

Facebook, Twitter and More:

What Life Sciences Companies Need to Know About Employee Use of Social Media

Sean Flynn, Associate General Counsel and Chief Compliance Officer, Abiomed, Inc.

Vito A. Gagliardi, Jr., Managing Principal, Porzio

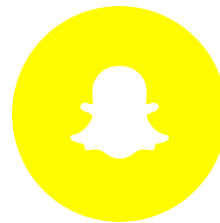
Najarian Peters, Assistant Professor, Institute For Privacy Protection, Seton Hall Law School

Rich Traynor, Associate General Counsel, Edge Therapeutics

Jennifer Romanski, Vice President, Porzio Life Sciences & Principal, Porzio (Moderator)

Social Media Overview

- Facebook: 2.13 billion monthly active users
- LinkedIn: 500 million users
- Snapchat: 178 million daily active users
- Twitter: 500 million Tweets sent per day
- YouTube: 300 hours of video are uploaded every minute



Oversight of Drug/Device Promotion

■ Food, Drug, & Cosmetic Act

- Demonstrate product is safe & effective for “intended uses” (21 U.S.C. 355(a) and 360b(a))
- Prohibits introduction of misbranded food, drug, device or cosmetic into interstate commerce (21 U.S.C. 331(a))

■ FDA Social Media Guidance

- Fulfilling Regulatory Requirements for Post-marketing Submissions of **Interactive Promotional Media** for Prescription Human and Animal Drugs and Biologics
- **Internet/Social Media Platforms** with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical
- **Internet/Social Media Platforms**: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices

Employee Posts: Potential Concerns

- Off-label or unsubstantiated claims
- Selective edits to third party sites / “cherry-picking”
- Employees might inadvertently – or deliberately – post confidential information about business or other employees
 - Intellectual Property / Trade Secrets
 - Financial Information
- Posts may include offensive or inappropriate remarks, photos, or videos that could negatively impact your business

Hypothetical

You are at a small start-up life sciences company in New Jersey and senior management has decided that it is vitally important to have a social media presence. Your company does not yet have a product on the market, but is conducting clinical trials for a product for adolescents to treat a prevalent food allergy.

- Your company does not have a social media policy. Do you start there? What considerations come into play?
 - What limitations, if any, should be placed on employees?
- Once it is complete, what is the best way to get the message out so that people understand it and adhere to it?
- How would your responses change, if at all, if you worked at a large established pharma company?

Hypothetical

While you are working on the social media policy, the company's marketing department is frantically working on a website, Facebook page and Twitter handle to raise awareness about food allergies. The Facebook and Twitter pages encourage viewers to share their food allergy stories.

- Is this a type of promotion?
- What type of privacy considerations come into play? Does it matter that the company's product will ultimately be indicated for adolescents? Does it matter if the social media presence is global or U.S. only?
- Must the company monitor likes and comments? Should the company interact directly with people posting comments?
- Can employees share the company's social media posts on their personal Facebook pages, retweet or post their own comments?



Hypothetical

Ten months after the launch of your disease awareness campaign, you receive approval for your product.

- Can your company now launch a branded product website page?
- Can it post information about your product on its social media sites?
- How does the review of materials for posting, and monitoring of comments change, if at all?

Takeaways

- Social media policies are important – language must be carefully crafted.
- For corporate posts, consider current regulatory guidance and responsible department/official and review process.
- For employee posts, consider balance of regulatory and compliance obligations with rights afforded to employees.
- Once the policy is in place, monitoring must follow.
- Stay current with regulations, guidelines and industry standards as technology continues to evolve.