Should Compliance have an "on-line" or "off-line" role?

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As a follow-up to my previous article, " Regulatory and Legal Roles in Promotional Review Committee Meetings: Is there really a difference?", I thought, why not continue the conversation and add another role to the mix… Compliance? Since the informal poll that I took for my original article was so well-received, I decided to conduct another one with my Legal, Compliance, Regulatory and Business colleagues by asking, "What do you think about the role of Compliance during promotional review meetings?" and, "What do you think the role of Compliance should be when interacting with Commercial/Marketing?" Throughout the article I have incorporated several of their responses.

I've often seen companies struggle to provide definitive answers to these questions since, as with the role of Legal and Regulatory, there is often overlap and many responsibilities are shared, which include ensuring the company complies with its obligations. There is no right or wrong answer, only what works best for each company given its status, policies, requirements, product lifecycle and general stage of development.

Promotional Review Committees – Are there too many cooks in the kitchen?

Does a promotional review committee really need any additional stakeholders at the table? I have heard this question asked repeatedly – half jokingly but mostly serious.

In my experience, I have seen Compliance fulfill more of an "ad hoc", less formal role and be brought into matters as necessary. How do you know when to make that decision? I will give you the traditional response… it depends! One colleague insightfully quoted, "The challenge with the ad hoc approach is making sure Compliance is brought into the loop on a consistent and timely basis." Very wise words indeed.

In addition to the role of Legal and Regulatory, Compliance can help to evaluate the overall compliance risk assessment of certain programs or activities. For example, Commercial/Marketing may approach Compliance with multiple proposals for a new concept in order to gauge where they may fall on the compliance risk spectrum. This can include assessing a speaker bureau program or defining a newly identified field facing role. Quite often Compliance and Commercial/Marketing may jointly decide to pilot a newly developed initiative in a smaller setting in order to make the process more manageable. Compliance can also assist with evaluating its execution, feedback and success. How long does a pilot last? I've seen companies pilot a program for three years!

A company may also bring in Compliance to comment or provide insights into newly developed materials or initiatives from a conceptual perspective, such as those that fall outside of the traditional scope of promotional advertising. This can include developing a new training concept or materials intended for external use with customers. Some of these areas may require either input from Compliance or just an overall understanding to help facilitate their roll out. Getting Compliance

involved at the beginning allows them not only to hear the different team perspectives, but it can help facilitate a more efficient and productive process.

While it may not be a formalized role, companies may also decide to invite Compliance to attend the promotional meetings as an optional team member. This often permits access to all reviewable materials, however, they are not required to review and/or comment. For example, if an educational item intended for a healthcare professional is going through the review process, Compliance may be notified in order to ensure it is consistent with company policies and, as necessary, be tracked and reported within current federal or state requirements. I've also seen where Compliance may become involved if during a promotional review meeting a matter requires escalation, such as if questions are raised from an execution perspective or perhaps Compliance is requested to look in totality at a strategy to assess its approach and potential compliance risk.

Additionally, other reasons companies have chosen to have Compliance be less active at the table is to help maintain some sort of distinction or separation from other disciplines, as Compliance is typically tasked with fulfilling monitoring and auditing obligations. A more disengaged role during the actual review may allow Compliance to more effectively monitor the promotional review process, audit for compliance with policy requirements, and conduct any necessary investigations. Some companies feel that this allows them to maintain their independence and more of an unbiased perspective. This may also assist Compliance when assessing the level of accountability for those involved if an investigation occurs or if remediation is necessary.

How else may Compliance be involved within a company's review process? Another colleague described the role of Compliance to be the "hands and feet/boots on the ground" for "pull through" of Legal and Regulatory decisions during a promotional review meeting. Compliance often ensures proper use of materials when interacting with customers as part of their field monitoring process. Most often Legal or Regulatory does not have the benefit of seeing how materials or strategies actually "play out" in a real world setting unless there is an opportunity to participate in a field "ride-along". This unique perspective allows Compliance to share practical experience, knowledge and observances regarding not only the level of success of an initiative, but also how it may resonate with customers. As one of my colleagues stated, Compliance can help "integrate the voice of the consumer into the review process and discussion". Having access to this information is extremely valuable and generally can help facilitate the role of Legal or Regulatory as part of the review process.

Why else would Compliance participate in a promotional meeting? Compliance may at times be obligated to attend meetings and review materials if it is mandated by the government, such as under a Corporate Integrity Agreement. Corporate Integrity Agreements are typically issued by the government if non-compliant behavior has been identified. Such Agreements often are intended to promote compliance with healthcare regulations in order to drive compliant behavior and set standards that a company must abide by in various situations. In order to ensure the company adheres to such an Agreement, Compliance may be required to monitor and/or participate in such meetings as necessary and take into consideration the elements of the Agreement.

General Commercial/Marketing Group Interactions with Compliance – Is there really a "one-size-fits-all" approach?

