

Standard Social Media Practices Are Risky For Big Pharma

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The days of patients relying solely on family physicians for health care information are long gone. As with many things, when we need information about an illness or a medical condition, we turn to “theGoogle.”[1] And though most online health queries begin at a search engine, a not-insignificant number start somewhere else, such as Wikipedia.[2] Those who are Internet-savvy tend to be avid social media users, spending more time with their social networks than on email, especially with their Facebook friends.[3] An estimated 200,000 people are likely to start there if they have a question.[4]

When dealing with a serious health issue, though, over 70 percent of Internet users still (sensibly) go to their physicians.[5] But Internet access and social media connections have altered this relationship. Patients now have the ability to research their conditions for themselves, and the physician-patient dynamic is impacted regardless of whether patients are actually well informed, or merely believe themselves to be. On balance, physicians tend to view this as a positive development.[6] Patients use online resources at diagnosis, at the onset of treatment, and throughout their course of treatment.[7] And they are not alone. On average, physicians spend twice as much time looking to online resources as they do to traditional sources.[8]



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Despite the clear interest in social media engagement by two of its key stakeholders — patients and physicians — the pharma industry has been relatively slow on the uptake.[9] Other industries have not been. Companies in the computer and software industry, for instance, have deputized thousands of their employees to engage consumers by acting as thought leaders within social media communities.[10] Social media has also been used as a rebranding tool, to appeal to an entirely new generation of consumers,[11] or to an entirely new demographic.[12] And some social media campaigns evolve so that they have less to do with an actual product, and everything to do with timely social commentary.[13]

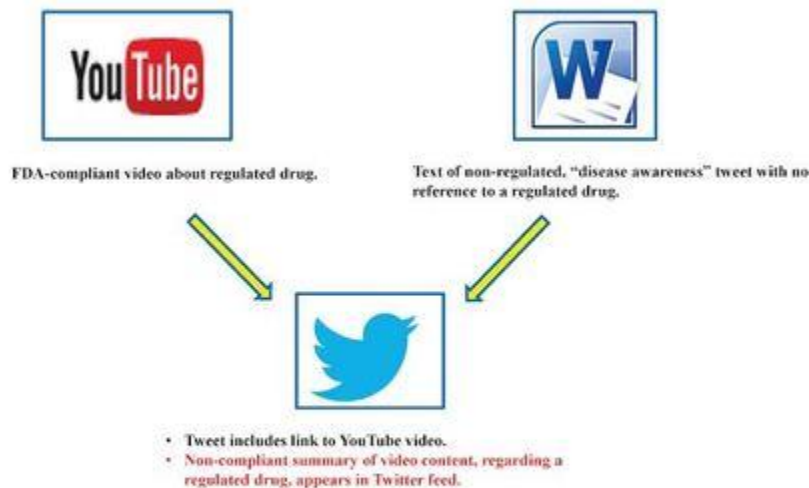
For every success story, there is also a cautionary tale. Twitter campaigns, in particular, are vulnerable to being hijacked.[14] A successful social media strategy cannot be generic,[15] and companies must be attuned to quickly moving developments or run the risk of cyberspace ridicule.[16] Of course, pharma companies and others in regulated industries have more to worry about. Chief among their concerns is inadvertently violating U.S. Food and Drug Administration regulations that are in place to guard patient welfare.

The whole point of social media is to interact with others in virtual space, to share information or ideas, and create relationships. Accordingly, “liking” a status update or a comment, sharing or retweeting, or adding content to someone else’s page are commonplace. Though these actions seem innocuous — and are standard practice in the social media sphere — they may result in letters from the FDA when the underlying content is noncompliant.

