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In Memoriam

The *Health Law and Policy Brief* family recently lost Jocelyn Sweet (nee Moore). She passed away on April 2, 2014 after battling bone cancer.

Jocelyn received her Juris Doctor from American University Washington College of Law in 2011, and she was involved with the *Health Law and Policy Brief* throughout her time at WCL. Jocelyn served as both Managing Editor and Editor-in-Chief of the brief. She led the publication during its transition from *Health Law and Policy* to the *Health Law and Policy Brief* – a significant shift in recognition for the publication at WCL and at large. She brought a tremendous work ethic to the brief, as well as humor and kindness to every situation. Jocelyn's colleagues recognized her intelligence, creativity, and humility. Jocelyn worked tirelessly to help establish the quality and reputation of the *Health Law and Policy Brief*, which continues to serve as part of the foundation of the publication today.

Jocelyn will be remembered as a champion of health law, working to advance legal scholarship in the field of health law and directly impacting access to healthcare through a career at the Center for Medicare and Medicaid Services. Those who befriended Jocelyn through the brief are devastated by her loss, and extend their deepest condolences to her loving family.

Two members of the WCL health law community, Professors Robert Dinerstein and Corrine Parver, each of whom knew and taught Jocelyn during her time at WCL, also have extended some thoughts about her:

ROBERT DINERSTEIN

Associate Dean for Experiential Education, Professor of Law and Director, Disability Rights Law Clinic, American University Washington College of Law

Certain things are not supposed to happen. Parents are not supposed to survive their children. Teachers are not supposed to survive their students. Friends are not supposed to die young. Jocelyn Sweet's passing is incomparably sad. She was a vibrant young woman who was still early in her legal career. In her life, she had to deal with illnesses and medical conditions that would have defeated others. She bore these challenges with grace, tenacity, and an unwillingness to have them define her.

I had the honor of having Jocelyn in two of my classes—in my Law & Disability Seminar (Spring 2010) and in the Disability Rights Law Clinic (AY 2010-11). Jocelyn was a wonderful student and student attorney. She was thoughtful, hard-working, and creative. She cared deeply about her clients, and they about her.

In one of her cases, her client sent her, and her partner Sharita Jennings, an email that read:

> I just wanted to say thanks again for all of the hard work and effort that you put in for today's hearing with Judge Banks. No matter what the

> decision and/or outcome, I will be eternally grateful to the two of you for what you accomplished, for your time, for your encouraging words, and for the professional way in which you conducted yourselves at all times.

As it happens, Jocelyn and Sharita prevailed at this hearing, in which we argued that the Social Security Administration should waive the requirement that our client repay benefits that had been overpaid to her (for which she was not at fault). Before the hearing, the administrative law judge asked the client to leave the hearing room and addressed Jocelyn and Sharita directly, telling them that his staff had complained to him that the students were too aggressive and demanding with them on the telephone. He said he was passing on this information to them for their benefit as young lawyers-to-be. Jocelyn plainly was disbelieving; when she began to protest, the judge upbraided her, seeing her desire to defend her actions as proof of the behavior of which she was accused. The judge then called the client back into the hearing room and the hearing proceeded. Having a judge reprimand one for being too aggressive right before a hearing could have thrown even an experienced lawyer, let alone two student attorneys. But Jocelyn and Sharita presented the case exactly as we planned. The client gave a plausible though hardly unassailable explanation for why her living expenses were necessities, such that requiring repayment would be unjust. (These expenses included a time share, retirement plan contributions, and her synagogue dues.) The judge took the case under advisement, though not before telling the client in our presence that the students had done a great job in representing her. Several weeks later, we received the decision upholding all of our claims and granting our request that repayment be waived.

CORRINE PARVER

Founder of the American University Washington College of Law Health Law and Policy Project

Lovely, caring, bright, responsible, organized, brave, and courageous. These are but a few descriptions that immediately come to mind when I remember, with great fondness, my former student, Jocelyn Sweet. Through oftentimes terribly harsh personal circumstances due to her wickedly invasive disease, Jocelyn persevered mightily, showing a strength of character and determination that few persons could have displayed under the same or similar circumstances. Always smiling through what must have been highly painful and discouraging setbacks, she nevertheless carried on to complete successfully a heavy course load and demanding schedule, both for overseeing the publication of the law school's *Health Law and Policy Brief* and fulfilling her duties as an executive of the WCL Student Health Law and Justice Society. I am profoundly saddened at her passing, and wish for her memory always to be a blessing for her family.

The *Health Law and Policy Brief* is proud to produce a monthly blog with content covering a range of topics related to the health law profession.

Health law is a dynamic field, and requires constant adaptation. The brief is dedicated to helping practitioners interpret the landscape by informing readers of changes in the field and providing analysis of what such news and innovations mean for the profession. The blog features posts from dedicated Senior Bloggers on the brief staff as well as guest bloggers.

Please visit the blog at www.healthlawpolicy.org.

If you are interested in writing a guest post for the blog, please email a statement of interest to hlp@wcl.american.edu.

One Click Away From Untangling the Web: The United States Food and Drug Administration & Interactive Promotional Media

*Abraham Gitterman**

* Mr. Gitterman graduated magna cum laude, in 2013 from the University of Maryland Francis King Carey School of Law, where he also received a Health Law Certificate. Mr. Gitterman wrote this article while in law school, and the article was awarded First Place in the 2013 Epstein Becker & Green Annual Health Law Writing Competition. A shorter version of this article was published by the Food and Drug Law Institute (FDLI), Daniel Kracov, Abraham Gitterman, Do We 'Like' FDA's 'First Social Media Guidance' or is it Nothing to 'Tweet' About? FDLI, Food and Drug Policy Forum, Vol. 4, No. 2 (Feb. 26, 2014).

I. INTRODUCTION

The United States is one of the only countries in the world that allows direct-to-consumer (DTC) advertisement of pharmaceuticals and medical devices.[1] The United States Food and Drug Administration (FDA) regulates all prescription drug advertising—to medical professionals and consumers—and promotional labeling.[2] DTC advertisements are directed to consumers rather than healthcare providers, and include, broadcast (e.g., television), print (e.g., newspaper), and internet (e.g., website) advertisements. In contrast, promotional labeling includes brochures or pamphlets that medical professionals provide to consumers or other non-healthcare providers.

DTC advertising has become an increasingly important topic because a growing number of Americans, across various populations and demographics, are looking online for health information,[3] and they are looking primarily to "learn more about" their disease or condition.[4] In 2010, eighty-nine million adults in the United States tapped into social media resources for health-related purposes, compared with sixty-three million in 2008 and thirty-eight million in 2007.[5] Moreover, fifty-nine percent of non-physician healthcare professionals who work directly with and on behalf of patients indicated that

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Mr. Gitterman is admitted only in Pennsylvania and New Jersey. He is practicing law in the District of Columbia during the pendency of his application for admission to the D.C. Bar and under the supervision of lawyers who are members in good standing of the D.C. Bar. The content of this article is intended for informational purposes only. It is not intended to solicit business or to provide legal advice. The opinions expressed are those of the author and do not necessarily reflect the views of the firm or its clients.

[1] U.S. Food and Drug Admin., *Keeping Watch Over Direct-To-Consumer Ads*, FDA.gov (Aug. 19, 2013), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107170.htm [hereinafter Watch Over DTC Ads]. New Zealand is the only other developed nation that permits DTC advertising of drugs and medical devices. *Id.*

[2] U.S. Food and Drug Admin., *Drug Advertising: A Glossary of Terms*, FDA.gov (Sept. 13, 2012), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm#promotional_labeling [hereinafter FDA Glossary] (defining promotional labeling as having the same purpose as advertising to sell prescription drugs but as being effectuated through different mediums).

[3] Richard Meyer, *Is ROI A Roadblock to New DTC Marketing Initiatives?*, WorldOfDTCMarketing.com (Oct. 12, 2012), http://worldofdtcmarketing.com/is-roi-a-roadblock-to-new-dtc-marketing-initiatives/business-of-the-drug-industry/ (noting that 72% of 18–29 year-olds; 71% of 30–49 year-olds; and 46% of 50 individuals and older use the internet to research health questions).

[4] *Engaging E-Patients In Dialogue*, WorldOfDTCMarketing.com (last visited Mar. 24, 2014), http://worldofdtcmarketing.com/wp-content/uploads/2012/10/Engaging-epatients-in-dialogue.jpg (explaining that 36% of patients visit online health communities to learn more about their disease)

[5] Richard Meyer, *Sanofi-Aventis Blazes Social Media Trails*, WorldOfDTCMarketing.com (Aug. 21, 2012), http://worldofdtcmarketing.com/sanofi-aventis-blazes-social-media-trails/social-media-and-healthcare/ (noting that consumers turn to each other on social media due to distrust of advertisers); *see also* Nat'l Research Corp., *1 In 5 Americans Use Social Media for Health Care Information*, NationalResearchCorporation.com (Feb. 28, 2011), http://hcmg.nationalresearch.com/public/News.Aspx?ID=9 (discussing the increasing influence of social media on Americans seeking healthcare information).

patients "often or sometimes bring information from the internet to discuss."[6] While pharmaceutical and medical device manufacturers[7] have decreased spending on DTC television advertisements in recent years,[8] digital advertising budgets were expected to reach fifteen percent in 2012 and twenty percent in 2013 out of total marketing budget, with big increases expected in "social media initiatives for consumers."[9] While declines in internet DTC spending were actually seen in 2013 by almost fifteen percent, this can be attributed to the lack of FDA guidance and manufacturers "well-known anxiety around all things 'e,' media."[10]

There are both proponents and opponents of the use of DTC advertising by drug and device companies. Proponents of DTC advertisements argue that they (1) provide useful information to consumers that may result in better health;[11] (2) advance public health by encouraging more people to talk with healthcare professionals about problems, particularly under-treated, under-diagnosed conditions, such as high blood pressure;[12] (3) help remove the stigma associated with certain diseases (e.g., depression); and (4) remind patients to refill prescriptions and help them adhere to their medication regimens.[13] Critics maintain that such advertisements are troublesome because they (1) may contain false or misleading information; (2) do not provide enough information

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[6] *Patient Ed: How Patients Learn In the Digital Age*, WorldOfDTCMarketing.com (last visited Mar. 24, 2014), http://worldofdtcmarketing.com/wp-content/uploads/2013/02/HealthEd-Academy-How-Patients-Learn.jpg (finding that non-MDs who work with and on behalf of patients use online videos like YouTube to educate their patients (44%), as well as blogs (18%), and patients themselves print out online materials to use patient visits (55%)).

[7] Pharmaceutical and medical device manufacturers, manufacturers, or companies may be used interchangeably throughout this paper to signify entities that manufacture or produce FDA regulated pharmaceuticals, biologics, medical devices, or medical supplies.

[8] Bruce Japsen, *Drug Makers Dial Down TV Advertising*, NYTimes.com, Feb. 2, 2012, http://prescriptions.blogs.nytimes.com/2012/02/02/drug-makers-dial-down-tv-advertising/?_php=true&_type=blogs&_r=0.

[9] Richard Meyer, *Digital Budget for Pharma Expected To Be 20% for 2013*, WorldOfDTCMarketing.com (Oct. 30, 2012), http://worldofdtcmarketing.com/digital-budget-for-pharma-expected-to-be-20-for-pharma/business-of-the-drug-industry/. *See also* Matt Kapko, *Pharma and Healthcare Drive Biggest Online Ad Spending Gains*, ClickZ.com (Oct. 11, 2012), http://www.clickz.com/clickz/news/2216594/pharma-and-healthcare-drive-biggest-online-ad-spending-gains.

[10] Larry Dobrow, *DTC Report: DTC Gets Smart*, Medical Marketing & Media (Apr. 1, 2014) *available at* http://www.mmm-online.com/dtc-report-dtc-gets-smart/article/339357/.

[11] *Branded Pharmaceutical Websites Continue to Generate Highest Lifts in Rx Conversion and Adherence*, comScore.com (Apr. 5, 2012), http://www.comscore.com/esl/Insights/Press_Releases/2012/4/Branded_Pharmaceutical_Websites_Continue_to_Generate_Highest_Lifts (determining that existing patients of a drug brand who visited the brand site increased their refill rate by 14.7% and also saw an 8.9% increase in beginning treatment compared to those with no exposure to the site).

[12] U.S. Food and Drug Admin., *Guidance for Industry: "Help-Seeking" and Other Disease Awareness Communications By or On Behalf Of Drug and Device Firms: Draft Guidance*, FDA.gov (Jan. 23, 2004), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070068.pdf [hereinafter FDA Help-Seeking Guidance] (listing also depression, hyperlipidemia, hypertension, and diabetes as under-treated, under-diagnosed illnesses).

[13] Watch Over DTC Ads, *supra* note 1.

about the risks and negative effects of certain treatments; (3) may not advance—and may even threaten—public health; (4) encourage overuse of prescription drugs; and (5) encourage use of costly treatments, instead of less expensive treatments that may be equivalent, raising healthcare costs.[14]

Despite concerns regarding DTC advertising, the FDA recognizes that drug and device advertisements "can provide useful information for consumers to work with their healthcare professionals to make wise decisions about treatment."[15] Moreover, removing DTC advertisements could "affect public health" by leaving people who would benefit from a new drug or device unaware of its availability, causing them not to seek treatment in absence of such advertising.[16] While the FDA has the jurisdiction to regulate online DTC advertisements, an increase in the number of materials submitted, coupled with a significant number of new online platforms, has made the FDA's job of review and enforcement with regards to such materials very difficult.[17]

The rate at which technology and social media or interactive promotional media[18] develops continues to surpass FDA's ability to stay up-to-date with the various ways in which companies are using such platforms for promotion. There are numerous types of interactive promotional media, including blogs,[19] microblogs,[20] podcasts,[21] video sharing,[22] widgets,[23] wikis,[24] social networking sites,[25] content communities, collaborative projects, and virtual social or game worlds. Moreover, more than fifty percent "of leading pharma[ceutical] companies expect social networking, [podcasts,] online video and other types of digital marketing to grow in use as critical tools for communicating disease state and product information."[26] To satisfy FDA's statutory

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[14] *Id*.

[15] *Id. See also* FDA Help-Seeking Guidance, *supra* note 12.

[16] Shelia Campbell, *Potential Effects of a Ban on Direct-to-Consumer Advertising of New Prescription Drugs*, CBO.GOV (May 26, 2011), http://www.cbo.gov/publication/42186.

[17] Thomas Sullivan, *Policy Updates and Enforcement Developments From FDA's Medical Products Centers: Tips on Social Media*, POLICY AND MEDICINE (Dec. 22, 2011, 5:28 AM), http://www.policymed.com/2011/12/policy-updates-and-enforcement-developments-from-fdas-medical-products-centers-tips-on-social-media.html.

[18] These words may be used interchangeably throughout this article but are meant to indicate the use of any interactive online platform that allows for real-time communications and interactions (e.g., Facebook, YouTube, Twitter, Instagram, etc.).

[19] Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing, 74 Fed. Reg. 48,083-01, 48,085, Sept. 21, 2009 [hereinafter FDA Social Media Hearing Notice]. Web logs, or "blogs," are generally informal journal-type updates that encourage dialog about a subject. *Id.* at 48,085.

[20] *Id.* A "microblog" is similar to a blog but much shorter. *Id.* Twitter is a microblog service. *Id.*

[21] *Id.* Podcasts are video or audio clips that users can listen to or watch from a remote location. *Id.*

[22] *Id.* Video sharing allows the public to upload video clips to the internet (e.g., YouTube). *Id.*

[23] *Id.* Widgets are a graphic control on a Web page that allows the user to interact with it. *Id.* Widgets can be posted on multiple sites, host 'live' content, and are often on-screen tools. *Id.*

[24] *Id.* Wikis are webpages that anyone with access can modify (e.g., Wikipedia). *Id.*

[25] *Id.* Social networks allow users to connect with others (e.g., Facebook and LinkedIn). *Id.*

[26] Tanya Irwin, *Pharma Jumps On Social Media Bandwagon*, MediaPost (Oct. 29, 2012), http://www.mediapost.com/publications/article/186133/pharma-jumps-on-social-media-bandwagon.html.

obligation to issue social media guidance by July 9, 2014,[27] the Agency released its "first" guidance in January 2014, entitled "Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" ("Guidance").[28] While this guidance primarily focuses on how manufacturers can fulfill their post-marketing submission requirements for interactive promotional media, the FDA's overall approach to interactive promotional media may provide useful insight for industry and stakeholders about the concerns noted above, and what the FDA's interactive promotional media regime may hold in the near future.

This article analyzes several issues for the FDA and manufacturers to consider in finalizing the post-marketing guidance and drafting future interactive promotional media guidance, which the Agency has already announced.[29] Part II provides a brief history of the FDA's regulation of DTC advertisements. Parts III and IV discuss the FDA's oversight and enforcement with regards to such advertisements. Parts V and VI examine the difficulties posed by internet and social media advertisements, and examines several current examples of such advertisements. Finally, Part VII proposes several recommendations for consideration by the FDA and industry when promulgating guidance.

II. HISTORY OF DTC ADVERTISING AND PROMOTION

The Pure Food and Drugs Act of 1906[30] was one of Congress' first attempts to regulate prescription drugs, however, the legislation only contained provisions about product labels.[31] In addition, the Federal Trade Commission (FTC) "did not have the authority to regulate deceptive advertisements unless it could prove that such advertisements injured another company."[32] To address this gap in regulation, Congress replaced the 1906 Act with the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).[33] The

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[27] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 1121, 126 Stat. 993, 1112 (2012) [hereinafter FDASIA].

[28] U.S. Food and Drug Admin., *Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, FDA.gov (Jan. 2014), www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf. [hereinafter FDA Post-Marketing Interactive Promotional Media Guidance].

[29] U.S. Food and Drug Admin., *Guidance Agenda: New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2014*, FDA.gov (Jan. 31, 2014), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM314767.pdf. These include: (1) Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices; (2) Internet/Social Media Platforms: Correcting Independent-Third Party Misinformation About Prescription Drugs and Medical Devices; and (3) Internet/Social Media Advertising and Promotional Labeling of Prescription Drugs and Medical Devices – Use of Links. *Id.*

[30] Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

[31] Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 Food & Drug L. J. 423, 424-25 (2002).

[32] *Id*. at 425.

[33] Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (as amended 21 U.S.C. §§ 301 *et seq.*).

passage of the FDCA was necessary because among other things, the United States had seen a significant evolution of advertising practices such as radio, and the use of drug and cosmetic advertisements in magazines and newspapers since 1906.[34] The final legislation, however, only granted the FDA jurisdiction over the labeling of all drugs and omitted advertising provisions. Instead, "Congress amended the Federal Trade Commission Act in 1938 to give jurisdiction over all drug advertising to the FTC."[35]

In 1962, "the Kefauver-Harris Drug Amendments to the FDCA transferred regulatory authority over prescription drug advertising from the FTC to the FDA, by enacting section 502(n)."[36] Although the FDA promulgated detailed drug advertisement regulations a year later, in 1963, the promulgated regulations were designed for promotions directed to physicians.[37] This was unsurprising, however, because Congress did not intend for the FDA to regulate drug advertisements to consumers and such advertisements barely existed in 1962.[38] Thus, under the FDCA, the FDA has responsibility for regulating the FDA-approved labeling,[39] promotional labeling,[40] and advertising for prescription drugs. Section 201(m) of the Act, defines labeling to include all "written, printed, or graphic" materials "accompanying" a regulated product.[41] The FDA argues that although this definition of labeling is not limited to materials that physically accompany a product the textual relationship between the materials and the product is fundamental, and the Supreme Court agrees with this position.[42]

The FDCA "does not specifically define" prescription drug "advertising" or "advertisement," but the FDA generally interprets the term to "include information (other than labeling) that is sponsored by a manufacturer and is intended to supplement or explain a product."[43] If a promotional activity or material is considered advertising or labeling, the activity or material must contain adequate directions and information for

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[34] Palumbo, *supra* note 31, at 425 (citation omitted).

