LOEB & LOEB LLP

FDA Regulatory and Compliance

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The New Promotional Rules: "There Are No New Promotional Rules"

Executive Summary:

There is resounding evidence that physicians and patients rely on the Internet—including social medial platforms—to research and communicate health information. FDA, however, has been slow to adapt even though the potential benefits to patients are great. In line with requirements set by the Food and Drug Administration Safety and Innovation Act, 2014 was supposed to be the year manufacturers finally got clear direction through the regulatory minefield of online promotion. The three draft guidances released to date fall short of expectations and give Industry little support in its efforts to keep up with communication strategies of the patients and healthcare practitioners who use its products.

The draft guidance on fulfilling regulatory requirements for postmarketing submissions nods at the pace of promotion on digital media with FDA's intent to allow Industry to bundle interactive material submissions. This provision reduces FDA's and Industry's potential administrative burdens but does not establish a new framework specific to digital media.

The draft guidance on presenting risk and benefit information in character space limited media emphasizes one core message—the promotional rules do not change just because the promotional medium does—that leaves Industry wondering whether it will ever be able to catch up with patients.

The draft guidance on correcting independent third-party misinformation online sets up consequences for manufacturers who choose to correct bad online information that others have posted about their products, discouraging Industry's participation in an activity that would greatly benefit the public.

These Guidances have not dispelled existing regulatory ambiguities or prioritized real-world risk to patients over the default policing of manufacturer's speech. Despite the agency's avowed efforts to address the specific opportunities and challenges surrounding digital media communications, the Guidances' struggle to find equilibrium with FDA's two necessary objectives to ensure products' safety, efficacy, and security and to speed medical innovation and facilitate the dissemination of health information for use by the public. The interactive nature of digital media must be matched by an equally dynamic regulatory understanding of this type of communication. FDA must develop a risk-based regulatory framework—one that allows the drug and device industry to take advantage of powerful digital resources to connect with the real human beings who need health information. Opting out of these media is not an option. Only a balanced, risk-based regulation of Industry's digital media use can facilitate medical advancement while preserving patient safety.

The New Promotional Rules: "There Are No New Promotional Rules"

"I am not an advocate for frequent changes in laws and Constitutions. But laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths discovered and manners and opinions change, with the change of circumstances, institutions must advance also to keep pace with the times. We might as well require a man to wear still the coat which fitted him when a boy as civilized society to remain ever under the regimen of their barbarous ancestors."

—Thomas Jefferson

As if calling from a landline to tell you it finally bought an iPhone, the Food and Drug Administration (FDA) struggles to keep pace and articulate clear regulatory policies for the 21st century. The life sciences industry (Industry) is hungry for guidance as it navigates promotional opportunities and challenges presented by the Internet and online social/interactive platforms (collectively "digital media"). With four draft guidances and one proposed rule related to digital media on FDA's published agenda, 2014 was going to be the year that FDA finally acknowledged that it is, indeed, 2014. Yet the three draft guidances released so far (Guidances) have fallen flat. A cumulative 31 pages, they contribute little new information to inform Industry's decision-making related to the promotion or even discussion of drugs and medical devices on the Internet. So how did we get here? Where can we go? And why does it matter?

I. Why does FDA give a hoot about a tweet?

The chore of regulating drug and device manufacturers' social media activity, in all its impracticality, is a product of legal history. The discussion of FDA's contemporary labors must, then, begin in 1906—exactly 100 years before Twitter was launched. Americans were sick from buying snake oil from charlatans, and publications like Upton Sinclair's *The Jungle* hit home.[1] Citizens were rightfully riled up about consumer safety, motivating Congress to finally do something about the unreliable quality of food and drugs sold in the United States. The Pure Food and Drug Act, "preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors," was signed into law by President Theodore Roosevelt, empowering the Bureau of Chemistry of the Department of Agriculture to regulate fraudulent, unsafe food and drug sales. In 1930, this Bureau came to be known as FDA, and in 1938, the Federal Food, Drug & Cosmetic Act (FDCA) superseded the Pure Food and Drug Act as the primary source of FDA authority.