This past June, a company marketing “natural” medications received a warning letter. It had “liked” comments made on its Facebook page, presumably by consumers who had found relief by using the company’s allergy medications, cough syrup and sleep aids.[17] Under FDA regulations, this was an inappropriate endorsement of testimonials. A nutritional supplement company found itself under similar scrutiny when it advertised purported benefits of compounds like cranberry concentrate and cinnamon bark extract, because it had not obtained FDA approval to market these compounds for the advertised purposes. No safety and efficacy studies had been performed.[18] As social media platforms develop, companies will have to be increasingly vigilant to avoid inadvertently violating regulations.[19]

Another characteristic of social media is brevity. Tweets cannot be any longer than 140 characters, but do better if they are between 120-130 characters.[20] And Facebook posts are most effective when they are even shorter than that.[21] The problem, here, for pharma companies is that FDA-approved labeling exceeds those character limits. This past February, Institut Biochimique SA and Akrimax Pharmaceuticals erred by failing to include any risk information on the Facebook page for a hypothyroidism treatment.[22] Though consumers were explicitly instructed to talk to their doctors, the companies were not excused from fully complying with FDA requirements.

Social media encourages sharing content, but this practice comes with associated risks.[23] Last August, for example, AstraZeneca PLC sponsored “disease awareness” tweets for acid reflux.[24] The sponsored tweet appeared in a Twitter feed, augmented with a link to an AstraZeneca YouTube video about Nexium. Linking from one social media platform to another, in particular to YouTube, is perfectly reasonable to do in the social media realm, because posts have greater impact when they include visual content.[25]



The Nexium YouTube video complied with all FDA requirements. In the process of linking the video to the tweet, however, a summary description of the drug was generated. That summary — based on metadata embedded in the YouTube page — appeared only in the tweet.[26] And because it did not contain all of the FDA-required safety information, it was noncompliant. AstraZeneca pulled the tweets down before the FDA ever got involved.[27]

Because regulatory compliance can be challenging on social media, the FDA has released draft guidance to address two aspects: (1) adequately representing risk and benefit information when character space is limited; and (2) correcting any misinformation about a regulated product that originates with a third party.[28] The guidance applies to any interactive media, including microblogs, social networking sites, online communities and live podcasts.[29]

When character space is limited, such as on Twitter, companies should consider the following:[30]

- Information about a drug’s benefits should be accurate, nonmisleading and reveal “material facts” within each individual communication (e.g., each individual tweet). Material facts include both the relevant patient population, and any limitations as to indications.

- Information about a drug’s benefits should be accompanied by information about its risks, within each individual communication.[31]
 - The communication should, at minimum, include the most serious risks associated with the drug, “generally include[ing] all risk concepts from a boxed warning, all risks that are known to be fatal or life-threatening, and all contraindications from the approved product labeling.”
 - The prominence of the risk information should be comparable to the prominence of the benefit information.
 - A hyperlink should be provided within the communication to a more complete discussion of risks, but does not substitute for including the requisite information within the communication itself.
 - If adequate risk and benefit information, “as well as other required information” cannot be communicated within the same communication, then use of the platform should be reconsidered.[32]

A company is responsible for ensuring that any of its own communications are compliant, including those (1) made by employees or agents acting on a company’s behalf; and (2) on which a company collaborates, or over which it exerts control or influence, including editorial or review privileges, or influence over promotional placement within a third-party site.[33],[34]

When a company is responsible for a site, the comprehensive, static site should be submitted to the FDA, along with an explanation regarding any interactive or real-time components.[35] Any changes should be annotated and resubmitted.[36] For restricted sites, all interactive content should be submitted, so that the agency understands the full context.[37] Companies should also submit the home pages of any third-party sites, along with interactive pages and their initial communications.[38] Thereafter, monthly updates are appropriate when the site is non-restricted.

