Regulatory and Legal Roles in Promotional Review Committee Meetings: Is there really a difference?

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This article provides perspectives on how legal and regulatory personnel and others view their roles when participating in promotional and other types of material reviews. The author defines and separates the roles and provides the results of an informal survey regarding what people in the industry think about the nature of the two roles in reference to promotional reviews. She concludes by suggesting that moving the company forward in a compliant way should be everyone's goal.

Introduction

When questions arise such as "What is the difference between legal and regulatory in Promotional Review Committee (PRC) meetings?" or "Why do we need both a legal and a regulatory reviewer in PRC?" what are the best answers? During my practice as an attorney in the industry for over 15 years, I have partnered with many regulatory legal colleagues and have sat across the table from commercial personnel who have tried to understand what those two roles and responsibilities include individually, where there may be overlap, and sometime ask if both roles are even necessary.

Companies may have difficulty defining the roles of legal and regulatory personnel during PRC, especially if the company is transitioning from Research and Development (R&D) to commercialization. Regardless of how those roles are defined, both ultimately strive to help their organizations promote or communicate information about a product or device in a successful, compliant way. However, neither an individual nor a company wants to put themselves at risk of "stepping over that line" or "stepping on someone else's toes." When participating in committees where the goal is to streamline the promotional and other material review processes, one question often raised is: "How can you get each discipline to stay in its own 'swim lane'?" Quite often someone (typically) responds, "Are you sure they know which swim lane is theirs?"

Operating in "gray" areas such as described above often makes our jobs more challenging, but not boring. If something is clearly legal, you just do not do it. If something falls into that "gray" area, regulatory and legal play important roles to help balance the potential risks and benefits. Regulatory relies on and cites regulations and guidance promulgated by the US Food and Drug Administration (FDA) and uses these principles to guide the company during the review of promotional or other materials such as:

- 21 CFR 201.100 (c)(1) and (d)(1)
- 21 CFR 202.1(e)(4)(ii)(b) and (c)
- 21 USC 352(a)

Regulatory also may consider certain FDA Guidance such as:

- *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities–Questions and Answers: Guidance for Industry and Review Staff*
- *Medical Product Communications That are Consistent With the FDA-Required Labeling-Questions and Answers: Guidance for Industry*
- *Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling-Final*

Legal tends to consider a broader scope of laws and industry codes/guidance while advising on legal risk. But wait—doesn't the *Federal Food, Drug, and Cosmetic Act*, which oversees FDA activities, include a set of laws passed by Congress? No wonder there is sometimes confusion.

Do you really need two separate reviewers?

Whether due to limited resources, the stage of the product lifecycle or a feeling that there is just "no need" for regulatory and legal to get involved, companies vary in their approaches to having legal and regulatory reviewers on PRC teams. Most companies still use the traditional method, which gives both regulatory and legal a seat at the table as well as equal responsibility during the material review process. However, some companies have moved toward a "consensus-type model" where only regulatory takes part in the process and has all final decision-making authority. Unless there is a matter that warrants attention by legal, regulatory may be the only and/or final decision-maker and the sole reviewer of pieces. This may include a new matter that requires a legal-only decision, such as one related to assessing potential risk from the perspective of a product's potential liability. As part of this model, regulatory typically makes the final call during any escalation process. If legal does review pieces as part of this model, some companies "allow" them to only attend the meeting if the reviewer's comments are not clear or they require additional interpretation.

Other questions may arise, such as: "Does having one designated reviewer slow down or help the process? What about when another discipline, such as legal, is necessary to review material—does that delay the process if legal wasn't initially included because the additional reviewer will need to 'catch up' on the material's background?"

Some companies have chosen more of a "divide and conquer" approach, which includes a pre-determined list of materials requiring a legal-only review or materials better suited for a regulatory review. The premise is that such materials would only require sign-off by the individual discipline. However, there should be a caveat saying if there are specific questions relative to the other discipline, similar to the "consensus-type model," then they should be brought to that function's attention. For example, regulatory may be the individual reviewer for an approved promotional piece requiring different sizing (e.g., banner ads, journal ads) or may be asked to review materials for which important safety information needs updating. Regulatory also would be involved if a piece is branded and would decide whether prescribing information and/or additional fair balance is needed or not. Legal may be the sole reviewer for sales training materials, internal company communications, materials associated with internal sales meetings or possibly market access/supply chain materials. Regardless of the approach, determining which discipline is necessary to review a piece, and when, is essential.

