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Title: “Pharmaceutical Promotion in Interactive Media – How the Statute and Regulations Applied in Digital Era”

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Introduction

An Historical Review of Direct-to-Consumer Advertising

The United States is one of the only two countries that prescription drug product can be legally marketed to consumers/patients via Direct-to-Consumer Advertising (DTCA); Pharmaceutical companies are particularly compelled to market in United States, spending upwards of \$4.2 billion annually in DTCA.¹ Traditionally, pharmaceutical companies' promotional efforts are exclusively directly toward physicians and healthcare providers.² In 1990s, the pharmaceutical companies took their promotional efforts one step further and began to market their prescription drugs directly to consumers; while at that time, the Food and Drug Administration (FDA) guidelines were primarily and almost exclusively tailored towards the printed media became impractical to the advertising of prescription drugs in television and broadcasting commercials due to extensive disclosure requirements.² In late 1990s, in response to pharmaceutical companies needs in the pharmaceutical markets and changing advertising media, the FDA updated its regulatory guidelines for broadcast direct-to-consumer, and clearly provided the guidance the ways that the prescription drug information could be presented and advertised to consumers directly in broadcasting media.² This regulatory updates also led to an exponential

¹ Sufrin CB, Ross JS. Pharmaceutical Industry Marketing: Understanding its impact on women's health. *Obstet Gynecol Surv.* 2008; 63(9): 585-596.

² Campbell S. Promotional Spending for Prescription Drugs. https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/12-02-drugpromo_brief.pdf. (Last visited Dec 10, 2016).

increase in television commercials for prescription drug products.² Thus, this late 90s regulation update opened a new marketing era, bringing broader opportunities for consumers to make informed decisions about their health-related concerns, in addition to flooding the pharmaceutical market with DTCA.³ Currently, the DTCA guidelines of broadcasting and print media encourage the consumers to visit the drug websites for further information about the product.⁴

Today, pharmaceutical companies take fully advantage of the online platforms and use more diverse approaches to reach consumers and patients than was possible even a decade ago; they are actively experimenting with new online media platforms such as Facebook, Twitter, or YouTube as means to reach consumers or patients directly.^{5,6} Use of social media is increasingly a part of pharmaceutical companies' marketing strategies.⁵ In particular, pharmaceutical drug product online direct-to-consumer advertising has become an increasing popular means for marketing in the United States among pharmaceutical manufacturers, with an estimated expenditure at \$1.86 billion for online advertising alone.⁷

However, as online DTCA becomes an integral part of means in pharmaceutical drug product promotion, lack of clear guidance from FDA regarding the promotion in social media has created uncertainty and challenges among the pharmaceutical manufacturers.⁵

This note will examine the question of whether the Food, Drug and Cosmetic Act (FD&C Act) enacted almost eighty years ago and the regulations promulgated by FDA afterwards should still be applicable to digital era when social media has been utilized extensive in prescription drug

³ Palumbo FB, Mullins CD. The Development of direct-to-consumer advertising of prescription drug advertising regulation. *Food Drug Law J.* 2002;57(3):423-443.

⁴ Lorence D, Churchill R. A study of the web as DTC drug marketing agent. *J. Med Syst.* 2007;31(6):551-556.

⁵ Liang BA, Mackey TK. Prevalence and global health implications of social media in direct-to-consumer drug advertising. *J. Me Internet Res.* 2011;13(3):e64.

⁶ Thomaselli R. Web thrives as DTC platform. <http://adage.com/article/digital/web-thrives-dtc-platform/96790/>

⁷ Iskowitz M. Pharm poised to up online ad spend: eMarketer. *Med Mark Media.* April 27, 2011.

product promotion. Part I of this note discusses the legal and regulatory landscape of pharmaceutical drug product promotion especially for direct-to-consumer advertising under the regulations promulgated with the authorization by the Food, Drug, and Cosmetic Act (FD&C Act). Common law litigation related to DCTA is also discussed in Part I. Part II examines the current digital landscape of pharmaceutical promotion, the FDA's enforcement means in online promotion, and discusses the most recent cases that violated FDA's social media promotion regulation.

Part I

Legal Landscape of Prescription Drug Labeling and Advertising

Before 1962, the Federal Trade Commission (FTC), not FDA, is the enforcement agency in regulating pharmaceutical drug promotion in general.⁸ In 1962, the Kefauver-Harris Amendments to the FD&C Act imposed pharmaceutical manufacturers the obligation to test new drug for safety and efficacy before they could market the new drug, and authorized the FDA, among other things, to regulate and enforce the regulations regarding the drug advertising.⁹ Today, Federal enforcement and regulations of DTCA laws concerning pharmaceutical drug products is divided in two agencies: the Federal Trade Commission (FTC) for over-the-counter drugs¹⁰ and the Food and Drug Agency for prescription pharmaceuticals.¹¹ The FTC's authority over OTC drugs is a subset of its general authority to monitor dissemination of false advertising generally. In this note the DTCA of OTC will not be discussed, since the paper's main focus is on the DTCA of the prescription drugs, thus, the FDA's regulations will be discussed in great details below.

⁸ Jaelyn CH. The learned Intermediary Doctrine and Beyond, exploring Direct-to-Consumer Drug advertising Liability in the new Millennium. *72 Def. Couns. J.* 362, 363.

⁹ *Id.*

¹⁰ *15 U.S.C. §52-54* (require advertisements to be truthful, non-deceptive, unfair, and with evidence to backup claims).