The FDA has also drafted guidelines that apply to user-generated content for which a company is not responsible.[39]

- To the extent that misinformation appears on a third-party site, for example a blog, and is posted by an individual without a relationship with the company, a company need not correct the misinformation, but may do so.[40], [41]
- If user-generated content appears on a forum for which the company is responsible, such as a corporate website, the site should include a clear and conspicuous statement that the company does not create or control the content. If a company influences user-generated content, for example, by inviting commentary, it may be responsible for the content.[42]
- When correcting misinformation, the correction should be: relevant and responsive; limited and tailored; nonpromotional in tone; accurate; consistent with FDA-labeling requirements; supported by sufficient evidence; and posted in conjunction with the misinformation.[43]

Maintaining compliance with FDA-labeling requirements is not the only challenge.[44] A January 2014 study by the IMS Institute for Healthcare Informatics highlights another concern — the obligation to report all known adverse drug reactions (ADRs).

Quite a lot of information can be found on blogs, Facebook groups and other online forums about people’s experiences with drugs, including those in clinical trials.[45] While “reportable adverse events are not common relative to the number of social media posts” in total — and the percentage of adverse events reported in general social media posts is estimated to be only 0.2 percent[46] — consider the sheer volume of activity on social media. There are over 500 new Facebook comments every minute, and over a billion new tweets are generated weekly.[47] If social media sites are monitored, companies “may also become responsible to report ADRs that come to light in this manner.”[48] This could lead to an overwhelming amount of data that a company would have to monitor and analyze. The investment cost could also be substantial because consumers expect to be part of a conversation.[49]

The health care industry has generally used social media in one of three ways: (1) to gather information; (2) to broadcast messages and content; and (3) to engage the public on health care-related topics, without implicating privacy concerns.[50] As of January 2014, about half of the top 50 pharma companies do not engage with consumers or with patients on health care-related topics on social media. Of those that do, only 10 companies used Twitter and Facebook and YouTube.[51] Moreover, midsize companies can use social media just as well, and in some cases even better than, the 10 largest companies.[52]

It remains to be seen whether companies can develop adequate information technology infrastructures, and sufficient marketing and communication systems, to effectively monitor social media platforms and strategically mine available data. They may be able to leverage technological advances, like natural language programming and better informatics tools. [53] Companies and regulatory agencies have both come to appreciate not only how prevalent social media is, but the frequency with which people access their social networks remotely.[54] Smartphone users may check their phones more than 100 times a

day,[55] so it is not surprising that apps have been developed to help recruit clinical trial participants, and to also leverage the fact that 20 percent of the population already tracks personal data, like fitness routines, diet and weight, through their phones.[56] Apps are currently under development in Europe to allow trial participants to easily report ADRs.[57]

To date, some companies have chosen to engage. They look outward, choosing to follow others on various platforms, including journalists, news groups, employees, nonprofits, popular political figures and hospitals.[58] They view social media as an educational platform, and as a way to disseminate general industry information.[59] They use their presence in cyberspace to create opportunities to build trust with individual consumers, such as by sending a private message, coordinating a phone call, or staging a real-world event.[60] And they encourage their stakeholders to engage with each other.[61] These avenues are well worth the investment because they provide companies with a better understanding of their stakeholders who, increasingly, will not hesitate to mount social media campaigns of their own.[62] Better to be part of the dialogue.

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[1] Pew Research Internet Project, Health Fact Sheet (<http://www.pewinternet.org/fact-sheets/health-fact-sheet/>) (reporting that 72 percent of Internet users looked online for health information between 2011 and 2012, with 77% starting at a search engine, and 1 percent starting at a social network site); IMS Institute for Healthcare Informatics, Engaging Patients through Social Media: Is Healthcare Ready for Empowered and Digitally Demanding Patients? at 6 (http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_Social_Media_Report_2014.pdf) (January 2014) (reporting that between 70-75% of people online in the U.S. seek healthcare information).

