Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
+1.202.637.5600 **Tel**
+1.202.637.5910 **Fax**

www.hhlaw.com

February 26, 2010

Meredith Manning
Partner
202-637-6585
MManning@hhlaw.com

Division of Docket Management
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket FDA-2009-N-0441
Promotion of FDA-Regulated Medical Products Using the Internet and Social Media: Comments

Dear Sir/Madam:

Hogan & Hartson LLP is an international law firm representing members of industry from the food, device, and pharmaceutical sectors. For many years, we have advised a large cross section of the FDA-regulated industry on issues surrounding the labeling, advertising, and promotion of products. We comment today not on behalf of any particular client or group of clients, but as lawyers familiar with the issues of advertising and promotion of FDA-regulated products and the complex legal issues posed by social media tools. We hope that these comments will allow FDA to critically evaluate the current regulatory structure governing product promotion and to fashion an alternative legal approach to social media that recognizes both industry's responsibilities under the Food, Drug, and Cosmetic Act (FDCA) as well as the public benefits that social media offers.

This comment addresses FDA's question "for what online communications are manufacturers, packers, or distributors accountable." As part of that topic, the agency identified a series of questions about which it seeks comments:

- What parameters or criteria should FDA apply to determine when user generated content (UGC) has been subject to "substantive influence" by a product sponsor;
- When should UGC be considered to be "performed by, or on behalf of" product sponsors;
- How should companies disclose their involvement or influence over discussions or materials;
- Are there considerations that should be weighed based on the specific social media platform used or the intended audience; and

- What are companies' experiences with respect to the potential to have their content altered by third parties?

This comment seeks primarily to inform the fourth sub-question regarding other "considerations" that the agency should consider in evaluating manufacturers' accountability for UGC. Specifically, in fashioning an enforcement policy for industry's sponsorship of social media tools, FDA should acknowledge that federal law provides limited immunity under the Communications Decency Act (CDA) to those entities operating "interactive computer services." 47 USC 230. Rather than merely assessing concepts of agency under the existing regulatory framework of the FDCA and its regulations, FDA should recognize the purpose behind the immunity that Congress granted to entities operating interactive computer services and fashion a regulatory approach that draws from both the FDCA and the CDA.

Such an approach would allow product manufacturers to develop and host interactive websites regarding their products. All manufacturers have an obligation to assure that their own statements regarding their own products conform to the FDCA's prohibition on false and misleading statements. 21 USC 331(a) and 352. But, the CDA should serve to immunize manufacturers acting as website hosts from liability for the statements of third parties. This regulatory structure would allow manufacturers to participate in the increasingly important world of social media in a responsible, truthful, and non-misleading way while encouraging third party participation in the flow of important information surrounding drugs, devices, and foods.

The Communications Decency Act

The CDA provides that "no provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider." 47 U.S.C. § 230(c)(1). Moreover, a provider or user of an "interactive computer service" shall not be held civilly liable for good faith actions to restrict availability of information that the provider or user considers to be "obscene, lewd, lascivious, excessively violent, harassing, or otherwise objectionable…." 47 U.S.C. § 230(c)(2). The statute provides immunity only for civil liability, not criminal liability.[1]

In order for an entity to receive this protection under section 230 of the CDA, the following three conditions must be met:

1. The entity or individual must be a provider or user of an "interactive computer service," defined to include "any information service, system, or access software provider that provides or enables computer access by multiple users to a computer server." 47 U.S.C. § 230(f)(2). This definition has been interpreted broadly by the courts to include many types of cyberspace services beyond internet service providers (such as website hosts or sponsors of internet bulletin boards).

[1] There are exceptions for liability from certain intellectual property and state laws consistent with the statute. 47 U.S.C. § 230(e).

2. The allegedly unlawful content must constitute information provided by another "information content provider" – a person or entity that is responsible, in whole or in part, for the creation or development of information provided through the Internet. 47 U.S.C. §§ 230(c)(1), (f)(3).

3. The attempt to impose liability must treat the provider or user of an interactive computer service as a "publisher" or "speaker." 47 U.S.C. § 230(c)(1).

Case Precedent

The CDA was passed by Congress in 1996 to reverse a state court ruling holding an internet service provider to state law standards applicable to publishers in the context of a common law defamation case. The court in *Stratton Oakmont, Inc. v. Prodigy Serv. Co.*,[2] held that Prodigy was liable under state defamation laws for "publishing" defamatory statements made by third parties on the company's website.

