HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

COMPLIANCE TODAY

Volume Fourteen
Number Three
March 2012
Published Monthly

Meet

Bret S. Bissey, Senior Vice President, Ethics and Compliance Officer at UMDNJ

PAGE 14

Feature Focus:

Focusing on Quality: CMS issues new quality-focused rules

PAGE 36

Earn CEU Credit

WWW.HCCA-INFO.ORG/QUIZ—SEE PAGE 66

STORM WARNING: ICE IN THE FORECAST

PAGE 9

From MSL to CSL: The evolving role of the medical science liaison

By Jamie Kendall Esq.

Editor's note: Jamie Kendall, Esquire, is a Senior Director of Compliance, Ethics & Legal Affairs at Compliance Implementation Services (CIS). Contact Jamie at jamiekendall@cis-partners.com.

Everyone has to start somewhere. For medical science liaisons (MSLs), that place was the Upjohn Company in 1967. A team of sales representatives with technical backgrounds was established to add credibility in the scientific community for the Upjohn sales and marketing staff. The original Upjohn MSLs interacted with key opinion leaders (KOLs), managed budgets, provided Upjohn products for research, disseminated educational information, and trained staff—but, they were a part of the Sales department. Individual MSLs had backgrounds in particular areas to assist in interacting with scientific customers, but didn't necessarily have advanced science degrees. Although this was a breakthrough in 1967, the propulsion of medical research and development (R&D) in the ensuing years, combined with the transforming landscape of the pharmaceutical market, necessitated that drug companies provide an even more robust medical knowledge resource for health care practitioners (HCPs).[1]

Indeed, in the 1980s and 1990s, the MSL role in pharmaceutical companies became divided, with some companies having their MSLs continue to sit within their Sales and Marketing function, while others chose to dedicate their MSLs to a Medical Affairs department. This increased recognition of the need to focus MSLs more on medical knowledge than on product promotion also brought with it a more scientific academic profile for the modern MSL: the PharmD degree has become the norm, along with PhDs and MDs. However, the utility of the MSL has since evolved very quickly into something independent of sales and marketing and product promotion, into something more of a medical information advisor—both internally across a manufacturer's departmental activities, and externally to glean research trends from the clinical and academic communities and to deliver up-to-date information to health care providers.

Today's MSL is a global medical knowledge conduit and resource, no longer a proactive technical sales and marketing guru. Rather, the current MSL model is that of a well-educated pharmacological expert who is ready to provide safety and best practice support to clinical trials, scientific exchange information to KOLs and HCPs, detailed on-label product information to customers, balanced and clinically-proven responses to unsolicited off-label inquiries, and disease state and formulary/health economics and outcomes research (HEOR) updates—all while maintaining productive KOL networks and, most importantly, remaining totally separate from Sales and Marketing. However, over the past decade, drug companies have endured intrusive government investigations regarding their marketing and promotion business practices, which have resulted in sales force reductions and restrictions upon sales force capabilities to communicate with physicians. It is these restrictions that now cause the government to shift its focus and scrutiny of activities from traditional sales to medical affairs, which includes the role of the MSL.

Continued on page 26

 ...continued from page 25

Regulatory guidance

The statutory framework under which the Food and Drug Administration (FDA) regulates the sale and marketing of drugs in the United States derives from The Food, Drug and Cosmetic Act of 1938, as amended (FDCA). A series of statutory provisions, as interpreted by the FDA, serve to proscribe off-label promotion and marketing. For example, FDA regulations regarding investigational drugs state that a sponsor "shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation."[2] The regulation then states that this prohibition is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media."[3]

However, neither the regulation nor its rulemaking history provides any meaningful discussion on the boundary between "promotion" and "scientific exchange." And the FDA remains silent on the bounds of what constitutes "scientific exchange."