In FDA's own words, "its responsibilities have undergone a metamorphosis since 1906. … Yet the core public health mission of the agency remains now as it did then." Industry, too, has undergone a metamorphosis. And like FDA, it also has adhered to its mission, the advancement of treatments and cures for disease. Both find themselves on new ground in the age of digital media. FDA is hesitant to regulate this new space, and Industry is hesitant to occupy it without clear regulations. Frankly, patients are leaving them both behind, which does not improve the public's access to truthful information or effective treatments.

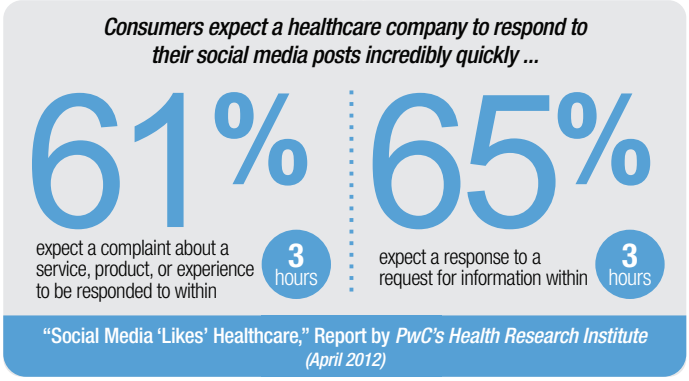
The broad-reaching authority for promotional review that we now associate with FDA was settled in 1948, when the U.S. Supreme Court issued its decision in *Kordel v. United States*.[2] The Court backed FDA's interpretation of promotional materials as product labeling, explaining, "One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment of one to the other is necessary. It is the textual relationship that is significant."[3] As a corollary, the Court also pointed out, "Every labeling is in a sense an advertisement."[4] Since that time, FDA's investigations and enforcement actions have expanded through its exercise of discretion, evolving from the original Poison Squad to now include an extensive program of

promotional monitoring and surveillance that includes manufacturers' use of social media platforms. Yet the expansion of FDA's regulatory reach hasn't translated into a regulatory scheme that fully comprehends the evolving realities of how medicine is practiced and information disseminated in the digital age.

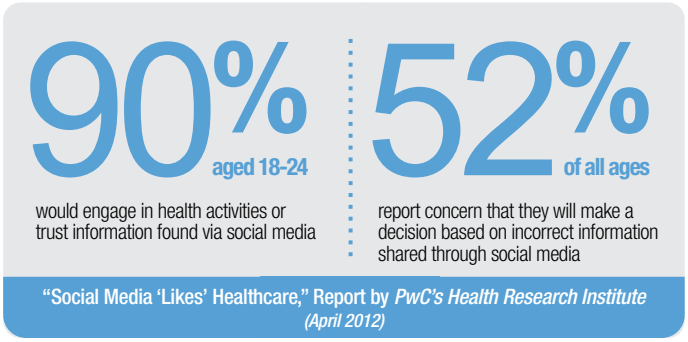
II. Some guy online said it worked for him …

Rather than prioritizing the management of real-world risk to patients, current regulation has led to default policing of manufacturers' speech. This cannot stand. As FDA itself is compelled to explore usage of digital media to meet its goals and serve the public, it is also imperative for Industry to engage digital media to remain functional in the contemporary world. *Kordel* was decided on a specific set of facts surrounding an individual defendant's criminal conviction for misbranding health food products[5]—not written in direct contemplation of the future of either medicine or advertising. As important as the Court's considerations in *Kordel* were and continue to be, current controversies such as the Second Circuit's 2012 *Caronia* ruling on off-label marketing[6] reveal the complexity of rule-making for an industry that is maturing faster than the laws by which it is bound.

