Legal Backgrounder

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2009 Massachusetts Avenue, NW
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202.588.0302 wlf.org

To Tweet or Not to Tweet:
How FDA Social Media Guidelines Violate the First Amendment

by Kirby T. Griffis and Tamara Fishman Barago

Suppose a pharmaceutical company, PharmaFirm, learns that the Food and Drug Administration (FDA) has approved its new diabetes drug, Insulate, as safe and effective. As part of the sales launch plan, the Insulate product manager prepares a tweet about the approval, and forwards a draft to Legal. Legal—living up to its killjoy reputation—vetoes the tweet. Why?

Recent FDA draft guidance[1] makes clear that the agency considers essentially all drug-specific Internet postings by pharmaceutical companies to be "promotional labeling," and it imposes restrictions on such speech that effectively foreclose many channels of communication altogether. FDA has demonstrated its intent to enforce those guidelines. Most recently, on August 7, FDA issued a warning letter related to an Instagram post by reality TV star Kim Kardashian that promoted a morning sickness drug, even though the post devoted a portion of its short text to a link with safety information.

The social-media guidance lays out a minefield that will deter pharmaceutical companies' use of consumer communications channels that effectively reach millions. Such restrictions not only disserve patients, they violate the First Amendment rights of those who wish to send and receive such truthful information. This Legal Backgrounder evaluates the FDA guidance's constitutional infirmities in the context of its application to character-limited social media (*i.e.*, platforms such as Twitter).

FDA's Efforts to Regulate Social Media

In January and June 2014, FDA issued three draft guidance documents intended to describe its "current thinking" on how pharmaceutical companies may use certain aspects of social media.[2] The first guidance details whether and how a firm should submit "interactive promotional media" to FDA in order to meet its postmarketing submission obligations.[3] Another guidance notes that pharmaceutical firms do not have to respond to misinformation about their products posted by independent parties on the Internet, but if they do, they should do so in a particular way.[4] The third—the subject of this Legal Backgrounder—specifies the information that, according to FDA, should be included within the confines of a character-limited post whenever a pharmaceutical company tries to communicate information about a product.[5]

Under the draft guidance for character-limited social media, any "benefit" information—which can include just mentioning the drug's approved indication—must include "relevant material facts … such as limitations to an indication or the relevant patient population."[6] A post that identifies a drug's approved indication (*e.g.*, "for diabetes") must also include risk information "comparable in scope"—which, to FDA, means that each communication "should, at a minimum, include the most serious risks associated with the product."[7] In addition, the communication should include a hyperlink to a webpage or PDF that "is devoted exclusively" to the product's risks.[8] Partial compliance will not do. Kim Kardashian's Instagram post gave a brief personal testimonial (eight

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Kirby T. Griffis is a Partner, and **Tamara Fishman Barago** is an Associate, with Hollingsworth LLP.

sentences, the first of which was "OMG") and concluded with a link to the company's full safety information page. This hyperlink was not enough and drew a warning letter.[9]

In Practice the Guidelines Would Suppress All Access to a Large Percentage of Social Media

Assessing several hypothetical tweets from PharmaFirm, the company that is bringing Insulate to the U.S. market, will help explain how the guidance on space-limited social media would work in practice.

> *Today FDA approved Insulate (insulin perfectus) for type 2 diabetes. See www.insulatedrug.com.* (94/140 characters)

This tweet is a seemingly innocuous statement providing news of a potentially important new product.[10] It concerns an entirely legal matter (an FDA-approved pharmaceutical) and provides only clear, accurate information. There is no specific description of purported benefits beyond the description of the indication. And the tweet provides a link to a web page with complete prescribing and risk information.

Nevertheless, FDA would likely consider the tweet a violation. Because it includes a drug name and a brief indication ("for type 2 diabetes"), the guidance requires a plethora of additional information to be squeezed into this single, space-limited tweet: (a) Insulate has only been approved for use when first-line therapies fail;[11] (b) Insulate should not be used in patients with kidney disease;[12] (c) clinical trials showed a small risk of cardiovascular failure associated with Insulate use;[13] (d) a hyperlink must direct users to a dedicated webpage or PDF discussing risks only.[14]

PharmaFirm's addition of use limitations significantly muddles the message:

> *FDA approved Insulate for type 2 diabetes; 2d-line therapy only; not for patients with kidney disease. See www.insulatedrug.com/risks.* (134/140 characters)

This tweet, too, would likely be deemed inadequate because it does not describe "the most serious risks." A different version:

> .@PharmaFirm: *FDA approved Insulate for type 2 diabetes; 2d-line therapy only; not for patients with kidney disease. May cause heart attack. See www.insulatedrug.com/risks.* (159/140 characters)

This tweet exceeds the character limit and only mentions two of the drug's "most serious risks." If PharmaFirm communicated its frustrations to FDA, the agency would likely point to the following language in the guidance: if the stated requirements are not possible "within the constraints of the platform," then "the firm should reconsider using that platform."[15] For practical purposes, the guidance not only chills companies' use of platforms like Twitter, but also their use of many other social-media tools where character-limitation is what consumers expect. Shutting down an entire mode of communication to commercial speech would require an extraordinary justification, and FDA has not provided one.

Truthful Pharmaceutical Marketing is Protected Speech

FDA claims jurisdiction over character-limited social media by asserting that all pharmaceutical company statements about a drug's indication for use constitute "promotional labeling."[16] FDA cites *Kordel v. United States*, 335 U.S. 345 (1948), as support for this sweeping authority.[17] The agency's support is misplaced. In *Kordel*, the Supreme Court held that literature that was shipped separately from the drugs it described, but that alone "explained their uses," was "an essential supplement" to the drug's package label because it "was designed for use in the distribution and sale of the drug" and, with the drug, was "part[] of an integrated distribution

program."[18] By contrast, social-media posts are not tied to any distribution program, are not clearly directed at a drug's sale, and are not "an essential supplement to the label attached to the package," because all required information is already contained in the drug's prescription insert.

Furthermore, according to the Supreme Court, commercial speech is "speech proposing a commercial transaction."[19] A stand-alone tweet that announces a prescription drug's approval, with nothing more, does not explicitly or implicitly "propos[e] a commercial transaction." And if it does not, then any content-based restrictions on it are presumptively invalid.[20]

Even if the post in question could be considered commercial speech, "[s]peech in aid of pharmaceutical marketing … is a form of expression protected by the Free Speech Clause of the First Amendment" and therefore any restrictions "must be subjected to heightened judicial scrutiny."[21] Restrictions on commercial speech must pass the *Central Hudson* test: As long as commercial speech concerns "lawful activity" and is not "misleading" it is protected by the First Amendment.[22] Restrictions on such speech withstand constitutional scrutiny only if (a) "the asserted governmental interest is substantial;" (b) "the regulation directly advances the governmental interest asserted;" and (c) the regulation "is not more extensive than is necessary to serve that interest."[23] Therefore, "[c]ommercial speech that is not false or deceptive and does not concern unlawful activities … may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest."[24] The requirement that companies disclose *all* mentions and uses of a drug entirely forecloses the use of some platforms of communication. The guidance thus proscribes far more speech than is necessary.

If FDA's "substantial governmental interest"[25] is to prevent pharmaceutical companies from offering potentially misleading information on space-limited social media, the guidance is an inapt tool for the task. The guidance requires no "benefit" information other than any qualifications on indication or patient population.[26] It does not mandate explicit claims of efficacy ("Insulate cut diabetes-related complications by 50%!") or safety ("Most users have zero side effects!"). Yet every space-limited communication must, "at a minimum," include a specific account of "the most serious risks associated with the product."[27] It is difficult to see how presenting detailed, serious risks alongside a bland recitation of indication for use could be considered "comparable in scope."[28] In requiring disclosure, specifically, of "the most serious risks," FDA also disregards the crucial detail of whether those risks are the most common risks or whether they occur at any notable rate. Without such up-front information, a Twitter user could well be misled into believing a drug is much more dangerous than it actually is. FDA's mission does not include discouraging the appropriate use of pharmaceuticals by alarming potential consumers with imbalanced risk information. Still less does it require barring a company from an entire channel of modern communication like Twitter.[29]

Conclusion

FDA guidance documents help inform companies about what conduct the agency is likely to find objectionable. This particular guidance, however, is entirely unworkable and arguably unconstitutional. Rules that might make sense in the context of magazines or journals are incompatible with the information-thin air of social media. No consumer of social media would expect to receive complete information on any topic in one communication, particularly a subject as complex as drug risks and benefits. The solution cannot be to bar pharmaceutical companies from these platforms.