[35] *Id.* at 426 (citing Wheeler-Lea Act, 52 Stat. 111, ch. 49 (1938)).

[36] *Id*. Prior to the 1962 Amendments, the FDA and the FTC had entered into a "Working Agreement" in 1954.

[37] Lars Noah, *Advertising Prescription Drugs to Consumers*, 32 Ga. L. Rev. 141, 142 (1997).

[38] *See* H.R. Rep. No. 87-2464, at 2 (1962) (describing as one of the principal purposes of the legislation . . . to make available "adequate information concerning safety and effectiveness of *drugs advertised to physicians"*).

[39] FDA Help-Seeking Guidance, *supra* note 12.

[40] *Id.* Promotional labeling is generally any labeling other than the FDA-approved labeling. *Id.*

[41] 21 U.S.C. § 321(m) (2012). The FDA regulations define advertising subject to regulation to include"[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the Physicians Desk Reference) for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor . . . ." 21 CFR § 202.1(l)(2) (2013). *See also V.E. Irons, Inc. v. United States*, 244 F.2d 34, 39 (1st Cir. 1957).

[42] *Kordel v. United States*, 335 U.S. 345, 349–350 (1948).

[43] Direct-to-Consumer Promotion; Public Hearing, 60 Fed. Reg. 42,581-01, 42,581 (Aug. 16, 1995) [hereinafter 1995 DTC Hearing]. This includes, "advertisements in published journals, magazines,

use that are the "same in language and emphasis" as the product's approved labeling.[44] This requirement can be fulfilled by including the product's full approved labeling (the "package insert") with the promotional material.[45]

Section 352(n) of the FDCA requires drug advertisements, in written or electronic form, to contain the brand name, list of ingredients, and a "brief summary" of side effects of the drug.[46] The brief summary must provide all of the drug's side effects or risks listed in the drug's FDA-approved prescribing information (PI), contraindications, warnings, precautions, and indications for use.[47] The FDA regulations also established the "fair balance doctrine," which provides that the entire advertisement must present a balanced account of all clinically relevant information.[48] A drug's risks must be presented prominently and legibly so that the advertisement does not put more emphasis on the drug's benefits than its risks.[49] Additionally, a drug is misbranded if its advertising is "false or misleading, fails to reveal material facts, or fails to present a fair balance of information."[50]

III. FDA Regulation of Prescription Drug Advertising

The FDA first addressed DTC promotion of pharmaceuticals in the mid-1970s by "issuing a regulation that authorized advertising of prescription drug prices to consumers so long as a company made no representations about the safety or effectiveness of the product,"[51] but was "shocked" by the rise of DTC advertisements in the 1980s.[52] In 1981, Boots Pharmaceuticals issued the first DTC prescription drug advertisement in the United States for Rufen, an anti-arthritis drug.[53] A 1982 speech by the FDA Commissioner, Arthur Hull Hayes, Jr. predicting the "exponential growth" in DTC advertisements, was seen by the industry as evidence that the FDA would permit such

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other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems." *Id.*

[44] 21 U.S.C. § 352(f) (2012); *see also* 21 CFR § 201.100(d) (2013).

[45] 1995 DTC Hearing, *supra* note 43.

[46] 21 U.S.C. § 352(n) (2012) (a drug is misbranded "unless the manufacturer . . . includes in all advertisements . . . [a] brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations. . . .").

[47] 21 C.F.R. § 202.1(e) (2013). This information includes: (1) who should not take the drug; (2) when the drug should not be taken; (3) possible serious side effects, and if known, what can be done to lower the chances of having them; and (4) frequently occurring, but not necessarily serious side effects.

[48] FDA Glossary, *supra* note 2.

[49] *See* 21 C.F.R. § 202.1(e)(5)-(7) (2013). For example, the risks should not appear in much smaller type than the benefits and be placed in a corner of the advertisement far from the benefits because they are likely to be overlooked.

[50] Noah, *supra* note 37, at 145 (citing 21 C.F.R. § 202.1(e)(5) (1997)).

[51] *Id*. at 147; *see also Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762–70 (1976).

[52] Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 Food & Drug L. J. 489, 491 (1999).

[53] Palumbo, *supra* note 31, at 424 (citation omitted).

advertisements, and consequently, the FDA received "a large influx of proposed DTC ad[vertisements]."[54]

Due to uncertainty regarding how to regulate DTC advertisements, the FDA issued a formal request to industry in September 1982 "for a voluntary moratorium on DTC advertisements, to allow FDA time to research the issue."[55] During the moratorium, the FDA sponsored a series of public meetings and conducted several studies on the effects of DTC advertisements.[56] In September 1985, FDA removed the moratorium stating that DTC advertisements must meet the same legal requirements as those directed at physicians.[57] Despite the FDA's recognition that there were differences between the expertise and knowledge of healthcare professionals and consumers as recipients of drug promotion,[58] the FDA maintained that pre-existing regulations governing drug advertisements would sufficiently safeguard consumers. Thus, DTC advertisements had to be fairly balanced and meet the brief summary requirements.

Companies, however, started to expand the types of DTC advertisements that they produced. As a result, FDA recognized three broad categories of advertisements: (1) reminder advertisements,[59] (2) help-seeking or disease-oriented advertisements,[60] and (3) product-claim or indication advertisements. Reminder and help-seeking advertisements are exempt from the brief summary and fair balance requirements because they do not reveal a drug's risks or benefits.[61] Most DTC promotions are product-claim advertisements, which must identify the drug's brand and generic names and accurately state an FDA-approved use for the drug.[62] The product claim advertisement must present the benefits and risks of a drug in a balanced fashion,[63] and should say that the drug is given by prescription only. While the distinction between advertisement types was useful to the FDA and drug or device companies, the tremendous growth in the use of DTC advertisements demanded more guidance from the Agency.

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[54] Pines, *supra* note 52, at 492.

[55] Palumbo, *supra* note 31, at 424.

[56] *See* Louis A. Morris & Lloyd G. Millstein, *Drug Advertising to Consumers: Effects of Formats for Magazine and Television Advertisements*, 39 Food Drug Cosm. L. J. 497 (1984).

[57] Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36,677-02 (Sept. 9, 1985).

[58] 1995 DTC Hearing, *supra* note 43.

[59] *Id.* Reminder advertisements call attention to the name of the drug product, but do not include specifications or the drug's use. *Id.*

[60] *Id.* Help-seeking advertisements describe the symptoms of a disease or condition, but must not reference a specific drug. *Id.*

[61] FDA Glossary, *supra* note 2. A benefit is help provided by a drug for the person who is taking it. *Id.*

[62] U.S. Food and Drug Admin., *Product Claim Ad (Correct)*, FDA.gov (Sept. 13, 2012), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm082284.htm.

[63] FDA Glossary, *supra* note 2. A claim says something about the advertised drug or what it does. *Id.*

i. FDA DTC Advertising Guidance

Reliance on pre-existing drug advertisement regulations created "confusion among consumers"[64] and several problems for manufacturers pursuing DTC broadcast advertisements. The FDA asked manufacturers in a July 1993 letter to voluntarily submit proposed DTC materials prior to use, providing the FDA with an opportunity to review and comment upon proposed materials before they reached consumers.[65] Two years later, FDA convened a public hearing to address the difficulties posed by new communication technologies.[66] At the time, broadcast advertisements were required to contain a brief summary, unless "adequate provision [was] made for dissemination" of the approved labeling in connection with the presentation.[67] While companies could meet this requirement for healthcare providers by "providing the page number for the advertised product in the Physicians' Desk Reference (PDR), along with a toll-free telephone number" to request a copy of the prescribing information (PI), this was inadequate for most consumers. It was also impractical for a thirty-second television advertisement to contain a brief summary because it would take minutes for the summary to play or scroll down a television screen. As a result of this issue, companies used mostly reminder and help-seeking advertisements on television, which were exempt from the brief summary and fair balance requirements.[68]

Once manufacturers started using the internet for DTC advertising, issues arose, prompting consumer groups, medical associations, and even some manufacturers to ask the FDA to adopt more comprehensive regulations.[69] As a result, the FDA held a series of meetings with manufacturers in 1995 and convened an Internet Conference in October 1996 to help guide the Agency in making policy decisions regarding the promotion of drugs on the internet.[70] The FDA, however, issued its first warning letter prior to the 1996 Internet Conference and began targeting websites that used improper drug promotion, "sweeping" approximately 1,200 internet websites in search of deceptive health claims.[71] Shortly thereafter, the FDA finalized guidance regarding DTC broadcast advertisements, which recognized a distinction between print and broadcast advertisements.[72]

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64 Pines, *supra* note 52, at 496.

65 FDA Form 3439, Interim Form for Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use; Availability, 61 Fed. Reg. 24313-02 (May 14, 1996).

66 FDA Public Hearing on Direct-to-Consumer Promotion (Oct. 18-19, 1995); *see also* 1995 DTC Hearing, *supra* note 43.

67 21 C.F.R. § 202.1(e)(1) (2013).

68 1995 DTC Hearing, *supra* note 43.

69 Leah Brannon, *Regulating Drug Promotion on the Internet*, 54 Food & Drug L. J. 599 (1999) (citation omitted).

70 FDA Social Media Hearing Notice, *supra* note 19.

71 Brannon, *supra* note 69, at 601 (citation omitted).

72 U.S. Food and Drug Admin., *Guidance for Industry, Consumer-Directed Broadcast Advertisements*, FDA.gov (Aug. 1999), http://www.fda.gov/RegulatoryInformation/Guidances/ucm125039.htm. [hereinafter 1999 DTC Broadcast Guidance]. *See also* 21 C.F.R. § 202.1(e)(1) (2013) (regulating print and broadcast advertisements differently).

While print advertisements must include the brief summary, broadcast advertisements must disclose the product's major risks in either the audio or audio and visual portions of the presentation—known as the "major statement."[73] The amount and type of included risk information will vary by drug because each drug has different risks. Sponsors of broadcast advertisements are also required to present a brief summary or make "adequate provision . . . for dissemination of the approved or permitted package labeling in connection with the broadcast presentation."[74] Thus, the regulations specify that the major statement, together with adequate provision for dissemination of the drug's approved labeling, can fulfill the mandated risk information disclosure.[75]

In February 2004, the FDA published several draft guidance documents pertaining to DTC advertisements.[76] The documents provide recommendations and factors industry should consider when creating help-seeking and disease awareness advertisement, and disclosing risk information in the brief summary in print advertisements. In 2007, Congress passed the Food and Drug Administration Amendment Act (FDAAA), which included Section 901, requiring that the major statement relating to side effects and contraindications in broadcast advertisements be presented in a clear, conspicuous, and neutral manner.[77] In addition, Section 906 requires advertisements to include a specific statement and contact information that encourages consumer reporting of negative side effects to the FDA.[78] Two years later, the FDA issued further guidance that outlined several factors that the FDA would consider when evaluating the presentation of risk information in DTC advertisements. These factors include (1) the amount of information conveyed by a promotional piece; (2) materiality and comprehensiveness; (3) the nature of benefit claims; and (4) format.[79] The guidance also provides recommendations

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[73] 1999 DTC Broadcast Guidance *supra* note 72.

[74] *Id.* Broadcast advertisements must reference: (1) directions to contact a healthcare professional; (2) a toll-free telephone number; (3) the current issue of a magazine that contains a print advertisement; and (4) a website address. *Id.*

[75] *Id*. at 2 (citing Section 502(n) of the FDCA).

[76] *See* FDA Help-Seeking Guidance, *supra* note 12. *See also* U.S. Food and Drug Admin., *Draft Guidance for Industry: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements*, FDA.gov (Jan. 2004), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069984.pdf. The third draft guidance addressed medical devices, not covered in this paper.

[77] U.S. Food and Drug Admin., *Draft Guidance for Industry: Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program*, FDA.gov, 1–2 (March 2012), http://www.fda.gov/downloads/Drugs/Guidances/UCM295554.pdf [hereinafter FDA TV Pre-dissemination Guidance].

[78] U.S. Food and Drug Admin., *Report to Congress: DTC Advertising's Ability to Communicate to Subsets of Population; Barriers to Participation of Population Subsets in Clinical Trials*, FDA.gov, 4 (Sept. 2009), http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/FDAAAImplementationChart/UCM213016.pdf [hereinafter FDA 2009 Rept. to Congress].

[79] U.S. Food and Drug Admin., *Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion,* FDA.gov, 10 (May 2009), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf [hereinafter FDA Risk Information Guidance].

regarding the use of text that is "superimposed on other images in videos or broadcast ad[vertisement]s (SUPERs) and other visual components, such as graphics, within an ad[vertisement]" that may be applicable to DTC advertisements online or in social media.[80]

In 2012, the FDA issued draft guidance to clarify "the requirements for product name placement, size, prominence, and frequency in promotional labeling" and drug ad[vertisment]s."[81] The guidance pertains to product names in "electronic and computer-based promotional labeling and advertisements, such as Internet promotion, social media, e-mails, CD-ROMs, and DVDs."[82] In addition, the guidance recognizes that electronic and computer-based media do not contain text pages like print media, but do contain "running text[83] equivalent to many pages of traditional printed text."[84] Although the guidance is not specific to DTC advertisements, it provides practical recommendations that may be applicable to social media and internet DTC advertisement.

ii. FDA's Off-Label Guidance

In late 2011, the FDA released draft guidance regarding industry's use of websites and emerging electronic media to respond to unsolicited requests for off-label information.[85] The guidance, however, was not the social media and internet guidance that industry had long awaited.[86] Nevertheless, the FDA provided examples in the guidance of what might constitute solicitation by a manufacturer through social media, including: "(1) [t]weeting study results and suggesting that an off-label use is safe and effective; (2) [e]stablishing standard response websites that in part include off-label information; (3) [e]ncouraging third-party bloggers to post about off-label use; (4) [c]reating a username, e-mail address, or URL that suggests off-label use; or (5) [r]equesting users to post videos about their product experience on a site such as YouTube, resulting in videos on off-label use."[87] The examples provided by FDA demonstrate that the Agency

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[80] *See id*. at 18. Factors include: (1) not presenting words in all upper case; (2) using competing or unrelated SUPERs; (3) using busy scenes, frequent scene changes, or vivid and compelling visuals; or (4) length of time a SUPER is on a screen.

[81] U.S. Food and Drug Admin., *Draft Guidance: Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling*, FDA.gov, 1 (January 2012), http://www.fda.gov/downloads/Drugs/.../Guidances/ucm070076.pdf [hereinafter FDA Ad and Promotional Guidance].

[82] *Id*. at 2.

[83] *Id*. at 3 (noting that FDA interprets the *running text* "to mean the body of text in a piece, as distinct from headlines, taglines, logos, footnotes, graphs, or pictures").

[84] *Id*. at 5.

[85] U.S. Food and Drug Admin., *Draft Guidance: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*, FDA.gov (Dec. 2011), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf [hereinafter FDA Off-Label Guidance].

[86] U.S. Food and Drug Admin., *Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools* (Nov. 12–13, 2009), http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm [hereinafter 2009 FDA Internet and Social Media Hearing].

[87] John Sullivan, et al., *The FDA and the Regulation of Social Media*, Corporate Counsel (Jun. 27, 2012), *available at* http://www.dechert.com/files/Publication/ef3f4a16-9d0a-4178-b84c-

"will hold companies responsible for their direct actions" and may also hold companies "responsible for third-party postings . . . if the company explicitly encouraged that third-party to post improper information" and even if the company did not request that content.[88] For example, if a user discusses off-label uses of a drug in a video posted on the internet, even though the company did not request off-label videos, the FDA may consider such videos solicited.[89]

Despite the FDA's recognition that the internet and social media have fundamentally changed the way that companies communicate with the public, the FDA recommended that any substantive responses from companies to unsolicited requests for information regarding off-label use of drugs not occur through the internet or interactive promotional media due to the inherently public and permanent nature of these communications.[90] Ultimately, industry expressed concern about the draft guidance issued by the FDA, maintaining that it "will unnecessarily stifle the flow of accurate scientific information that has otherwise been intended both by the industry and FDA, as well as handicap the unique benefits of social media that FDA should embrace in order to further public health."[91] As a result, most drug and device companies have remained risk averse when it comes to using social media or the internet for DTC advertisements and are far behind in their implementation and use of social media.[92] Ironically, the FDA has become increasingly skilled with using social media tools on its own behalf.[93] The FDA's failure to articulate clear internet and social media guidelines and its use of regulatory letters and enforcement actions to hold companies accountable has generated additional uncertainty within the industry.

iii. FTC ".com" Guidance and Current Use of Social Media

The FTC recently released guidance on ".com Disclosures,"[94] which could have several implications for products regulated by the FDA, if the FDA decides to follow the FTC's approach. For example, the FTC guidance recommends that disclosures which are an "integral part of a claim or inseparable from it should not be communicated through a hyperlink."[95] Specifically, the FTC states that hyperlinks, even one labeled "Important Health Information,"[96] "should not be used . . . [for] important health and safety

ac2ee9197917/Presentation/PublicationAttachment/c775d639-aa34-4047-97c4-b27872755ac2/FDA%20Dechert.pdf.

[88] *Id.*

[89] FDA Off-Label Guidance, *supra* note 85, at 5.

[90] *Id*. at 10.

[91] Jamie Kendall & Noah Mallon, *Does FDA's Draft Guidance on Responding to Unsolicited Off-Label Requests Align With FDA's Mission to Promote the Public Health?*, 2-3 FDLI, Food and Drug Policy Forum (Mar. 14, 2012).

[92] Digital Budget for Pharma Expected to be 20% for 2013, *supra* note 9.

[93] *FDA's Social Media Assets – Twitter Overview*, EyeonFDA (June 23, 2011), http://www.eyeonfda.com/eye_on_fda/2011/06/fdas-social-media-assets-twitter-overview.html.

[94] Federal Trade Commission, *.com Disclosures: How to Make Effective Disclosures in Digital Advertising*, 10 (Mar. 2013), http://www.ftc.gov/os/2013/03/130312dotcomdisclosures.pdf [hereinafter FTC Online Guidance].

[95] *Id*.

[96] *Id*. at 10 (example 4).

information" because "required disclosures about serious health and safety issues are unlikely to be effective when accessible only through a hyperlink."[97] The FTC, however, provides no evidence as to why such health information hyperlinks are unlikely to be effective. Nevertheless, the FTC maintains that "integral" or "inseparable" disclosures "should be placed on the same page and immediately next to the claim, and be sufficiently prominent so that the claim and the disclosure are read at the same time."[98] The FTC also reiterates that "any disclosure that is integral to the primary claim should be immediately adjacent to that claim."[99]

The FTC recognized that when disclosure in a space-constrained advertisement is not possible, "it may, under some circumstances, be acceptable to make the disclosure clearly and conspicuously on the page to which the advertisement links."[100] When using a hyperlink to lead to a disclosure, the FTC recommends: (1) making the link *obvious*; (2) labeling the hyperlink appropriately to convey the importance, nature, and relevance of the information that it leads to;[101] (3) using consistent hyperlink styles; (4) placing the hyperlink *as close as possible* to the relevant information it qualifies and make it noticeable; (5) taking consumers directly to the disclosure on the click-through page; and (6) assessing the effectiveness of the hyperlink by monitoring click-through rates.[102]

The FTC also recommended designing advertisements so that "scrolling" "is not necessary in order to find a disclosure"; however, if scrolling is necessary, the FTC recommended using text or visual cues to encourage consumers to scroll to view the disclosure.[103] Moreover, the FTC indicated that companies should consider how linking or "mouse-overs" may work on computers but may not work mobile devices.[104] The guidance explains that if an advertisement without a disclosure would be deceptive, unfair, or violate one of the FTC rules, and "if a particular platform does not provide an opportunity to make clear and conspicuous disclosures, then that platform should not be used to disseminate advertisements that require disclosures"[105] Although not directly applicable to products regulated by the FDA, the FDA may use the FTC's guidance as it begins drafting additional guidance regarding DTC advertisements in online media and social media platforms in 2014.