[2] IMS Institute for Healthcare Informatics, Engaging Patients through Social Media: Is Healthcare Ready for Empowered and Digitally Demanding Patients? at 16-17 (http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_Social_Media_Report_2014.pdf) (January 2014) (hereinafter “IMS Study”)

[3] Business Insider, Adler, E., Social Media Engagement: The Surprising Facts About How Much Time People Spend On The Major Social Networks, <http://www.businessinsider.com/social-media-engagement-statistics-2013-12#ixzz3Cklh5GUh> (Aug. 21, 2014)

[4] Supra n. ii; and see Internet Users by Country (2014), <http://www.internetlivestats.com/internet-users-by-country/> (last accessed Sept. 8, 2014) (reporting 279,834,232 Internet users in the U.S.).

[5] Supra, n. ii.

[6] IMS Study at 14, 32.

[7] IMS Study at 18, 20.

[8] IMS Study at 2.

[9] IMS Study at 9, 25-26.

[10] Forbes, Rooney, J., In Dell Social-Media Journey, Lessons For Marketers About The Power Of Listening (<http://www.forbes.com/sites/jenniferrooney/2012/09/25/in-dell-social-media-journey-lessons-for-marketers-about-the-power-of-listening/>) (Sept. 25, 2012); Content Boost, Neuman, B., Oracle Encourages Employees to Use Personal Social Media Accounts for Business (<http://www.contentboost.com/topics/content-marketing/articles/370574-oracle-encourages-employees-use-personal-social-media-accounts.htm>) (Feb. 18, 2014); MarketingProfs, Gorgone, K.O.S., Employees as Brand Advocates: IBM's Ethan McCarty Talks to Marketing Smarts (Podcast) (transcript available at <http://www.marketingprofs.com/podcasts/2013/11758/employees-as-brand-advocates-ibms-ethan-mccarty-talks-to-marketing-smarts-podcast#ixzz3CqErxuhf>) (Oct. 2, 2013).

[11] Old Spice, The Man Your Man Could Smell Like, <https://www.youtube.com/watch?v=owGykVbfgUE> (uploaded Feb. 4, 2010). Proctor & Gamble “launched the fastest growing online viral video campaign ever,” getting over 23 million views in a day and a half. Inspire Analytics, Lessons Learned from the Biggest Social Media Campaign Downfall in History (<http://www.inspireanalytics.com/lessons-learned-from-the-biggest-social-media-campaign-downfall-in-history/>) (Feb. 10, 2013).

[12] Under Armour, Misty Copeland— I Will What I Want (https://www.youtube.com/watch?v=ZY0cdXr_1MA) (published July 30, 2014); Forbes, O’Connor, C., Under Armour Goes After Lululemon With Gisele And ‘Womanifesto’ (<http://www.forbes.com/sites/clareoconnor/2014/09/04/under-armour-goes-after-lululemon-with-gisele-and-womanifesto/>) (Sept. 4, 2014).

[13] Bloomberg Businessweek, Brustein, J., An Interracial Cheerios Super Bowl Ad, Minus YouTube's Hateful Comments (<http://www.businessweek.com/articles/2014-01-31/an-interracial-cheerios-super-bowl-ad-minus-youtubes-hateful-comment>) (Jan. 31, 2014)

[14] The Financial Brand, 8 Lessons from JPMorgan’s Twitter Fail (<http://thefinancialbrand.com/35532/8-lessons-from-jpmorgan-twitter-disaster/>) (Dec. 10, 2013).

[15] Business Insider, Stamper, L., American Airlines Will Respond To Every Tweet — No Matter How Offensive

(<http://www.businessinsider.com/american-airlines-will-respond-to-every-tweet--no-matter-how-offensive-2013-2#ixzz3CqqIVu8T>) (Feb. 14, 2013).

[16] Search Engine Journal, Costill, A., 35 Examples of #SocialMedia Fails (<http://www.searchenginejournal.com/35-social-media-fails/95613/>) (Mar. 27, 2014).

[17] FDA, Inspections, Compliance, Enforcement, and Criminal Investigations: Zarbee’s, Inc., June 27, 2014 (<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm403255.htm>)

[18] FDA, Inspections, Compliance, Enforcement, and Criminal Investigations: M.D.R. Fitness Corp., Jan. 29, 2013 (<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm338405.htm>).