Scientists, manufacturers, physicians, consumers—we all know so much more about medicine than we used to. The public is more widely educated about science. The rise of the primary care physician in the mid-20th century[7] created a learned intermediary who can assist consumers in making medical purchasing choices. To an extent, the learned intermediary served as the gatekeeper for medical information and the guide for medical decision-making. Subsequent technological advancements, especially the Internet, broadened access to information for every stakeholder. As Google noted in a public comment to FDA, "More than in any other media, consumers online are constantly and actively involved in sorting and selecting information sources."[8]

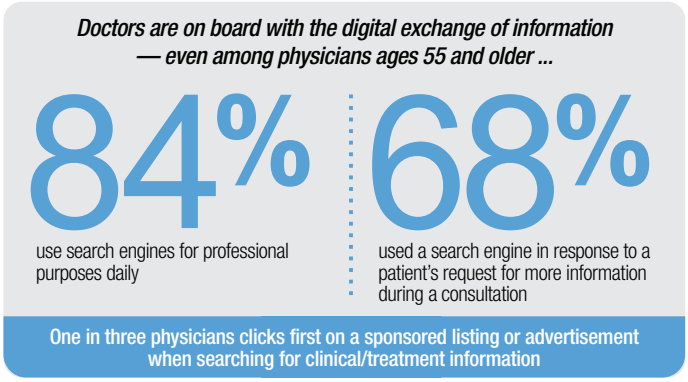


According to a 2012 study, consumers expect a healthcare company to respond to their social media posts incredibly quickly, with 61 percent expecting a complaint about a service, product, or experience to be responded to within three hours and 65 percent expecting a response to a request for information within three hours.[9] Not only are these response-time expectations startling, but significant also is the fact that patients are going directly to the source rather than an intermediary. Meeting these expectations would not leave a manufacturer enough time to prepare an FDA-compliant response. Yet while 90 percent of individuals



aged 18-24 would engage in health activities or trust information found via social media, 52 percent of consumers of all ages report concern that they will make a decision based on incorrect information shared through social media.[10] It is not hard to see the value in manufacturers providing information directly to these patients—they are demanding it. It is also not difficult to see the value in FDA ensuring that online information is accurate—the public is relying on it.

The issue of online promotion is not limited to direct-to-consumer concerns, though. Doctors are on board with the digital exchange of information—even among physicians ages 55 and older, 84 percent use search engines for professional purposes daily.[11] One in three physicians clicks first on a sponsored listing or advertisement when searching for clinical/treatment information.[12] Since 68 percent of physicians have used a search engine in response to a patient's request for more information during a consultation,[13] the role of the physician as learned intermediary seems to be greatly supplemented by new technology.



While FDA and Industry contemplate regulatory solutions for hypothetical uses of digital media, the actual users of FDA-regulated products—patients and physicians—are already embracing and relying on these technologies. Twitter, for example, may be capturing three times as many adverse event reports as FDA.[14] What happens to all that data? Turns out, not much.[15] Industry has been left twiddling its thumbs, waiting for FDA to provide a map of the FDCA minefield that is digital media.

III. The Exceptions That Prove the Rules

For its part, FDA has sustained its worthy goal of protecting consumers. But its approach may be too dogmatic to be effective. The Guidances are clear that the limitations of a medium will not be grounds for relaxed requirements or enforcement on the presentation of legally required information or the requisite submission of promotional materials on Form 2253. Rather than attempting to bring FDA's process up to speed with digital promotion, the Guidances outline a few exceptions to existing rules. Digital media are, by nature, interactive—built on responsive designs and opening new multi-way communication channels. As illustrated in Figure 1, there are benefits from digital engagement that are necessary to the continued protection and enhancement of public health.

The Guidances, however, seem more like expressions of habit than thoughtfully structured directions to use digital resources to serve FDA's twofold mission to protect public health by "assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, [etc.]" and advance public health by "helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health."[16] Although the Guidances acknowledge the challenges presented by digital media, it's difficult to pinpoint how FDA's gestures will provide new benefits to consumers. In *Sorrell v. IMS*, Vermont did not contend that the detailing at issue was false or misleading within the Court's First Amendment precedents or that the provision central to the case would prevent false or misleading speech. As the Court wrote, "[Vermont's] interest in burdening the speech of detailers instead turns on nothing more than a difference of opinion."[17] These Guidances also leave one wondering not only whether manufacturers' speech is being unfairly burdened but also, if that burden is indeed fair, whether it serves the public it was designed to protect.