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[97] *Id*. at 10, A6.

[98] *Id*. at 10.

[99] *Id*. at A6 (example 4).

[100] *Id*. at ii.

[101] *Id*. at 11–12 (noting that hyperlinks that say "'disclaimer,' 'more information,' 'details,' 'terms and conditions,' or 'fine print' do not convey the importance, nature, and relevance of the information to which they lead and are likely to be inadequate." The FTC added that labels such as "important information" or limitations may also be inadequate. While the FTC said there is "no one-size-fits-all" word or phrase to use in a hyperlink label, "more specificity" is better).

[102] *Id*. at ii (emphasis added).

[103] *Id*. For example, "see below for important information"; but not "details below" because it provides "no indication about the subject matter or importance of the information that consumers will find and are not adequate cues." *Id*. at 9.

[104] *Id. at 12*.

[105] *Id*. at iii.

IV. FDA OVERSIGHT AND ENFORCEMENT OF DTC ADVERTISING

The FDA's Office of Prescription Drug Promotion (OPDP)[106] regulates drug advertising and promotion. OPDP has four DTC review groups that review final DTC materials, provide advisory comments on draft materials that companies submit voluntarily, and review materials cited in complaints submitted by competitors or consumers.[107] Because the FDA regulations require that companies submit final DTC promotional materials to the FDA at the time of their initial dissemination to the public[108] (often referred to as "postmarketing submission" requirements), the OPDP review groups monitor television, magazines, and manufacturer websites to ensure compliance. OPDP also monitors DTC advertisement to ensure that advertisements are not false or misleading;[109] that advertisements have adequate contextual and risk information; and that advertisements are presented in understandable language to fulfill the fair balance requirement.[110] Additionally, OPDP monitors DTC advertisements through a routine surveillance and monitoring program, including the "Bad Ad" Program.[111]

If OPDP finds a DTC advertisement or promotional piece that violates the law or guidelines issued by the FDA, it issues a regulatory letter to the manufacturer disseminating the violative material.[112] There are two types of letters that OPDP issues: a Notice of Violation (NOV) Letter (or "untitled letter") for minor violations, and a Warning Letter for more serious violations.[113] Other enforcement actions include product seizures, criminal actions, injunctions, and consent decrees.[114] The FDA may also hold any person who disseminates a false or misleading drug DTC advertisement liable for civil monetary penalties.[115] Despite having these enforcement tools, OPDP has previously faced difficulty prioritizing and taking enforcement actions against

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106 This office was previously DDMAC, and before that had several other names. Pines, *supra* note 52, at 495–96.

107 *Prescription Drugs: Trends in FDA's Oversight of Direct-to-Consumer Advertising, Testimony Before the Subcomm. on Oversight and Investigations, Comm. on Energy & Commerce, U.S. Gov't Accountability Office,* GAO-08-758T, 5 (May 8, 2008) (statement of Marcia Cross, Director, Health Care) [hereinafter GAO-08-758T].

108 21 C.F.R. § 314.81(b)(3)(i) (2013). This is to be transmitted on an FDA Form 2253.

109 U.S. Food and Drug Admin., *From the manufacturers' mouth to your ears: Direct to consumer advertising* (June 6, 2013), http://www.fda.gov/drugs/resourcesforyou/specialfeatures/ucm319379.htm. Drug promotion is considered false or misleading if it: (1) promotes the drug as being more effective than actually demonstrated; (2) implies that a drug is safer or has fewer or less severe side effects than demonstrated; (3) claims, without substantial evidence, that its product is better than a competitor's drug; (4) gives a false, misleading or unbalanced presentation of risk information; and (5) promotes the product as being able to treat conditions not approved by FDA. *Id.*

110 FDA Risk Information Guidance, *supra* note 79, at 4.

111 U.S. Food and Drug Admin., *Truthful Prescription Drug Advertising and Promotion* (Nov. 26, 2013), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.htm.

112 GAO-08-758T, *supra* note 107, at 1–2.

113 *Id*. at 6. FDA may require a "correction advertisement" for serious violations. *Id.*

114 *Id*. at 6, note 8.

115 FDA 2009 Rept. to Congress, *supra* note 78, at 4.

submitted promotional materials that may be violative due to the increasing number of materials submitted.[116]

Although the FDA established criteria to prioritize review of DTC advertisements in 2008, the criteria still do not ensure that OPDP systematically screens the DTC materials it receives against the established criteria to identify those advertisements that are the highest priority for review.[117] Further, a policy change requiring the FDA's Office of Chief Counsel (OCC) to review all draft regulatory letters (e.g., NOVs and Warning Letters) that took place in 2002 led to the FDA issuing about half as many letters as it had previously.[118] Moreover, while companies complied with the FDA requests to remove materials that were still being disseminated and issuing corrective materials, these actions generally did not occur until five to twelve months after the FDA's regulatory letter was sent.[119] As a result, some products remained on the market, on average for about seven months, despite their violative nature.[120] In addition, regulatory letters did not always prevent drug companies from later disseminating similar violative materials for the same drugs.[121]

OPDP began to refocus its attention on DTC advertising on the internet in 2010, when it issued thirteen regulatory letters related to online media including "emails, websites, website videos, social media, and/or webcasts."[122] In 2011, the FDA issued seven warning letters related to misleading online promotion, most involving "the placement and/or lack of prominence of risk information."[123] Some commentators have attributed the decrease in internet-promotion related Warning Letters issued by the FDA to companies relying more on help-seeking and reminder type sponsored links in order to avoid the brief summary requirement.[124] In 2012, OPDP issued twenty-five untitled letters and three Warning Letters for promotional violations, bringing its total to 173 regulatory action letters regarding communications about FDA regulated drugs or devices between 2008 and 2012.[125] Overall, between 2008 and 2012, the FDA found

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116 In 2008, DDMAC received 10,861 Internet DTC materials. *See id*. at 6.

117 GAO-08-758T, *supra* note 107, at 8–9.

118 *Id*. at 3–4, 11. As a result, letters were issued on average 8 months after violative materials were first disseminated; when "companies had already discontinued more than half of the violative" advertisements.

119 *Id*. at 12.

120 *Id*.

121 *Id*. at 5. For example, of the 89 drugs for which FDA cited violative DTC materials from 1997 through 2005, 25 drugs had DTC materials cited in more than one regulatory letter, sometimes for similar types of violations.

122 Kassity Liu, *FDA and Social Media: The Impact of Social Media on Prescription Drug Advertising*, Jolt Digest (Apr. 17, 2012), http://jolt.law.harvard.edu/digest/digest-note/fda-and-social-media-the-impact-of-social-media-on-prescription-drug-advertisin.

123 Jacqueline West, *National Marketing Gone Unintentionally Global: Direct-to-Consumer Advertising of Pharmaceutical Products and the Internet*, 11 J. Int'l Bus. & L. 405, 414–15 (2012).

124 *Id*. at 415 (citing 2009 FDA Internet and Social Media Hearing, *supra* note 86, at 438–40).

125 Mark Senak, *FDA Communications: Oversight in a Digital Era, 2008-2013*, eyeonFDA (Apr. 2013), http://www.eyeonfda.com/wp-content/uploads/2013/03/FDA-Communications-Oversight-in-a-Digital-Era1.pdf.

"290 digital violations."[126] Of these violations, over half were for companies that failed to include risk information or minimized the risk, while eighteen percent overstated efficacy.[127] However, of the 173 regulatory action letters, "less than 1 percent involved a social media platform as the basis for the letter."[128]

Nevertheless, the lack of transparency in the FDA's enforcement discretion, coupled with the FDA's vague guidance is problematic for several reasons. First, these new avenues of communication create ways for companies to reach millions of patients who may need treatments or are avoiding seeing a doctor. As a result, patients may not be receiving information that could change their health and lives. Second, the lack of guidance and transparency raises First Amendment issues because advertisements are a form of commercial speech.[129] Third, the current regulatory regime hurts physician training and education because doctors may also be motivated to learn about new drugs through DTC advertisements they see directly or through conversation with their patients.[130] Despite these negative effects, the FDA has been unable to tackle the challenges of DTC promotion online.

V. THE DIFFICULTIES POSED BY SOCIAL MEDIA AND INTERNET DTC ADVERTISEMENTS

The use of DTC advertisements in social media and on the internet creates several challenges for companies. First, providing fair balance is difficult because Twitter, sponsored links, and share widgets generally do not have enough space for the FDA required risk disclosures. For static websites, companies had been using an industry-created practice known as the "one-click-away" rule, which assumes that it is sufficient to present some information about a drug, absent risk disclosure, so long as information regarding the risk is only "one-click away."[131] However, "the mere possibility of access to risk information does not necessarily translate into a realistic presentation of risks."[132] Drug and device companies widely used "one-click away" until April 2009, when the FDA issued fourteen (NOV) letters to manufacturers who sponsored search-engine advertisements on Google for drugs.[133]

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[126] Mark Senak, *Comparing Types of Violations Between Digital and Non-Digital*, EYEONFDA (Apr. 11, 2013), http://www.eyeonfda.com/eye_on_fda/2013/04/comparing-types-of-violations-between-digital-and-non-digital.html. This represented only 43% of the total violations. *Id.*

[127] *Id.* (finding 56% of digital violations failed to include risk information or involved minimization of risks).

[128] Senak, *supra* note 125.

[129] *See e.g.*, *Thompson v. Western States Med. Ctr.*, 122 S.Ct. 1497 (2002) (striking down a provision in the FDA Modernization Act (FDAMA) that prohibited pharmacies from advertising compounded products); *Virginia Board of Pharmacy v. Citizens Consumer Council, Inc*., 425 U.S. 748 (1976) (invalidating a ban on drug price advertising).

[130] *See Patient Ed: How Patients Learn in the Digital Age*, *supra* note 6.

[131] Doug Flora, *The FDA and Social Media: A Primer*, THE FOSBURY FLOP (Sept. 27, 2010), https://reputationcommunications.wordpress.com/2010/09/27/the-fda-and-social-media-a-primer/.

[132] Jeremy A. Greene & Aaron S. Kesselheim, *Pharmaceutical Marketing and the New Social Media*, 363 NEW ENG. J. MED. 2087, 2088 (2011).

[133] Stephanie Clifford, *FDA Rules on Drug Ads Show Confusion as Applied to Web*, NYTIMES.COM, Apr. 16, 2006, http://www.nytimes.com/2009/04/17/business/media/17adco.html?_r=0.

The NOV letters asserted that information in a sponsored link that includes a website address consisting of the trade name for a drug, and that appears on the results page of an internet search engine when a keyword search is conducted, is not a reminder advertisement but instead is "labeling" and "advertising."[134] As a result, OPDP asserted that all of the mandatory risk information "must likewise appear on the face of the sponsored link and will not be considered in the disclosure analysis even if fully . . . available one-click away."[135] The FDA stated that its promotional laws "are the same regardless of the medium."[136] Thus, the FDA found the sponsored link misleading because it suggested efficacy without disclosing risk information.[137] The FDA also found a sponsored link misleading, even though it made "no explicit claim about the drug."[138] These actions illustrate how the FDA may find an "implied connection and require risk disclosures in the link text," even if the sponsored link or widget does not explicitly state that the product treats the disease.[139]

In 2010, the FDA also sent its first untitled letter regarding information generated by the "Facebook Share" widget on one of Novartis's websites. Clicking on the widget sent Novartis-authored information about the leukemia drug Tasigna to a user's Facebook page. The FDA stated that the "shared content [wa]s misleading because it ma[de] representations about the efficacy of Tasigna but fail[ed] to communicate any risk information associated with the use of this drug."[140] In order for promotional materials to be truthful and non-misleading, "they must contain risk information in each part as necessary to qualify any claims made about the drug."[141] As a result, the FDA may determine that placing risk disclosures "one-click away" is sufficient if the text of the sponsored link discusses only the disease, does not name the product, makes no implied or express product claims, and the product is instead first named, along with risk disclosures, on the other side of the link.[142] Until the FDA issues further guidance, however, the requirements in this area remain uncertain. While the FDA

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134 Thomas Sullivan, *FDA: Examination of Online DTC Promotion*, Pol'y & Medicine (Jun. 1, 2011), http://www.policymed.com/2011/06/fda-examination-of-online-direct-to-consumer-prescription-drug-promotion-notice-for-comment.html.

135 *Id*. The FDA was especially concerned because one drug had a boxed warning, and another a bolded warning.

136 Clifford, *supra* note 133 (risk information "was required despite the length limitation of Internet search ads").

137 U.S. Food and Drug Admin., *Letter from Sangeeta Vaswani*, *DDMAC*, *to Christopher Graham, sanofi-aventis U.S. LLC.*, FDA.gov (Mar. 26, 2009), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM166248.pdf.

138 Sullivan, *supra* note 87.

139 *Id*. (noting that the FDA has issued over a dozen such untitled letters on sponsored links or share widgets).

140 U.S. Food and Drug Admin., *Letter from Karen R. Rulli, DDMAC, to Lisa Drucker, Novartis Pharmaceuticals Corp*, FDA.gov. (Aug. 4, 2010), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf.

141 *Id*.

142 Sullivan, *supra* note 87.

could potentially adopt an approach similar to the use of "major statements" adopted by the FTC for broadcast advertisements, "possibly via a link to another web page," this may be "unworkable, since the text of a 'major statement' may be too lengthy . . . for the space limitations of Internet links and widgets."[143] Accordingly, a link to safety information is not likely to suffice.

An approach that is "more consistent" with the FDA's guidance is to present safety information on the vertical display of a webpage, which may allow an individual to "utilize scrolling in order to view the complete information."[144] If this approach is utilized, risk information should be visible when the user first opens the webpage. The FDA's guidance also addresses the use of headers and signaling.[145] Thus, companies should use "signals such as 'continued,' 'more' and 'select,'" if safety information continues from page-to-page, which is likely "given the smaller footprint and displays" available in social and mobile platforms.[146]

Unlike television, social media is unique because consumers have the opportunity to respond to online promotional material and communicate their opinions with others. This capability, however, presents risks for drug companies because dissatisfied patients can post harmful information that may discourage others from taking the medication and may even discourage online viewers from seeing a doctor, which may have public health implications. There is also concern that companies may be influencing or controlling content on web-based social media by supporting "third-party bloggers, posters, and Twitter users who make flattering claims and discredit negative claims about their products in online discussions."[147] Moreover, it may no longer be technically possible for companies to distinguish a manufacturer website from a manufacturer initiated chat room or comment area because applications such as Google's "Sidewiki" can "layer a social network of commentary onto any existing static Web site, with or without the site owner's consent."[148]

Without further guidance from the FDA, the difficulties posed by interactive promotional media will continue. For example, in December 2012, the FDA sent a Warning Letter to AMARC Enterprises regarding its cancer supplement (non-FDA approved) Poly MVA. The letter–the first of its kind–cited a March 10, 2011 post on AMRAC's Poly MVA Facebook page, in which a consumer noted how the product had "done wonders for me."[149] FDA took issue with the fact that AMRAC "liked" this favorable consumer

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143 *Id*.

144 Sara Stults, *It Doesn't Have to Hurt: A Social Media Primer*, FDLI Update Magazine (Sept.-Oct. 2011).

145 *Id.*

146 *Id*.

147 Greene & Kesselheim, *supra* note 132.

148 West, *supra* note 123 (explaining the application left no control over the content of the Sidewiki to the site owner).

149 U.S. Food and Drug Admin., *Warning Letter to Mr. Albert Sanchez, CEO, AMARC Enterprises, Inc.*, FDA.gov (Dec. 11, 2012), http://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm340266.htm which states: "We also note claims made on your Facebook account." "The following are examples of the claims: In a March 10, 2011 post which was "liked" by "Poly Mva": *"PolyMVA has done wonders for me. I take it intravenously 2x a week and it has helped me*

testimonial, however, FDA did not "restrict consumers from 'liking' a drug or device company's Facebook page or posts."[150] Nevertheless, it is unclear whether "liking" is akin to "favoriting" a Twitter user, "retweeting" a post, "sharing" or "re-posting" content from other uses, or "+1" a post on Google+.[151] Waiting for further guidance from the FDA, however, is not an option for drug or device companies because consumers have used these platforms for years to discuss products, and the industry's absence from this conversation is counterproductive.

Research suggests that DTC advertising has a number of benefits for patients and consumers. For example, a recent study found that DTC advertisement for aromatase inhibitors "was associated with increases in appropriate prescriptions with no significant effect on inappropriate prescriptions."[152] Another study showed "no strong indication that either consumer- or provider- directed promotion substantially raised retail-level prices."[153] In fact, while some physicians believe that DTC advertisements misinform patients, overemphasize drug benefits, encourage drug overutilization, and ultimately increase the cost of healthcare,[154] such beliefs fail to recognize that over seventy-five percent of the prescription drugs patients receive are generic.[155] Moreover, even if patients ask for a branded drug, insurers often mandate the generic and most state laws require generics unless a physician indicates the brand-name drug is medically necessary.[156] In addition, a recent survey of physicians showed that almost fifty percent agreed that DTC advertisements inform, educate, and empower patients; sixty-eight percent agreed that DTC advertisements encourage patients to contact a physician; sixty-four percent agreed that DTC advertisements promote patient dialogue with healthcare providers; and over fifty percent agreed that DTC advertisements removed

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tremendously. It enabled me to keep cancer at bay without the use of chemo and radiation…Thank you AMARC."

[150] Jose Sierra, *Navigating FDA Guidance on Facebook and Social Media*, PHARMARISC.COM (Mar. 18, 2013), http://pharmarisc.com/2013/03/navigating-fda-guidance-on-facebook-and-social-media/.

[151] *Id*.

[152] *Industry on DTC Advertising Study: An Informed Patient Enables Better Care,* COALITION FOR HEALTHCARE COMMUNICATION (Dec. 3, 2012), http://www.cohealthcom.org/2012/12/03/industry-on-dtc-advertising-study-an-informed-patient-enables-better-care/.

[153] *Study Cites Benefits of Pharma's Promotional Efforts*, COALITION FOR HEALTHCARE COMMUNICATION (Mar. 4, 2013), http://www.cohealthcom.org/2013/03/04/study-cites-benefits-of-pharma%E2%80%99s-promotional-efforts/.

[154] *Majority of physicians believe DTC ads should be cut back*, WORLD OF DTC MARKETING.COM (Apr. 30, 2013) , http://worldofdtcmarketing.com/majority-of-physicians-believe-dtc-ads-should-be-cut-back/prescription-drug-dtc-marketing/ (showing that of 104 physicians, 48% somewhat agreed that DTC advertisements misinform patients; 46% somewhat agreed that DTC advertisements overemphasize drug benefits; 56% somewhat agreed that DTC advertisements encourage drug overutilization; and 78% agreed that that DTC advertisements ultimately increases the cost of healthcare).

[155] Thomas Sullivan, *Prescription Drug Sales 2009 – IMS Data*, POL'Y & MEDICINE (Apr. 7, 2010), http://www.policymed.com/2010/04/prescription-drug-sales-2009—-ims-data.html.