¹¹ *21 U.S.C. §§301-392.*

The FDA has very broad scope in regulating pharmaceutical promotion materials utilized by pharmaceutical manufacturers, which extends to detail aids, convention displays, and other materials used by sales representatives; advertisements in medical journals, on the internet, and elsewhere that target physicians and other healthcare providers; and advertisements on television, in print, and on the internet that target consumers/patients directly (DTCA). The FDA’s authorization in regulating pharmaceutical promotion also extends to oral statements made by company’s personnel or any one on the behalf of the company in doctor’s office, at medical conventions, and elsewhere, as well as promotional speeches by outside physicians on the behalf of the company. When a company’s promotion activities violates the law, the FDA is authorized to use broad remedy tools for its enforcement, including but not limited what the FDA terms “untitled letters”, warning letters, injunctions, seizure, civil and criminal fines, imprisonment, and ultimately withdraw product approval.¹²

Under FD&C Act, Pharmaceutical promotion essentially consists of all branded communications disseminated by or on the behalf of a drug company, which includes both labeling and advertising. Labeling encompasses all labels and *any* written, printed or graphic materials that are (1) attached to, or part of *any* article or *any* of its containers or wrappers, or (2) accompanying such article.¹³ The Supreme Court has held that what is means to accompany a drug or device to include anything that “*supplement or explain*” the nature of the product.¹⁴ Thus, the scope of labeling is very broad, including anything that the FDA-approved label, package insert, and any printed materials used to promote the drug product; such materials when disseminated by or on the behalf of a drug company, packer or distributor “labeling” includes but not necessarily limited

¹² 21 U.S.C. §§ 332, 333, 334, 335a, 335b & 336.

¹³ 21 U.S.C. § 321 (m); 21 C.F.R. § 201.1-201.25.

¹⁴ *Kordel v. United States*, 335 U.S. 345, 350 (1948)

to brochures, mailing pieces, detailing pieces, catalogs, letters, videos, sound recordings, medical literatures, journal reprints, “similar” pieces of printed, audio, or visual matter descriptive of a drug , and reference published for use by medical practitioners.¹⁵

The FD&C Act set forth twenty-three requirements for labeling; if the labeling materials disseminated by a drug company do not meet these requirements, the drug is deemed “misbranded.”¹⁶ Among these requirements, despite all of them are essential with respect to compliance, two of them are noteworthy. A drug is misbranded when (1) its labeling is “false or misleading in any particular”,¹⁷ or (2) the label does not include “adequate directions for use.”¹⁸ A drug will be considered misbranded, if along other requirements, either of the two requirements is not met. Therefore, the company may expose itself to legal liability.

The FD&C Act does not define the term “advertising”, nor do the regulations. Instead, the statute uses the word “advertising” itself to describe its meaning. The regulation states that “Advertisements that are subject to¹⁹...include advertisements in published journals, magazines, other periodicals and newspapers, and advertisements broadcast through media such as radio, television and telephone communication system.”²⁰ And logically, as per the most recent FDA draft guidance, drug advertisements posted on internet and social media are included.²¹

Despite that both labeling and advertising are promotional in nature, it is important to properly distinguish between labeling and advertising, because each one has its own set of legal

¹⁵ 21 C.F.R. § 202.1(l)(2).

¹⁶ 21 U.S.C. § 352.

¹⁷ 21 U.S.C. § 352(a). Note that labeling or advertising can be false or misleading because of what it states or because of what it fails to state. 21 U.S.C. § 352(n).

¹⁸ 21 U.S.C. § 352(f).

¹⁹ The misbranding provision of the FD&C Act. 21 U.S.C. § 352(n).

²⁰ 21 C.F.R. § 202.1(l)(1).

²¹ Draft Guidance for Industry: Fulfilling Regulatory requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf> (last visited Dec. 10, 2016).

and regulatory requirements. Although either statute or regulation does not define the term of advertising, it would be helpful in practice if such distinguish being established. The FDA has suggested that the major difference between these two is the method of dissemination of the drug product information; a labeling is distributed to consumers or prescribers directly “accompanying” to the prescribed drug without other forms of media involved, while advertising “usually broadcast on TV or Radio, or published in newspapers or magazines,”²² and recently internet social media is also included.²⁵

The statute requires that all drug advertising must contain a “*true statement*” regarding the product advertised, which includes (1) the product’s established (generic) name; (2) the drug formula; and (3) “such other information in a brief summary relating to side effects, contradictions and effectiveness as shall be required in regulations which shall be issued....”²³ The FDA regulations require disclosure of “each side effect and contradiction (including warnings, precautions, special considerations, etc.) contained in required, approved, or permitted labeling or advertising for the drug.”²⁴ These requirements have been revisited in the context of social media draft guidance released by FDA.²⁵

The statute requires that the FDA approves every “intended use”/“claim” for a drug by “*substantial evidence*” or “*substantial clinical experience*” provided by the drug company via two “adequate and well-controlled clinical investigations.”²⁶ Hence the drug labeling or advertising

²² *Drug Advertising: A Glossary of Terms*, U.S. Food and Drug Administration, <http://www.fda.gov/drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm#P> (last visited Nov. 28, 2016).

²³ 21 U.S.C. § 352(n).

²⁴ 21 C.F.R. § 202.1(c)(3).

²⁵ Draft Guidance for Industry: Fulfilling Regulatory requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf> (last visited Oct 28, 2016).

²⁶ 21 U.S.C. § 355(d)(5); 21 C.F.R. § 202.1(e)(4)(ii)(b).

must comply with the intended use/claim of the drug as approved by the FDA; an advertisement *is* deemed “false, lacking in fair balancing, or otherwise misleading” if, among other reasons, it contains “a representation or suggestion, not approved, that a drug is better, more effective, useful in a broader range of conditions or patients [or] safer ... than has been demonstrated by *substantial evidence* or *substantial clinical experience* ... whether or not such comparison are made by comparison with other drugs” and/or “a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated ... by *substantial evidence* or *substantial clinical experience*.”²⁷ And an advertisement *may* also be considered “false, lacking in fair balancing, or otherwise misleading” if it fails to provide sufficient emphasis on side effects and contradiction information with a prominence and readability reasonably comparable with the effectiveness information; it uses statistical analyses on a retrospective basis to discover and cite findings not soundly supported by the *substantial evidence* or *substantial clinical experience*; and/or it uses the tables and graphics to misrepresent the relationships, trends, differences, or changes among the variables or products studied.²⁸

Therefore, within the context of drug advertising, as defined in the federal regulations, the term “true statement” must have three substantive elements.