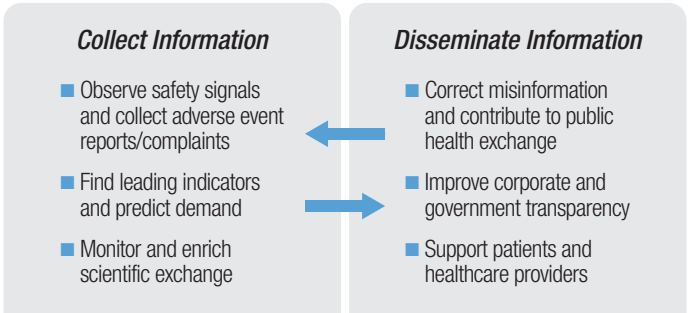


Fig. 1 **Healthcare's Digital Imperative: The Value in Digital Health Data**

a. *Draft Guidance for Industry for Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, January 2014 (Postmarketing Submissions)*

When *Postmarketing Submissions* was slated for release, Industry was giddy with excitement—receiving guidance in this area was expected to be a green light to go forth and Facebook. But then everyone read it. There is no practical "one-click rule," and while the influence and control standard it establishes for Form 2253 submission is fairly straightforward, it provides no instruction on how Industry can compliantly use digital media. The only exception included in *Postmarketing Submissions* that nods at the pace of promotion on digital media is FDA's intent to allow Industry to bundle interactive material submissions.

FDA writes, "While [FDCA's requirement to submit] 'at the time of initial dissemination' does not refer to submissions on a weekly, monthly, or other routine schedule, FDA intends to exercise its enforcement discretion under certain circumstances due to the high volume of information that may be posted within short periods of time using interactive promotional material that allows for real-time communications."[18] Although it provides no indication of what frequency of communication FDA would consider to be "high volume," the guidance goes on to clarify that firms can simply submit a list of interactive sites for which they are responsible with no screen shots as long as the sites are unrestricted. This provision reduces FDA's and Industry's potential administrative burdens but does not establish a new framework specific to digital media.

b. *Draft Guidance for Industry for Internet/ Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices, July 2014 (Space Limitations)*

Space Limitations emphasizes one core message: The promotional rules do not change just because the promotional medium does. Since FDA "is aware of the challenges in balancing benefit and risk information within the character space constraints of certain Internet/social media platforms," it "believes that a concise disclosure of specific risk information may be presented together with benefit information … if supplemented by a prominent reference to the presence and location elsewhere of a more complete discussion of the risks …"[19] This concise presentation is further qualified in the guidance but provides little clarity to Industry.

Additionally, FDA does not intend to object when posts in character-space-limited media present the brand name and established name side by side or omit the dosage form and quantitative ingredient information. The caveat here is that these elements appear in their traditionally required form "on the landing page associated with each hyperlink provided."[20]

Despite its focused message, *Space Limitations* requires careful reading for Industry to absorb its many footnotes. Here's a list of some of the more salient additions:

> "This guidance document focuses on use of character-space-limited platforms by firms to make claims about their legally marketed drugs and devices that are consistent with their approved or required labeling. Representations by a firm in character-space-limited platforms may also provide evidence of the intended use of the product, but that issue is not the focus of this draft guidance."[21]

> "This draft guidance does not apply to those *reminder* promotions (labeling or advertising that calls attention to the name of a drug or device but does not include indications, dosage recommendations, or other information) that are exempted by regulation from the requirements under the FD&C Act for the disclosure of risk information."[22]

> "For prescription human drugs, if the only contraindication listed in the PI is hypersensitivity, the Agency would not expect that contraindication to be included as part of the risk disclosure within the character-space-limited communication unless there were documented cases of hypersensitivity occurring in patients who took the product."[23]
>
> "… However, note that a link to a brief summary or PI should not be used **in place of** disclosing risk information within the original character-space-limited communication."[24]

Returning to the main text, *Space Limitations*' repeated instruction that if a firm cannot meet the required minimum presentation of information, "then the firm should reconsider using that platform for the intended promotional message,"[25] is troubling. Given that anyone, including a non-expert, is free to post on these media without regard for truth, never mind fair and balanced presentations of risk and benefit information, Industry is left in a bind.

c. Draft Guidance for Industry on Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices, June 2014 (Correcting Misinformation)