[156] William H. Shrank, et al., *State Generic Substitutes Can Lower Drug Outlay Under Medicaid*, HEALTH AFFAIRS (July 2010), http://scholar.harvard.edu/files/nkc/files/2010-generic-substitution-laws-healthaffairs.pdf (detailing how all states have adopted some variation of a generic substitution law).

stigma associated with certain diseases.[157] These findings should encourage industry to increase its presence and investment in interactive promotional media.[158]

In fact, pharmaceutical companies have approximately 200 Twitter feeds, over 150 sponsored or funded YouTube channels, and over 100 Facebook pages,[159] several of which are very successful. The explosion of social media use by pharmaceutical companies has led to some companies creating guidelines for their employees governing what can and cannot be posted online. For example, in 2010, Roche distributed a guidance letter to employees that outlined personal and professional principles for online activities when speaking about Roche.[160] Similarly, AstraZeneca published a white paper that "outlin[es] its guidelines for social media use"[161] and hosted a Twitter chat to raise awareness about its patient prescription program.[162] Manufacturers can also utilize social media to control their image; Eli Lilly has an online presence with a blog, Facebook page, and a Twitter feed, which focus on public policies about pharmaceuticals, as well as a YouTube page that features videos about Eli Lilly's research and philanthropic work.[163]

In 2011, Pfizer Canada posted a flow chart online that instructs companies on how to respond to social media communications.[164] Johnson & Johnson has created an active social presence that utilizes a blog that is supplemented with YouTube and Facebook pages.[165] Manufacturers have also utilized social media for more specific, targeted campaigns that focus on particular illnesses and treatments. For example,

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[157] Majority of physicians believe DTC advertisements should be cut back, *supra* note 154.

[158] *See* Clark Herman, *Companies Trim Social Media Spending, While Platform Priorities Shift*, PharmExec.com (Dec. 4, 2012), http://blog.pharmexec.com/2012/12/04/companies-trim-social-media-spending-while-platform-priorities-shift/ (noting that while social media use among pharmaceutical employees shot up, "29% of companies spent less than 5% of their budgets on social media in 2011 and 50% have spent only that much in 2012; spend in the 5-10% range increased by a mere one percent and declined in the 10% and beyond range by an average of 4.5%").

[159] Mark Senak, *Offshore Tweets and Pharma*, eyeonfda (Feb. 21, 2013), http://www.eyeonfda.com/eye_on_fda/2013/02/offshore-tweets-and-pharma.html.

[160] Roche, Social Media Principles (August 2010), http://www.roche.com/social_media_guidelines.pdf.

[161] AstraZeneca, White Paper: Social Media in the Pharmaceutical Industry, http://www.brandchannel.com/images/papers/522_2011-02_AZ_Social_Media.pdf (last visited Mar. 24, 2014).

[162] AstraZeneca, Healthcare Engagement Strategy 2012 'Open Dialogue' Award #hesawards, http://engagementstrategy.com/articles/astrazeneca-healthcare-engagement-strategy-2012-open-dialogue-award/

[163] Ed Silverman, *Lilly and Social Media*, Pharmalot (Sept. 14, 2012), *available at* http://web.archive.org/web/20120921045628 / http://www.pharmalot.com/2012/09lilly-and-social-media. *See also* Eli Lilly and Co., Facebook, https://www.facebook.com/elilillyandco (last visited Mar. 24, 2014); Newsroom, newsroom.lilly.com, http://newsroom.lilly.com/ (last visited Mar. 24, 2014) (featuring Eli Lilly's three different Twitter accounts, press releases, and a media center); and Lily Health, YouTube, https://www.youtube.com/user/lillyhealth (last visited Mar. 24, 2014).

[164] Jim Edwards, *Pfizer Goes on Facebook Offensive with "Social media Playbook" and Blog Response Flowchart*, CBS News, Jan. 8, 2011, http://www.cbsnews.com/news/pfizer-goes-on-facebook-offensive-with-social-media-playbook-and-blog-response-flowchart/ (indicating how to deal with both congenial commenters and "trolls" who make more inflammatory comments).

[165] Blog, Johnson & Johnson, http://www.jnjbtw.com/ (last visited Mar. 24, 2014).

Boehringer Ingelheim started the "Drive4COPD," a campaign that calls on consumers to get screened for chronic obstructive pulmonary disease (COPD), and uses Twitter, Facebook, YouTube, and Flickr to promote the campaign.[166] Similarly, Novo Nordisk has a Twitter feed, "Race with Insulin," which features IndyCar racer Charlie Kimball, who discusses his experience with diabetes.[167] In addition, UCB, Inc. collaborated with PatientsLikeMe to establish a free online community for people with epilepsy.[168] More recently, Janssen posted what appears to be a branded Facebook advertisement for Axert, a migraine treatment.[169] Finally, Sanofi launched Facebook and Twitter pages for diabetes.[170] On the company's Facebook page, any clinical questions are directed to a separate tab and often answered privately; on the company's Twitter page, medical concerns are addressed via direct message.[171]

While these examples demonstrate promise, manufacturers that decide to use such social media platforms should use caution until the FDA produces more specific guidance regarding the use of interactive promotional media. Such guidance is particularly important given that the FDA recently issued an Untitled Letter notifying Institute Biochimique SA (IBSA) that it's Facebook page for Tirosint was "false and misleading because it ma[de] representations about the efficacy of Tirosint, but fail[ed] to communicate any risk information associated with its use and it omit[ted] material facts."[172] FDA was particularly concerned because Tirosint is associated with a number of serious risks and includes a Boxed Warning, and by failing to "communicate **any** of the risks associated with its use," the "Facebook webpage misleading suggests that Tirosint is safer than has been demonstrated."[173]

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166 Drive4COPD, http://drive4copd.org/ (last visited Mar. 24, 2014).

167 Charlie Kimball, @racewitinsulin, https://twitter.com/racewithinsulin (last visited Mar. 24, 2014); *see also* Deborah Weinstein, *Charlie Kimball talks Novo Racing with insulin*, Medical Marketing & Media (Apr. 16, 2013), http://www.mmm-online.com/charlie-kimball-talks-novo-racing-with-insulin/article/289037/.

168 *UCB and PatientsLikeMe Partner to Give People With Epilepsy a Voice in Advancing Research*, patientslikeme (Jun. 15, 2009), http://www.patientslikeme.com/press/20090615/18-ucb-and-patientslikeme-partner-to-give-people-with-epilepsy-a-voice-in-advancing-research-.

169 Wendy Blackburn, *Pharma's First Branded Facebook Ad?*, ePharma Rx (Oct. 12, 2012), http://blog.intouchsol.com/2012/10/first-branded-pharma-facebook-ad.html.

170 Sanofi US Diabetes, https://www.facebook.com/SanofiUSDiabetes (last visited May 6, 2014); Sanofi Diabetes, http://twitter.com/Diabetes_Sanofi (last visited May 6, 2014)

171 Ben Paynter, *How Sanofi Is Writing The Social Media Rules For Big Pharma Without Running Afoul Of The FDA*, Fast Company (Aug. 20, 2012), http://www.fastcompany.com/3000457/how-sanofi-writing-social-media-rules-big-pharma-without-running-afoul-fda.

172 U.S. Food and Drug Admin., *Warning Letter to Mr. Clarence E. Johns, Ph.D., Institut Biochimique SA*, FDA.gov (Feb. 24, 2014), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM388800.pdf.

173 *Id*. (bold in original).

VI. RECOMMENDATIONS: WHAT CAN WE LEARN FROM FDA'S "FIRST" SOCIAL MEDIA GUIDANCE?

Answering the calls from industry, patients, and Congress, the FDA issued its "first" draft social media guidance in January 2014, entitled "Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" ("Guidance").[174] The Guidance document acknowledges the "unique technological features" and "novel presentation and content features" of "interactive promotional media," which FDA defines to include "modern tools and technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs, social networking sites, online communities, and live podcasts) that firms use to promote their drugs."[175] The Guidance: (1) "describes FDA's current thinking on what the Agency considers to be interactive promotional media"; (2) "outlines the considerations taken into account in determining if product communications using interactive technologies are subject to the FDA's postmarketing submission requirements"; and (3) makes "recommendations for how companies can fulfill the regulatory requirement to submit postmarketing promotional materials to the FDA in a practical manner to address the potential volume of real-time information that is continuously posted and shared through various interactive promotional media platforms."[176]

Specifically, the Guidance states that companies are responsible for submitting post-marketing information if they "own, control, create, influence, or operate" the interactive promotional media platform.[177] The FDA emphasizes that a manufacturer is responsible for promotion both on websites that it owns or controls *and* third-party websites, if the manufacturer or firm "exerts influence over a site in any particular, even if the influence is limited in scope," such as "collaborat[ing] on or ha[ving] editorial, preview, or review privilege over the content provided."[178] Manufacturers are generally "not responsible for [user generated content (UCG)] that is truly independent of the firm (i.e., is not produced by, or on behalf of, or prompted by the firm in any particular)," such as content posted on social media sites by third-parties or individual users.[179]

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[174] U.S. Food and Drug Admin., *Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, FDA.gov (Jan. 2014), www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf [hereinafter FDA Post-Marketing Interactive Promotional Media Guidance].

[175] *Id.*

[176] *Id.* at 1.

[177] *Id.* at 3-4. This would include product websites, discussion boards, chat rooms, or other public electronic forums that a firm uses to promote its products, which the firm maintains, and over which it has full control. The FDA further explained that manufacturers would be responsible for product promotional communications if the manufacturers exert influence over a website in "any particular, even if the influence is limited in scope," such as content collaboration, "preview, or review privilege over the content." *Id*.

[178] *Id*.

[179] *Id.* at 5 (citing 47 U.S.C. § 230(c)(1) (2012)) ("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"). The Communications Decency Act further defines "information

The FDA also explained that manufacturers are responsible for content generated by an employee or agent who is acting on behalf of the manufacturer to promote the manufacturer's product.[180] The remainder of the Guidance explains the frequency with which firms must submit promotional materials generated on interactive promotional media platforms.[181]

While the Guidance focuses on post-market submission requirements, the FDA's general approach to interactive promotional media may be instructive to industry and stakeholders that are trying to address concerns such as: (1) the reporting of adverse events; (2) the use of links; (3) required financial or employee disclosures (e.g., transparency); (4) the ability to comment or correct independent third-party misinformation about drugs or devices; and (5) the presentation of risk and benefit information in light of the space limitations and visual appearance of interactive promotional media platforms. Given that the FDA has already announced plans to publish three additional guidance documents on interactive promotional media this year, there are several factors that FDA and industry should consider.[182]

A. The Use of Links & Risk Information

The FDA should formally permit companies to use the "one-click away" rule. The "one-click away" rule is consistent with FDA's approach to DTC television advertisements, which direct viewers to look for full prescribing and risk information either on the internet or in a print advertisement due to the lack of time and/or space in the television advertisement. Adopting this rule would satisfy concerns previously expressed by the FDA because the nature and use of hyperlinks on the internet makes it more likely that consumers would click on the hyperlink enabling them to view the risk information. In drafting this guidance, the FDA should consider the FTC's recently released guidance on ".com Disclosures." For example, the FDA should consider allowing the use of hyperlinks when disclosure in a space-constrained advertisement is not possible. Under these circumstances, the FDA could recommend (consistent with the FTC's guidance): (1) making the link obvious; (2) labeling the hyperlink appropriately to convey the importance, nature, and relevance of the information it leads to; (3) using consistent hyperlink styles; (4) placing the hyperlink *as close as possible* to the relevant information it qualifies and making it noticeable; (5) taking consumers directly to the disclosure on the click-through page; and (6) assessing the effectiveness of the hyperlink

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content provider" as someone "responsible, in whole or in part, for the creation or development of information provided through the Internet or any other interactive computer service." 47 U.S.C. § 230(f)(3) (2012).

[180] FDA Post-Marketing Interactive Promotional Media Guidance, *supra* note 174.

[181] *Id*.

[182] U.S. Food and Drug Admin., *Guidance Agenda: New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2014*, FDA.gov (Jan. 31, 2014), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM314767.pdf. These include: (1) Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices; (2) Internet/Social Media Platforms: Correcting Independent-Third Party Misinformation About Prescription Drugs and Medical Devices; and (3) Internet/Social Media Advertising and Promotional Labeling of Prescription Drugs and Medical Devices – Use of Links. *Id.*

by monitoring click-through rates.[183] The FDA could also monitor websites and social media to ensure that risk information truly was only one-click away and that a hyperlink actually takes consumers to a website or information that the FDA has actually reviewed and approved (e.g., labeling or PI).[184]

The FDA's guidance should also address the use of "rollover and scrolling functions" that can "enable direct connections to safety and efficacy information," when using social media tools with limited space.[185] The FDA could recommend that advertisements, which require "scrolling" to find required risk disclosure information, include text or visual cues to encourage consumers to scroll to view the disclosed information.[186] Moreover, the FDA could allow companies to use "mouse-overs" on computers to display required disclosures such as risk information, as long as the "mouse-overs" otherwise complied with the FDA's guidance on displaying risk information. Conversely, manufacturers may want to avoid scrolling or "mouse-overs" on mobile devices since use of such mechanisms on these platforms may prevent fair and balanced presentations of information. Manufacturers should also consider working with mobile medical application developers to address these issues early in the design and testing process to prevent any unnecessary updates or modifications once the application has launched, which may be costly or interrupt user functionality. For example, mobile applications that display promotional advertisements could be designed to prominently display links to risk information on all necessary screens.

Manufacturers should also consider factors unique to different platforms. For example, Twitter can inform many people quickly about drug approvals or the release of new data at a scientific meeting. Companies may also use unbranded tweets to allow linking to other branded sites. Tweets about drugs that do not carry a boxed warning, may use a BRAND (generic) name and "include other links directly to the brand site or other information mentioned in the Tweet;" the FDA may treat such tweets as reminder advertisements. [187] When the tweet is used to communicate about a drug with a "boxed warning, the tweet should include a URL that navigates directly to display the full PI; . . . format of the URL to the PI is important."[188] This page that is navigated to by the URL can contain "other fixed links to the brand website or other related information."[189] The use of claims in a tweet, however, is "problematic because the safety information cannot display completely with the 140-character limit."[190] Because the FDA does not consider linking to such information sufficient, the FDA regulations require that all risk information appear on the face of the sponsored link. One option that companies may pursue is "Deck.ly," a new technology that allows for the creation of tweets that

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183 FTC Online Guidance, *supra* note 94.

184 *Id*.

185 Liu, *supra* note 122 (citing 2009 FDA Internet and Social Media Hearing).

186 FTC Online Guidance, *supra* note 94, at ii. For example, "see below for important information"; but not "details below" because it provides "no indication about the subject matter or importance of the information that consumers will find and are not adequate cues." *Id*. at 9.

187 Stults, *supra* note 144, at 27.

188 *Id*.

189 *Id*.

190 *Id*.

are much longer than 140 character posts that were traditionally allowed on Twitter.[191] Interestingly, OPDP Director, Tom Abrams said that companies should be able to promote their drugs "using a space limited venue, such as 140 characters."[192]

Because FDA also regulates pre-approval promotion, tweets describing new data, either for a marketed drug's investigational use or for an investigational drug, "should not state any specific investigational uses or potential indications or include any claims of safety or efficacy."[193] Manufactures may "'disseminate[e] . . . scientific findings in scientific or lay media' without engaging in promotional activity, but promotional claims of safety or effectiveness for a use for which the product is under investigation are subject to FDA regulation as advertising or labeling."[194] When not using the product name for the drug, the tweet may include the manufacturer name, data presented, and the study phase.[195]

The use of social bookmarking and sharing widgets pose different challenges for companies. When the "share" button is selected, a display of the widgets for bookmarking or sharing is provided for the user to select from and there is an option for email. Once a user selects share, content is passed from the original website and posted on a social sharing site. If a user posts branded promotional content without any modification, the content reflects what was reviewed and approved on the original website, thus attaching the manufacturer to the message.[196] Users, however, can edit content and post the content on a social sharing site. As a result, companies should consider establishing separation between what is manufacturer sponsored and what is not. If the manufacturer "does not create, control, maintain or participate in content on the social sharing site or someone's social media page,"[197] the FDA may consider there to be enough separation. Thus, companies may benefit from deciding whether users can edit material, and if so, opt to permit posting of edits only after the manufacturer has reviewed the edited content.

Manufacturers should also consider paying close attention to comments added to company sponsored or supported websites by individual users of those sites due to the various differences from site-to-site. For example, "YouTube allows disabling the commenting feature, so a company can post a video without allowing comments" and Google added a "Safe Watch" feature, which allows channel owners with ten or more videos to control what videos show up on the watch pages of YouTube.[198] It is also possible to "disable video embedding to limit the use of company videos outside of

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[191] John Mack, *Breaking the 140-character Limit of Twitter Opens the Door to FDA-Compliant Branded Tweets*, Pharma Marketing Blog (Feb. 11, 2011), http://pharmamkting.blogspot.com/2011/02/breaking-140-character-limit-of-twitter.html.

[192] Rachel Slajda, *FDA to Help Drugmakers Take to Twitter, Official Says*, Law360, http://www.law360.com/articles/432841/fda-to-help-drugmakers-take-to-twitter-official-says (last visited March 24, 2014).

[193] Stults, *supra* note 144, at 27.

[194] FDA Help-Seeking Guidance, *supra* note 12, at 3 (citing 21 CFR § 312.7(a) (2013)).

[195] Stults, *supra* note 144, at 27.

[196] *Id*.

[197] *Id*.

[198] *Id*.

the company's more controlled YouTube environments."[199] Google recently created the YouTube One Channel to give users a more friendly and flexible template.[200] The channel still allows companies to "turn off comments, and their content, while shareable, could be set to play only on YouTube" to prevent a video from playing on someone's Facebook feed "where companies could not necessarily monitor or respond to comments, but might be held to adverse events reporting requirements."[201]

Facebook's official policy indicates that it will no longer grant companies the ability to disable comments on wall posts, photos, and videos, unless the company's Facebook page is a branded page "solely dedicated to a prescription drug;" companies, however, are still able to control the creation of original content or posts.[202] In response to these changes, some companies shut down their Facebook pages.[203] Other companies screen for and remove improper comments, but this creates additional responsibilities and costs associated with training personnel to screen for and remove such comments.[204] Companies should consider disclosing policies or "terms of use" that govern their interactive social media platforms, specifically accounting for the nuances and differences noted above, which some companies are already doing.[205] Such policies should be clear as to what UGC can consist of, which type of topics and language are permissible and prohibited (e.g., off-label uses), and how the manufacturer will pre-screen and remove content. Such policies may assist manufacturers in addressing third-party misinformation, as discussed below.

B. Correcting Independent-Third Party Misinformation

The FDA should consider allowing companies to have broad latitude in taking a proactive approach—wholly at their discretion—to correcting misinformation about their products that appears in interactive promotional media, including with respect

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199 *Id*.

200 Matthew Arnold, *YouTube's Channels reboot gives pharmas pause*, Medical Marketing & Media (Mar. 26, 2013), http://www.mmm-online.com/youtubes-channels-reboot-gives-pharmas-pause/article/286156/.

201 *Id*.

202 Jim Dayton, *How Facebook's new comment policy impacts your pharma Facebook page*, Insights (May 19, 2011), https://www.intouchsol.com/Blog/how-facebooks-new-comment-policy-impacts-your-pharma-facebook-page.

203 Stephen Richer, *Facebook and FDA Put Drug Companies in Catch-22 Situation on Social Media*, WLF Legal Pulse (Aug. 17, 2011), http://wlflegalpulse.com/2011/08/17/facebook-and-fda-put-drug-companies-in-catch-22-situation-on-social-media/ (noting that Johnson & Johnson closed four pages and AstraZeneca closed one page).

204 Christian Torres, *Drug companies lose protections on Facebook, some decide to close pages*, Wash. Post, Aug. 12, 2011, http://www.washingtonpost.com/national/health-science/pharmaceutical-companies-lose-protections-on-facebook-decide-to-close-pages/2011/07/22/gIQATQGFBJ_story.html.