First, a drug advertisement must conform to approved labeling, i.e. a drug advertisement must accurately communicate the product’s indications and include the context for any claims/labeling approved by FDA; a drug advertisement must not be “false or misleading with respect to side effects, contradictions, or effectiveness.”²⁹ Furthermore, all claims/labeling must be supported by “substantive evidences or substantive clinical experience.”³⁰

²⁷ 21 C.F.R. § 202.1(e)(6).

²⁸ 21 C.F.R. § 202.1(e)(7).

²⁹ 21 C.F.R. § 202.1(e)(5)(i).

³⁰ 21 U.S.C. § 355(d)(5); 21 C.F.R. § 202.1(e)(6)(i).

Second, a drug advertisement must be adhesive to the fair balancing principle. The drug advertisement must “present a fair balance between information relating to side effects and contradictions and the information relating to effectiveness; and the format of the presentation is also important regarding proper inclusion of fair balance.”³¹ In other words, the content and the presentation of a drug’s most serious side effect and contradiction must be reasonably proportional to the content and the presentation of the drug’s benefits.³² Without a doubt, the fair balance standard is very subjective, and there is no simple formula can be used to determine whether the fair balance requirement has been satisfied with respect to the acceptable space and/or time spent on either side of the balance. However, practically, the regulations provide that there will be not a violation of the balancing principle if the weights on both side of the balance is “comparable”, i.e. the information relating to the side effects and contradictions are comparable to the information relating to the safety and effectiveness claims.³³ Hence, while there is not a necessarily even split between the explanation of the risks versus the benefits in an advertisement, the amount of time and space devoted to the risk information proportionally depends on the risks and the manners in which the risks and benefits presented.³⁴

Third, a drug advertisement shall disclose all material facts.³⁵ Significant and important information may not be omitted. The material fact disclosure requirement will not be satisfied if the drug advertisement fails to disclose material facts with respect to consequences that may result from the use of the drug as recommended or suggested by the advertisement.

³¹ 21 C.F.R. § 202.1(e)(5)(ii).

³² 21 C.F.R. § 202.1(e)(3)(i).

³³ 21 C.F.R. § 202.1(e)(5)(ii).

³⁴ *Drug Advertising: A Glossary of Terms*. U.S. Food and Drug Administration, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm07202.htm#P> (Last visited Oct 28, 2016).

³⁵ 21 C.F.R. § 202.1(e)(5)(iii).

All branded advertisement, with the exception of reminder ads,³⁶ must include a “brief summary”³⁷ relating to side effects, contradictions, warnings, precautions, and effectiveness of the drug. The information presented in the summary “shall present information from labeling required, approved, permitted, or granted” in a new drug application (NDA), abbreviated new drug application (ANDA), or biological license application (BLA).³⁸ Because the information must be from the FDA-approved labeling, to ensure the accuracy and precision of the information, it is not uncommon for many companies to comply with the requirement by simply reprinting the packaging insert next to main body of the advertisement.³⁹ However, it should be aware of that the inclusion of the brief summary cannot be facilitated to correct any untrue and misleading information in any part of the advertisement.

In general, pre-approval of promotional material by the FDA for already approved prescription drug is not typically required regardless of whether the material is intended for medical professionals or is directed to consumers. But, although neither statute nor regulation requires the promotion materials, including advertising and labeling, being approved by the FDA prior to dissemination or publication, must submitted to the FDA at the time of initial dissemination.⁴⁰ Each submission must be accompanied in the Form FDA-2253.

³⁶ Reminder ads give the name of the drug but not the drug’s use. *21 C.F.R. § 202.1(e)(2)(i)*. A reminder ad does not have to contain risk information because the ad does not address the drug’s effectiveness and safety.

³⁷ *21 C.F.R. § 202.1(e)(1)*. While broadcast advertisements are exempted from the brief summary requirement, they are required to include a disclosure of the “major side effect and contradictions of the advertised drugs in the audio or audio and visual part of the presentation.” *21 C.F.R. § 202.1(e)(1)*. Moreover, if they do not include a brief summary, they must make “adequate provision...for dissemination of the approved or permitted package labeling in connection with the broadcast presentation.” *Id.*

³⁸ *21 C.F.R. § 202.1(e)(4)*.

³⁹ American Health Lawyers Association, *Fundamentals of Life Sciences Law: Drugs, Devices and Biotech* (2007).

⁴⁰ *21 C.F.R. § 314.81(b)(3)(i)*. Advertisements for drug s that are approved on accelerated basis must be submitted in advance of initial publication or dissemination. *21 C.F.R. § 314.550*.

Alternatively, before launch a marketing campaign for a new drug or airing a new television advertisement, a firm may also submit its draft promotional materials to the FDA's Office of Prescription Drug Promotion for advisory review in seeking for comments from the authority with respect to the contents of the draft promotional materials.^{41,42} In addition, from industry perspective, the Pharmaceutical Research and Manufacturers of America (PhRMA) recommends that manufacturers "submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast."⁴³ Note that the FDA has no obligation to respond to the submitted draft promotional materials. Recently this practice has been incorporated into the context of social media.²⁵

The FDA, OIG (Office of Investigation General, under HHS), and DOJ (Department of Justice) have authority to impose civil and/or criminal sanctions against a pharmaceutical manufacturer that violates prescription drug promotional statute and regulations.⁴⁴ Whenever possible, however, the FDA's policy is to afford the responsible individuals and organizations an opportunity to correct violations before the agency initiates a formal legal enforcement action. Thus, most enforcement action against the violator brought by the FDA in the form of regulatory letters.⁴⁵ A Notice-of-Violation letter notifies a manufacturer for a relatively minor and first time violation in an advertisement of prescription drug, while a more serious or repeated violation would result a Warning Letter from the FDA with warnings that further actions from the FDA will

⁴¹ *Requests for Advisory Comment on Promotional Materials Other than Proposed DTC TV Ads*, U.S. Food and Drug Administration, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm075128.htm> (last visited Nov. 28, 2016).