Correcting Misinformation, while laying out FDA's standards for "appropriate corrective information," may result in a number of undesired consequences. One example it presents is a manufacturer's public-facing disagreement with a blogger stemming from attempts to correct misinformation.[26] Here the manufacturer posts promotional material in an act of self-defense, thereby subjecting it to a higher standard of scrutiny by FDA. By highlighting risks and penalties, *Correcting Misinformation* implies to Industry that the best way to avoid censure is to ignore the spread of misinformation by unregulated parties. FDA writes, "When a firm voluntarily undertakes the correction of misinformation in a truthful and non-misleading manner pursuant to the recommendations in this draft guidance, FDA does not intend to object if these voluntary corrections do not satisfy otherwise applicable regulatory requirements, if any."[27] A statement of intentions as vague as this discourages Industry's participation in an activity that would greatly benefit the public.

Correcting Misinformation further qualifies: "If a firm chooses to provide information outside the scope of this draft guidance, the firm should ensure that the information it provides complies with any applicable requirements related to labeling or advertising."[28] The fact that the draft guidance even contains a section titled "The Consequences of Correcting Misinformation" conveys the irony that consumers are protected from Industry's attempts to communicate corrections while the proliferators of misinformation carry on unchecked. Although manufacturers would not be using digital media in opposition to the goals of FDA by correcting misinformation online, the split in the treatment of Industry's and other parties' speech leads back to *Sorrell*, in which regulators "burdened a form of protected expression that it found too persuasive" at the same time it "left unburdened those speakers whose messages are in accord with its own views."[29]

IV. IRL[30]

The Guidances are far removed from the digital speech they attempt to regulate. The requirement for manufacturers to communicate risks "in clear, understandable, and non-technical language for consumer audiences" was already right there in FDA's 2009 guidance on presenting risk information.[31] To the Internet—by which we mean the individual users who interact with digital content every day—a hyperlink probably seems a lot clearer and less technical than the folded-up PI that comes stapled behind the pharmacy receipt. But FDA's "current thinking" treats a hyperlink as if it is a way to hide information rather than to deliver it.

The interactive nature of digital media must be matched by an equally dynamic regulatory understanding of the communications that take

place online. As AstraZeneca noted in a public comment back in 2010, an existing guidance offers a "precedent for regulating social-media real-time participation content in context and as a whole."[32] That 2009 guidance says, "FDA looks not just at specific risk-related statements, but at the ***net impression***—i.e., the message communicated by all elements of the piece as a whole. The purpose of the evaluation is to determine whether the piece ***as a whole*** conveys an accurate and non-misleading impression of the benefits and risks of the promoted product. Manufacturers should therefore focus not just on individual claims or presentations, but on the promotional piece as a whole."[33] AstraZeneca posited that "It is similarly appropriate for the agency to view a social media conversation as a whole and not regulate each and every 'post' as if it were, in itself, a promotional piece. We recommend a framework that understands that a conversation may include text, video, sounds, and other elements that are appropriate to consider together."[34] This idea, simply, is that FDA should regulate digital communications with a mind toward the consumers' view. Pfizer also pointed to this need in a public comment, writing, "Clear, enforceable, evidence-based regulatory requirements that reflect real-world user expectations in the Internet and social media context are necessary to encourage manufacturers to provide truthful and non-misleading product information, subject to FDA regulatory oversight, to improve the overall quality of health information available to users online."[35]

FDA has done its part over time to ensure the dissemination of truthful and non-misleading information by medical manufacturers and to keep deleterious medicines out of Americans' cabinets. Along the way, the U.S. has become the world's largest pharmaceutical market[36] with what are commonly recognized as the world's most stringent regulations. To get here, however, FDA has regulated slowly. In replacing and withdrawing outdated draft and final Guidances, it moves even more slowly. Even the Ranking Member of the Senate Committee on Health, Education, Labor and Pensions has expressed concern about the guidance process.[37] Despite FDA's establishment of Good Guidance Practices, its stated intention to review, reevaluate, and announce changes to existing Guidances has yielded little in terms of actual withdrawals.

In this environment of stale and ambiguous Guidances, FDA often leaves Industry to rely on enforcement actions to guess the best path through regulatory gray areas. These enforcement actions include Form 483s, Warning/Untitled Letters, corporate integrity agreements, and settlements related to FDCA and the False Claims Act. The unpredictable speed at which new technology emerges demands a new regulatory framework—one that focuses on risk in order to allow Industry to take advantage of powerful digital resources to connect with the real human beings who need health information.

