

Ending Physician Speaker Programs May Not Be A Good Thing

Law360, New York (March 11, 2014, 6:36 PM ET) -- With GlaxoSmithKline PLC's December 2013 announcement that it would stop recruiting and paying physicians to conduct promotional programming for their pharmaceutical products, many have questioned when, or whether, other companies will follow GSK's lead. Interestingly, fewer people appear to be asking whether GSK's decision marks a positive development in advancing the public health and reducing actual or potential conflicts of interest. Or is the GSK decision just another sign that government enforcement activities are driving companies to further minimize their legal risks by cutting programs and activities that may benefit clinicians and patients?

Given today's enforcement environment, it appears likely that additional manufacturers will follow GSK's lead in ending these physician relationships, in the hope that by doing so, they will lower their risk of receiving warning or untitled letters from the U.S. Food and Drug Administration, being sued for consumer protection violations by state attorneys general, or facing whistleblower lawsuits, among other things.

It remains much less clear, however, whether the elimination of these arrangements will yield material benefits in the form of reducing or eliminating bias or reducing health care costs. It is also questionable whether eliminating these arrangements will reduce or eliminate meaningful access to useful information (particularly in the context of rare disease therapies).

To be clear, decisions by manufacturers to reduce or eliminate physician promotional programs have not been driven entirely by a desire to reduce legal risks. Over the past few years, dozens of health systems and academic medical centers have instituted policies prohibiting their faculty and/or staff physicians from participating in promotional speaker bureaus (e.g., Stanford, University of Wisconsin, Mayo Clinic).

As academic physician leaders increasingly are precluded from engaging in this type of manufacturer-sponsored programming, companies are faced with the question of whether to recruit community physicians to take their place at the podium. This has required not only an examination of the community physicians' clinical expertise relative to academics in the same field, but also tests of the physicians' name recognition to determine whether other clinicians in their local area, or another part of the country, will remain interested in attending a physician-led presentation by someone who may be less well-known in the relevant field.

Getting the Word Out

Regardless of any specific company's rationale for ending or limiting physician promotional speaker

programs, the fact remains that manufacturers need to get current information about their products, and the diseases or symptoms they address, out to the physician community.

In recent years, industry has turned to forms of physician education other than speaker bureaus to ensure that product information is both available and disseminated. For example, some companies have increased the size and capabilities of their in-house medical affairs teams to provide in-person or remote disease state or evidence-based medicine programming, and answer unsolicited physician questions about specific products and research developments.

Others have focused their energies on developing medical teams to prepare for and present at payer pharmacy and therapeutics committee meetings, when such presentations are permitted, or to otherwise educate payers who may become more directly involved in physician education.

Going forward, we expect those teams to become even more sophisticated as payers continue to exert an increasing degree of control over what medications will be covered for their members and utilize value-based patient outcomes data to support their decisions. Still other companies have targeted direct to consumer advertising as a means to drive requests for additional physician education, as patients wanting information about a drug they have heard about via print, television, or social media advertisements often turn to their personal clinicians for answers.

One or more of these speaker bureau alternatives may work well for larger companies that can afford significant direct-to-consumer advertising, target large patient population that can be counted on to generate sufficient conversation and education about their products, or develop well-staffed medical affairs departments. For smaller companies with tinier marketing budgets, and for those companies more heavily focused on rare diseases, however, these alternatives may not be viable options.

As a result, the elimination of a relatively low-cost but effective means of promotion and education via the use of academic and other experienced clinician speakers may do more harm than good. Furthermore, it remains unrealistic to expect clinicians to carve out sufficient time to sort through and keep up with the latest research while maintaining full patient panels and satisfying other obligations. It is also unrealistic to expect that academic detailing (defined to include university or noncommercial educational outreach, usually conducted in person) or government sponsored evidence-based medicine programs will be able to conduct the same level of outreach as industry-backed promotional programs in the near future.

GSK's decision to prohibit physician promotional speaker programs comes at a particularly interesting time — just prior to the first reports to be compiled and issued under the Affordable Care Act's aggregate spend/transparency provisions. These provisions have been anticipated, and debated, for years and implemented in modified forms by a handful of states (e.g., Massachusetts, Minnesota) and for specific companies based on Office of Inspector General corporate integrity agreement requirements. One of the driving theories behind the implementation of such provisions has been that public transparency may mitigate, if not eliminate, the potential bias that accompanies the payment a physician receives for engaging in promotional activities.

For example, if I know that my doctor has been paid to promote Product A, I may be more apt to question his recommendation that I take that product or I may be more prone to seek a second opinion about my treatment options. Of course, this assumes that individual patients are going to seek out this information and are also capable of distinguishing legitimate relationships from those that may provide tangible evidence of bias. Ironically, if more companies choose to stop traditional physician promotional

activities, the ability to prove the theory that transparency is the right answer to the conflict of interest conundrum becomes more difficult.

Aren't Current Controls Enough?

So what is really to be gained by eliminating physician speaker programs? At this point, most pharmaceutical and medical device companies already have significant controls in place governing the selection of and payments to promotional speakers. Many of these controls are the outgrowth of CIA provisions imposed upon those entities settling off-label promotion or kickback allegations with the government.

However, a number of these controls have been adopted voluntarily by others as a matter of best practice and risk management. For example, many companies now have formal needs assessment processes to limit the number and location of programs to that which is defensible and consistent with on-label promotion of the product. Companies also have instituted centralized speaker selection and training processes to ensure that all speakers are working from a common knowledge base and understand what the company will and will not allow.

Physicians now expect that their programs will be periodically monitored and their contracts often make explicit the consequences of a failure to abide by company policies regarding the dissemination of off-label information. Moreover, caps on individual program fees and annual physician compensation also have helped limit the potential for undue influence. These controls, when combined with institutional policies requiring speakers to have control over final presentation content, would appear to reduce concerns about programs being used principally as social opportunities for clinicians, or as a means to reward physicians who have been loyal prescribers.

Looking beyond speaker programs specifically, CIAs and OIG guidance documents have imposed or suggested, respectively, that additional limits also be placed on interactions with physicians. For example, sampling restrictions, restrictions on post-marketing research, transparency requirements with respect to physician authorship, educational grant limitations, and restrictions on consulting arrangements have become standard fare in the industry and appear in nearly every pharmaceutical company CIA executed within the past several years.

Perhaps the elimination of speaker programs is just the next logical step in the evolution of managing potential conflicts of interest, but without viable and plentiful alternatives, their demise may also be premature. In fact, it may just further shift the locus of medical decision-making to payers, which itself is not a risk- or bias-free proposition. But that is a story for another day.

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