⁴² *OPDP Submission of Proposed DTC TV ads for Advisory Review*, U.S. Food and Drug Administration, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm075128.htm> (last visited Nov. 28, 2016).

⁴³ PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines 6 (2005).

⁴⁴ 21 U.S.C. § 333.

⁴⁵ FDA Enforcement Statistics Summary.

<http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM285781.pdf> (latest visited Nov 28, 2016)

take, either civil or criminal, if the warned manufacturer does not correct or cease the concerned advertisement.⁴⁶ In general, vast majority of manufacturers that violated the regulations, promptly respond to the letters issued by the FDA to avoid further liabilities of the alleged violation that may escalate to criminal and/or civil penalties.⁴⁷

A manufacturer who violated the regulations, besides facing government actions towards alleged violation, also exposes itself to *ex post* private actions, among others, mainly involving failure to warn claims under state tort laws that have not been deemed as preempted by federal law.⁴⁸ The doctrine of failure to warn has been used successfully in state courts, and confirmed by the U.S. Supreme Court, resulting in large tort rewards. In *Wyeth v. Levine*, 555 U.S. 55 (2009), the Supreme Court rejected defendant Wyeth Pharmaceutical's claim that since the product is approved by the FDA for marketing, thus federal law had preempted state tort law claim for injury allegedly caused by the drug product. The Court held that the pharmaceutical company's inadequate product labeling failed to warn the plaintiff of the risk associated with administration of the drug product.

Moreover, within the context of Direct-to-Consumer Advertisement (DTCA), by communicating directly with consumer, a drug manufacturer does not participate in the patient-physician decision making process, the drug manufacturers had planted the seeds for erosion of the protective shield of the Learned Intermediary Doctrine,⁴⁹ which holds that if the manufacturer adequately informs the physician to whom it sells its drugs, it cannot held liable for subsequent harm to a patient to whom the physician prescribed the drug. With the rising prevalence of DTCA

⁴⁶ Ashley Porter, *Old Habits Die Hard: The Learned Intermediary Doctrine in the Era of Direct-to-Consumer Advertising*, 43 *McGeorge L. Rev.* 433, 446 (2012).

⁴⁷ Misbranded drug promotion could be criminally charged under FD&C Act; and civilly liable for false claim under False Claim Act.

⁴⁸ *Wyeth v. Levine*, 555 U.S. 555 (2009).

⁴⁹ Heather Harrell, *Direct-to-Consumer Advertising of Prescription Pharmaceuticals, the Learned Intermediary Doctrine, and Fiduciary Duties*, 8 *Ind. Health L. Rev.* 69, 75-78 (2011)

begun to carve out exceptions to the doctrine.^{50,51,52} Indeed, most commentators have attributed the recent judicial carve out to DCTA⁵³ or have blamed the rise of DCTA for the degradation of the physician-patient relationship.

Part II

The Digital Landscape and the Case Studies

The pharmaceutical companies are moving forward rapidly into the digital marketing world, because such online media platform allows a company to reach a larger number of patients/consumers than traditional forms of promotion media, and are more cost effective than television or printed media.^{54,55} In order to reach the patients/consumers directly online, pharmaceutical companies have posted their advertisements on online banners, streaming videos, sponsored ads on search engines, and product websites.² Among those online promotion types, product websites currently serve as the primary sources for patients/consumers to obtain a variety of information about a specific prescription drug information, such as the risk information, efficacy information, and indication information of the drug.⁵⁶ However, unsurprisingly, some studies had revealed that nearly half of the online websites controlled by pharmaceutical companies failed to include the risk information about the drug being advertised.⁵⁷ Even if in the cases that the risk

⁵⁰ *Perez v. Wyeth*, 161 NJ. 1 (1999) (DTCA has so eroded the physician –patient relationship that the NJ court cannot rely on physician to prove adequate warning).

⁵¹ *Davis v. Wyeth*, 399 F.2d 121 (9th Cir. 1968) (in mass immunization programs, where healthcare providers administering the drug are not usually physicians).

⁵² *Odgers v. Ortho Pharmaceuticals*, 609 F. Supp. 67, 875 (E.D. Mich. 1985) (for oral contraceptives because the physician often plays a “passive role” in this decision).

⁵³ Timothy S. Hall, *Regulating Direct-to-Consumer Advertising with Tort Law: Is the Law Finally Catch Up with Market?*, 31 *W. New Eng. L. Rev.* 333 (2009).

⁵⁴ Liang BA, Mackey TK. Prevalence and global health implications of social media in direct-to-consumer drug advertising. *J Med Internet Res.* 2011;13(3):e64.

⁵⁵ Gibson S. Regulating direct-to-consumer advertising of prescription drugs in the digital age. *Laws.* 2014;3(3):410-438.

⁵⁶ Sheehan K. Direct-to-consumer (DTC) branded drug web sites risk presentation and implications for public policy. *J Advert.* 2007;36(3):123-135.