FDA has two forthcoming items on its 2014 agenda that relate to digital media. A further guidance, *Internet/ Social Media Advertising and Promotional Labeling of Prescription Drugs and Medical Devices—Use of Links*, may elucidate some of the murkier areas that have arisen around hyperlink usage. Perhaps it will address a "one-click rule" or give more information about the "www.product.com/risk" recommendation for referring to full risk information in *Space Limitations* and the ban on linking to risk information with "promotional" URLs from *Correcting Misinformation*.

The second is a proposed rule concerning *Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products*. It will "require electronic package inserts for human drug and biological prescription products with limited exceptions, in lieu of paper, which is currently used."[38] We see this as a sign that FDA is adopting contemporary communication strategies and looking at a digital medium as an effective tool. Electronic PIs "would ensure that the information accompanying the product is the most up-to-date information regarding important

safety and efficacy issues about these products."[39] Straightforward updates should be a constant in FDA's rule-making and guidance. Keeping in stride with the communications of patients is the best practice for continued public safety.

V. "If you want something new, you have to stop doing something old."—Peter Drucker

In his dissent in that pivotal *Kordel* opinion, Justice Black wrote, "The Court's interpretation … seems to me to create a new offense to make it a crime to introduce drugs into interstate commerce if they should subsequently be misbranded[.]"[40] Looking at phrase after phrase in the Guidances hedging FDA's bets on what they might one day consider appropriate uses of digital media ("Firms are generally not responsible for third party [user-generated content]," "FDA would not intend to object to this [example of an appropriate] Tweet," "the firm should reconsider using that platform") leaves a feeling that what is appropriate today might later be deemed inappropriate without any change to laws, regulations, or Guidances.

This regulatory seesaw has a chilling effect on Industry. After launching a medical device project with Novartis, the co-founders of Google made clear that they weren't interested in participating in the healthcare industry. Sergey Brin said, "I think the regulatory burden in the U.S. is so high that I think it would dissuade a lot of entrepreneurs." Larry Page continued, "I do worry that we regulate ourselves out of some really great possibilities that are certainly on the data-mining end." Two of the greatest digital innovators in the world believe regulations are so stringent that "It's just a painful business to be in. It's just not necessarily how I want to spend my time."[41] We must ensure that innovation, which is integral to solving the public's health problems, is not stifled by those safety regulations with which it must go hand in hand.

It won't work for Industry to "opt out" of digital engagement because the old rules are a poor fit in the new digital world. The digital imperative at work in the Industry right now is creating tension among all stakeholders because it is clear that the potential of digital engagement is not being realized due to regulatory uncertainty. The benefits outlined in Figure 1 are far-reaching. Their potential has been illustrated in other sectors already. As Steven Johnson writes in *The Ghost Map*, "Increase the knowledge that the government has of its constituents' problems, and increase the constituents' knowledge of the solutions offered for those problems, and you have a recipe for civic health that goes far beyond the superficial appeal of 'quality of life' campaigns."[42] This conclusion is drawn from empirical evidence. An excellent example is New York City's 311 program. Johnson explains that "the radical idea behind the [311] service is that the information transfer is genuinely two-way. The government learns as much about the city as the 311 callers do. You can think of 311 as a kind of massively distributed extension of the city's perceptual systems, harnessing millions of ordinary 'eyes on the street' to detect emerging problems or report on unmet needs. (Bloomberg himself is notorious for calling in to report potholes.)."[43] This concept applies equally well to Industry as it does to government bodies like FDA. Both can be more successful through the incorporation of digital media into their communication strategies. As illustrated in Figure 1, the exchange of information among stakeholders has a synergistic effect. Collections and disseminations of information inform one another, elevating the health knowledge base. The two- and multi-way communication channels opened by digital media allow us not only to create, collect, and analyze data, but also to respond to it and to allow it to continually shape the healthcare paradigm.

