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8 Ways Life Sciences Cos. Can Adapt to the Social Media Era

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Social media usage worldwide is showing no signs of slowing as it permeates all aspects of our daily lives.

As new platforms explode and the stalwarts continue to deepen their connections with consumers, pharmaceutical and medical device companies are no exception in seizing social media's potential for promotion.

As employers, such companies simultaneously see the lines between professional and personal increasingly blurred, with team members' desiring to use personal social media accounts to share corporate news and achievements.

Both avenues — corporate sponsored content and individual use — are fraught with legal, regulatory and reputational risk for pharmaceutical and medical device companies, which operate in an environment subject to an intersecting framework of federal, state, industry and financial rules and guidelines where compliance is essential.

A single wayward tweet, Instagram post or like could be enough for significant implications.

Consider an influencer who posts a video about his or her product experience on YouTube, which strays into a gray area for approved uses.

A medical science liaison or paid speaker comments on a third-party site about the company's product.

An announcement is made on Twitter of study results, with a suggestion that an off-label use is safe and effective.

A sales representative enthusiastically shares a personal achievement on TikTok, proudly touting a product feature that has contributed to his success, as well as the expertise and skill of a certain physician whose practice he services.

Social media compliance is hardly ever simple. Here we provide context for the hypotheticals posed above, and myriad others, as well as considerations that pharmaceutical and medical device companies grappling with social media challenges and opportunities should proactively address.

Watchers and Regulators

FDA

The U.S. Food and Drug Administration, part of the U.S. Department of Health and Human Services, is the gatekeeper to and primary enforcer of the pharmaceutical and device markets in the U.S.

Pursuant to the Federal Food, Drug, and Cosmetic Act of 1938 and its amendments, the FDA's reach is consequential, fundamentally impacting medical products throughout their life cycle, including but not limited to:

- Branding, from failing to identify risks or provide adequate directions for use to promoting products for uses or indications not on the approved label, also known as off-label uses;
- Labeling or promotional labeling, which the FDA interprets broadly to include materials that supplement or explain a product, even if not physically connected to it; and
- Distinct from promotional labeling, advertising of prescription drugs and restricted medical devices.[1]

Though social media's swift adoption as a tool by pharmaceutical and medical device companies may have outpaced regulatory response, the FDA has made clear that its core principles for evaluating labeling and promotion still apply:

- Fair balance required: Risk and benefit communications must be reasonably similar, though not precisely equal, in terms of space, time, or prominence devoted to each component.
- Claims must not be false or misleading: Issues include minimizing risks, omitting material facts, overstating efficacy, making misleading comparisons and misrepresenting data.
- Claims must be consistent with FDA-approved labeling: Communication of information that is not contained in FDA-required labeling cannot conflict with the label's approved uses, populations and instructions, and must not alter the risk-benefit profile of a product in a way that may result in increased harm.
- No preapproval promotion: Information about pipeline products, like discussions of off-label uses, generally is limited to carefully circumscribed nonpromotional means of communications with health care providers.
- Include required information: Prescription drug advertisements must include a brief summary that includes risk information, and restricted medical device advertisements must contain a brief statement of intended uses and relevant risk information.

The FDA also has made notable efforts to tailor its principles and speak practically about emerging electronic media. Through its guidances — the FDA's current thinking on a topic[2] — warning letters and untitled letters,[3] the FDA increasingly has communicated publicly its interpretation of regulatory issues arising from manufacturer

use of social media, including:

- Responding to unsolicited requests for off-label information, which the FDA recognizes may reflect an important therapeutic option or be in the interest of public health;
- Fulfilling prepublication approval requirements for advertising in the context of interactive promotional media, i.e., blogs, social networking sites and online communities;
- Assigning responsibility for user-generated content, with consideration not only of control, but also influence, including editorial or review privilege;
- The risks of attempting to promote a product benefit while satisfying regulatory requirements in 280 or some other unreasonably small number of characters, as is commonplace on Twitter and sponsored links on Google;
- Correcting third-party misinformation; and
- Ensuring clear and conspicuous disclosures for endorsements and testimonials, from passive tags to influencer posts.

In January 2022, after triaging and issuing a deluge of letters in 2021 and 2020 related to the marketing and sale of COVID-19 products, the FDA reprimanded a pharmaceutical company in an untitled letter for an Instagram ad about its popular diabetes medication.

In dissecting the video portion of the post, the FDA said that the company prominently communicated the drug's ability to lower blood sugar for all patients while not sufficiently communicating that the drug is indicated only for Type 2 diabetes.