Since its enactment, the CDA's immunity provision has been broadly interpreted to provide immunity to providers and users of "interactive computer services" for certain activities that might run afoul of civil Federal or state laws. For example, Craigslist was found to be immune from claims that it was violating the Fair Housing Act by posting discriminatory notices by third parties regarding available housing opportunities. *Chicago Lawyers' Committee v. Craigslist, Inc.*, 519 F.3d 666 (7th Cir. 2008). *See also Carafano v. Metrosplash*, 339 F.3d 1119 (9th Cir. 2003) (operator of dating website is not liable for invasion of privacy, misappropriation of right of publicity, defamation, or negligence, for the posting of a false profile authored by a third party); *Batzel v. Smith*, 333 F.3d 1018 (9th Cir. 2003) (*cert. denied*, 541 U.S. 1085 (2004)) (list serve operator is not liable for distributing allegedly defamatory email authored by a third party even though it edited the message for spelling, grammar, and length); *Ben Ezra et al. v. America Online Inc.*, 206 F.3d 980 (10th Cir. 2000) (online service provider is immune from state law negligence and defamation claims for allegedly false stock information posted by a third party stock quote provider on its website); *Zeran v. AOL*, 129 F.3d 327 (4th Cir. 1997) (host of online bulletin board is immune from state law negligence claim for failure to remove defamatory messages posted by a third party); *Murawski v. Pataki et al.*, 514 F.Supp.2d 577 (S.D.N.Y. 2007) (search engine focused on politics is not liable for defamatory statement about candidate on a third party site or for failing to block such information from its system); *Noah v. AOL Time Warner, Inc.,* 261 F.Supp.2d 532 (E.D.Va. 2003) (internet service provider is immune from class action alleging that its failure to protect plaintiffs from harassing postings by third parties resulted violations of Title II of the Civil Rights Act of 1964 and state common law).

Under the logic of these cases, "interactive computer service" providers and users under the Act cover a broad range of cyberspace services, including internet service providers and operators of websites (including retail sites), list serves, comment boards, and search engines. In

---

2 1995 WL 323710 (N.Y. Sup.Ct. May 24, 1995).

addition, the legal precedent supports the position that these entities may take reasonable steps to delete offensive website postings and perform some limited monitoring functions (e.g., correct spelling or grammar and limit length) without implicitly adopting those statements or being held liable for all such postings as "information content providers."

Last year, the Ninth Circuit decided a case under the Fair Housing Act that could alter somewhat the interpretation of the CDA's immunity based on the evolving uses and growing interactive nature of the internet. *Fair Housing Council, et al. v. Roommates.com*, 521 F.3d 1157 (9th Cir 2008). In *Roommates.com*, a coalition of housing advocates objected to the use of drop-down menus by a roommate search website operator that allegedly drove users to search results that were inherently discriminatory. An *en banc* decision by the Ninth Circuit held that CDA immunity did not apply because the website operator's involvement in the activity at issue also qualified it as the "information content provider." *See id*. at 1171-72. The court distinguished between the provision of neutral tools used for unlawful purposes by third parties and the creation of a system designed to promote discriminatory practices. *See id*. at 1169. Because the case was on appeal from dismissal at the district court, it was remanded so that the district court could determine whether any activity by Roomates.com was in fact a violation of the Fair Housing Act.

And, in an unfair business practices case brought by the FTC against a website operator selling telephone records, the Tenth Circuit last year discussed at length the principle of immunity under the CDA for website operators who are engaged in unlawful conduct. *FTC v. Accusearch*, 570 F.3d 1187 (10th Cir. 2009). Accusearch purchased from telephone companies use data regarding telephone numbers and resold the data via a website. It claimed immunity from civil liability on the basis that it merely provided internet search capabilities for a fee. The court disagreed, holding that Accusearch did more than simply "publish" information available from other sources – it procured the information, advertised its availability, and then re-sold it for a fee, all while understanding that such information was protected by law. In reaching this decision to deny liability under the CDA, the court made clear that website operators engaged in *lawful* publishing or speaking activities may claim protection from liability for the actions of third parties under the CDA. *Id.* at 1198. Accusearch did not operate as a neutral platform on which third parties could post information – instead it participated in an illegal activity. The Tenth Circuit clearly distinguished Accusearch's activities from that of lawful actors:

> one is not 'responsible' for the development of offensive content if one's conduct was neutral with respect to the offensiveness of the content (*as would be the case with the typical Internet bulletin board*.) We would not ordinarily say that one who builds a highway is 'responsible' for the use of that highway by a fleeing bank robber, even though the culprit's escape was facilitated by the availability of the highway.

