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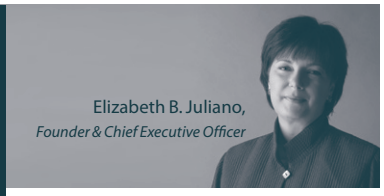

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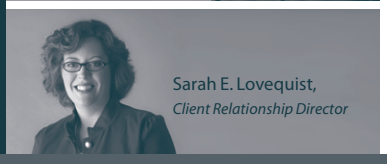

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MIM Reporter

THE REVIEW OF
MEDICAL INFORMATION MANAGEMENT
FOR LITIGATION

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Will Regulation Extinguish DTC TV Advertising?

Marketing and promotion of pharmaceutical products throughout the last decade has been greatly affected by direct-to-consumer (DTC) advertising regulations. The Food and Drug Administration Amendments Act of 2007 (FDAAA) added section 503B to the Federal Food, Drug, and Cosmetic Act (FD&C Act), requiring a pre-dissemination review of DTC ads. Section 503B gives the U.S. Food and Drug Administration (FDA) the authority to require sponsors of human prescription drugs to submit "any television advertisement for a drug" no later than 45 days before airing the ad; the FDAAA also sets out specific requirements for FDA review and comment on such ads.[i]

On March 13, 2012, the FDA released draft guidance that outlines the specific submission process and documentation needed for its review of all new DTC advertising claims.[ii] The draft guidance describes the full array of DTC TV ads that the FDA intends to subject to pre-dissemination review. To be sure, pre-dissemination review under Section 503B is separate from the FDAAA's voluntary advisory review, and sponsors may still submit proposed TV ads to the FDA for review regardless of whether an ad also requires review per Section 503B.[iii]

Under Section 503B, sponsors must submit TV ads for pre-dissemination review if they fit into the following categories:

- Category 1: The initial TV ad for any prescription drug or the initial TV ad for a new or expanded approved indication for any prescription drug.
- Category 2: All TV ads for prescription drugs subject to a Risk Evaluation and Mitigation Strategy (REMS) with elements to assure safe use (see section 505-1(f) of the FDAAA).

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- Category 3: All TV ads for Schedule II controlled substances.
- Category 4: The first TV ad for a prescription drug following a safety labeling update that affects the Boxed Warning, Contraindications, or Warnings & Precautions section of its labeling.
- Category 5: The first TV ad for a prescription drug following the receipt by the sponsor of enforcement letter (i.e. a Warning or other untitled letter) for that product that either cites a TV ad or causes a TV ad to be discontinued because the TV ad contained violations similar to those cited in the enforcement letter.
- Category 6: Any TV ad that is otherwise identified by FDA as subject to the pre-dissemination review provision.[vi]

While at first glance it seems that the FDA is limiting review to only certain categories of ads, a closer review of the above list reveals that virtually any and all types of TV ads are in fact subject to pre-dissemination review; only ads that repeat the same basic information without asserting new claims, concepts or creative themes appear to be exempt. Further, ads within Categories 4 and 5 may potentially be subject to continuous review, regardless of whether new information is included.

Although the draft guidance indicates that the FDA will notify drug sponsors when ads must be submitted for review, either through direct written correspondence or via notice in the Federal Register, sponsors still bear the ultimate burden of determining whether their ads fall into any of the six categories and require pre-dissemination review:

> *". . . if a sponsor is developing a TV ad for a product that falls into one of the categories described above and has not yet received written notification, [the FDA recommends] that the sponsor submit the TV ad for pre-dissemination review . . ."*[v]

Sponsors who either mistakenly or deliberately air a TV ad without complying with Section 503B may be enjoined from doing so and/or subject to criminal penalties and potential civil monetary penalties. Ironically, after a drug sponsor complies and submits its pre-dissemination review package, compliance with the FDA's suggestions is optional, save for disclosure of serious risks listed in the labeling and/or inclusion of the date of the product's approval for up to two years post-approval. Without a doubt, sponsors who follow the draft guidance but opt to disregard the FDA's suggestions may face a more severe enforcement action if the advertisement is ultimately deemed a violation.

Per the draft guidance, the FDA will aim to complete its review and provide comments within 45 calendar days. The FDA estimates that approximately 32 sponsors will submit approximately 80 ads per year for pre-dissemination review. The FDA further estimates that based on the information required in the draft guidance, it will take each sponsor

approximately 25 hours to prepare and submit the pre-dissemination review package. The 45-day review clock begins only if the FDA receives a complete review package. Incomplete submission packages will be returned to the sponsor for correction and resubmission – the FDA anticipates receiving 6 incomplete packages from 6 different sponsors annually, and that each sponsor will spend 5 hours correcting and resubmitting its package.[vi]

The sponsor will be notified if the FDA is unable to provide comments within 45 days. At this point, the sponsor is placed in the undesirable position of deciding whether it will wait beyond 45 days for FDA comments, or whether it will disseminate the TV ad and notify the FDA to discontinue its review. Should the sponsor elect the later option, it may potentially subject itself to civil monetary penalties under the FDAAA and/or traditional enforcement actions for disseminating a false or misleading advertisement.