Rather, this and other key details were displayed in "small, fast-paced scrolling font in a small window below the video," and according to the FDA, had to compete for consumers' attention with several distracting video elements, including frequent scene changes, large-moving superimposed text and a strong fast-moving musical beat.

The overall effect of the post, the FDA wrote, "undermine[d] the communication of important risk information and thereby misleadingly minimize[d] [the drug's] risks."

As video consumption continues to grow for all manner of consumer research and education — and with video now accessible on every major social media network — we know the FDA continues to focus on advertising and promotion violations in video and other novel formats where fair balance and full disclosure may rub against platform- or technology-imposed content barriers.

For example, on Aug. 11, 2023, the FDA issued an untitled letter to a manufacturer taking issue with its promotion of a product on a sponsored Facebook post.

Among other violations, the FDA criticized the post for not including any risk information. While not noted in the FDA's letter, the failure to disclose any risk information may have been because Facebook has character limitations for promotional posts.

Justice Department and Inspector General

Though the FDA is hailed as one of the world's toughest regulators, it is does not stand alone in policing the health care industry.

Since the Anti-Kickback Statute was enacted in 1972, amendments and seminal court cases have sharpened the statute into one of the U.S. Department of Justice's and the HHS' Office of Inspector General's most potent weapons in fighting health care fraud.

The AKS makes it a criminal offense knowingly and willfully to offer, pay, solicit or receive any remuneration to induce or reward referrals for items or services reimbursable by a federal health care program.

Kickback concerns arise when medical products companies provide anything of value, directly or indirectly, overtly or covertly, in cash or in kind, to prescribers or pharmacies in an effort to increase their market share.

"Anything of value" can take various forms — from a lavish meal to a trip or, as relevant here, advertising or marketing support. Notably, under the reigning interpretation, each and every claim submitted by a provider for payment to a government health care program that is tainted by a kickback becomes doubly unlawful as false or fraudulent under the False Claims Act.

On Sept. 1, 2022, for example, Philips RS North America LLC, a medical device manufacturer formerly known as Respironics Inc., agreed to pay over $24 million to resolve FCA allegations that paid kickbacks to medical supply companies in the form of free data on prescriptions to aid those companies' marketing efforts with physicians.

FCA liability also may arise in the context of false or misleading promotion, including where promotion encourages the prescribing of products for uses that are not medically necessary or clinically supported.

For example, in 2020, global pharmaceutical company and manufacturer Indivior resolved civil and criminal investigations involving false and misleading statements it made while promoting to physicians and the Massachusetts Medicaid program relating to the safety of the opioid treatment's film version for children versus other buprenorphine products and tablets.

A portion of the $300 million civil settlement under the FCA also went addressing allegation that the company also knowingly "promoted the sale and use of its drug to physicians who were writing prescriptions that were "not for a medically accepted indication and that lacked a legitimate medical purpose."[4]

Although to date the DOJ has not publicly pursued enforcement or resolved any FCA cases involving advertising support or misleading promotion via social media, there were more new FCA cases filed in 2022 than in any year in history.[5]

Given the growing use of social media to sell and increased expectations that employers "adapt to the realities of modern life,"[6] according to Assistant Attorney General Kenneth Polite Jr., by implementing compliance policies and practices for personal communication platforms, we anticipate that the DOJ to begin focusing more on this space.

Evolution of Social Media Policies: Compliance Tips and Considerations

Instant access combined with ever-evolving platforms and regulation, and the omnipresent chance of errors render social media use a vital part of any company's compliance policy.

With the government's continued emphasis on the development and implementation of effective, holistic compliance programs and heightened focus on employees' use of personal devices for business, a clear and decisive social media advertising policy is the best first line of defense.

From our sampling of policies in the pharmaceutical and medical device space and study of emerging FDA and OIG guidance and enforcement activities, companies considering how they and/or their employees might productively engage with social media need to consider the following.

1. Establish who can speak for your company and where.

Define who is authorized to create, maintain and delete official company accounts or posts, which platforms can and cannot be used, as well as the procedures for accessing and posting to approved accounts and preserving account content, as appropriate.

2. Define activities that are not permitted on social media in a business capacity and include standards for posted content.

Familiarize yourself with FDA regulations and guidance documents, and at a minimum, require company posts on social media to be consistent with the law.

In that vein, pay careful attention to the global reach of your company's social media, given that indications and regulatory guidelines differ by country.