As a result, on July 5, 2011, seven medical product manufacturers filed a Citizen's Petition requesting clarification of FDA regulations regarding communications and activities related to marketed drug products.[4] Although the FDA recognizes mechanisms for the sharing of truthful and non-misleading scientific information, there is a significant lack of clarity as to the practices they permit. Consequently, companies develop, among other things, medical personnel policies and internal guidelines governing the dissemination of scientific information and may either over- or under-communicate clinically relevant information with potentially significant impacts upon public health.[5]

Moreover, most guidance from the FDA on this issue is difficult to find and non-binding, further compounding the need for clarity as manufacturers have no choice but to refer to Department of Justice (DOJ) settlements or informal statements from FDA officials to learn what may be expected prospectively. In an attempt to remedy the situation, the Citizen Petition requests that (1) the FDA promulgate binding regulations embodying current FDA policy re: responses to unsolicited requests to assure manufacturers are afforded a meaningful "safe harbor"; and (2) the FDA clarifies its position on "scientific exchange" by stating that to qualify, the statements must make clear that a use/product is not FDA-approved/cleared, make no claims that a use/product has been proven to be safe/effective; and be truthful and non-misleading when measured against available info on the use/product. [6]

Further, Corporate Integrity Agreements (CIAs) contain provisions that, on their face, directly impact the role of the MSL, but serve as an additional layer of prospective guidance for manufacturers. Recent CIAs require that sales representatives refer all off-label information requests directly to Medical Affairs departments. Additionally, MSLs must enter all requests for information through a detailed database that tracks the date, form, and nature of the request, along with the name of the HCP who requested the information, the company representative who had contact with the HCP, and the nature and form of any response, including a record of materials provided in response to the request. CIAs also mandate that the role of any MSL in meetings or events with HCPs be non-promotional, purely scientific, and that prior to any such encounter, the MSL should clarify the medical or scientific need for his/her attendance and decline any participation if such a need is not expressed.

Internal oversight

In addition to these external interaction mandates, CIAs clarify MSLs' internal roles through provisions relating to the varying oversight duties of Medical Affairs in company activities, such

as the establishment of research monitoring programs, Medical Educational Grants offices (i.e., the exclusive mechanism by which companies should review and award medical education grants), and publication activity monitoring. It is of particular note that CIAs require that Sales/Marketing has no participation in educational grant procedures, and also that companies must demonstrate a scientific need for any research or publication that it approves.[7] These CIAs further show that governmental focus has begun to veer from monitoring sales interactions with HCPs, to tracking MSLs and their roles as direct communicators with HCPs and as reactive internal gatekeepers to non-promotional, scientific, and educational company activities.

The ongoing interplay between the FDA, the DOJ, and the pharmaceutical industry pertaining to the proper role of the MSL is a smaller example of a more general game of "Whack-a-Mole" that has been occurring between the FDA and drug companies when it comes to product marketing. After the original MSLs "popped up" at Upjohn in 1967, the FDA responded through guidelines and regulation in order to push back on their promotional duties and limit the messages the MSLs and sales forces could deliver and their channels of communication. As these regulations and guidelines have been followed, however, there has been a pattern of general applicability of their terms to both sales personnel and MSLs.

Transparency

Because the FDA issuances do not delineate how their rules and guidance apply to the differing roles of the Sales and Medical Affairs departments, the pharmaceutical industry has begun to limit their sales forces and increase their MSLs, presumably due to a perception that the MSLs will be allowed to provide more of the information that the FDA will find permissible and relevant in communications with health care providers. Regulations regarding off-label promotion and the permissible use of "scientific exchange" information, while not always clear in what they permit, represent an indication that the FDA wants pharmaceutical companies to provide more transparent and comprehensive information to health care providers. However, due to the decrease in messages a sales force can permissibly convey and the limited promotional capabilities of the MSL, how is this transparency of information to be effectuated?

One large pharmaceutical company has taken a measured approach and utilizes their MSLs in a purely reactive capacity. Rather than run the risk of putting MSLs in a situation where, due to vague statutory definitions, they may be perceived as acting in a promotional role, the company's MSLs only respond to non-solicited inquiries for information from HCPs, in addition to their internal advisory roles and KOL network development. That is, instead of going to the HCPs and providing them with on-label scientific information on company products, MSLs will not supply such information independently, unless requested by the HCPs themselves. Other companies will likely follow suit, in order to avoid any potential official action prompted by an image of impropriety.