⁵⁷ *Id.*

information was included in the advertising, the risk information was not designed or presented in a way that should be comparable to the benefits of the drug advertised; for example, the risk information was not explicitly visible, when a visitor reached the site, he or she was forced to scroll down to reach the risk information, which could minimize a visitor's chance obtaining the risk information.⁵⁸ In the same vein, another study demonstrated that the benefit information was presented in a way to attract more attention from visitors, whereas other side of the token, the risk information was presented in less eye-catching manner.⁵⁹ Thus, these studies revealed that the fundamentally primary issue, the fair balancing, has remained unchanged, whether a prescription drug advertisement was posed in a printed medium, aired in a television station, or broadcast, and/or on a website.

A recent study "*Trouble spots in online direct-to-consumer prescription drug promotion: a content analysis of FDA warning letters*"⁶⁰ well described the current digital/online landscape of pharmaceutical promotion. This study analyzes FDA's warning letters or notice of violation (NOV) letters regarding the online promotions issued to pharmaceutical companies over a ten-year period, from 2005 to 2014. The study identified six categories of violations: risk information, efficacy information, indication information, product labeling, material information issues, and approval issues.⁶¹

The findings are summarized in the Table below.⁶²

⁵⁸ *Id.*

⁵⁹ Huh J, Cude B. Is the information "fair and balanced" in direct-to-consumer prescription drug websites? *J health Commun.* 2004;9(6):529-540.

⁶⁰ Kim H. Trouble spots in online direct-to-consumer prescription drug promotion: a content analysis of FDA warning letters. *Int. J. Health Policy Manag.* 2015;4(12):813-821.

⁶¹ *Id.*

⁶² *Id.*

Category of Alleged Violation	Website	Online paid Ads (text/Banner)	Online Video/webcast	Social Media	email
Risk Information	27	16	15	2	2
Efficacy information	26	1	11	2	1
Indication information	13	12	6	1	2
Product Labeling	1	15	0	0	1
Approval Issues	6	0	2	0	0
Material Information Issues	8	1	2	2	0
Total	81	45	36	7	6

The study results indicate that near 95% of alleged violations were found in promotional content from branded drug website, online paid ads, and online videos.⁶³ Similar to traditional media presentations, such as broadcast, television, and printed media, the most significant finding, that concerning the fair balancing issue, suggests that the online promotion also fails to sufficiently present the fair balancing principle in the content of the promotion.⁶⁴

This study also revealed that in evaluating the advertisements at issue, the FDA applied its traditional custom of regulating based on a comparison of the claims in the advertisement with the approved medical labeling information,⁶⁵ indicating that the FDA does not intend to fundamentally amend its regulatory approaches, as applied to traditional printed media, broadcast, and television ads (see Part I of the note), in the internet and social media landscape.

Probably the most impactful enforcement actions taken by the FDA with respect to promotions using internet and social media took place in April 2009, during that month, the FDA simultaneously issued fourteen notice of violation letters to pharmaceutical firms for the use of sponsored links on internet search engines.⁶⁶ The FDA stated that in the cases cited, the pharmaceutical firms had made representations and/or suggestions about their products' efficacy

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Fisherow WB. Shape of prescription drug advertising: a survey of promotional techniques and regulatory trends. *Food Drug Cosmetic Law Journal*. 1987;42:213-236.

⁶⁶ Jeremy A. Greene, Aaron S. Kesselheim, Pharmaceutical Marketing and the New Social Media. 363 *New Eng. J. Med.*, 2087-2089 (2010).

without mentioning any requisite risk information, had overestimated the efficacy of the products, and had failed to use the required established names for the products. Moreover, these letters had made a significant impact on the so-called “one-click” rule, which is placing the “risk” information only one click away from the “benefits” part of the advertisement (mostly used in sponsored link and twitter websites with space constraints). And these issued FDA letters caused most pharmaceutical companies virtually stopped using the “one-click” rule. The letters stated that although the sponsored links provided a link to the products website, which presumptively contained all required information both “risk” and “benefits”, this was insufficient to communicate risk.^{67,68} The regulatory risk associated with the “one-click” practice is generally regarded as a significant limitation on the promotional use of the internet and social media, a source of tremendous marketing interest.

The early representative case involved internet and social media promotion, especially for the “one-click” rule, is the FDA’s NOV letter issued to Novartis on July 29, 2010,⁶⁹ regarding the company’s promotion of Tasigna®. According to the FDA approved PI (Packaging Insert), the drug is approved for second-line treatment of chronic or accelerated Philadelphia chromosome positive myelogenous leukemia (CML). The drug is also associated with several serious risks, including QT prolongation and sudden deaths, serum lipase, liver function abnormalities, hepatic impairment, etc.. To mitigate these risks, the drug is subject both to a Boxed Warning and a Risk

⁶⁷ *Id.*

⁶⁸ U.S. Food and Drug Administration, Drugs, Warning Letters 2009, <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm055773.htm> (last visited Dec. 8, 2016).

⁶⁹ U.S. Food and Drug Administration, Drugs, Warning Letters 2010, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf> (last visited Dec. 8, 2016).

Evaluation and Mitigation Strategy (REMS), which requires the education of physicians and patients with regard to drug risks and proper dosing strategies.⁷⁰

The FDA letter took issue with the “Facebook Share widget”⁷¹ feature on the drug product website. The drug product website contained a “Facebook Share widget,” which allowed website visitors to post Tasigna information on their Facebook profile and to share that information with other Facebook users. Especially, the widget displayed Novartis-created Tasigna content such as graphics, website links, and short descriptions of the linked sites, known collectively as “shared content.”⁷² According to the FDA letter, the widget misbranded Tasigna.