Id. at 1199 (emphasis added).

Thus, the DCA case law stands for a straightforward proposition: To the extent that a website host develops and posts lawful information in the first instance and does not steer or direct website users to engage in improper conduct, the CDA shields the website host from

liability for third-party speech. Thus, to the extent that a drug manufacturer develops truthful and non-misleading content about its products, whether in a promotional or non-promotional context, without steering the on-line conversation to improper topics through drop-down menus or otherwise, it cannot be held liable for the content later provided by a third party user.[3]

Applicability to Manufacturer's Websites

There is absolutely nothing contained within the CDA or caselaw interpreting its scope to suggest that it somehow does not apply to immunize website hosts from civil liability under the FDCA.[4] As such, it provides useful guidance as the agency considers the questions identified in the Federal Register notice regarding manufacturer's accountability for UGC. Instead of attempting to apply the broad scope of FDA's intended use regulation to attribute to manufacturers the statements posted to their websites by third-parties, the agency should recognize that the CDA provides limited immunity to manufacturers for UGC. *See* 21 CFR 201.128

Under such immunity, a manufacturer that hosts an interactive site for or about its products and makes only proactive statements about the product that comply with the FDCA and its implementing regulations could not be held responsible for the comments of third party "information content providers." Manufacturers are able, under the CDA, to host websites, perform reasonable editing steps to delete offensive statements made in UGC (e.g. profanity), correct spelling or grammar, or limit the length of third-party posts. They may establish clear terms of use making clear the manufacturer's role in providing a forum for discussion that is premised on truthful and non-misleading information in the first instance and seek users' agreement to post information in good faith that is similarly truthful and non-misleading. Manufacturers would not be able to perform what would otherwise be regarded as "publishing" functions, such as selectively choosing which posts to permit based on content or to respond to postings, for example, by correcting information posted by third-parties.

By adopting this approach, FDA could continue to enforce the FDCA's regulatory scheme against regulated industry and monitor industry's conduct. It would continue to enforce the FDCA as it applies to manufacturer statements under the misbranding provisions. FDA

---

[3] This concept is especially relevant where the content provided by a third party is lawful when provided by that user but would arguably be improper when supplied by a manufacturer. Were a manufacturer of a drug to open a promotional website to comments and ask patients to describe their experiences with the drug, a user could appropriately describe an experience with an off-label use. The manufacturer merely hosts the site, and the patient describes a lawful activity – the lawful prescribing by a healthcare provider of an approved product for an off-label use. No liability should apply to either the site host or the user.

[4] On its face, the CDA does nothing to immunize anyone from criminal liability. As such, the CDA is not a barrier to the enforcement of criminal restrictions on the sale of adulterated, misbranded, unapproved or counterfeit devices, drugs, or food over the internet. The CDA also does not immunize product manufacturers or sponsors from liability to the extent that they publish material or content about their own products on websites operated by or hosted by third-parties. The latter conduct appears to fall squarely into the CDA's definition of a "information content provider" as opposed to that of an "interactive computer service."

could also encourage manufacturers to open their significant website assets to public comment, thereby providing a consolidated platform for third party speech about regulated products. To the extent that comments included information about adverse events, nothing under the CDA would prohibit the manufacturer from gathering that information on a regular basis and submitting it to FDA's MedWatch system. Because website hosts are not responsible for UGC under the CDA, however, nothing would appear to require industry website hosts to submit UGC to FDA at the time of its posting. *See* 21 USC 314.81(b)(3).

This approach offers simplicity to regulated industry, website users, and FDA. It balances the agency's need for truthful and non-misleading speech by manufacturers with the public's demand for a platform on which members of the public can openly discuss the attributes of healthcare products. It allows FDA to continue to monitor criminal activity on the internet by both website hosts and information content providers. And, it allows everyone to comply with adverse event reporting obligations.

Importantly, it implements Congress's intent to encourage the use of the internet as a large "bulletin board" for public ideas. FDA should not stand in the way of the expansion of the internet by imposing on manufacturers the "intent" of third-parties simply because they open up an on-line forum for speech.

Conclusion

We appreciate the agency's willingness to consider these complex issues and hope that this suggested approach provides useful guidance.

Sincerely,

Meredith Manning
Partner