THE INDUSTRY RESPONDS

From March 13, 2012 through May 14, 2012, the FDA invited the pharmaceutical industry to comment on the draft guidance, specifically on whether the proposed collection of information is necessary, whether the FDA has correctly estimated the burden that information production will place on ad sponsors and ways to minimize the burden, and ways to enhance the quality of the information collected.[vii] In both the draft guidance and the *Federal Register* notice, the FDA asserts that it cannot provide final comments on the "acceptability of a TV ad without reviewing a final recorded version in its entirety."[viii] Recognizing that sponsors may want FDA feedback before producing a final recorded version, the FDA suggests that sponsors submit to a voluntary advisory review before submitting the final recorded version for pre-dissemination review.

Industry responders have unanimously taken issue with the FDA's need to review only final recorded versions of TV ads prior to dissemination. Sanofi specifically comments that submitting a final recorded version to the FDA for pre-dissemination review would be "costly and resource intensive for the sponsor" due to the amount of time and money needed to plan and produce same.[ix] As Sanofi states in its comments, "a final recorded version provides insights into the intended tone, use of visuals and speed of information being presented, but this can be delineated in a pre-recorded version quite adequately and should be appropriate for FDA review."[x] Sanofi further points out that, should the process set out in the draft guidance become regulation, drug makers may need to stop using TV ads as a consumer educational vehicle due to the "significant production challenges" that would arise from the proposed process, which in turn would deprive consumers of the education needed to make an informed decision and engage in informed discussions with his or her healthcare provider regarding various pharmaceutical products.[xi]

In the same vein, Boehringer Ingelheim notes that it has routinely and voluntarily submitted DTC broadcast ads containing new or revised efficacy and/or safety information to the FDA for review prior to airing, and is committed to adhering to the FDA's existing regulations on DTC communications – Boehringer believes sponsors will generally continue following this practice if additional clarification or guidance is needed, regardless of pre-dissemination review regulations.[xii] Boehringer, like Sanofi, encourages the FDA to accept storyboards in lieu of actual recorded ads for pre-dissemination review, noting that it believes sponsors will submit complete and detailed storyboards, eliminating the need for submission of final recordings: "…it behooves sponsors to ensure storyboards submitted for advisory comments are representative of the final ad and to ensure that the Agency's advisory comments are incorporated into the filmed version."[xiii]

Likewise, The Pharmaceutical Research and Manufacturers of America (PhRMA) agrees that, "the requirement to submit a final recorded version of a TV advertisement will place a substantial financial burden on submitting companies," because any FDA comments could force a company to "rework material that has already been fully produced at a significant cost."[xiv] PhRMA further suggests that the FDA completely withdraw the draft guidance in favor of promulgating official regulations for implementation of a DTC Review Program pursuant to Section 503B of the FD&C Act.

Based on the comments received to date and the significant time and cost associated with producing final recorded TV ads, it is quite possible that drug makers will forego DTC TV advertising should the draft guidance become final.

INFRINGEMENT ON CONSTITUTIONAL RIGHTS

Beyond cost and time constraints, PhRMA boldly asserts that the draft guidance is overly broad and, therefore, unconstitutional, stating it is "concerned" that the FDA's proposal infringes on the drug industry's First Amendment rights: "The Supreme Court recently affirmed that '[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment.' Thus, when the FDA restricts the speech of pharmaceutical manufacturers and other regulated entities, the restrictions are subject to scrutiny under the First Amendment. DTC promotion – like other forms of advertising and promotion is commercial speech that is protected by the First Amendment."[xv]

PhRMA further advises that the DTC Review Program be implemented in a manner that maintains a balance between protecting consumers and public health and allowing for the free-flow of crucial health-related information as protected by the First Amendment: "PhRMA recommends that FDA reconsider the proposed broad scope of the DTC Review Program and narrowly target those advertisements where it can provide justification supported by empirical evidence to support a legitimate need for a pre-dissemination review and delay of commercial speech and the absence of other less restrictive alternatives."[xvi] PhRMA suggests that, rather than enacting regulations based on the draft guidance, the FDA should pursue "notice and comment rulemaking in a tailored, risk-based approach that conforms with the Supreme Court's directive that the First Amendment mandates that the speech restrictions be narrowly drawn."

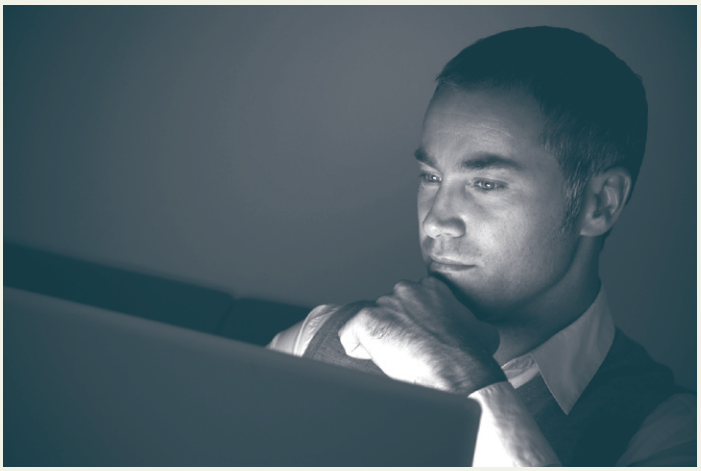
THE SOCIAL MEDIA TWIST

The Fall 2011 MIM Reporter[xvii] highlighted the FDA's lack of industry guidance on social media advertising. As it turns

out, this lack of guidance may work in the industry's favor in terms of complying with the draft guidance. At least one drug company has publicized a potential loop-hole in the draft guidance, specifically that the guidance only applies to television ads and not ads circulated via the internet.