First, the Facebook shared widget omitted risk information. The shared content in its professional and consumer-directed web pages did not explicitly disclose risk information of Tasigna and instead directed users to click on links to Tasigna websites that contained the full risk profile for the product. The FDA asserted that the hyperlinking was insufficient. To be truthful and non-misleading, promotional materials must contain risk information in each part to offset claims about the drug; especially the product was subject to a Boxed Warning and REMS.⁷³

Second, the shared content broadened the drug’s indication. The shared content referred to CML and affected patients, which the FDA interpreted such statement would imply that the product was applicable to all patients with the disease. The FDA’s letter emphasized that the

⁷⁰ *Id.*

⁷¹ Facebook Share is a way for users of Facebook to share articles, pages, video, or flash content of a site with other Facebook users. Over two million pieces of content are shared each week through Facebook. With two clicks, visitors to a website can share any page of that website through Facebook by generating a link to the page, along with a thumbnail image and a brief description (i.e. shared content) that will appear on the users' profiles and, depending on privacy settings, in the home page stream of all the users’ friends. Each time a link is shared by one user, potentially hundreds of new people may see and/or click through on the link.

⁷² U.S. Food and Drug Administration, Drugs, Warning Letters 2010, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf> (last visited Dec. 8, 2016).

⁷³ *Id.*

product's indication as in the approved PI at the time was limited to patients with chronic or accelerated CML and was approved for second-line treatment only.⁷⁴

Third, the shared content made an unsubstantial superiority claim. Without the support of “substantial evidence,” i.e. clinical data, the shared content baselessly classified Tasigna as a “next generation” treatment to demonstrate its superiority over other products in the class.⁷⁵

Hence, as stated in the letter “the shared content is misleading because makes representations about the efficacy of Tasigna but fails to communicate any risk information associated with the use of the drug. In addition, the shared content inadequately communicates Tasigna’s FDA-approved indication and implies superiority over other products. Thus, the shared content for Tasigna misbrands the drug in violation of the Federal Food, Drug and Cosmetic Act and FDA implementing regulations.”⁷⁶

The three issues cited in the FDA letter clearly manifested the agency’s intent to apply the traditional and fundamental tenets of drug advertisement and promotion, the truthfulness, non-misleading, and fair balanced, to the internet and social media landscape, despite the unique nature of internet and social media. This case indeed exemplified the findings in aforementioned studies that the FDA will apply its traditional regulatory approach towards internet and social media drug promotions.⁷⁷

In responding to the growing interest in the use of the Internet and social media in promotion of FDA-regulated product, and the pressure of continues calling from the pharmaceutical industry for guidelines, in November 12 to 13, 2009, the FDA held a long overdue two-day public hearing on promotion of FDA-regulated medical products, including both

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Id.

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Id.

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21 U.S.C. §§ 352(a)&(n), 321(n); 21 C.F.R. §§ 202.1(e)(3)(i), (ii) &(e)(6)(i).

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Kim H. *supra* note 60.

prescription drugs and medical devices, using the internet and social media tools. At the hearing, more than seventy-five presentations were given by wide variety of interest groups, ranging from patient and consumer groups, Internet vendors, trade representatives, to advertising and pharmaceutical companies. Public comments were also filed. Both solicited and unsolicited questions from public were posed in the *Federal Register* prior to the meeting. Those questions were centered around topics of accountability for the online communications; fulfilment of regulatory requirements specially relating to fair balance and disclosure of indication and risk information under the real-time communication capacity and the space limitations of certain website applications; corrective actions for alleged misleading information, and adverse event reporting.⁷⁸

More than four years after the public hearing, in January 2014, the FDA eventually issued its first draft social media focused guidance, entitled “*Draft Guidance for Industry: Fulfilling Regulatory requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics.*”⁷⁹ The draft guidance reflects the FDA’s current thinking on the interactive promotional media, including (1) what the agency considers to be the interactive promotional media; (2) outlines the considerations taken into account in determining if product communications using interactive technologies are subject to the FDA postmarketing submission requirements; and (3) makes recommendations for how firms can fulfill the regulatory requirement to submit postmarketing promotional materials to the agency in a

⁷⁸ Food and Drug Administration, Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools: Notice of Public Hearing, *74 Fed. Reg.* 48, 083-088 (Sept. 21, 2009).

⁷⁹ Draft Guidance for Industry: Fulfilling Regulatory requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (Jan 2014). <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf> (last visited Dec 09, 2016).

practical manner to address the potential volume of real-time information that is continuously posted and shared via various interactive media platforms.⁸⁰

Specifically relevant to industry is that the draft guidance states that firms are responsible for submitting postmarketing information if they “own, control, create, influence or operate” the interactive promotional media platform,⁸¹ which would include product website, discussion boards, chat rooms or other public electronic forums that a firm uses to promote its products, and the firm maintains and has full control over. The FDA further emphasizes that a firm, not only responsible for a site that is owned and controlled by the firm, and also the firm would be responsible for product promotional communications if the firm exerts influence over a third party site in “any particular, even if the influence is limited in scope,” such as content collaboration, “preview or review privilege over the content.”⁸²

Furthermore, the guidance also explains that firms are responsible for content generated by an employee or agent who is acting on the behalf of the firm to promote the firm’s product.⁸³

However, the agency acknowledges that a firm is not responsible for user generated contents (UGC) that is truly independent of the firm, i.e., is not produced by, or on behalf of or promoted by the firm in any particular.⁸⁴

Consequently, on June 17, 2014, the FDA issued two more draft guidances for industry on internet and social media drug promotion matters. These two draft guidances separately address

⁸⁰ *Id.*

⁸¹ *Id.* at 3-4.

⁸² *Id.*

⁸³ *Id.* This position is consistent with a 2011 FDA Untitled Letter that cited a YouTube video, posted by a Warner Chilcotte sales representative, for being misleading, failing to disclose the drugs indication, failing to present risk information and omitting material facts (FDA, Untitled Letter to Mr. Brian Deutsch, Associate, Regulatory Affairs, Warner Chilcott (US) LLC, May 2, 2011)

⁸⁴ *Id.*

the specific issues of independent third party communications, and character space limitation in internet and social media platform.