[19] Regulatory Affairs Professional Society, Gaffney, A., FDA Targets Companies for Facebook ‘Likes.’ Is Twitter Next? (<http://www.raps.org/Regulatory-Focus/News/2014/08/12/20014/FDA-Targets-Companies-for-Facebook-Likes-Is-Twitter-Next/>) (Aug. 12, 2014).

[20] BufferSocial, Seiter, C., How to Make Your Posts Stand Out on Twitter, Facebook & LinkedIn: The Complete Guide to Social Media Formatting (<http://blog.bufferapp.com/the-complete-guide-to-social-media-formatting-make-your-content-stand-out>)(Feb. 26, 2014)

[21] Id.

[22] FDA, NDA#021924., Feb. 24, 2014 (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivities/byfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm388800.pdf>)

[23] Pharma Marketing Blog, Implications of FDA’s Warning Letter to Novartis Regarding Facebook Share Widget (<http://pharmamktg.blogspot.com/2010/08/implications-of-fdas-warning-letter-to.html>) (Aug. 5, 2010).

[24] InTouch Solutions, Social Media is Still Safe for Pharma Despite AstraZeneca Pulling Their Sponsored Twitter Ads (<https://www.intouchsol.com/blog/social-media-is-still-safe-for-pharma-despite-astrazeneca-pulling-their-sponsored-twitter-ads>) (Sept. 10, 2013)

[25] Supra n. xxiv.

[26] InTouch Solutions, Social Media is Still Safe for Pharma Despite AstraZeneca Pulling Their Sponsored Twitter Ads (<https://www.intouchsol.com/blog/social-media-is-still-safe-for-pharma-despite-astrazeneca-pulling-their-sponsored-twitter-ads>) (Sept. 10, 2013); and see Clinical Informatics News, FDA Issues Letter to Gilead Calling for Removal of Sponsored Links (http://www.clinicalinformaticsnews.com/eCliniqua_article.aspx?id=139733) (July 8, 2014) (FDA letter discussing metadata glitch in connection with Gilead’s sponsored Google link about the antiviral Viread)

[27] Drugs.com, Burns, M., Pharmas need quality control, tech knowledge, and eagle eyes for social media (www.drugs.com/news/pharmas-need-quality-control-tech-knowledge-eagle-eyes-social-media-47316.htm) (Sept. 2013)

[28] Infra at n. xxxi, xxxiv. The FDA has come under fire itself for failing to comply with its own draft guidance. Law360, Overley, J., FDA Twitter Rules Unconstitutional, Big Pharma Says (Sept. 22, 2014) (noting that some of the FDA’s tweets regarding drug approvals would not comply with labeling requirements, and that the FDA’s most recent tweets about approvals do not contain drug names).

[29] Chong, B., Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (Social Media Draft Guidance Webinar) (July 10, 2014) at 6.

[30] FDA, Guidance for Industry. Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (June 2014) at 6-10.

[31] Id. at 7.

[32] Id. at 7.

[33] FDA, Guidance for Industry. Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014) at 3-4.

[34] Chong, B., Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (Social Media Draft Guidance Webinar) (July 10, 2014) at 9.

[35] Id. at 14.

[36] Id. at 15.

[37] Id. at 22.

[38] Id. at 17-21.

[39] FDA, Guidance for Industry. Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014).

[40] Id. at 5.

[41] Id. at 5-6.

[42] Id.

[43] Id. at 5-6.

[44] IMS Study at 9-13.

[45] WSJ, Marcus, A.D., Researchers Fret as Social Media Lift Veil on Drug Trials. Online Chatter Could Unravel Carefully Built Construct of 'Blind' Clinical Trials. (<http://online.wsj.com/articles/researchers-fret-as-social-media-lift-veil-on-drug-trials-1406687404>) (July 29, 2014).