Due to the limited nature of the information that a sales representative can directly provide an HCP, the MSL has the bulk of the scientific knowledge that an HCP may want when determining whether a given product is right for a patient. To get such information, the HCP must bypass the sales personnel and direct his/her questions to the MSL. Is it then possible that by limiting the methods and messages that both Sales and Medical Affairs personnel can communicate to physicians, the FDA is nudging MSLs back into the promotional box they have been working to avoid? If so, taken in tandem with the promotional restrictions put on MSLs, it may indicate a

Continued on page 28

 ...continued from page 27

seismic shift from a dominantly-proactive promotional model to one in which promotions are heavily reactive. Such a swing of the pendulum may have already begun.

For example, in July 2010, GlaxoSmithKline announced that it was going to implement a new compensation program for its US sales force, beginning in 2011. Under the new bonus program, sales professionals who work directly with HCPs and other customers are no longer compensated based upon individual sales targets. Rather, bonuses will be based primarily upon the service that they deliver to customers as HCPs "[s]ee a need to provide greater value in helping improve patient health" and HCPs "[w]ant to see fewer sales professionals."[8] The company sees this effort as "part of a wider evolution to align the company's sales and marketing programs with societal and customer expectations."[9] This "wider evolution" is likely one of the first of many such actions pharmaceutical companies will begin to take due to changes in the regulatory terrain.

From a policy standpoint, does this create dissonance with the FDA's mission of "promoting and protecting the public health and [striving] to provide useful and credible information to consumers"?[10] Now, rather than encouraging manufacturers to be transparent and provide HCPs with comprehensive scientific information, the current guidelines and emerging practices are steering the industry to a point where HCPs have to gather the information on their own initiative. If leading manufacturers are keeping MSLs in a reactive role to avoid non-compliance, yet at the same time acknowledging HCP preference for more transparent and comprehensive information in sales and marketing interactions, it would seem there is a need for HCPs to be more proactive in obtaining the information they seek. Is the industry then about to enter an era, not of the manufacturer's MSL, but rather of a Consumer Science Liaison (CSL) that seeks out relevant scientific data from a reactive MSL for an HCP's use? While the idea of a CSL may appear to focus far in the horizon, until the FDA provides further guidance, these are questions the industry will have to consider. Indeed, it seems such consideration is already under way, but it remains to be seen how far the MSL will continue to evolve. ■

1. Donna K. Morgan, et al: History and Evolution of Field-Based Medical Programs, *Drug Information Journal*, Vol. 34, 1049-1052, (2000).
2. See 21 C.F.R. §312.7(a).
3. Id.
4. Citizen Petition, Docket #FDA-2011-P-0512 (submitted July 5, 2011). Available at http://druganddevicelaw.net/7_11%20FDA%20off%20label%20citizen%20petition.pdf
5. Id. Pg. 4-5
6. Id. Pg.6-9
7. See Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Novartis Pharmaceuticals Corporation, 9/29/2010. Available at http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp.
   Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Allergan, Inc., 8/30/2010. Available at http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp
   Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services And AstraZeneca Pharmaceuticals LP AND AstraZeneca LP, 4/27/2010. Available at http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp
8. Reuters: GlaxoSmithKline to Implement New Compensation Program for U.S. Sales Professionals, July 26, 2010. Available at http://www.reuters.com/article/2010/07/26/idUS174073+26-Jul-2010+PRN20100726 on October 3, 2011.
9. *The Wall Street Journal Online*: GlaxoSmithKline Implements Next Phase of New Incentive Compensation Program for U.S. Sales Representatives, July 5, 2011. Available at http://online.wsj.com/article/PR-CO-20110705-903963.html
10. U.S. Food and Drug Administration: How to Partner With FDA; FDA Consumer Health Information Co-Branding Policy Statement, December 1, 2008. Available at http://www.fda.gov/ForConsumers/ucm126390.htm