The first draft guidance is entitled “*Draft Guidance to Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices*”⁸⁵. As stated in the draft guidance, the agency allows firms to correct misinformation about drug product made by an independent third party, “when a firm is not responsible for product-related communication that appears on the firm’s own forum, an independent third-party website, or through social media, and the firm chooses to correct misinformation about its own product contained in that communication.” The corrective information may be posted on the independent medium or supplied to the author to include on the independent medium.⁸⁶ The corrective information should, among other things, be accurate and responsive to the misinformation, non-promotional in nature, consistent with FDA-required labeling, and disclose that the corrective information is provided by or on the behalf of the pharmaceutical company.⁸⁷ And a company is not responsible if a third party who provided the misinformation does not correct any misinformation.⁸⁸ This guidance also provides many examples of different approaches to responding to third party misinformation on social media, and should be consulted before acting by a firm.⁸⁹

On the other side of the token, however, the draft guidance does not apply to any product communication that is “owned, controlled, created, or influenced, or affirmatively adopted or

⁸⁵ Draft Guidance to Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014). <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf> (last visited Dec 09, 2016).

⁸⁶ *Id.*
⁸⁷ *Id.*
⁸⁸ *Id.*
⁸⁹ *Id.*

endorsed, by, or on behalf,” of a pharmaceutical company, “and the company is responsible for communications on the internet and internet-based platforms, such as social media, made by its employees or any agents acting on behalf of the firm.”⁹⁰ This position is clearly consistent with the draft guidance issued in Jan., 2014.⁹¹

The second draft guidance, “*Draft Guidance to Industry: Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices*”⁹², was drafted specifically to clarify the confusion and conundrums around the application of the “fair balance” principle in a social media platform inherently with very limited character space by its design, such as Twitter. In the guidance, the FDA expresses its reservations about such social media platform’s capability to present the “fair balance” of risk and benefit of a given drug product, stated that “if a firm concludes that adequate benefit and risk information, . . . , cannot *all* be communicated within the same character-space-limited communication, then the firm should reconsider using that platform for the intended promotional message.”⁹³ Thus, for a firm intent to utilize the platform for its product promotion, at minimum, each character limited promotional communication should include “the most serious risks associated with the product together with the benefit information.”⁹⁴ This guidance also addresses the hyperlink issue, which the industry has been leery for years. The guidance suggests that supplemental hyperlinks to a product’s home page, Package Insert, or brief summary be included in the character limited communications.⁹⁵ This guidance also provides many examples of what

⁹⁰ *Id.*

⁹¹ *Id. supra* note 79.

⁹² Draft Guidance to Industry: Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (June 2014). <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf> (last visited Dec 09, 2016).

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

constitutes permissible or impermissible communications, a firm should consult when developing its own character-space-limited drug promotional communication. The guidance makes clear that the FDA expects a fair balance and will gauge the adequacy using the tenets of the traditional media regulation; and the FDA is not entirely confident that an adequate fair balance can be achieved in the context of character limited social media platform.

The three draft guidances issued after 2009 hearing, clearly revealed that the FDA will apply the statutory and regulatory tenets that are applied to traditional media promotion to the drug promotional communications in the context of the internet and social media platforms.

The recent warning letter the FDA issued to the pharmaceutical firm, Duchesnay Inc., well represented the FDA's current enforcement practice in the internet and social media platform. On August 7, 2015, the OPDP (U.S. Food and Drug Administration Office of Prescription Drug and Promotion) issued a warning letter⁹⁶ to Duchesnay Inc., addressing the promotional issues contained in certain Facebook, Instagram and Twitter social media posts made by Kim Kardashian.⁹⁷ Kardashian's posts in the social media were about the company's product DICLEGIS, which, based on approved PI, is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management; but the PI also includes Warnings and Precautions regarding activities requiring mental alertness and concomitant medical conditions.⁹⁸

⁹⁶ U.S. Food and Drug Administration, Drugs, Warning Letters 2015, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM457961.pdf> (last visited Dec 10, 2016).

⁹⁷ U.S. Food and Drug Administration, Drugs, Warning Letters 2015, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM457965.pdf> (last visited Dec 10, 2016).

⁹⁸ *Id. Supra* note 96.

According to the warning letter, the posts initially submitted by Duchesnay via Form FDA 2253 were immediately deemed false and misleading because the posts only presented efficacy claims of the product, but failed to communicate any risk associated with its use, thus the posts omitted material facts.⁹⁹ Moreover, the OPDP asserted in the letter that the posts not only misbranded the drug product, but also raised serious concerns from public safety perspective because they manifested that the drug is safer than has been demonstrated.¹⁰⁰ Furthermore, the OPDP expressed concerns that the firm is “continuing to promote DICLEGIS in a violative manner” since the OPDP had previously issued an Untitled Letter to the firm in November 2013, regarding DICLEGIS approval announcement letter.¹⁰¹

The Warning Letter primarily addressed three issues involved in the social media posts by Kardashian.¹⁰² First, the letter took the issue of the fact that Kardashian’s posts “entirely omitted all risk information,” thus implying that DICLEGIS was “safer than has been demonstrated.”¹⁰³ Because in Kardashian’s Instagram post, she claimed that “I am partnering with Duchesnay USA to raise awareness about treating morning sickness”,¹⁰⁴ despite not explicitly, the OPDP concluded that Kardashian was acting as an agent and/or on the behalf of Duchesnay in publishing the social media posts.¹⁰⁵ Thereby, the OPDP held that Duchesnay is responsible the contents posted by Kardashian, because she was an agent acting on the behalf of Duchesnay, who was “a paid

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Id.

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Id.