The Guidances we have now, however, struggle to find equilibrium with FDA's two necessary objectives: 1) ensure products' safety, efficacy, and security; and 2) speed medical innovation and facilitate the dissemination of health information for use by the public. These goals must not conflict. Yet Industry today finds itself facing a catch-22. The Food and Drug

Administration Safety and Innovation Act (FDASIA) of 2012 called for the creation of these Guidances by 2014 to "describe [FDA] policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration."[44] This was the impetus for FDA to publish the Guidances now. But digital media requires balanced, pragmatic regulation in the form of a risk-based approach. These drafts would greatly benefit from revision in line with the "risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication" also required by FDASIA.

The Medical Device Amendments of 1976 established this idea, saying that the safety and effectiveness of a device are to be determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." Industry saw this approach applied recently in the final *Guidance for Industry and Food and Drug Administration Staff on Mobile Medical Applications (Mobile Apps)* and *Draft Guidance for Industry and Food and Drug Administration Staff on Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements (Intent to Exempt)*. As FDA articulated in its FDASIA Health IT Report, it "recognizes the importance of implementing a balanced, transparent approach to medical device oversight and seeks to strike the right balance by focusing its regulatory resources to provide a risk-based approach to the oversight of those products that present a greater risk to patients if they do not work as intended."[45] A risk-based approach as adopted in *Mobile Apps* and *Intent to Exempt* would be more prudent and effective in regulating tweets and other communications made via digital media.

There are rich benefits to be had from Industry participation. The status quo—FDA saying that if manufacturers cannot meet the old requirements in a new medium, they should opt out of the medium—presents risk to patients by creating unrealistic barriers to Industry's digital communication with them.

The enforcement tactics that FDA and the Department of Justice have relied upon for so long have been questioned by the recent *Caronia* and *Sorrell* decisions. With Industry and the government yet again going head-to-head over First Amendment issues in *Solis v. Millennium Pharmaceuticals*,[46] attention has been drawn to the use of the False Claims Act as a cause of action for discipline related to manufacturers' speech beyond a product's label. This tension between FDA's current attempts to regulate promotional speech and Industry's attempts to disseminate information to patients in need can seem irreconcilable when compressed into the microcosm of a tweet. The problem is often framed as FDA's failure to keep pace with Industry—we have put it that way ourselves—but as 2014 advances, we've started to see that the real trouble is that it cannot keep up with patients. At a time when tech-enabled personalization is emerging as the leading strategy in patient care, FDA should be looking for new ways to enable Industry to participate. Rather than trying to make old regulations keep working in a new era, balanced, risk-based regulation of Industry's digital media use can facilitate medical advancement while preserving patient safety. That's the only way to create a better public health future.

For more information, please contact:

Scott S. Liebman
212.407.4838
sliebman@loeb.com

Loeb & Loeb LLP's FDA Regulatory and Compliance Practice

Loeb & Loeb's FDA Regulatory and Compliance Practice comprises an interdisciplinary team of regulatory, corporate, patent, and litigation attorneys who advise clients on the full spectrum of legal and business issues related to the distribution and commercialization, including marketing and promotion, of FDA-regulated products. Focusing on the health and life sciences industries, including pharmaceuticals, biologics, medical devices, wellness products, dietary supplements, and organics, the practice counsels clients on regulatory issues, compliance-related matters, and risk management strategies; advises on laws and regulations related to product advertising and labeling; counsels on FDA exclusivity policies and related Hatch-Waxman issues; and provides representation in licensing transactions and regulatory enforcement actions.

[1] The FDA website provides an overview of the agency's origins, history, and functions, available at: http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/default.htm.)

[2] 335 U.S. 345 (1948).

[3] *Id*. at 350.

[4] *Id*. at 351.

[5] *Id*. at 346-47.

[6] *United States v. Caronia*, 703 F.3d 149 (2d. Cir. 2012) (holding that "the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug").

[7] *See generally* Joel D. Howell, "Reflections On The Past And Future Of Primary Care," *Health Affairs*, 29, no.5, 760-765 (2010).

[8] "Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools," Docket No. FDA-2009-N-0441, Feb. 28, 2010, available at: http://www.regulations.gov/#!documentDetail;D=FDA-2009-N-0441-0088.

[9] "Social Media 'Likes' Healthcare," Report by PwC's Health Research Institute (April 2012), available at: http://pwchealth.com/cgi-local/hregister.cgi/reg/health-care-social-media-report.pdf.

