitant to continue using social media until existing advertising rules are updated and clarified to provide guidance on how best to navigate cyberspace. Above all, companies want and need the FDA to resolve the extent to which a drug company may be held liable for its own advertisements, as well as posts and blogs left by consumers.

If a company chooses to navigate the digital landscape, it must be "prepared to defend those decisions if questioned by the FDA."[xxxv]

This includes, at a minimum, creation of new, or amendment of existing, internal social media policies that clearly set forth a company's goals and objectives in using social media, and which department(s) or individual(s) will be responsible for policy enforcement and monitoring use.

Given that the FDA has yet to satisfy the industry's requests for guidance, the industry can either abandon social media altogether or "make rational decisions about what is and is not justified, or at least what should be justified, from a legal, policy, and communications standpoint."[xxxvi]

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