205 *See e.g.*, Pfizer "Comment Missing?, Facebook, https://www.facebook.com/Pfizer/app_103822229704881 (last visited March 24, 2014); Sanofi US "Rules of Engagement", Facebook, https://www.facebook.com/sanofiUS/app_232554210116120 (last visited Mar. 24, 2014); Merck "Commenting Guidelines," Facebook, https://www.facebook.com/MerckBeWell/app_165561146901142 (last visited Mar. 24, 2014).

to third-party interactive media that they do not control or influence.[206] The FDA's revised and future guidance, therefore, should include recommendations for industry and stakeholders on how to correct such misinformation in a compliant manner, with realistic requirements for disclosures and balance appropriate for the space and other limitations of such media. In such guidance, FDA should also explain acceptable ways, using examples,[207] that manufacturers can correct misinformation without triggering full requirements applicable to promotional materials (e.g., postmark submission). For example, an exemption from promotional labeling requirements could be established if: (1) language used to correct third-party misinformation remains consistent with the product's PI; (2) addresses the specific misinformation only; (3) provides a link to the approved labeling, if possible; and (4) is reviewed by an appropriate internal compliance process before posting. FDA could request additional information if necessary and monitor corrective statements through general surveillance or recordkeeping requirements. Alternatively, FDA could ask companies to certify annually that they are correcting third-party misinformation in compliance with FDA's future guidance.

C. Transparency & Disclosure

Manufacturers that post promotional content or corrective information on interactive promotional media should be transparent and make full disclosure about the relationship of the author to the manufacturer, to promote trust with consumers and reduce confusion about the source of the information. Transparency is critical for establishing an online community where members feel comfortable sharing information and learning from each other.[208] Consistent with the FDA's first Guidance, manufacturers should clearly identify UGC and communications of its employees or third-parties acting on behalf of the manufacturer. The FDA stated that such disclosure could be achieved by including a manufacturer's identifier (e.g., name or logo) as part of the communication. However, in future guidance, the FDA should provide greater clarity and/or additional examples regarding the identification issue. For instance, on Facebook, Twitter, LinkedIn, or other social media platforms, users have profiles that may indicate their place of employment (e.g., "Social Media Manager, Company XYZ"). Thus, the FDA should clarify whether communications in these platforms require any further disclosure. Similarly, in blogs, chat rooms, or other forums where users may not have profiles or are anonymous, the FDA should clarify whether the use of a disclaimer (e.g., "I am an employee at Company X …") in posts is sufficient. The FDA should also clarify how prominent disclosures

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[206] 2009 FDA Internet and Social Media Hearing, *supra* note 86, at 64, 90, 407 (Nov. 12, 2009) (featuring Rohit Bhargava, Senior Vice President, Ogilvy 360 Digital Influence; John Mack, Publisher, Pharma Marketing News; and Maureen Miller, Account Supervisor & Social Media Lead, Compass Healthcare Communications).

[207] For example, if manufacturers should: (1) use large or bolded font, (e.g., **NEW or CORRECTION**); (2) include the date next to the corrected information and/or reference to the date of the misinformation; (3) include a hyperlink to the misinformation; (4) place the correction on a main webpage or directly where the misinformation was posted (e.g., subpage, Facebook comment); (5) give notice to all users of the interactive platform or only those users in the particular forum, blog or chat room; and (6) email or message users directly with corrected information (e.g., "Dear Consumer" letters).

[208] *State of Social Media and Healthcare*, WorldofDTCMarketing.com, http://worldofdtcmarketing.com/social-media-healthcare/ (last visited Mar. 24, 2014).

should be (e.g., larger text, bold, at the beginning of the content, etc.) and where they should be place within an interactive platform. Disclosure is important not only to promote trust with consumers, but also to minimize the appearance of impropriety or creation of misleading impressions.

Transparency and disclosure are also important on interactive promotional media because the FDA clarified in its first Interactive Promotional Media Guidance that the FDA regulates product promotion "conducted on [a] firm's behalf," and that companies are responsible for UGC and communications of its employees, agents, or anyone "who is acting on behalf of the firm to promote the firm's product."[209] The FDA explained that a manufacturer is responsible for content such as "comments on a third-party site about the firm's product" that were written by a manufacturer's "medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf."[210] Likewise, the FDA explained that a manufacturer is responsible for the content on a blogger's site "if the blogger is acting on behalf of the firm."[211] Thus, to the extent manufacturers allow employees, consultants, or agents to create corrective statements or UGC on the manufacturer's behalf, they should require such individuals to disclosure the relationship of the author to the manufacturer.

Manufacturers and/or their corporate executives may also implicate the FDA promotional regulations by using interactive promotional media. For example, the FDA recently sent a Warning Letter to Aegerion Pharmaceuticals, Inc., based on comments their chief executive officer (CEO) had made on the CNBC television show "Fast Money" suggesting that Aegerion's drug, Juxtapid could be used effectively for unapproved indications.[212] Prior to this instance, the former CEO of InterMune was investigated and convicted of wire fraud for the creation and dissemination of a press release that contained false and misleading information about the efficacy of Actimmune.[213] Corporate executive use of interactive promotional media could also implicate Regulation Fair Disclosure (RegFD), which requires "that whenever a company, or a person acting on its behalf, discloses material, nonpublic information to analysts, investment professionals or company stockholders, the company must make that information simultaneously

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209 FDA Post-Marketing Interactive Promotional Media Guidance, *supra* note 174, at 4.

210 *Id*.

211 *Id*.

212 U.S. Food and Drug Admin., *Letter from Robert Dean, Div. Dir., FDA, to Marc Beer, Chief Exec. Officer, Aegerion Pharms. Inc.*, FDA.gov (Nov. 8, 2013), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm374338.pdf.

213 *See* U.S. Dep't of Justice, *Former InterMune Ceo Sentenced for False & Misleading Statements Related to Pulmonary Fibrosis Drug's Clinical Tests* (Apr. 14, 2011), http://www.justice.gov/opa/pr/2011/April/11-civ-475.html. The headline of the press release read, "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," with the subheading "Reduces Mortality by 70% in Patients With Mild to Moderate Disease." *Id.* Department of Justice (DOJ) said that a specialty pharmacy then distributed the misleading information in the press release to more than 2,000 pulmonologists and to patients taking Actimmune. *See* U.S. Dep't of Justice, *Former Intermune CEO W. Scott Harkonen Indicted for Wire Fraud and FDA Violations* (Mar. 18, 2008), http://www.justice.gov/opa/pr/2008/March/08_civ_217.html.

available through broadly disseminated public disclosure."[214] Consequently, the Securities and Exchange Commission (SEC) could bring an enforcement action against a manufacturer or its executive who uses interactive promotional media to communicate about the success or failure of certain drugs or devices already on the market or in FDA approved clinical trials. Because such information is likely material, the manufacturer could face action unless investors and the markets "have been alerted as to which specific social media outlets would be used to disseminate such key information."[215] As a result, manufacturers should consider updating internal policies, procedures, and training as necessary to outline the requirements that employees (including executives), consultants, or agents must follow if permitted to use interactive promotional media.

Manufacturers may also need to address whether licensed physicians who engage as paid contributors to a particular platform (e.g., blog) or as audience members need to make disclosures about their financial relationships with the manufacturer.[216] For example, a physician may receive funds for research or education from a manufacturer, but also be commenting about the same manufacturer's product or a different product independent from this research or education. Given the increased transparency requirements stemming from the Physician Payments Sunshine Act,[217] manufacturers may need to require that such physicians include disclaimers that they are being compensated for the content or messages they generate or that their comments are not on behalf of the manufacturer, but they may receive compensation from the manufacturer for unrelated services. Lack of disclosure by physicians who contribute to interactive promotional media platforms (e.g., chat rooms or blogs) may result in decreased patient trust, as well as scrutiny from Centers for Medicare and Medicaid Services (CMS), the FDA, and federal or state prosecutors. Such scrutiny may even occur under state consumer protection laws, for a physician or other healthcare professional that fails to disclose their financial interests. These added risks further demonstrate the need to closely monitor manufacturers and corporate executives use of interactive promotional media.

D. Adverse Event Reporting

The FDA should articulate clear standards and guidance that instructs industry and related stakeholders about adverse event[218] reporting obligations in connection with interactive promotional media. Several FDA regulations require companies to report

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214 *Disclosing Corporate Information Via Social Media: After Investigating the CEO of Netflix, the SEC Releases Helpful Guidance*, Arnold & Porter LLP (Apr. 2013), http://www.arnoldporter.com/resources/documents/ADV413DisclosingCorporateInformationViaSocialMedia.pdf.

215 *Id*.

216 Susan D. Hall, *Does lack guidance for disclosing conflicts of interest on social media*, FierceHealthIT (Nov. 13, 2012), http://www.fiercehealthit.com/story/docs-lack-guidance-disclosing-conflicts-interest-social-media/2012-11-13.

217 Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9518 (Feb. 8 2013) (to be codified at 42 C.F.R. pt. 402, 403). In general, the Sunshine Act requires applicable manufacturers to report certain payments they make to physicians to CMS, which in turn will post these payments on a public, searchable database with certain identifying and contextual information.

218 Food and Drug Admin., *What is a Serious Adverse Event?*, FDA.gov (Jan. 10, 2013), http://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm (defining an adverse event as a patient

adverse events associated with drugs to the FDA.[219] Generally, manufacturers must report to the FDA when they "become aware" of a drug, biologic, or medical device adverse event (AE). The source of the adverse event information is generally not determinative of a manufacturer's obligation to report (e.g., physician versus patient or consumer). Hundreds of millions of Americans are creating UGC on firm owned and third-party websites, including information on symptoms, side effects, and other health information. The FDA should carefully balance the need to report safety and risk information with the undue burden on industry associated with constantly monitor this kind of UGC on these platforms. The FDA should permit manufacturers to use a flexible approach for monitoring and reporting AE's on interactive promotional media, and should articulate criteria that manufacturers could use to evaluate whether UGC contains sufficient information for a manufacturer to become "aware" of an AE.

For example, on a monthly or quarterly basis, the FDA could recommend that manufacturers monitor the interactive promotional media they have listed with the FDA or risk information that is contained in the products PI. Manufacturers could incorporate into their monitoring and surveillance for misinformation described above, key terms or phrases that may indicate possible AE's (e.g., hospitalization, emergency room, etc.), which the FDA could provide examples of in future guidance. However, the FDA should not require—at least in terms of AE reporting—manufacturers to monitor or further investigate UGC that may reference commonly known side effects of a product (e.g., nausea, sweating, fever, etc.). While a manufacturer may collect or monitor this information voluntarily for other reasons (e.g., update labeling, learn of effects of drug combinations or interactions), it would be too burdensome for industry to investigate each instance in which a patient is having a side effect that is well known to the FDA and the manufacturer, and does not amount to an AE. To ensure compliance with AE reporting regulations, the FDA could ask manufacturers to initially submit a sample of AE's (e.g., ten percent) that the manufacturer has identified (and reported to the FDA as required by the guidance) for the first month or quarter of each calendar year, rather than requiring the manufacturer to submit *every* suspected AE.[220] Thereafter, the FDA could require companies to certify in their monthly post-marketing submissions that the manufacturer is continuing to monitor and report AE's consistent with their initial submission.

While companies may need to invest significant resources to monitor such reported AE's,[221] companies that follow posts may: (1) help reduce the number of AE's by getting early warnings of potential problems; (2) learn of any unexpected side effects

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experience associated with a drug that can include death, a life-threatening condition, hospitalization (initial or prolonged), disability or permanent damage, or a congenital anomaly or birth defect).

[219] 21 C.F.R. § 310.305 (2013) (NDAs); 21 C.F.R. § 312.32 (2013) (Investigational New Drug Safety Reports); and 21 C.F.R. § 314.80 (2013) (Post-Market).

[220] This could include screenshots of the UGC that the company identified, any response from the company (e.g., "please contact our AE hotline at 1-800-XXX-XXXX"), and a copy of the AE report if the company eventually chose to report it.

[221] *Id*. *See also* Jonathan Richman, *Monitoring Adverse Events in Social Media for Pharma's Biggest Brands: Hopeless Task or Simple Project?*, Dose of Digital (Dec. 8, 2009), http://www.doseofdigital.com/2009/12/monitoring-adverse-events-social-media-pharmas-biggest-brands/.

in any specific populations; (3) get more information on the effects of various drug combinations or interactions; and (4) identify new information to educate physicians. Moreover, using interactive promotional media can expedite the process of capturing post-marketing data, which is critical for determining if a drug's label needs updating or a black box warning, or if the manufacturer should recall the drug. Incorporating this kind of system may build trust with patients and the FDA because it demonstrates a concern for patient safety and a commitment to post-market surveillance. Manufacturers may also want to restrict users from posting or commenting on personally identifiable health information (PHI) or AE's in public forums and should instead create a mechanism within the interactive promotional media platform (or application) for patients to report AE's, similar to FDA's MedWatcher Mobile App.[222] Such measures may help protect patient privacy and avoid the chance that users may request medical advice, including requesting advice from healthcare professionals who may provide content on the interactive platform.

E. Practical Considerations for Industry

The FDA's recent guidance coupled with existing internet and social media campaigns, offer several factors for companies to consider moving forward. When addressing current interactive promotional media platforms as well as proposed new platforms, companies may want to form cross-cutting groups of medical, legal, regulatory, and marketing staff to ensure compliance with the FDA regulations and guidance.[223] When a manufacturer chooses to begin an online or social media presence, they should use a wireframe[224] to understand how the navigation and links for particular environments of website content flow. The website should have a home page that displays certain buttons (e.g., "Indications,") that remain consistent and available throughout the mobile presentation as a user navigates "through the different branded content options" or if the user "decides to share . . . the branded content . . . ."[225] Companies should also optimize their websites for mobile device use to eliminate the need for consumers to scroll right or left and to avoid making consumers zoom in to locate benefit or risk information. All promotional materials should be on-label if branded, and companies should post the full PI on any interactive promotional media for branded content or if the drug has a boxed warning or REMS.[226]

When using websites and interactive promotional media, companies should be careful about having pop-ups, scrolling information, banners, comments, or videos that "causes [the] messages" of a disease awareness or help-seeking advertisement and a reminder advertisement "to be linked together by the audience."[227] Such combined communication—with information about the disease and the name of a drug—could

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222 Food and Drug Admin., *MedWatcher Mobile App*, FDA.gov (Feb. 13. 2014), http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/ucm348271.htm

223 James Chase, *Pharma execs: MLR teams are friendlier on digital*, MMM (Oct. 22, 2012).

224 Stults, *supra* note 144 (explaining that a wireframe is a digital tool that shows a visual structure, function and content description of the website pages, and how the navigation and links flow).

225 *Id*.

226 *Id.*

227 FDA Help Seeking Guidance, *supra* note 12, at 6.

constitute an advertisement that communicates a drug's indication and efficacy, and thus, without the required risk disclosures and other required information, could cause the advertised product to be misbranded.[228] In designing platforms that may have overlapping messages or use different kinds of interactive promotional media, companies should account for perceptual similarities and timing of presentation.[229] However, manufacturers may have more flexibility in using different kinds of online media because a recent FDA study found no evidence that consumer understanding of risk information was effected by the "emotional (affective) tone of visual images or the consistency of the visual images with the risk information on the screen during the major statement."[230] Specifically, the FDA concluded that its Distraction Study showed that "presenting risk information at the same time in text and in audio improves consumers' understanding of the risk information."[231] Despite this flexibility, manufacturers designing interactive promotional media will have to pay close attention to consumers understanding of "composite scores"[232] in DTC advertisements. While the FDA is surveying print advertisements, the Agency noted that such research "[may] apply to any similar medium including static elements of Web sites."[233]

Next, companies should update (or where necessary create) and implement internal policies and procedures regarding the use of social media and the internet for DTC advertisements. Manufacturer policies should outline: (1) the requirements and standards for branded and unbranded social media activity; (2) how employees can interact with company sponsored or created websites as well as third-party websites; (3) who is responsible for monitoring and maintaining such websites; (4) who has the ultimate authority over the website; and (5) potential scenarios when legal counsel should be notified of consumer concerns. Moreover, companies should train employees on all social media-related or internet policies,[234] and set regular reviews to identify weaknesses and areas for new or additional training, particularly given the constant changes and updates to social media platforms and websites. In light of the AMARC letter, this training is particularly important to prevent employees who have control

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228 *Id*. (also applicable to a disease awareness ad combined with a product claim ad or promotional labeling piece).

229 *Id*. Companies should consider similarities in disease awareness communications and reminder or product claim promotions in terms of their themes, such as story lines, colors, logos, tag lines, graphics, etc. *Id*. at 7.

230 Thomas Sullivan, *FDA Distraction Study – Shows No Distractions After All*, Pol'y and Medicine (Feb. 20, 2012), http://www.policymed.com/2012/02/fda-distraction-study-shows-no-distractions-after-all.html.

231 *Id*.

232 Communication Composite Scores in Direct-to-Consumer Advertising, Meeting Notice, 78 Fed. Reg. 28224 (May 14, 2013) (explaining that "[t]he efficacy of a drug is measured by multiple endpoints that are sometimes combined into an overall score called a composite score").

233 *Id*. at 28227.

234 *See e.g.*, Food and Drug Admin., Letter from Michelle Safarik, Regulatory Review Officer, FDA, to Brian Deutsch, Assoc. Regulatory Affairs, Warner Chilcott (US), LLC (May 5, 2011), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm254562.pdf.

over Facebook or related social media platforms from "liking" content not created by the company, which may render it promotional and suggest to the FDA that there is some form of manufacturer control, influence, or further dissemination, even if an independent third-party created the content.

In addition, companies may want to set standard response times for comments or questions posted by users of websites and publicize such information regarding standardized response times. When responding to comments, companies should try to use language that patients can understand to avoid confusion.[235] Internal policies may also want to address: (1) use of rollovers to help define complicated medical terms; (2) use of images of real people, not actors, to tell compelling stories that highlight drug benefits, as long as these stories comply with FDA regulations; (3) use of callouts to highlight key brand messages; and (4) regular update of the website content, especially when there is news on a product or health condition to entice patients to come back to the website.[236]

F. The FDA's Implementation of Interactive Promotional Media Standards

The FDA's future guidance should take into account the various aspects of social media (e.g., type of medium) and the rapid advances and updates that social media technology and platforms undergo. For example, similar to the FDA's regulations and guidance governing current good manufacturing practices (cGMP) for drugs and devices, the FDA should ensure that social media and internet guidance reflect the same "current"[237] status. Specifically, the FDA should establish a streamlined process or mechanism by which the Agency can regularly update interactive promotional media guidance and standards or establish so called "current Good Social Media Practices" (cGSMP).

To accomplish this goal, the FDA could convene an Advisory Committee on Interactive Promotional Media, which could include members from the pharmaceutical and social media industry, the FDA, patients, and consumers. This Committee could meet on a quarterly basis, or more frequently as needed, to address key changes affecting interactive promotional media and meetings would be open to the public. The Committee could also propose specific topics for the FDA to research regarding interactive promotional media to determine its affect on consumers. For example, the FDA could study the effectiveness of conveying drug risk information through hyperlinks. The Committee could make recommendations to OPDP, such as those listed above, that the FDA could adopt after public notice and comment, unless OCC or the FDA's Office of the Commissioner objects or a Citizen's Petition[238] is filed. The FDA could publish the new changes immediately on its website and social media platforms, as well as in the Federal

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235 Amy Norton, *Web info on prostate cancer tough to understand*, Reuters (Oct. 25, 2012), http://www.reuters.com/article/2012/10/25/us-prostate-cancer-idUSBRE89O1G620121025.

236 Richard Meyer, *Why Branded Websites Are So Important to Pharma*, WorldofDTCMarketing.com (Nov. 9, 2012), http://worldofdtcmarketing.com/why-branded-websites-are-so-important-to-pharma/prescription-drug-dtc-marketing/.

237 *See* Food and Drug Admin., *Facts About Current Good Manufacturing Practices (cGMPs)*, FDA.gov (May 2, 2013), http://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm. The "c" in cGMP stands for "current." *Id.*

238 *See* 21 C.F.R. § 10.30 (2013).

Register. The FDA could also create a list-serve for stakeholders to register and receive notification of these types of updates and changes.