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Id.

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The social media posts were as follows:

OMG. Have you heard about this? As you guys know my #morningsickness has been pretty bad. I tried changing things about my lifestyle, like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, and I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com; www.DiclegisImportantSafetyInfo.com

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Id. Supra note 96.

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Id. Supra note 97.

¹⁰⁵

Id. Supra note 79. 21 C.F.R. § 255.

speaker...acting on the firm's behalf [who] comments on a third party site about the firm's product", consistent with the definition delineated in the FDA's draft guidance.¹⁰⁶

Second, the letter took the leery issues of hyperlinks embedded in the posts. Despite the social media comments posted by Kardashian contained hyperlinks to the DICLEGIS product website and safety information, the OPDP reasoned that the links did not "mitigate the misleading omission of risk information."¹⁰⁷ This reasoning is in perfect concurrence with the hyperlink's insufficient concerns delineated in the draft character limitation guidance.¹⁰⁸ Ironically, two of the three Kadarshain's social media posts, Facebook, and Instagram, are not character and space limited; she and/or Duchesnay could have included all risk information or even take advantages of the FDA's recommendations given in its draft guidance documentation.¹⁰⁹

Third, the OPDP asserted that the social media posts were misleading since they failed to provide the drug product's full approved indication, especially the failure to include the limitations of such indications.¹¹⁰

Consequently, the OPDP requested that Duchesnay immediately cease these promotional activities with specific timeline and milestones. Since the promotional activities were deemed to be "serious and repeated", the OPDP also required that Duchesnay "include a comprehensive plan of action to disseminate truthful, nonmisleading and complete corrective message about the issues discussed in this letter to audience(s) that received the violative promotional materials."¹¹¹ As a

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Id.

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Id. Supra note 96.

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Draft Guidance to Industry: Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (June 2014). <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf> (last visited Dec 09, 2016).

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Id.

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Id. Supra note 97. The posts failed to mention that the product is lack of indication for hyperemesis gravidarum: A pregnancy condition that can lead to nausea, vomiting, dehydration, and even drowsiness.

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U.S. Food and Drug Administration, Drugs, Warning Letters 2015, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/>

result of the letter, Kardashian made specific corrective statements¹¹² in the social media she posted her violative statement.

This Kardashian warning letter demonstrates the agency's power and ability to swiftly threaten enforcement action and consequently demand broad corrective action when the agency had concerns about any social media communications that the firm is responsible for its content.¹¹³ This unprecedented speed of the enforcement was driven largely by Duchesnay's repeated violations, the potential public health risk for pregnant women due to lack of conveying of risk information, coupled by Kardashian's celebrity status, for instance, after the initial post on about July 19, Kardashian's posts had over 464,000 likes and almost 11,000 comments; and her Twitter had almost 600 retweets and over 2,300 favorites.¹¹⁴ The warning letter once again highlighted continuing concerns and lack of clarity regarding the use of links as means of providing required warnings and safety information.¹¹⁵

Path Forward

[WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM457961.pdf](#) (last visited Dec 10, 2016).

¹¹² Kardashian's Facebook and Twitter correction statement:

"I guess you saw the attention my last #morningsickness post received," Kardashian wrote next to a picture of her holding up a bottle of Diclegis.

"The FDA has told Duchesnay, Inc., that my last post about Diclegis (doxylamine succinate and pyridoxine HCl) was incomplete because it did not include any risk information or important limitations of use for Diclegis," she added.

¹¹³ *Id.* Footnote 2. According to the warning letter, Kardashian's posts were visited by the FDA on July 7, 2015, published at about July 19, and the warning letter was issued on Aug 7, 2015.

¹¹⁴ Daniel Kracov, etc. Even The FDA Is Keeping Up With The Kardashians, *Law360 Expert Analysis*, August 20, 2015

¹¹⁵ *Id.*

Although these three main guidances issued since Jan 2014, provide outlines of what could constitute nonviolative social media promotional communication, uncertainty remains, especially those guidances are labeled “draft,” and are nonbinding by its very nature. Furthermore, besides addressed some narrowly defined issues on space limitation, third party liability, etc., the issuance of the guidances at least at this time, does not resolve the fundamental issues encountered by industry in the internet and social media promotional activities, such issues include, but not limited to, how to comply with regulatory requirements governing labeling and advertising and adverse events reporting; how to ensure the use of social media is useful in providing information to physicians and patients and it is used appropriately; how to counteract fraudulent or inaccurate information; and how to assess utility and impact.¹¹⁶

While as the guidance documents and the recent cases illustrated that the FDA applied its traditional custom of regulating based on a comparison of the claims in the advertisement with the approved medical labeling information,¹¹⁷ indicating that the FDA does not intend to fundamentally amend its regulatory approaches, in the internet and social media landscape; the pharmaceutical industry, on the other hand, has urged the agency to adopt a more innovative think on the regulation of the internet and social media communication in general, engaging more industry involvement in shaping these guidelines.¹¹⁸

Finally, it is worth to mention that as of today, there is no judicial intervention on any pharmaceutical social media promotion cases. We are eager to see in the near future whether a case involving drug product social media promotion could be brought to a court for judicial review;

¹¹⁶ Pharmaceutical Compliance and Enforcement Answer Book, Chapter 4, Page 108.

¹¹⁷ Fisherow WB. Shape of prescription drug advertising: a survey of promotional techniques and regulatory trends. *Food Drug Cosmetic Law Journal*. 1987;42:213-236.

¹¹⁸ <http://www.forbes.com/sites/joannabelbey/2016/05/15/pharma-the-fda-and-social-media/#2596be395a73>
(last visited Dec 10, 2016)

maybe in that fashion the issue could be eventually resolved at legal level, rather than the current almost mere technical arguments evolving “how many characters needed to present the fair balance doctrine.”