Also address how and if the company and/or employees can interact with physician and customer accounts on social media to avoid or mitigate the risk of posts being construed as providing impermissible advertising or marketing support.

3. Respect your employees' privacy with respect to personal accounts, but provide clear guidelines for social media use in their professional capacities.

Nearly three-quarters of all working adults in the U.S. use social media before, during and after work each business day, according to a 2019 Pew Research Center survey.

With so many employees now working remotely, the boundaries between personal and professional use of social

media are blurrier than ever. Consider requiring a disclaimer like, “The postings on this site are my own and do not necessarily reflect the views of Company X.”

Several company policies we reviewed explicitly prohibited referencing the company’s interests — its business, products, colleagues and former colleagues, policies, research, relationships and competitors — without a disclaimer.

Although this may seem expansive, if not all-encompassing, it is for good reason. For instance, employees or agents referencing or explaining a specific product could be classed as labeling.

Similarly, statements an employee makes through a personal LinkedIn account where he or she identifies as an employee may be attributable to the company and held to same standards as the company’s corporate accounts.

4. Ask first, post later.

Most policies we reviewed mandated that social media content discussing or relating to a company product must receive prior approval. Define responsibility for making sure all posted content is accurate and approved on the front end. Carefully consider what structure is best for your business given social media’s demanding pace.

5. Understand your external advocates.

Make all reasonable efforts to know what partners and others are saying about your products. Ensure there are appropriate disclosures of the company’s involvement or of nonemployee’s relationship with the company, such as a paid speaker. Develop a clear approach for all other user-generated content, including monitoring and correcting — or not correcting — misinformation.

6. Define responsibility and procedures for correcting social media content.

Not all partners and employees will abide by your policy and guidelines, and even if they do, mistakes happen. Moreover, on many platforms, context and content continually evolves — a blog post and series of comments following it may change or get deleted.

Ensure there are clear steps for timely, consistently, and — again — accurately remedying misinformation by employees, partners, or, as appropriate, unaffiliated third parties.

7. Test.

Avoid becoming a paper tiger by regularly assessing and auditing the information you post and gather on social media, particularly on trickier platforms — for instance, is your policy being followed despite tight character limitations on some of the most popular sites?

As with the preapproval function, define who is responsible for monitoring policy compliance, including whether technology assistance is desirable or necessary, and how results from such reviews or audits are addressed.

8. Store content and communications with care.

Social media often poses unique challenges for preservation.

As the $1 billion plus in fines levied against Wall Street firms in less than a year by the U.S. Securities and Exchange Commission, including adding to its hefty tally in May, and the DOJ's March rollout of new guidance on corporate communications have revealed, regulators are highly attuned to new technology like off-channel communications — i.e., messaging tools and apps — and will not make exceptions to essential record-keeping requirements for new media.

Conclusion

Social media platforms are fundamentally changing the way global professionals in the pharmaceutical and medical device industries work and engage with their employees, customers and partners — empowering innovation, interactive discussion, idea exchange and better health.

As your business works to understand the nuances of regulation and compliance on the social media frontier, begin with, and regularly review, a practical, sound, yet adaptable policy to guide your and your employees' approaches to using and embracing these powerful tools.

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[1] Advertising of over-the-counter drugs and unrestricted medical devices is regulated by the FTC.

[2] 21 C.F.R. §10.115(d)(3). FDA guidance documents are a significant and closely-watched method for FDA to communicate with industry and the public about its regulations. Guidances are particularly instructive in the realm of advertising and promotion, and in relation to technological advances and trends, as they often feature specific examples for FDA comment on what does—and does not—violate regulations.

[3] Warning Letters are issued for violations of regulatory significance that may lead to enforcement action if not promptly and adequately corrected (though FDA may take action without sending such letters), while Untitled Letters are issued for violations that do not meet the threshold of regulatory significance, but nevertheless serve as an initial notification that FDA is aware of a violation. As public documents, they inform the industry of issues to avoid. In turn, companies can minimize risks—not just from FDA directly, but also from competitors who maybe incentivized to report perceived violations. For instance, FDA's Bad Ad Program, launched in 2010, allows anyone to anonymously submit a complaint if he or she believes false and misleading prescription drug promotion has occurred.

[4] https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million.

[5] See U.S. Dep't of Justice, Fraud Statistics Overview (Feb. 7,

2023), https://www.justice.gov/opa/press-release/file/1567691/download.

[6] https://www.justice.gov/opa/speech/assistant-attorney-general-kenneth-polite-jr-delivers-keynote-aba-s-38th-annual-national.

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