This process could appease potential concerns from industry or consumers because groups would have several mechanisms to participate in the process to update social media and internet guidance and standards. If the FDA is unable to create this Committee, due to regulatory hurdles, Congress could authorize its creation by statute in the next User Fee Act negotiations[239] or through separate user fees for interactive promotional ideas, which Congress considered doing in the past. Companies may now be willing to pay user fees given the significant demand for clarity in using interactive promotional media, the fear of enforcement, the tremendous potential such tools have for public health and marketing, and the negative effects that accompany a continued lack of companies presence online.

VII. CONCLUSION

With social media guidance amongst "the highest of FDA's priorities,"[240] companies must begin to prepare their advertising and marketing departments accordingly, particularly with the FDA's first Guidance, and three more on the horizon in 2014. This includes forming employee teams comprised of individuals with regulatory, marketing, legal, and medical experience to help the company navigate the current regulatory environment and learn how to market their products to consumers using interactive promotional media. Given the rapid increase in social media users, the benefits associated with company use of such platforms likely outweigh the risks and regulatory hurdles discussed in this article.

While there may be legal or regulatory consequences, "[t]he monetary costs of gaining access to social media are negligible, whereas the benefits associated with its use—increased brand awareness, greater market reach, quicker and more comprehensive feedback—are endless."[241] Furthermore, continuing to delay social media use may only harm patients further because companies will be unable to fight the continued rise of third-party misinformation.[242] In addition, social media allows companies to grow new markets, "gain insight about new products, develop more targeted marketing practices,"[243] and better understand how factors such as drug availability, packaging, and pricing could be affecting usage patterns. Understanding the regulatory landscape of interactive promotional media will also be critical for companies to gain access to patients using mobile medical applications by sending effective patient educational information through general health and wellness applications, as well as those applications designed for medication adherence and drug-interaction warnings. Until

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239 *See* Food and Drug Admin., *User Fees*, FDA.gov (Jan. 10, 2014), http://www.fda.gov/ForIndustry/UserFees/default.htm.

240 Slajda, *supra* note 192.

241 Liu, *supra* note 122.

242 Brian Reid, *The 5 Consequences of the Lack of FDA Social Media Guidance*, Common Sense (Dec. 8, 2011), http://blog.wcgworld.com/2011/12/the-5-consequences-of-the-lack-of-fda-social-media-guidance.

243 *Id*.

the FDA finalizes guidance on the use of links and character space limitations on such applications, however, much uncertainty remains in this area.

Because many patients use interactive promotional media to share and obtain information about drugs, the FDA's future guidance should enable companies to use these platforms in ways that can advance public health by disseminating reliable and accurate information about their products, without imposing undue regulatory burdens and requirements that infringe upon First Amendment rights. Ultimately, ensuring that patients and consumers can receive benefit and risk information about specific treatments and other disease information through interactive promotional media will accomplish the FDA's goals and purpose as a public health agency by informing patients and enhancing their health and safety.

A Business Case for Universal Healthcare: Improving Economic Growth and Reducing Unemployment by Providing Access for All

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METHODOLOGY

Many of this report's conclusions revolve around comparisons between the levels of success of the United States economy with those of other countries, juxtaposed with whether those other countries have government-supervised systems to ensure universal access to healthcare.

Although many people equate the term "single-payer" with universal healthcare systems, this report uses the term "government-directed universal care" to signify countries that have systems in place to ensure affordable access to care for all. This distinction exists because some universal healthcare systems are not technically single-payer systems.

Technically, a single-payer system is one in which a single government entity collects money to pay for healthcare and pays the bill. Systems in Canada and the United Kingdom are often deemed "single-payer," although they differ in the significant respect that the Canadian system involves provincial governments reimbursing private-sector providers, whereas providers in the United Kingdom are employees of the government.[1]

France, Germany, and Japan employ government-directed systems in which residents and employees must pay into healthcare funds, which are typically highly regulated non-profit organizations.[2] The funds, which essentially act as insurance companies, pay providers for care rendered.[3] Because of their provisions to cover the unemployed and their success at achieving virtually universal access to care, these systems are sometimes referred to colloquially as "single-payer," although they are technically multi-payer.

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policy. She is particularly interested in food and drug law, and will be pursuing a career in that field. Ashley is on the editorial board of the Administrative Law Review and is an articles editor for the *Health Law & Policy Brief*.

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[1] In reality, neither Canada nor the United Kingdom truly have single-payer systems because residents of both of those countries make significant out-of-pocket payments, such as to purchase private insurance to gain access to additional benefits. *See* Sean Boyle, European Observatory on Health Sys. and Policies, United Kingdom (England): Health System Review 2011 96 (2011), *available at* http://www.euro.who.int/__data/assets/pdf_file/0004/135148/e94836.pdf (explaining that sometimes patients must make direct payments for services that National Health Service does not cover or make co-payments); *see also* Sarah Kliff, *Everything You Ever Wanted to Know About Canadian Health Care in One Post*, Wash. Post, (July 1, 2012, 4:37 AM), http://www.washingtonpost.com/blogs/wonkblog/wp/2012/07/01/everything-you-ever-wanted-to-know-about-canadian-health-care-in-one-post/ (asserting that while thirty percent of healthcare spending comes from private sources, a large portion of Canadian spending on dental care came from either employer-sponsored plans).

[2] *See* Naoki Ikegami, *Japanese Health Care: Low Cost Through Regulated Fees*, 10 Health Affairs 93 (1991); Anne Underwood, *Health Care Abroad: Germany*, N.Y. Times, Sept. 29, 2009, http://prescriptions.blogs.nytimes.com/2009/09/29/health-care-abroad-germany/?_php=true&_type=blogs&_r=0; Joseph Shapiro, *Health Care Lessons From France*, Nat' Pub. Radio (July 11, 2008, 1:41 AM), http://www.npr.org/templates/story/story.php?storyId=92419273.

[3] *See* Underwood, *supra* note 2.

The purpose of this report is to compare the economic performance of the United States with that of countries with government-directed systems to ensure universal access to care.

INTRODUCTION

Much of the controversy over our nation's healthcare policy is rooted in a widely perceived tradeoff between improving access to care or nurturing the economy. Some conservative economists argue that a government-directed program to provide healthcare to all Americans would reduce economic growth, possibly even leading to a decrease in access to healthcare itself.[4] Conversely, others argue that treating healthcare as a fundamental human right might willingly sacrifice some economic growth in exchange for the security and social value of ensuring that everyone has access to affordable healthcare.[5] This report will show that the perceived tradeoff between prosperity and universal access to care is a false choice. A survey of other countries' healthcare systems compared with their relative levels of economic vitality suggests that providing universal care is more likely to foster economic growth than inhibit it.

The need to reform the United States healthcare system is beyond dispute. We spend more than two-and-one-half times more per capita ($8,508) than the average amount spent ($3,322) by the thirty-four countries in the Organization for Economic Cooperation and Development ("OECD").[6] However, life expectancy, which is arguably the most important healthcare indicator, is almost one-and-one-half years lower in the United States (78.7 years) than the OECD average (80.1).[7] Despite the extraordinary spending in the United States, about forty-eight million Americans lack health insurance, diminishing their access to necessary care and jeopardizing their financial security.[8] Medical bills are the greatest cause of bankruptcy in the United States.[9] Furthermore, a 2010 study published in the *New England Journal of Medicine* ranked the United States just thirty-seventh in the world on an index of global health systems.[10]

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[4] Zachary A. Goldfarb and Amy Goldstein, *Health-care Law will Prompt Over 2 Million to Quit Jobs or Cut Hours, a CBO Report Says*, Wash. Post, Feb. 4, 2014, http://www.washingtonpost.com/business/economy/cbo-botched-health-care-law-rollout-will-reduce-signups-by-1-million-people/2014/02/04/c78577d0-8dac-11e3-98ab-fe5228217bd1_story.html.

[5] *Id.*

[6] Office of the Sec'y-Gen., Org. for Econ. Co-operation and Dev., Health At A Glance 2013: OECD Indicators 155 (Nov. 21, 2013), *available at* http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf.

[7] *Id.* at 25.

[8] *See* Robert Pear, *Percentage of Americans Lacking Health Coverage Falls Again*, N.Y. Times, Sept. 17, 2013, http://www.nytimes.com/2013/09/18/us/percentage-of-americans-lacking-health-coverage-falls-again.html?_r=2&.& (providing that while the proportion of people who have private health insurance declined, the proportion of people with government coverage increased).

[9] *See, e.g.*, Dan Mangan, *Medical Bills Are the Biggest Cause of US Bankruptcies: Study*, CNBC (June 25, 2013), http://www.cnbc.com/id/100840148 (claiming that healthcare coverage does not ensure financial hardship).

[10] Christopher J.L. Murray & Julio Frenk, *Ranking 37th—Measuring the Performance of the U.S. Health Care System*, 362 N. Eng. J. Med. 98, 98 (2010).

This report does not expound further on these generally accepted findings about the shortcomings of the United States system. Instead, the aim of this report is to debunk the perception that instituting a government-directed—or, colloquially, "single payer"—system to provide universal access to care would be harmful to the United States economy.

This report will illustrate that the United States economy is currently hampered in numerous ways by having an inefficient, inequitable healthcare system.[11] The research on which we relied was completed before the full implementation of the Patient Protection and Affordable Care Act (ACA). However, we expect that even if the law works as intended, it will not resolve the problems that we raise because the law largely preserves our employment-based healthcare system.[12] In Part I, we discuss specific harms to the economy inflicted by our system's reliance on employers to provide healthcare benefits.[13] Part II examines how the United States economy compares through the lens of several indices, including some published by conservatives.[14] These comparisons illustrate that most countries with more vibrant economies than the United States have government-directed, universal healthcare systems.[15]

I. THE NEGATIVE EFFECTS OF NON-PORTABLE HEALTH INSURANCE ON ECONOMIC GROWTH AND UNEMPLOYMENT

A. 'Job Lock' Reduces Economic Growth

Unlike people who live in other industrialized countries, most Americans rely on employer-sponsored health insurance for access to medical services.[16] Our system is a historical accident that resulted from World War II economic controls.[17] To dodge government-imposed wage controls, businesses began offering health insurance and other fringe benefits to attract workers.[18] The federal government made this system permanent in 1943 by making employer-sponsored healthcare a tax-free benefit.[19]

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[11] Arnold S. Relman, *For-Profit Health Care: Expensive, Inefficient and Inequitable*, Physicians for a Nat'l Health Program (Feb. 21, 2002), http://www.pnhp.org/news/2002/february/for-profit-health-care-expensive-inefficient-and-inequitable.

[12] Elizabeth Hagen, *Job-Based Health Coverage and the Affordable Care Act: Why the Law Won't Cause Employers to Drop Coverage*, Families USA (May 2013), http://familiesusa.org/product/job-based-health-coverage-and-affordable-care-act-why-law-wont-cause-employers-drop-coverage.

[13] Henry R. Hyatt & James R. Spletzer, U.S. Census Bureau, U.S. Dep't of Commerce, The Recent Decline in Employment Dynamics 1 (Feb. 14 2013), *available at* http://www.frbatlanta.org/documents/research/seminars/seminar_spletzer_021913.pdf.

[14] *See e.g.*, Neeraj Sood, Arkadipta Ghosh, & José J. Escarce, *Employer-Sponsored Insurance, Health Care Cost Growth, and the Economic Performance of U.S. Industries*, 44 Hsr: Health Serv. Research 1449 (2009).

[15] *Id.*

[16] Hubert Janicki, U.S. Census Bureau, U.S. Dep't of Commerce, Employment-Based Health Insurance: 2010 1 (2013), *available at* http://www.census.gov/prod/2013pubs/p70-134.pdf.

[17] *See* Alex Blumberg & Adam Davidson, *Accidents Of History Created U.S. Health System*, Nat'l Pub. Radio (Oct. 22, 2009), http://www.npr.org/templates/story/story.php?storyId=114045132 (attributing the inadvertent spread of employer-based health insurance to the Great Depression).

[18] *Id.*

[19] *Id.*

Fifty-five percent of all Americans, and more than sixty-eight percent of working-age Americans—those ages eighteen to sixty-five—rely on employer-based insurance for access to healthcare.[20] Although the United States has health insurance programs for the very poor (Medicaid) and those sixty-five and older (Medicare), there is no reliable, reasonably affordable means for Americans who lack access to government programs or employer-based insurance to obtain access to healthcare. Some would argue that the health insurance exchanges being created under the ACA will meet this need, but costs to obtain insurance through the new exchanges, especially for older people, will likely put this solution out of reach for many.[21]

Our employer-reliant system has caused health insurance to become an overriding consideration in Americans' career decisions.[22] This phenomenon has resulted in lower "employment dynamics," which are "the rate at which workers and businesses exchange jobs."[23] An employee's unwillingness to change jobs for fear of losing health insurance benefits is known as "job lock."[24] Job lock inhibits workers from gravitating to the jobs most suited to them or pursuing entrepreneurial endeavors. Likewise, it frustrates employers' ability to find and hire the best potential employees.[25] Studies have found that job lock reduces mobility by 22.5 percent,[26] makes employees sixty percent less likely to leave their jobs,[27] and decreases the rate of self-employment by two-to-four percent.[28]

A system that provides universal access to health coverage, on the other hand, is "far more likely to promote entrepreneurship than one in which would-be innovators remain tied to corporate cubicles for fear of losing their family's access to affordable healthcare," wrote Jonathan Gruber, who was one of the chief architects of the healthcare reform law

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[20] Janicki, *supra* note 16, at 1.

[21] *See* Robert Pear, *On Health Exchanges, Premiums May be Low, but Other Costs Can Be High*, N.Y. Times, Dec. 9, 2013, http://www.nytimes.com/2013/12/09/us/on-health-exchanges-premiums-may-be-low-but-other-costs-can-be-high.html?pagewanted=all.

[22] Scott J. Adams, *Employer-Provided Health Insurance and Job Change*, 22 Contemp. Eco. Pol'y 357, 358 (2004).

[23] *See* Henry R. Hyatt & James R. Spletzer, U.S. Census Bureau, U.S. Dep't of Commerce, The Recent Decline in Employment Dynamics 1 (Feb. 14 2013), *available at* http://www.frbatlanta.org/documents/research/seminars/seminar_spletzer_021913.pdf (citing a decline in job-to-job flows from forty-seven to fifty-three percent).

[24] *See* Alan C. Monheit & Philip F. Cooper, *Health Insurance and Job Mobility: Theory and Evidence*, 48 Indus. & Lab. Rel. Rev. 68 (1994) (asserting that job lock can have far-reaching economic implications because such lack of mobility "can eliminate potential gains in productivity and income, adversely affect worker satisfaction, and alter the volume and quality of goods and services produced").

[25] *See* Alan C. Monheit & Philip F. Cooper, *Health Insurance and Job Mobility: Theory and Evidence*, 48 Indus. & Lab. Rel. Rev. 68 (1994).

[26] Scott J. Adams, *Employer-Provided Health Insurance and Job Change*, 22 Contemp. Eco. Pol'y 357, 366 (2004).

[27] Inas Rashad and Eric Sarpong, *Employer-provided Health Insurance and the Incidence of Job Lock: A Literature Review and Empirical Test*, 8 Expert Rev. of Pharmacoeconomics and Outcomes Research 583, 583 (2008).

[28] Alison J. Wellington, *Health Insurance Coverage and Entrepreneurship*, 19 Contemp. Econ. Pol'y 465, 477 (2001).

passed in Massachusetts in 2005 and whose work greatly influenced the structure of the ACA.[29] It is estimated that 1.6 million small business workers suffer from job lock and that providing universal healthcare coverage would bring that number close to zero.[30] In addition, instituting a system to ensure universal coverage would add 1.5 million entrepreneurs,[31] which would significantly increase our gross domestic product (GDP), according to a study by the Kauffman Foundation.[32]

The Kauffman Foundation study goes further to explain how eliminating job lock benefits the economy on a micro-level. Through the process of new and expanding businesses replacing the market share of established companies and the ongoing efforts of businesses and workers seeking their most productive matches, entrepreneurs create new products, which allows employees to accomplish more tasks in less time and ultimately creates more jobs.[33] This increased activity is associated with higher economic growth.[34] By enabling workers to do the type of work that they do best and enjoy the most, eliminating job lock increases the GDP.

B. 'Job Lock' Drives Up Unemployment, Reducing the Number of Potential Customers for Businesses

A 2009 study by researchers at the Rand Corporation shows a link between the healthcare system in the United States and unemployment levels.[35] The study examined the effects of "excess healthcare costs," which the study defined as the difference between the inflation rate for healthcare services and the increase of the GDP of the United States.[36] For example, if the rate of medical inflation were five percent and the rate of GDP growth were three percent, "excess healthcare costs" would be calculated as equaling two percent.

By looking at the experience of close to seventy million workers in thirty-eight industries over nineteen years, the researchers measured the impact of rates of growth of healthcare costs in certain industries and extrapolated that data across the United States economy.[37] The average excess healthcare costs over the period in which the Rand study

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[29] Jonathan Gruber, *A Shot in the Arm*, Wash. Monthly (May-June 2009), http://www.washingtonmonthly.com/features/2009/0905.gruber.html.

[30] Small Bus. Majority, The Economic Impact of Health Care Reform on Small Business 17 (2009), *available at* http://www.smallbusinessmajority.org/pdfs/SBM-economic_impact_061009.pdf.

[31] Linda Blumberg et al., The Affordable Care Act: Improving Incentives for Entrepreneurship and Self-Employment, Timely Analysis of Immediate Health Pol'y Issues 3 (2013), *available at* http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2013/rwjf406367.

[32] *Inventive Billion Dollar Firms: A Faster Way to Grow*, Ewing Marion Kauffman Found., (Dec. 2010), http://www.innovationcenteroftherockies.com/PDF/Downloads/KauffmanFoundationbilliondollarfirms.pdf.

[33] *Id.*

[34] *Id.*

[35] *See generally* Neeraj Sood, Arkadipta Ghosh, & José J. Escarce, *Employer-Sponsored Insurance, Health Care Cost Growth, and the Economic Performance of U.S. Industries*, 44 Hsr: Health Serv. Research 1449 (2009).

[36] *Id.* at 1453.

[37] *Id.*

was conducted (1986-2005) were 2.2 percent.[38] Meanwhile, the Rand study found that an excess healthcare cost of just 0.2 percent—one-tenth the actual experience for the period—would exact a toll of 120,803 lost jobs.[39] Taken together, Rand study findings yield the conclusion that excess healthcare costs led to the loss of more than a million jobs over a twenty-year period.[40] This means that businesses were left with about a million fewer employed potential customers.[41]

Instituting a system that provides care to all Americans would end the problem of non-portable healthcare benefits, freeing the United States economy from a long-standing burden and create jobs.

II. IMPLEMENTING A UNIVERSAL CARE SYSTEM WOULD IMPROVE AMERICAN COMPETITIVENESS INTERNATIONALLY

Although many Americans believe as an article of faith that the United States enjoys the strongest, most entrepreneurial, most resilient economy in the history of the world, recent empirical assessments comparing the economies of the United States and other countries have not been so charitable.[42] Meanwhile, most of the countries that rate higher than the United States, even by the scorecard published by the conservative Heritage Foundation, offer universal healthcare through government-directed systems.[43] In fact, most other developed countries in the world have universal access to care through government-directed systems, which partially explains why all of the countries that outrank the United States in various economic indices have such systems.[44]

Despite conservatives' reflexive view that a government-directed healthcare system would be a pox on the economy, there are many common sense reasons that such systems foster economic growth. Aside from enabling greater job mobility, as discussed in Part I of this report, a government-directed system would diminish the burden on businesses by (1) slowing (or, potentially, reversing) increases to health costs, (2) decreasing businesses' obligations to bear the burden of those costs, and (3) distributing the costs that remain on businesses' shoulders more equitably.