In addition to trying to decipher its function within a promotional review committee, another question that is often raised is, "What is the role of Compliance while interacting with the Commercial/Marketing group?" Is there a specific matter or situation that would require Compliance to get involved? Again, each company's Legal and Compliance department structure will of course vary based upon several different factors. However, overall, as many of my colleagues would agree, there are many components of any relationship that help to make it more successful, including these two key factors: patience and trust. Business should be able to rely on Compliance to think strategically, and do it in a way that takes into consideration business objectives and goals. If Commercial/Marketing does not feel it can approach Compliance with questions or that they are functioning as a "barrier to business opportunity," it may hinder a successful, creative, confident

and collaborative relationship. What is the point of an "open door policy" if you actually have that door physically (or figuratively) closed all the time?

Compliance can play an integral role in creating an environment for all employees, including members of the Commercial/Marketing team, whereby the importance to act ethically, with integrity, and in compliance with applicable policies, rules and regulations is a priority. We all want to try to do the right thing, but sometimes that "right thing" may not always be as clear as we would like it to be. One role of Compliance is to promote and encourage high ethical standards and help create structure. One way this is done is by being the gatekeeper of company policies and associated trainings. These may cover areas related to kickback concerns, fraud and abuse, data privacy, tracking and reporting, conflicts of interest, or the general values of a company's code of conduct. Quite often as part of their role in the development of an effective compliance plan, they will collaborate with, and request feedback from, various departments including Commercial/Marketing in order to establish such policies, guidelines and trainings that help to facilitate a successful and effective compliance program. What is the benefit of a compliance plan if it looks good on paper but cannot be executed appropriately and understood by each employee?

When I used to work in-house in the Legal Department, one of the things that I always promoted to my business colleagues, especially Commercial/Marketing was that I would rather be an "ally" than a "fixer". What do I mean by that? I prefer someone reach out at the inception of an idea or initiative before implementation. Be proactive so that I do not have to be reactive. Let's work it out together to help mitigate potential compliance, legal or regulatory risk and come up with alternative solutions. This philosophy, which I have also often seen adopted by my Compliance and Regulatory colleagues, can work for any individual group, and has helped me tremendously throughout my career to create and sustain healthy and trustworthy business relationships.

I have also often viewed Legal, Regulatory and Compliance as "teachers" to an extent, since as part of our jobs we share knowledge and experiences so it will resonate with, and empower, our "students" to make decisions. I have been very fortunate to have worked with several Compliance, Legal, Regulatory and Commercial/Marketing individuals who have taught me the importance of collaborating, listening, and being responsive. No one wants to hear Compliance, Legal or Regulatory say "no" but sometimes that may need to be the answer which then hopefully is followed by a "however" that provides the "why" behind a decision, and then possibly an alternative solution to find the path to "yes". It has been one of my most rewarding accomplishments when a business colleague or client identifies an area that may potentially be of concern based upon our previous discussions and brings it to my attention. Again, be proactive versus reactive. Many Compliance colleagues also share this same sentiment which has contributed to the establishment of more successful relationships.

Here's an example provided by a couple of my Compliance colleagues of a situation that demonstrates the importance and relevance of initiating early conversations that will most likely resonate with many, as it did with me. Have you been in a situation when Commercial/Marketing reaches out to ask what field personnel can do to better understand how to respond to healthcare professionals asking, "Why should I prescribe your product or therapy instead of competitor X?" In this particular situation, a member of Marketing approached Compliance to ask how they could be "more competitive" given the market. Those conversations can be interesting and may be somewhat challenging. Commercial/Marketing may respectfully push the boundaries which therefore prompts Compliance to consider the appropriate level of compliance risk, and help determine mitigation strategies in coordination with Legal and Regulatory. What may Compliance consider? Ask questions to get a clear understanding of the request. This may include: What is the business need? What exactly are you hearing from your customers? What are you trying to accomplish at the end of the day? In this particular situation, after gaining a general understanding of the market and environment and the business rationale, and coordinating with Legal and Regulatory, Compliance delivered training on the do's and don'ts of such conversations, reminders of the basics principles of interacting with customers, and the importance of responsible communications. Frequently Asked Questions were then developed to help appropriately address anticipated customer queries. This exemplifies the importance of a

coordinated effort to promote compliance and support of promotional activities. Again, be proactive, raise questions and invest more time on the front end to help prevent potential issues on the back end.

What is the final takeaway?

No matter who you are, what your role is, or what is going on at a company, what anyone looks for in a valuable, effective "partner" in order to help advance business operations in a compliant way is to have a relationship that is collaborative, flexible, trustworthy, open and attentive. Encourage questions, interaction, and communication. As I have previously mentioned in other forums, we often have said to others, sometimes in the heat of the moment, to "stay in your own swim lane." Although it may be challenging at times to distinguish between the roles of Compliance, Legal and Regulatory, a very wise colleague once said to me (and this is absolutely something that I agree with), sometimes in order to have an effective meeting, you may need to "navigate that shared lane together."