In its comments, Shire Development, LLC, points out that, "there has been increasing availability and use of vehicles other than broadcast TV to present video advertising, such as on-demand viewing via the Internet."[xviii] Shire further requests that the FDA confirm whether the scope of the draft guidance is limited to only DTC ads disseminated through broadcast television - making this distinction will "avoid any confusion on the part of sponsors concerning whether the guidance also applies to video advertisements disseminated through other viewing platforms."[xix] Shire reasons that sponsors will still have the option of voluntarily submitting to the FDA video ads intended for media platforms other than broadcast television, allowing time for comment prior to dissemination and eliminating the need for sponsors to produce final recorded versions of TV ads.

At this point, neither the FDA nor the pharmaceutical industry has formally issued mandatory or voluntary guidelines specifically targeting advertising through social media outlets such as You Tube. Until the FDA clarifies what is meant by "dissemination," it is likely that sponsors will take matters into their own hands and begin airing advertisements via the internet before receiving FDA approval to disseminate the same ad on TV.



CONCLUSION

With the close of the comment period, the industry has alerted the FDA that the draft guidance will not only create significant new burdens on it, but will also keep critical information from reaching consumers in a timely manner. The proverbial ball is now in the FDA's court, and it can either finalize regulations based on the draft guidance, or consider the industry's comments and make revisions based on same.

While the draft guidance is not currently binding, it does reflect how the FDA intends to handle pre-dissemination reviews for DTC TV ads. Sponsors should become intimately familiar with the draft guidance and how it differs from the FDA's voluntary submission and review practice. Until the FDA responds to the comments received, several questions remain unanswered, including whether the FDA, regardless of its volume estimates, is sufficiently staffed to complete its review within 45 days. As with outstanding questions regarding industry use of social media, the pharmaceutical industry must again wait an undetermined length of time for the FDA to provide final direction.

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ENDNOTES

i. See 21 U.S.C. §§ 301-399d (2006); see generally 21 C.F.R. 202.1 (2011).
ii. "Draft Guidance for Industry on Direct-to-Consumer Television Advertisement – the Food and Drug Administration Amendments Act of 2007 Direct-to-Consumer Television Ad Pre-Dissemination Review Program; Availability (Notice)." Federal Register 77:49 (March 13, 2012) p. 14811. Available from: ProQuest Congressional; Accessed: 6/1/12.
iii. See 21 CFR 202.1(j)(4) (2011).
iv. U.S. Department of Health and Human Services, Food and Drug Administration. "Guidance for Industry Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program (Draft Guidance)." March 2012. June 1, 2012. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM295554.pdf.
v. Id.
vi. See "Draft Guidance for Industry on Direct-to-Consumer Television Advertisement . . .", *supra*.
vii. Id.
viii. Id.
ix. Bowen, Linda. "Docket No. FDA-2012-D-0022; Guidance for Industry Direct-to-Consumer Television Advertisement – FDAAA DTC Television Ad Pre-Dissemination Review Program." Sanofi. May 11, 2012. June 1, 2012. http://www.forums.pharma-mkting.com/showthread.php?p=81589#post81589.
x. Id.
xi. Id.
xii. Palmisano, Joanne. "Docket No. FDA-2012-D-0022; Draft Guidance for Industry on Direct-to-Consumer Television Advertisements – the Food and Drug Administration Amendments Act of 2007 Direct-to-Consumer Television Ad Pre-Dissemination Review Program." Boehringer Ingelheim. May 11, 2012. June 1, 2012. http://www.pharma-mkting.com/forums/showthread.php?p=81633#post81633.
xiii. Id.
xiv. Francer, Jeffrey R. "Docket No. FDA-2012-D-0022; Comments on Draft Guidance for Industry on Direct-to-Consumer Television Advertisements." Pharmaceutical Research and Manufacturers of America. May 14, 2012. June 1, 2012. http://wlflegalpulse.files.wordpress.com/2012/05/phrma-dtc-prereview-comments.pdf.
xv. Id.
xvi. Id.
xvii. MIM Reporter. "The Social Media Shuffle." Litigation Management, Inc. Fall 2011 Issue. http://www.medicineforthedefense.com/Portals/0/LMI_MIM_Fall_2011.pdf.
xviii. Shire Development, LLC. "Comments on FDA's Draft Guidance to Industry." May 14, 2012. June 1, 2012. http://www.pharma-mkting.com/forums/showthread.php?p=81633#post81633.
xix. Id.