A. The United States Trails Many of Its Competitors by Various Economic Measures

As discussed above, the United States fares worse than many countries with universal healthcare systems by various measures, including some maintained by conservative organizations. For example, the Heritage Foundation/Wall Street Journal Index of Economic Freedom ranks countries based on ten benchmarks under the four broad

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[38] *Id.* at 1457.

[39] *Id.* at 1449

[40] *Id.*

[41] *Id.* at 1449 (increasing the number of unemployed reduces the number of potential customers by the same amount).

[42] *2014 Index of Economic Freedom*, Heritage Foundation, http://www.heritage.org/index/ranking (2014).

[43] *Id.*

[44] *Id.*

headings of Rule of Law, Limited Government, Regulatory Efficiency, and Open Markets.[45] The United States ranks twelfth in this index.[46] Ten of the eleven countries outranking the United States have government-directed universal care systems. [See Table 1].

Table 1: Heritage Foundation / Wall Street Journal Index of Economic Freedom, 2014

Country (Rank)	Has a Government-Directed Universal Healthcare System
1. Hong Kong	Yes
2. Singapore	Yes
3. Australia	Yes
4. Switzerland	No
5. New Zealand	Yes
6. Canada	Yes
7. Chile	Yes
8. Mauritius	Yes
9. Ireland	Yes
10. Denmark	Yes
11. Estonia	Yes
12. United States	**No**

Sources: Heritage Foundation and Public Citizen Analysis of National Health Care Systems

On another list, the Organisation for Economic Co-operation and Development (OECD) ranks its members on what it terms the "employer enterprise birth rate," which it defines as the rate at which new enterprises with at least one employee are formed.[47] The United States ranked last or second-to-last in this category in every year from 2008 to 2011, the most recent year for which United States data are available.[48] In fairness, these years mostly coincided with the worst recession in the United States since the Great Depression. But those seeking to find solace in pre-recession data will be disappointed. The United States ranked twenty-one out of twenty-six countries included in the OECD's rankings for 2006.[49] [See Table 2].

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[45] *Id.*

[46] *Id.*

[47] OeCD, Birth rate of employer enterprises, Entrepreneurship at a Glance (2013), *available at* http://dx.doi.org/10.1787/entrepreneur_aag-2013-en.

[48] *Id.*

[49] *Id.*

Table 2: Employer-Enterprise Birth Rate, Total Economy

Country (Rank)	Has a Government-Directed Universal Healthcare System
1. Estonia	Yes
2. Australia	Yes
3. Portugal	Yes
4. Romania	Yes
5. Italy	Yes
6. New Zealand	Yes
7. Netherlands	Yes
8. Denmark	Yes
9. Lithuania	Yes
10. Hungary	Yes
11. Spain	Yes
12. Luxembourg	Yes
13. Brazil	Yes
14. Finland	Yes
15. Czech Republic	Yes
16. Slovak Republic	Yes
17. Bulgaria	Yes
18. Sweden	Yes
19. Slovenia	Yes
20. Canada	Yes
21. United States	**No**
22. Israel	Yes
23. Austria	Yes
24. Norway	Yes
25. Latvia	Yes

Source: Organisation for Economic Cooperation and Development, http://stats.oecd.org/, and Public Citizen Analysis of National Health Care Systems

Patents are indicative of business innovation and economic performance.[50] The OECD also ranks its members on the rate of patents issued by start-ups younger than five years old in relation to each country's GDP.[51] Here, the United States ranks nine out of twenty-

[50] Patents and Innovation: Trends and Policy Changes, Oecd 5 (2004), *available at* http://www.oecd.org/science/sci-tech/24508541.pdf.

[51] Jordan Weissman, *Think We're The Most Entrepreneurial Country in the World? Not So Fast*, Atlantic (Oct. 2, 2012, 10:01 AM), http://www.theatlantic.com/business/archive/2012/10/think-were-the-most-entrepreneurial-country-in-the-world-not-so-fast/263102/.

two countries, another indicator that the United States is not as strong at innovation as several other countries.[52] [See Table 3].

Table 3: Rate of Patenting Firms Less Than Five Years Old (per GDP)

Country (Rank)	Has a Government-Directed Universal Healthcare System
1. Denmark	Y
2. Sweden	Y
3. Finland	Y
4. Norway	Y
5. Netherlands	Y
6. Ireland	Y
7. Austria	Y
8. United Kingdom	Y
9. United States	**N**
10. Germany	Y

Source: Organisation for Economic Cooperation and Development, http://stats.oecd.org/, and Public Citizen Analysis of National Health Care Systems

B. How the Employer-Funded United States Healthcare System Harms Businesses

United States businesses that furnish healthcare benefits are shouldering costs that go well beyond their own employees' needs. A health insurance premium paid by a business in the United States has been characterized as a triple tax (and in reality might conceivably be called a quadruple tax).[53] First, as might be expected, part of the payments cover insurance for their employees (and often their employees' families), but that is just a portion of what business' healthcare premiums cover.[54] Secondly, the payments indirectly subsidize Medicaid and, possibly, Medicare.[55] This is because hospitals pad their bills to private insurance companies to compensate for lower Medicaid and Medicare reimbursements.[56] This phenomenon is known as "cost shifting."[57] Third, the

[52] The United States does fare well by some measures. For example, the Global Entrepreneurship Monitor ranks the United States number one in the world in the rate of start-up businesses. Donna J. Kelly et al., Global Entrepreneurship Monitor: 2011 Global Report 11 (2012), *available at* http://www.gemconsortium.org/docs/download/2409.

[53] Toni Johnson, *Healthcare Costs and U.S. Competitiveness*, Council On Foreign Relations (March 26, 2012), http://www.cfr.org/competitiveness/healthcare-costs-us-competitiveness/p13325.

[54] *Id.*

[55] *Id.*

[56] *Id.*

[57] The extent of cost-shifting as applied to Medicare is controversial. Some contend that Medicare reimbursements are adequate to cover costs. *See*, *e.g.*, Steven Brill, *Bitter Pills*, Time (Feb. 20, 2013), healthland.time.com/2013/02/20/bitter-pill-why-medical-bills-are-killing-us/print/ ("'When

amounts hospitals bill private insurance companies is also increased to help hospitals recoup losses for services rendered to uninsured patients who are unable to pay their bills.[58]

A fourth "tax" wrapped up in hospitals' insurance payments is a subset of the first item listed above—money that pays for benefits to employees or their families. Employers that provide healthcare benefits are often covering costs for other businesses that avoid doing so. For example, in 2004, seventy-one percent of PepsiCo's hourly employees were covered on someone else's healthcare.[59] This suggests that PepsiCo was foisting costs onto other businesses that would be its responsibility if it were to pay its fair share.[60] These costs hurt those businesses doing the right thing.

Companies in the United States that must pay large amounts to private insurance companies to cover their employees with healthcare are at a competitive disadvantage against companies in countries with single-payer healthcare or other universal healthcare systems. This is illustrated in cases in which different divisions of the same company operate in different countries.[61] In 2002, Ford Motor Co., General Motors, and DaimlerChrysler signed a joint letter entreating the Canadian government to take steps to preserve the Canadian National Health System.[62] In it, they specifically cited the fact that labor costs in Canada are lower than in the Unites States in part because businesses do not have to pay for their employees' health insurance.[63] Savings for Canadian divisions amounted to as much as "several dollars per hour of labor worked."[64] This savings is a "significant factor in maintaining and attracting new auto investment to Canada."[65]

Although this letter was written in 2002, it is important to note that the cost of employer-sponsored health insurance in the United States has escalated greatly since then. Between 2000 and 2011, the cost of the average annual employer-sponsored premiums in the United States doubled.[66] In fact, General Motors estimated as recently as 2012 that the rising healthcare costs it faces in the United States add "between $1,500 and

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hospitals say they are losing money on Medicare, my reaction is that Central Florida is overflowing with Medicare patients and all those hospitals are expanding and advertising for Medicare patients,' says [Jonathan] Blum, deputy administrator of the Centers for Medicare and Medicaid Services. 'Hospitals don't lose money when they serve Medicare patients.'").

[58] *Id.*

[59] Morton Mintz, *Single Payer: Good for Business*, The Nation (Oct. 28, 2004), http://www.thenation.com/article/single-payer-good-business?page=0,3.

[60] *Id.*

[61] *General Motors, Ford, DaimlerChrysler, Big Three Auto Joint Letter on Publicly Funded Health Care, Canadian Auto Workers Union* (June 7, 2012), http://www.caw.ca/en/campaigns-issues-past-campaigns-issues-big-three-auto-joint-letter-on-publicly-funded-health-care.htm (last viewed Apr. 27, 2014).

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] *Number of Americans Obtaining Health Insurance Through an Employer Declines Steadily Since 2000*, Robert Wood Johnson Found. (Apr. 11, 2013), http://www.rwjf.org/en/about-rwjf/newsroom/

$2,000 to the sticker price of every automobile it makes."[67] Len Nichols, Director of the Health Policy Program at the New American Foundation, estimates that United States manufacturing companies spend almost three times as much on healthcare per worker per hour as foreign companies do.[68]

C. Why a Universal Care System Would Lessen Burdens on Businesses

No universal care systems, including pure single-payer systems, are a free lunch for businesses. In one way or another, often through a payroll tax, businesses end up providing at least some of the money to finance the system.[69]

There are several reasons to believe that a universal care system would mitigate this impact on businesses. Primarily, such a system would cause future costs to be lower, or at least stem the trend of cost-increases far exceeding inflation.[70] Secondly, businesses' overall share of healthcare bills would likely be lower.[71] Finally, a universal care system would distribute costs far more equitably among businesses.[72]

1. Future Overall Healthcare Costs Would be Lower Across the Board

There are two primary reasons that future costs in a government-directed, universal care system would be lower than they would be if we remained on our current trajectory: such a system would result in reduced administrative costs and would lower costs for procedures and prescriptions.[73]

A 2003 study published in the *New England Journal of Medicine* concluded that administrative costs account for thirty-one percent of healthcare spending in the United States compared to just 16.7 percent in Canada, which has a single-payer system.[74] United States healthcare costs in 2011 were about $2.7 trillion.[75] If the United States

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newsroom-content/2013/04/number-of-americans-obtaining-health-insurance-through-an-employ.html.

[67] Toni Johnson, *Healthcare Costs and U.S. Competitiveness*, Council On Foreign Relation (Mar. 26, 2012), http://on.cfr.org/J0oMeD.

[68] Len Nichols, Paul N. Van de Water et al., *Squaring Healthcare With the Economy,* Council on Foreign Relations (Dec. 8, 2009), http://on.cfr.org/1cxaIkJ.

[69] *See e.g., Single Payer*, Single Payer New York (2011), http://www.singlepayernewyork.org/single-payer/ (last viewed Apr. 27, 2014) (suggesting employers would fund a single-payer system through a payroll tax).

[70] *See* Gerald Friedman, Funding HR 676: The Expanded and Improved Medicare for All Act 1 (July 2013), *available at* http://www.pnhp.org/sites/default/files/Funding%20HR%20676_Friedman_7.31.13_proofed.pdf (noting that a single-payer system would "bend the cost curve" and save approximately $ 1.8 trillion in health costs over the next decade).

[71] *See e.g., Single Payer*, Single Payer New York (2011), http://www.singlepayernewyork.org/single-payer/ (last viewed Apr. 27, 2014).

[72] *See* Mintz *supra* note 59.

[73] *See* Friedman *supra* note 70, at 5.

[74] Steffie Woolhandler et al., *Costs of Health Care Administration in the United States and Canada*, 349 New Eng. J. Med. 768, 772 (Aug. 31, 2003), *available at* http://www.pnhp.org/publications/nejmadmin.pdf.

[75] *National Health Expenditures; Aggregate and Per Capita Amounts, Annual Percent Change and Percent Distribution: Selected Calendar Years 1960-2011*, Centers for Medicare and Medicaid

were able to shave 14.3 percent off of its healthcare bill, it would save approximately $415 billion a year.[76]

Additionally, governments that coordinate their countries' healthcare delivery are able to negotiate lower rates for procedures and prescription drugs.[77] The example below compares costs for medical procedures and prescriptions in the United States with those in France, which the World Health Organization in 2000 ranked as having the best healthcare services in the world.[78] [See Table 4].

Table 4: Comparison of Costs for Selected Procedures and Drugs, United States v. France

	United States	France	Pct. Difference
Angiogram	$914	$264	+246.2%
CT scan, abdomen	$630	$183	+244.3%
CT scan, head	$566	$183	+209.3%
CT scan, pelvis	$567	$183	+209.8%
MRI	$1,121	$363	+208.8%
Total hosp. & phys. cost: Appendectomy	$13,851	$4,463	+210.4%
Total hosp. & phys. cost: normal delivery	$9,775	$3,541	+176.1%
Cost of hospital per day	$4,287	$853	+402.6%
Drugs: Nasonex	$108	$17	+535.3%
Drugs: Lipitor	$124	$48	+158.3%
Drugs: Nexium	$373	$30	+1,143.3%

Source: International Federation of Health Plans. http://bit.ly/J0rQYi

It is doubtful that costs for procedures and drugs would be cut to the levels in France if the United States were to adopt a government-directed, universal care system as that would require reducing drug and provider reimbursement rates in Medicare, which is extremely difficult politically. A more likely scenario is that the rate of increase of payments to providers in the United States would be slowed or temporarily stopped.[79]

A window of insight into the potential cost savings that could be realized by converting to a universal care system can be gleaned by comparing the rate of increase in per-patient private insurance costs versus per-patient Medicare costs. Although some single-payer purists disagree with this characterization, Medicare is essentially a single-payer system for people sixty-five years of age and older. Advocates for single-payer systems

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Services, http://go.cms.gov/1fhvt7k.

[76] *See* Woolhandler, *supra* note 74, at 772. (such an astounding outcome would likely be unrealistic to achieve, but even saving half that much would be a widely welcomed development.)

[77] *See id.*

[78] Improving Performance, World Health Organization 153 (2000).

[79] *See id.*

often express their proposed policy as Medicare for All or Improved Medicare for All.[80] Private insurance costs outpaced Medicare over the four decades concluding in 2010.[81] The discrepancy was particularly pronounced for the most recent decade. [See Table 5].

Table 5: Annual Growth Rate in Per-Capita Healthcare Spending, Common Benefits

	Private Insurance	Medicare
1969-2010	9.4%	8.1%
2001-2010	7.8%	5.2%

Source: New York Times (citing Kaiser Family Foundation data), http://nyti.ms/18qo4n9

Critics of the hypotheses that a universal Medicare system would generate cost savings argue that hospitals simply charge private sector insurers more to compensate for insufficient payments from Medicare.[82] But many dispute this "cost shifting" theory. Anecdotally, as noted above, Medicare payments have been sufficiently large to fund vast expansions of medical infrastructure.[83] Meanwhile, hospitals spend money on advertising to compete for Medicare patients, which defies common sense because this would never happen if Medicare were not at least covering providers' costs.[84]

A study published in 2011 by Austin Frakt of the Veterans Affairs Administration concluded that cost-shifting is a factor in determining medical providers' pricing but only one of many factors.[85] "Policymakers should take hospital and insurance industry claims of inevitable, large scale cost shifting with a grain of salt," Frakt wrote.[86] "Though a modest degree of costs shifting may result from changes in public payment policy, it is just one of many possible effects. Moreover, changes in the balance of market power between hospitals and healthcare plans also have a significant impact on private prices."[87]

2. Businesses' Overall Share of Costs Would Be Lower

Nearly every European country has a more regulated healthcare system than the United States, and most have provisions in place to ensure virtual universal coverage of their residents. A 2010 survey of financing systems published by Kaiser Permanente and a series of reports by the World Health Organization indicate that European systems are funded by an array of sources, often including general taxes and payroll taxes in

[80] *See* H.R. 676, The Improved Medicare for All Act.

[81] Brill, *supra* note 57.

[82] *Id.*

[83] *Id.*

[84] *Id.*

[85] Austin Frakt, *How Much Do Hospitals Cost Shift? A Review of the Evidence*, 3 Health Care Financing & Economics, Working Paper No. 2011-01 (2010), *available at* http://1.usa.gov/1908e0A.

[86] *Id.*

[87] *Id.*

which employers and employees pay equal shares, as well as individual user fees.[88] If a universal healthcare system were implemented in the United States, chances are that the burden would be lifted at least to some extent from employers and thus reduce the overall costs.[89] Residents would probably be required to pay some additional taxes that would be dedicated to healthcare, but their contribution would likely be mitigated because they would no longer have to pay private health insurance premiums.[90]

3. Healthcare Costs Would be Distributed More Equitably In a Universal Care System

To the extent that a single-payer or other government-directed universal care system would be funded with payments from businesses, those payments would likely be made according to a formula to ensure equity.[91] This type of system would protect businesses in low-margin industries that currently seek to provide their employees with access to healthcare because it would ensure that those businesses' competitors are not gaining an advantage by dodging the cost. Thus, businesses would pay more in healthcare fees on behalf of employees whom they pay more and less on behalf of lower-paid employees.

CONCLUSION

If the United States were to implement a system to ensure universal care, American companies would no longer face a disadvantage in competing with businesses from countries, such as Canada, that provide national healthcare systems. Additionally, healthcare would cease to be a large factor guiding individuals' career decisions. A national, universal care system would level the playing field among domestic businesses, and eradicate the free-rider problem. For all of the above reasons, economic growth would likely improve, which would yield additional self-perpetuating benefits.

There is an argument that the taxes to finance such a system would constrain business. This claim is seriously undercut by examples from around the world. For instance, Hong Kong, viewed by many as a "beacon of capitalism," has universal healthcare. So does Denmark, which has higher levels of entrepreneurship than the United States.[92] What is becoming increasingly clear now is that the current employer-sponsored healthcare system in the United States does hurt business.

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[88] *See, e.g.*, *Selected European Countries' Health Care Systems and the United States*, Kaiser Permanente Int'l (2010), *available at* http://bit.ly/1dpBOfe.

[89] *See* OECD, *supra* note 47.

[90] *See id.*

[91] *See id.*

[92] Andrew McMurphy, *The Conservative Case for Single Payer Health Care (It's the Competitiveness, Stupid)*, Free Republic (June 16, 2012), http://www.freerepublic.com/focus/news/2896163/posts; *see also Number of Americans Obtaining Health Insurance Through an Employer Declines Steadily Since 2000*, Robert Wood Johnson Found. (April 11, 2013), http://www.rwjf.org/en/about-rwjf/newsroom/newsroom-content/2013/04/number-of-americans-obtaining-health-insurance-through-an-employ.html.

The Patient Readmission Rate Penalty in the Affordable Care Act

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I. INTRODUCTION

On March 23, 2010, President Barack Obama signed the Patient Protection and Affordable Care Act (ACA), which represents the most significant regulatory overhaul of the United States healthcare system since the 1965 Social Security Amendments, establishing Medicare and Medicaid.[1] By 2020 healthcare is expected to account for twenty percent of the Nation's economy, making it one of the most important economic issues facing Americans.[2] Irrespective of race, gender, or socioeconomic status, healthcare is a reality that all individuals must face at some point in their lives.

The ACA was enacted as an effort to address the overwhelming disparities that exist with regards to the access to and affordability of healthcare in the United States.[3] The law's provisions, including the Hospital Readmission Reduction Program (HRRP), take substantive steps that are intended to work towards mitigating these shortcomings. Using readmission rates as its metric of quality, the HRRP imposes a penalty on any hospital that exceeds the national mean readmission rate within a particular year.[4] These penalties are collected from hospitals through a percentage reduction in the annual Medicare payments they receive for inpatient service claims.[5] The expectation is that hospitals will respond to this incentive by improving operational process and patient care in a manner that will benefit all hospital patients.[6] This article argues, however, that this incentive system is flawed, as readmission rates are not an accurate way to evaluate a hospital's performance because they are not useful indicators of quality of care.[7] Moreover, in practice, the HRRP may have at least three unintended consequences: a decrease in quality of care, a decrease in access to care for minorities, and an increase in hospital financial distress.[8]

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[1] Julia Balch Samora et al., *Where the Candidates Stand on Health Care*, Am. Acad. of Orthopedic Surgeons (Jan. 2014), http://www.aaos.org/news/aaosnow/oct12/advocacy2.asp.