FDA claims to be protecting consumers from false and misleading information. Each hypothetical tweet that this Legal Backgrounder has presented contains truthful, non-misleading information. As has been explained, though, FDA would likely object to each one according to its guidance. First Amendment jurisprudence dictates that such a sweeping approach, absent a compelling justification, is unconstitutional.[30] FDA has not offered a sufficiently compelling reason for its actions, nor can it. The agency would do well to consider the likelihood of a successful First Amendment challenge when contemplating the release of final social-media guidance.

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Endnotes

[1] Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Draft Guidance, June 2014).
[2] Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics at 2 (Draft Guidance, Jan. 2014), available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm.
[3] *Id.* at 2 (noting that if a firm follows the rules as described therein, "FDA intends to exercise enforcement discretion regarding the regulatory requirements for postmarketing submissions related to promotional labeling and advertising").
[4] Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices at 5-6 (Draft Guidance, June 2014).
[5] Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations at 5.
[6] *Id.* at 6.
[7] *Id.* at 8-9.
[8] *Id.* at 10.
[9] FDA Warning Letter re Diclegis, Aug. 7, 2015.
[10] *See Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2664 (2011) (A consumer's concern for the free flow of commercial speech "has great relevance in the fields of medicine and public health, where information can save lives.").
[11] *See* Space Limitations Guidance at 6 (the firm should "reveal material facts … such as limitations to an indication").
[12] *Id.* at 9 ("the most serious risks would generally include … all contraindications").
[13] *Ibid*. at 9 ("the most serious risks would generally include … all risks that are known to be fatal or life-threatening").
[14] *Id.* at 10 (the hyperlink destination must be "devoted exclusively to the communication of risk information").
[15] Space Limitations Guidance at 5.
[16] *See id.* at 2-5 (discussing FDCA and CFR sections covering "promotional labeling for drugs and devices and advertisements for prescription drugs and restricted devices", including FDCA §§ 502(a), 201(n); 21 CFR 201.1); *id.* at 4 n. 10 (singling out "*reminder* promotions (labeling or advertising that calls attention to the name of a drug or device but does not include indications, dosage recommendations, or other information)" as exempt from the disclosure requirements and, alone, not covered by the Guidance). Note that the term "promotional labeling" does not occur in any of these statutes or regulations.
[17] *See id.* at 2; 21 U.S.C.A. § 321(m) ("The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.").
[18] *Kordel*, 335 U.S. at 348, 350.
[19] *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of NY*, 447 U.S. 557, 561 (1980); *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983) (noting that "the core notion of commercial speech" is "speech which does no more than propose a commercial transaction" (internal quotation marks & citation omitted)).
[20] *Sorrell*, 131 S. Ct. at 2667 (quoting *R.A.V. v. City of St. Paul, Minn.*, 505 U.S. 377, 382 (1992)); *see also Bolger*, 463 U.S. at 65 & 65 n.7 (1983) (noting that the U.S. Supreme Court "has sustained content-based restrictions" on noncommercial speech "only in the most extraordinary circumstances" and citing libel, obscenity, fighting words).
[21] *Sorrell*, 131 S. Ct. at 2659.
[22] *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 566.
[23] *Ibid.*
[24] *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638 (1985).
[25] *Ibid.*
[26] Space Limitations Guidance at 6.
[27] *Id.* at 9.
[28] *Id.* at 8.
[29] *Sorrell*, 131 S. Ct. at 2664 ("The Court has recognized that the distinction between laws burdening and laws banning speech is but a matter of degree and that the Government's content-based burdens must satisfy the same rigorous scrutiny as its content-based bans."); *see also Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 72 (D.D.C. 1998) ("A commercial speech restriction will fail if it burdens 'substantially more speech than necessary.'") (quoting *U.S. v. Edge Broadcasting Co.*, 509 U.S. 418, 430 (1993)).
[30] *See Thompson v. Western States Medical Center*, 535 U.S.357, 374 (2012) ("We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."); *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 562 ("Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all."); *see also U.S. v. Caronia*, 703 F. 3d 149, 169 (2d Cir. 2012) ("We conclude simply that the government cannot prosecute pharmaceutical manufacturers or their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.").

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