Senior management of smaller companies, including those who have submitted investigational products for approval, may question whether there is a legitimate need for a regulatory role within the company prior to the product having an approved label. Some believe it is only essential when a product's approval is imminent, when label negotiations are necessary and, of course, to assist generally once the product is commercialized. So, why would there be a need for a regulatory reviewer of external communication materials prior to approval? Most companies utilize regulatory to review investigational product presentations to different audiences, including payors or formulary committees. Regulatory, as well as legal, may review external materials for inappropriate claims or

conclusions, especially when product has a pending approval. Regulatory also can assess any branding elements to maintain non-promotional intent or to decide whether or not materials require submission to the Office of Prescription Drug Promotion (OPDP).

How are the roles of legal and regulatory defined?

An informal survey conducted with about 30 regulatory, legal, compliance and business professionals who have been in this industry for different periods of time, sought to see how they would (or have) answered the question: "What is the difference between legal and regulatory?" during a product/material review process. Below are some of their responses, which include some overlapping answers. Some asked if there was a “difference” between regulatory and legal.

Perspectives on the Regulatory Role	**Perspectives on the Legal Role**
Assist with business strategy	Advise on business strategy
Review materials based upon interpretation of regulatory requirements, enforcement actions (e.g., warning/untitled letters) and regulations	Advise on intellectual property, anti-kickback, privacy, product/company liability, consumer protection laws, *Lanham Act*, Federal Trade Commission and other laws and regulations, as well as enforcement actions, including warning/untitled letters and Department of Justice investigations and settlements
Key liaison/interface with FDA or other regulatory authorities	Foster compliance with company policies
Guidance on competitive activity	Advise on competitive activity/interactions
Benefit-risk assessment	Benefit-risk assessment and advice
Provide appropriate disclosures	Provide appropriate disclosures
Guide on whether or not the intended audience for a promotional piece is appropriate to understand the content	Advise on the appropriateness of the intended audience for a promotional piece
"Owner" of the prescribing information	"Owner" of reputational risk questions
"Problem Solver," "Regulatory Expert"	"General Advisor," "Therapist," "Mediator"
Help ensure promotional pieces are aligned, non-misleading, truthful and balanced	Help ensure promotional materials are aligned, non-misleading, truthful and balanced
Not clearly defined	To slow down the process

Conclusion

Whether individually collectively, we all bring different value to the table, and most often that value is supplemented and strengthened by each other's experience and knowledge. Whether you wear a legal, regulatory, compliance or business “hat,” supporting the business and moving a company forward in a compliant way should be everyone’s goal. However, at the end of the day, what good is any individual, role or team if you can't laugh, have fun and "keep it real," while aligning with and supporting each other? We all try to avoid confusion, “forum shopping” and plain old frustration, which sometimes, as many of us have experienced, may include hour upon hour of sitting at that table reviewing materials. My advice during such meetings has always been to remember the three "C's": Communication, Collaboration and, of course, Chocolate!

About the Author

Alicia Whittlesey, Esq, is a counsel at Porzio, Bromberg and Newman PC and director of compliance services at Porzio Life Sciences, the firm's wholly-owned subsidiary. She is a member of the firm’s life sciences compliance and regulatory counseling department. Her practice includes advising pharmaceutical, medical device and biotechnology companies on the laws, regulations and enforcement measures governing the life sciences industry in areas such as advertising and promotion, compliance, privacy, internal, and external communications, and interactions with patients, HCPs, payors and advocacy. For more than 15 years, Whittlesey worked as in-house counsel in the pharmaceutical industry providing legal, regulatory and compliance guidance on programs, policies and activities, including a key role in promotional and other materials review. She can be contacted at AAWhittlesey@pbnlaw.com.

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