[10] *See id*.

[11] "Screen to Script: The Doctor's Digital Path to Treatment," June 2012 PowerPoint Presentation by Google/Manhattan Research, available at: https://docs.google.com/viewer?url=http://ssl.gstatic.com/think/docs/the-doctors-digital-path-to-treatment_research-studies.pdf&chrome=true.

[12] *See id*. (Slide 20).

[13] *See id*. (Slide 16).

[14] C.C. Freifeld et al, "Digital Drug Safety Surveillance: Monitoring Pharmaceutical Products in Twitter," *Drug Safety* 37(5): 343–350 (2014).

[15] Alexander Gaffney, "FDA Data Mining Project Proposal Once Again Withdrawn," online publication by Regulatory Affairs Professionals Society, available at: http://www.raps.org/regulatoryDetail.aspx?id=18441.

[16] *See* "What We Do" on FDA website: http://www.fda.gov/AboutFDA/WhatWeDo/default.htm.

[17] *Sorrell*, 131 S.Ct. at 2672.

[18] *Draft Guidance for Industry for Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, January 2014 (Postmarketing Submissions)*, available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf.

[19] *Draft Guidance for Industry for Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices, July 2014 (Space Limitations)*, available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf.

[20] *Id*. at 13-14.

[21] *Id*. at 2, n. 4.

[22] *Id*. at 4, n. 10.

[23] *Id*. at 9, n. 15.

[24] *Id*. at 10, n. 16.

[25] *Id*. at 5.

[26] *Draft Guidance for Industry on Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices, July 2014 (Correcting Misinformation)*, available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.

[27] *Id*. at 3.

[28] *Id*. at 9.

[29] *Id*. at 2672.

[30] If you are like the author of this white paper, someone younger needs to tell you this means "in real life."

[31] *Draft Guidance for Industry Presenting Risk Information in Prescription Drug and Medical Device Promotion, May 2009 (2009 Guidance)*, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm155480.pdf.

[32] AstraZeneca's February 26, 2010, Response to FDA Call for Comments: Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools (Docket No. FDA-2009-N-0441) (AstraZeneca Letter), available at: http://www.regulations.gov/#!documentDetail;D=FDA-2009-N-0441-0028.

[33] *See 2009 Guidance*, at 4.

[34] *See* AstraZeneca letter.

[35] *See* February 26, 2010, Letter from Pfizer Inc. commenting Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools (Docket No. FDA-2009-N-0441), available at: http://www.regulations.gov/#!documentDetail;D=FDA-2009-N-0441-0039.

[36] *See* IMS Institute for Healthcare Informatics, Global Use of Medicines Outlook Through 2017 Report, Exhibit on Geographic Distribution of Medicine Spending, available at: http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Global_Use_of_Meds_Outlook_2017/Geographic_Distribution_Medicine_Spending.pdf.

[37] *See* May 6, 2014, Letter to Commissioner Margaret Hamburg, available at: http://www.hpm.com/pdf/blog/AlexanderFDAGuidanceLetter.pdf.

[38] Summary of rule, available at: https://www.federalregister.gov/regulations/0910-AG18/electronic-distribution-of-prescribing-information-for-human-prescription-drugs-including-biological.

[39] *See id*.

[40] *Kordel*, 335 U.S. at 354.

[41] Video and transcript of discussion with Page and Brin, available at: http://www.khoslaventures.com/fireside-chat-with-google-co-founders-larry-page-and-sergey-brin.

[42] Johnson, S. (2006). *The Ghost Map*: The story of London's most terrifying epidemic—and how it changed science, cities, and the modern world (p. 226). New York: Riverhead Books.

[43] *Id*. at 225.

[44] Public Law 112–144—July 9, 2012. (Full text available at: http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf.)

[45] *See* FDA's April 2014 FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework, available at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf.

[46] *See* Amaris Elliott-Engel, "Argument Is Whether Off-Label Drug Claims Were Truthful," *The National Law Journal* (Sept. 3, 2014), available at: http://www.nationallawjournal.com/id=1202668692655/Argument-Is-Whether-OffLabel-Drug-Claims-Were-Truthful#ixzz3FViEUMF5.