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Pharmaceutical Compliance Congress

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PATIENT-CENTRICITY AND COMPLIANCE IN THE DIGITAL REVOLUTION

EXECUTIVE SUMMARY

FEATURED SPEAKERS: Brian Barry, Deputy Chief Compliance Officer, Vertex Pharmaceuticals; Clarissa Crain, Senior Manager, Deloitte; Chad Morin, Vice President, Chief Compliance Officer, bluebird bio; Melissa Tearney (Moderator), Government Enforcement Partner, Choate, Hall & Stewart

IDEAS THAT MATTER

- In a world of digital interaction, companies must prepare sales materials that **communicate information** in compliant ways.
- **Nurse educators need coaching** to clarify the boundaries of their role.
- **Pharmaceutical firms must support patient advocacy groups,** while avoiding pre-approval promotion.
- Before engaging with influencers, companies must **define clear guidelines.**

KEY TAKEAWAYS

As the pandemic pushes pharmaceutical sales and promotional materials to digital platforms, compliance is top of mind.

Pharmaceutical companies have focused on two innovation streams for promotional materials:

1. **Reviewing on-demand resources for digital platforms.** Compliance teams are applying the core review and approval standards used in the past to resources like product and medical websites.
2. **Creating sales resources to use across new media.** Companies are developing materials to use across new digital platforms. Here too, compliance with core review and approval standards is essential.

Keys to success include anticipating, understanding, and mitigating risk and then thoroughly training sales representatives. When sales teams pivot to digital platforms, they must understand how to use the technology effectively and recognize who is listening on the other end. The goal is to deliver the right message with approved materials.

Exception memoranda are an important tool for pharmaceutical companies, since decisions made today under extreme circumstances may be revisited years from now. If companies deviate from policy, they must document the reasons why and create a clear record.

"It's crucially important to provide reps with prepared materials so they are communicating in appropriate ways and not creating their own content."

Brian Barry, Vertex Pharmaceuticals

Companies are re-examining supply-side initiatives like nurse educators and other clinical programs.

The drive toward a more patient-centric approach for supply-side programs has been slow, but COVID-19 has served as a catalyst. Companies are rethinking how to deliver nurse educator programs to patients.

One of the first challenges presented by the pandemic was serving patients safely and protecting nurse educators. Some patients demanded more access to advice from nurse educators because they were afraid to leave home. Others were reluctant to allow anyone into their homes. Telehealth and e-coaching have been viable solutions.

Another concern is that clinical programs may slip into the demand side of generating more business. Nurse educators may receive more medical questions but aren't supposed to give patients advice. Nurse educators need coaching about the line they can't cross.

"The pandemic and the shift to telehealth have created new slippery slopes. Changing the way we deliver information doesn't mean that our obligations have changed. Nurse educators must understand that the boundaries of their role are the same."

Clarissa Crain, Deloitte

When interacting with patient advocacy organizations, pharmaceutical companies must maintain independence.

Pharmaceutical companies must strike a balance between supporting patient advocacy groups and maintaining an arm's-length distance. This tension has grown due to the pandemic.

Larger numbers of patient advocacy groups are asking industry how to transition to virtual interactions. This is particularly true among rare diseases, where small "mom and pop" advocacy groups are unfamiliar with digital tools.

Another challenge is avoiding pre-approval promotion. Pharmaceutical companies can't engage directly with patients or caregivers about medical information requests. Instead, patient advocacy groups must turn to their medical advisors to engage companies in scientific exchange.

Compliance teams are taking several actions to minimize risk.

The panelists offered insights into how their compliance teams are addressing the risks of digital communication. They are:

- Training employees. Vertex Pharmaceuticals is re-educating employees about smart communications. Employees are encouraged, for example, to use pre-approved email templates from the CRM system.
- Reviewing communications. Bluebird bio's legal, regulatory, and compliance team is paying closer attention to meeting content. In some instances, they send a follow-up email to ensure that information can't be taken out of context. If teams engage with parties outside the United States, companies must collaborate with their MLR team and privacy officer.

- Monitoring selection of new digital tools. Some IT teams engage with third parties to implement new tools. Compliance must participate in the evaluation and selection process. Minimizing the number of platforms minimizes the operational and monitoring risks.

Social media influencers represent the future of pharmaceutical marketing, but regulatory, compliance, and ethical concerns abound.

As pharmaceutical companies consider valuation mechanisms for patient involvement in trials, questions arise about patients who are social media influencers. For example:

- Should companies pay trial participants different rates based on their market influence?
- If influencers are under contract, should companies prohibit them from discussing products without prior approval?
- Are there clear company guidelines for engaging with influencers? These should define the requirements that influencers must comply with every time the company pays them.

"Influencers are where many marketing departments are moving. I'm concerned by 'professional patients' who proactively try to get business from companies. Is there a true business need to engage with these people? How is that viewed from an enforcement perspective?"

Chad Morin, bluebird bio

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