[2] Ricardo Alonso-ZaldivarI, *Health Care Costs to Account For One-Fifth Of U.S. Economy By 2020: Report*, Huffington Post (July 28, 2011, 11:17 AM), http://www.huffingtonpost.com/2011/07/28/health-care-costs-economy-us_n_911917.html.

[3] *See generally* Mary Naylor, *Unintended Consequences of Steps to Cut Readmissions and Reform Payment May Threaten Care of Vulnerable Older Adults*, Health Aff. 1623 (July 2011).

[4] *Id.*

[5] Julia James, *Medicare Hospital Readmissions Reduction Program: To Improve Care and Lower Costs, Medicare Imposes a Financial Penalty on Hospitals with Excess Readmissions*, Health Aff. 3 (Apr. 2014), *available at* http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_102.pdf.

[6] Elizabeth H. Bradley, Leslie Curry, Leora I. Horwitz et al., *Hospital Strategies Associated with 30-Day Readmission Rates for Patients with Heart Failure*, *Circulation: Cardiovascular Quality and Outcomes* (June 2013), *available at* http://www.medpagetoday.com/upload/2013/7/16/Circ%20Cardiovasc%20Qual%20Outcomes-2013-Bradley-444-50.pdf.

[7] Sharon Silow-Carroll, Jennifer N. Edwards, Aimee Lashbrook et al., *Reducing Hospital Readmissions: Lessons from Top-Performing Hospitals*, The Commonwealth Fund 3 (Apr. 2011), *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Case%20Study/2011/Apr/1473_SilowCarroll_readmissions_synthesis_web_version.pdf.

[8] Joel D. Sweider, Note, *A Dose of Reality: Unintended Consequences of Penalizing Hospital Readmissions in the PPACA*, 9 Ind. Health L. Rev. 361, 363 (2011).

II. BACKGROUND

Hospital readmission is a relatively broad, yet simple concept: a patient, upon initial discharge from a hospital, is shortly thereafter readmitted to the same or different hospital for the same or a different condition.[9] Within the context of Medicare, readmissions have generally been measured within thirty-days of initial discharge.[10] According to a 2009 study in the *New England Journal of Medicine*, almost one fifth of hospitalized Medicare patients are readmitted within that thirty-day window.[11] Furthermore, more than sixty-seven percent of patients discharged following a hospitalization for a medical condition and fifty-one percent of those discharged after undergoing surgical procedures were readmitted or died within a year.[12] The primary problem with readmitting a patient is that it may be indicative of poor care or an inefficient coordination of post-discharge care.[13] For example, research has suggested that excessive readmission can be reduced by enhanced communication between caregivers and patients and better coordination of post-discharge care.[14]

As an incentive based system, the intended purpose of HRRP is to encourage hospitals to adopt strategies that better improve patient services and operating practices;[15] however, this objective is based on the faulty premise that readmission rates are solely reflective of the quality of care provided by hospitals.[16] In 2000, a survey of some nineteen readmission studies, carried out over the previous ten-years, concluded that most readmissions seem to be caused by modifiable causes and that global readmission rates are not useful indicators of quality of care.[17] As such, using readmissions as a yardstick to evaluate the quality of healthcare provided by a hospital becomes inherently problematic. There are many factors that are not related to quality of care, such as socio-economic status of patients that nonetheless influence readmission rates.[18]

Indiscriminately imposing penalties on hospitals with excess readmission rates, without accounting for the contributing factors for those readmissions, may adversely impact hospitals, particularly hospitals that serve large populations of individuals from low

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[9] *Id.* at 365.

[10] *Id.* at 363.

[11] Stephen F. Jencks et al., *Rehospitalizations Among Patients in the Medicare Fee-for-Service Program*, 360 New Eng. J. Med. 1418, 1426 (2009).

[12] *Id.* at 1421.

[13] *See generally* Sweider, *supra* note 8, at 366 (discussing how excess readmission rates may indicate poor care or missed opportunities to better coordinate care).

[14] *See id.* 365 (noting that enhanced communication between caregivers and patients has a direct correlation with a reduction of readmission rates).

[15] *See generally* Naylor, *supra* note 3, at 1623 (discussing the overall purpose of HHRP is to improve the quality of service hospitals provide to their patients).

[16] *Id.*

[17] Jochanan Benbassat & Mark Taragin, *Hospital Readmissions as a Measure of Quality of Health Care: Advantages and Limitations*, 160 Archives Internal Med. 1074, 1074 (2000).

[18] James, supra note 5, at 3 (arguing that an emphasis on readmission rates to improve quality of care is a flawed strategy because readmissions are tied into factors outside of a hospitals' control).

socio-economic backgrounds.[19] Readmissions tend to be higher in hospitals that treat a great proportion of indigent patients, since there is a direct correlation between lower socio-economic conditions and overall poor health.[20] Hospitals that treat primarily these types of patients are most susceptible to the financial hardships that the penalties associated with the HRRP could potentially create.[21] This is particularly problematic because many of these hospitals are already reliant on federal aid to maintain operation since many of their patients are uninsured.[22] If these hospitals are penalized for readmissions then they will experience increased financial pressure, leading to cuts in patient services and other efforts to minimize costs, harming the entire community served by the hospital.[23] Moreover, the need to reduce readmissions will create a conflict of interest between quality of care delivered and the hospital's bottom line.[24]

A. The HRRP Will Increase the Level of Financial Distress Experienced by Some Hospitals and in Turn Decrease Access to Care by Socio-Economically Disadvantaged Groups

The HRRP was designed in a manner that will disproportionally impact hospitals in urban neighborhoods that treat socio-economically disadvantaged groups, including indigent and uninsured patients.[25] With limited funding and fewer resources, the financial implications that these penalties will have on such safety-net hospitals cannot be dismissed.

While many readmissions can be easily avoided by implementing simple changes in patient discharge procedures, many of the underlying causes of readmissions involve factors that are beyond the hospital's control, including patient behavior, poor follow-up, and the socio-economic status of the patient population.[26] The computation used by the Department of Health and Human Services (DHHS) sets a readmission threshold for each hospital, and the hospital is subsequently penalized whenever they exceed this threshold.[27] Since the methodology used by the DHHS to compute excess readmission rates do not adjust for factors that can impact readmission rates, hospitals become victims of their surroundings.[28]

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[19] *See generally* Sweider, *supra* note 8, at 364 (noting that since there is a direct correlation between lower socio-economic conditions and poor population health conditions, hospitals that treat these patients will have a higher readmission rate more often than others).

[20] James, *supra* note 5, at 3.

[21] *Id.*

[22] Christie Provost Peters, *The Basics: Medicaid Disproportionate Share Hospital (DSH) Payments*, Nat'l Health Policy Forum 1 (2009), *available at* http://www.nhpf.org/library/the-basics/Basics DSH 06-15-09.pdf.

[23] *Id.*

[24] Amanda Bronstad, *Suit Over Hospital's Closure Could be a Harbinger,* Nat'l L. J. (Aug. 23, 2010), http://www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1202470936728&slreturn=1&hbxlogin=1#.

[25] *See generally* Sweider, *supra* note 8, at 364.

[26] James, *supra* note 5, at 4.

[27] *Hospital Compare*, U.S. Dep't of Health & Human Servs., http://www.hospital compare.hhs.gov/ (last updated Jan. 26, 2012).

[28] James, *supra* note 5, at 4.

i. Many of the Readmission Reduction Strategies are Impractical or too Costly for Hospitals to Implement.

While the ACA lays out a number of readmission reduction strategies for hospitals to implement, the success of these strategies do not necessarily translate from hospital-to-hospital.[29] Furthermore, a number of the strategies are simply not feasible for hospitals with limited resources and uninsured patients.[30] For example, many patients at large inner city hospitals are readmitted because they do not always follow the nurse's or physician's discharge instructions usually because they lack the resources to do so.[31] To ameliorate this phenomenon, hospitals could implement regimented follow-ups by nurses,[32] but this strategy is very costly and such expenditure would serve as a misappropriation of resources.

ii. There are Underlying, Non-Care Related, Causes for Readmission.

Hospitals that are frequented by a high proportion of uninsured patients are generally referred to as safety-net hospitals. These hospitals are typically found in low-income communities, where many of our nation's health and economic disparities are present. In adherence with federal law, a hospital must treat a patient in need of care regardless of insurance status.[33]

One of the reasons that many patients are readmitted to safety-net hospitals is related to an inability to afford their prescriptions, rather than the underlying care that the patient received while in that hospital.[34] Take for instance a patient admitted to a hospital with a laceration to the hand that requires stitches. The patient is treated and released from the hospital with a prescription for antibiotics. However, the patient is uninsured and cannot afford to fill the prescription. With no other option, the patient is forced to deviate from the recommended course of treatment. This decision makes the patient more susceptible to health complications that will later require readmission. The prior scenario is a regular occurrence in many of these safety-net hospitals. As such, these hospitals typically have higher readmissions rates than hospitals in more affluent communities.[35]

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[29] *Id.* at 3-4 (stating "CMS has made additional funding available for readmission reduction strategies through initiatives, such as the Community-based Care Transitions Program and the Partnership for Patients").

[30] *Id.* at 3.

[31] *Id.* at 4 (arguing that indigent patients generally lack the resources to fill their prescriptions resulting in an eventual readmission to the hospital they are initially discharged from).

[32] *See* 42 U.S.C § 2717(a)(1)(B) (2010) (noting that nurse follow-ups have typically resulted in a reduction in readmission rates because it allows hospitals to ensure that the patients are following their discharge instructions properly).

[33] *See Baber v. Hosp. Corp. of Am*., 977 F.2d 872, 880 (4th Cir. 1992) (stating that "all Americans, regardless of wealth or status, should know that a hospital will provide what services it can when they are truly in physical distress" and stating that Congress enacted EMTALA to address its concern with the practice of patient dumping) (quoting 131 Cong. Rec. S13904 (daily ed. Oct. 23, 1985) (statement of Sen. Durenberger)).

[34] James, *supra* note 5, at 4.

[35] Karen E. Joynt et al., *Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care*, 305 JAMA 675, 675 (2011).

iii. Expected Disproportionate Share Hospital Cuts As Well As Costs Associated with Decreasing Readmissions May Jeopardize Access to Care.

Medicare does not provide any direct payment for strategies that may help these hospitals reduce readmission rates.[36] The cost of employing these strategies, coupled with the reduced revenue from fewer readmissions, makes it less likely that attempts to reduce readmissions will be cost efficient. The financial difficulties that hospitals will face are not only tied to the HRRP of the Affordable Care Act; others provisions within the law also stand to significantly contribute to financial hardship for safety-net hospitals.[37]

Currently many safety-net hospitals are funded by the federal government through the Medicare Disproportionate Share Hospitals (DSH) payment program;[38] however, the Department of Health and Human Services (DHHS) expects a seventy-five percent reduction in DHS payments by the beginning of the 2015 fiscal year.[39] Through DSH payments, hospitals have been able to improve the access to care for much of the indigent population in this country.[40] Significant cuts to DSH payments could create more of an incentive for hospitals to alter the types of services they provide, focusing on those services that are more profitable and less often used.[41] The harm is that less profitable services that have proven long-term benefits to a patient's health, such as preventive screening, could be significantly cut. An emphasis on preventive care, however, is important because it will help stifle the rising healthcare costs for patients by improving the likelihood that life-threatening conditions will be detected much sooner.[42]

B. Financial Strain Caused by the HRRP as well as Other Provisions of the Affordable Care Act Will Lead to Larger Problems, Including a Decrease in Services or Closure of Facilities.

The Committee of Medicaid and Medicare Services predicted that beginning this fiscal year, at least 2,225 hospitals will be penalized $227 million dollars because of excess readmissions.[43] As with any other financially strained institution, when there are added expenses, cuts must be made. While it would be difficult to speculate precisely how these hospitals will absorb the added expenses, cuts to staffing and supporting services are likely possibilities.[44] Although a reduction in operating costs does not necessarily

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[36] *See* Sweider, *supra* note 8, at 376 (arguing that these hospitals will be hit doubly hard, losing reimbursements for readmissions while no longer getting the Disproportionate Share Hospital (DSH) payments to which they are accustomed).

[37] *See* 42 U.S.C. § 1395ww(d)(5)(F)(i) (2010).

[38] *See* Peters, *supra* note 22, at 1.

[39] 42 U.S.C. § 1395ww(d)(5)(F)(i) (2010).

[40] *See* Peters, *supra* note 22, at 1.

[41] Arnold M. Epstein et al., *The Relationship between Hospital Admission Rates and Rehospitalizations*, 365 New Eng. J. Med. 2287, 2287 (2011) (noting that among the money saving initiatives that struggling hospitals could adopt is offering more profitable services to patients).

[42] *See* 42 U.S.C. § 300gg-13 (2010) (providing that private insurers are required to cover screening services and preventive treatments which have been given a recommendation of "A" or "B" by the U.S. Preventive Services Task Force).

[43] James, *supra* note 5, at 3.

[44] Bronstad, *supra* note 24.

imply a reduction in the quality of treatment, it does create the potential that such an outcome may occur.

Faced with mounting debts and added expenses from the new penalties associated with the HRRP, hospital that cannot compete in the readmission game will likely cut cost by offering fewer services to their patients or shedding facilities.[45] These hospitals may no longer have the resources to invest in innovative technology that is aimed at enhancing treatment and patient care.[46] Hospitals, with mounting financial pressure from HRRP penalties, may also cut critical services that could comprise the quality of care provided to patients.[47]

To avoid penalties hospitals may attempt to avoid treating elderly patients. The sickest and oldest patients place an increasing burden on hospitals trying to reduce their readmission rates because, generally, these patients are readmitted more often.[48] Currently, more than six million elderly Americans suffer from chronic medical conditions that require long-term homecare as well as frequent physician visits.[49] Long-term care, by its nature, involves many providers and several different types of treatment. For example, hip fractures are among the most common orthopedic injuries in the elderly population.[50] They are debilitating injuries that require surgical intervention and inpatient care of, what are more often than not, patients with many chronic medical issues.[51] These patients require orthopedic intervention for surgery, medical intervention for health status monitoring, physical therapy during and after hospital discharge, as well as regular follow-up with their primary care physician.[52] Such patients often require multiple readmissions for pain management, infection, and rehabilitation that arise as a result of their injury and made worse by their pre-injury healthcare status.[53] Fully aware of this reality, hospital may be less inclined to treat elderly patients to avoid the potential for facing readmission penalties.[54]

Another tactic that hospitals may employ is manipulating billing information to circumvent some key measures of readmissions in order to avoid being penalized by the HRRP.[55] For example, while under observational care, a patient is provided with outpatient services to determine whether hospitalization is required thereby changing

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[45] Suzanne Sataline, *Cash-Poor Governments Ditching Public Hospitals*, The Wall St. J., Aug. 29, 2010 (Health Industry Section).

[46] *Id.*

[47] Mark Levine, *St. Vincent's is the Lehman Brothers of Hospitals*, N.Y. Mag., Oct. 17, 2010, http://nymag.com/news/features/68991/.

[48] *Id.*

[49] H. Stephen Kaye, *Long-Term Care: Who Gets It, Who Provides It, Who Pays, and How Much?*, Health Aff., 11 (2010).

[50] *Fractures of the Pelvis & Acetabulum*, Ctrs. For Orthopedics, http://www.orthoassociates.com/SP11B26/ (last visited Apr. 21, 2014).

[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] Levine, *supra* note 47.

[55] *See* Naylor, *supra* note 3 (discussing how coding allows hospitals to avoid or obscure measurement of some hospitalizations).

the patient's designation from an inpatient to an outpatient.[56] Prolonged use of this designation allows hospitals to avoid a potentially necessary hospitalization, which de facto reduces their readmission rate.[57] Although this tactic is illegal and would potentially comprise the quality of treatment provided to patients, this tactic would reduce a hospital's readmission rate.

Moreover, the HRRP presumes that penalties will prompt hospitals to improve patient services and treatment facilities; however, since the penalty is capped annually at a percentage of a hospital's total Medicare payments, hospitals could bear the penalties and avoid the high costs of implementing changes in their operations and services.[58]

Hospitals unable to sustain the costs associated with readmission penalties will be forced to shut down.[59] The remaining hospitals will be overwhelmed by the flux of new, mostly indigent, patients left behind by the hospitals that shut down.[60] Such a wave would create overcrowded and understaffed hospitals where long waits and uneven care become the standard.[61]

III. PROPOSED SOLUTIONS

To ensure that the penalty associated with the HRRP are enforced consistently and fairly, socio-economic status of patients and other patient population characteristics should be taken into consideration when computing the acceptable readmission rates for each hospital. The overall goal of the program is to eradicate the gaps that exist with patient care as a means of reducing hospital readmissions. Subjecting all hospitals to the same standards implies that all hospitals are subjected to similar patient populations and have the same resources to manage their inpatient complications. While there are legitimate concerns that adjusting for these sorts of factors may mask the potential disparities in care for the disadvantaged, it is clear that this program's intended model of enforcement is flawed and ought to be adjusted appropriately. Additionally, the HRRP should not do away with DHS payments at this time. DHS payments are vitally important for increasing and maintaining access to care, as they fund hospitals that treat indigent populations. Eliminating DHS payments creates incentive for hospitals to focus on more profitable services, despite that they might be less commonly used by needy patients. Overall, the ACA should ensure that hospitals provide the treatments that patients need, not just the ones that are more economically beneficial for the hospital.

Currently, the HRRP is trying to accomplish too much all at once.[62] The program simultaneously gathers uniform data among hospitals, publicizes those results, and then

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[56] *See id.*

[57] *See id*.

[58] *See id.* (discussing how in some cases the cost of implementing these new readmission reduction strategies would be greater than the penalty that would be imposed on them).

[59] *See* Levine, *supra* note 47 (discussing the added pressures that hospitals would have to deal with including growing costs, decreasing revenues, and unsustainable debt loads).

[60] *Id.*

[61] *Id.*

[62] Sweider, *supra* note 8, at 382.

dispenses out penalties to various hospitals.[63] Given the relatively short time frame in which providers must comply with the new regulations, such a process may lead to an overextension of DHHS resources.[64] Gathering more data on this issue is undeniably crucial in appropriately resolving excess readmissions; however, the fact that hospital readmission data will become public will inevitably penalize hospitals that require more time to find a mechanism best suited for their particular situation. As such, a sensible solution would be to lengthen the timetable in implement the HRRP. Delaying its commencement would give Congress time to revisit and improve the program, while also allowing hospitals a sufficient period to research and formulate their individuals plans prior to placing their federal reimbursement dollars at jeopardy.

IV. CONCLUSION

Hospital readmission is an important and costly epidemic that needs to be addressed in order to improve the healthcare system in this country. A system premised on financial incentives for hospitals can be an effective solution to resolve this problem if governed and implemented properly. As currently structured, however, the HRRP will not produce the intended benefits on the delivery of healthcare in the United States. Moreover, the program has a potential to have a number of negative consequences, including a decrease in indigent access to care, a reduction in senior quality care, and increased financial strains on hospitals.

The main problem with the HRRP is that it fails to appreciate the material differences in the patient base of hospitals that contribute to disparities in readmission rates. There are often factors entirely outside of the hospital's control that, nonetheless, cause a patient to be readmitted. Rather than assessing penalties purely by readmission rates, the program ought to account for the processes and safeguards that hospitals have implemented in addressing these challenges.

Applying the same standard to each hospital, without accounting for their inherent differences, raises the potential that the existing disparities in healthcare system will be magnified. With some common sense adjustments, however, the program's implementation could affect the positive change it was intended to have on the quality of healthcare in the United States.

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[63] *Id.* at 385-86.

[64] *Id.* at 382.