[46] IMS Study at 10.

[47] Zephoria Internet Marketing Solutions, The Top 20 Valuable Facebook Statistics — Updated June 2014 (<https://zephoria.com/social-media/top-15-valuable-facebook-statistics/>) ; Statistic Brain, Twitter Statistics (<http://www.statisticbrain.com/twitter-statistics/>) (last accessed Sept. 11, 2014)

[48] IMS Study at 10.

[49] Polaris Marketing Research, MR Perspectives, Five Ways Social Media is Changing Branding (http://www.polarismr.com/Portals/58820/newsletters/other_research/MRP_01-2014_Branding_Social_Media.html) (Jan. 2014)

[50] IMS Study at 26.

[51] Id.

[52] Id. at 27, 29.

[53] Id. at 11-12.

[54] People access social media through a mobile device 60% of the time. Business Insider, Adler, E., Social Media Engagement: The Surprising Facts About How Much Time People Spend On The Major Social Networks, <http://www.businessinsider.com/social-media-engagement-statistics-2013-12#ixzz3Cklh5GUh> (Aug. 21, 2014); PMLive, Digital Intelligence blog, Tyer, D., Novartis turns from social networking to apps for trial recruitment (http://www.pmlive.com/blogs/digital_intelligence/archive/2013/march/novartis_turns_from_social_networking_to_apps_for_trial_recruitment) (Mar. 19, 2013);

[55] LifeHacker, Nield, D., How to Break Your Smartphone Addiction (<http://www.seomworld.com/2013/09/on-average-we-check-our-smart-phones.html#.VBSkr1duVCo>) (Aug. 23, 2014)

[56] Outsourcing Pharma.com, Stanton, D., Pfizer: Active role for patients as smartphones lead way in clinical trials (<http://www.outsourcing-pharma.com/Clinical-Development/Pfizer-Active-role-for-patients-as-smartphones-lead-way-in-virtual-trials>) (Nov. 25, 2013).

[57] In-Pharma.Technologist.com, Stanton, D., MHRA and Novartis Lead Consortium to Develop Adverse Drug Reaction App (<http://www.in-pharmatechnologist.com/Regulatory-Safety/MHRA-and-Novartis-lead-consortium-to-develop-adverse-drug-reaction-app>) (Sept. 8, 2014).

[58] See e.g. Twitter, @JNJNews; IMS Study at 27.

[59] See e.g. Paynter, B., How Sanofi is Writing the Social Media Rules for Big Pharma without Running Afoul of the FDA (<http://www.fastcompany.com/3000457/how-sanofi-writing-social-media-rules-big-pharma-without-running-afoul-fda>) (Aug. 20, 2012); Entrepreneur, Rampton, J., Safe Use of Social Media in Regulated Fields (<http://www.entrepreneur.com/article/232693>) (Apr. 8, 2014)

[60] Entrepreneur, Rampton, J., Safe Use of Social Media in Regulated Fields (<http://www.entrepreneur.com/article/232693>) (Apr. 8, 2014); Blogwell, Novartis, Mackey, M., Elevating Novartis' social media reputation: A case study in MHealth (<http://www.slideshare.net/socialmediaorg/smorg-bw28-nycpresentationnovartis>) (Apr. 2, 2014); IMS Study at 11.

[61] Entrepreneur, Rampton, J., Safe Use of Social Media in Regulated Fields (<http://www.entrepreneur.com/article/232693>) (Apr. 8, 2014).

[62] The Wall Street Journal, FDA Approves Merck's New Wave Cancer Drug (<http://online.wsj.com/articles/fda-approves-mercks-cancer-drug-1409856320>) (Sept. 4, 2014); Newsobserver.com, Murawski, J., Virginia boy treated with Chimerix drug leaving hospital (http://www.newsobserver.com/2014/07/16/4009499_virginia-boy-treated-with-chimerix.html?rh=1) (July 16, 2014)