Medical Affairs – Not a Sunshine Day

Analyzing the Impact of the Sunshine Act on Medical Affairs: Challenges for 2014 and Beyond

Jodi Smith, PhD and Peg Crowley-Nowick, PhD, MBA

ZIPHER® Medical Affairs, LLC

Medical Affairs – Not a Sunshine Day

Analyzing the Impact of the Sunshine Act on Medical Affairs: Challenges for 2014 and Beyond

-Jodi Smith, PhD and Peg Crowley-Nowick, PhD, MBA

What does the Physician Payment Sunshine Act ("Sunshine") have to do with medical affairs? If medical science liaisons (MSLs) in the field or medical affairs in-house personnel were asked this question, the most common answer would likely be "not much." A few thought leaders or community physicians may decline participation on an advisory board or involvement in research, but MSLs will still continue to meet with thought leaders, medical education will still facilitate independent and continuing medical education, and scientific communications will still manage abstracts and manuscripts. Frankly, it is someone else's job to track all of those physician payments and medical affairs will just continue to focus on ensuring appropriate use of drugs.

However, does the practice of medical affairs need to change in the new Sunshine era? At Zipher Medical Affairs, we believe the answer is definitely yes. We have looked closely at both the direct and indirect impact of Sunshine on the practice and function of medical affairs, and we feel the impact of Sunshine has only just begun.

Fall 2014: Public Release of Sunshine Data

As part of the Affordable Care Act, the Physician Payment Sunshine law was adopted in March 2010, and then in February 2013, the final regulations were released. The rules require industry to translate the value of payments or other transfers of value to a physician or teaching hospital (e.g., courses, meals, and speaker fees) into a dollar amount, even if actual dollars are not exchanged. Reports of these values are required to be submitted to the Centers for Medicare & Medicaid Services on an annual basis and data from these reports will be made available and searchable by the public in September 2014. The development of Sunshine was based on the assumption that the more value a physician receives from industry, the more biased a physician will be toward the pharmaceutical industry.

Although the rationale for Sunshine was noble, there is a high likelihood of a harmful, snowball effect, beginning with misinterpretation of the Sunshine reported data and a negative public reaction, and ending with a potentially chilling effect on legitimate and necessary engagements between medical experts and the pharmaceutical industry. Instead of being seen as an expert who is working *with* industry (and compensated accordingly) to develop new and meaningful treatment options for patients, physicians may be seen as agents working *for* industry and may no longer be considered objective when analyzing clinical data and recommending therapies. Organizations like ProPublica.org already provide a

list of questions to "talk to your physician about pharmaceutical company payments."[1] While this increasing level of skepticism from the public is certainly concerning, there is also the possibility of active discrimination from payers who may discourage industry-physician collaborations through network-design decisions (e.g., creating a designation of "preferred" status to those physicians who do not accept money from industry).[2] The result of this is a well-recognized phenomenon of decreasing physician engagement with industry and an ever-shrinking pool of important and valuable thought leaders.

Historic Perspective: the Massachusetts Experience

A recent study in the New England Journal of Medicine (NEJM) examined the transparency reporting database in Massachusetts and provides a glimpse of several worrying trends.[2] Thirty months of data collected between 2010 and 2012 included 32,227 reported payments to 11,734 physicians for a total of $76.1M. Although 88% of payments were for "bona fide services" defined as research projects, clinical trials, and rendering advice on disease treatment, the overall number of payments and number of physicians receiving payments declined during the reporting period. These data suggest an immediate change in physician and industry behavior. However, public reporting was only one piece of the pressure for change as academic centers in Massachusetts also instituted strict policies on physicians during this time period. The actions of payers in Massachusetts have not been analyzed to date; however, the NEJM data suggest that the new regulations and policies are already changing behaviors.

Sunshine Impact on Medical Affairs

The first and most obvious medical affairs function directly impacted by diminished engagement and a waning thought leader pool as a consequence of Sunshine is the liaison team. This field force is medical affairs' boots on the ground, and if any MSL regardless of therapeutic area is asked what their top priority is, the response will invariably be "thought leader engagement." Scientific exchange between MSLs and thought leaders is a critical activity and any perturbation or disturbance impacts who MSLs can meet, how often they meet, and what they discuss with physicians. Post-Sunshine, some thought leaders may discontinue relationships with MSLs or may meet less frequently. A number of academic centers already ban their physicians from participating in advisory boards or at a minimum, frown upon it. And while there are certainly thought leaders who are still willing to participate in promotional programs, those numbers are also dwindling, thus lessening the need for MSLs to assist with speaker training or other external training-related activities.

The second area affected by Sunshine is independent research. Upon approval of a new indication, independent research is a critical way to learn more about drug safety, efficacy, and investigational uses. This impacts medical affairs because independent research dollars may now be associated with the principal investigator rather than the institution. Consequently, it will misleadingly appear that the physician received large payments from industry rather than showing that industry is simply supporting research at an institution, and this will have harmful effects on the number of researchers willing to

work with industry or apply for funding from industry despite the desire to continue clinical work. Medical affairs will be affected in this area by Sunshine first in limiting potential post-approval research initiatives that often fall to medical affairs, and second in potentially eliminating research as a key reason for the MSL team to engage with top researchers.

Medical education and scientific communications are two other critical areas that are likely to be greatly impacted by Sunshine. Scientific publications generated from corporate-sponsored trials provide a significant source of information about investigational and approved drugs. These articles are produced through collaboration between research physicians at pharmaceutical companies and academic clinicians. Release of trial data alone is not sufficient; careful analysis and interpretation of the data is equally important to support appropriate clinical application. In order for these medical education programs to succeed, physicians must be willing to write or speak about either a specific product or therapeutic area. As the pool of physician collaborators diminishes, it will become more and more challenging for these initiatives to move forward.

Considerations for 2014 and Beyond

Based on our analysis, we anticipate that medical affairs will encounter a number of significant challenges as a consequence of the Sunshine Act. In fact, according to a recent article by Eric Sagara at ProPublica, between 2011 and 2012 the industry reduced payments to physicians by approximately 7 to 47% depending on the category of payment.[3] Therefore, medical affairs is at present facing the prospect of fewer thought leaders, reduced budgets, shrinking depth and frequency of engagements, and a potential reduction in publications. Medical affairs professionals need novel methods of engagement, a strong scientific and medical focus and a strategy to lead them into the future.

Key questions to consider in 2014 and beyond:

1. Thought Leader Engagement
    a. What other tools are available for MSLs to build and maintain thought leader relationships?
2. Filling the Thought Leader Gap
    a. Advisory Boards: Are there other ways to gather information on a therapeutic area or space that does not involve remuneration? Webcasts? Surveys? Big data?
    b. Education: Do we need to redefine the MSL role and increase its emphasis on education to make up for disappearing thought leaders and speakers?
    c. Publications: How do you encourage collaboration and demonstrate the legitimacy of these collaborations in this new environment?
    d. Research: Will clinical development have to incorporate post-approval studies into their operations?

Contact Information

Contact Zipher directly to learn more about our Medical Affairs and MSL Optimization programs.

Phone: 508-748-3007 or Email: info@ziphermed.com

About the Authors

Jodi Smith, PhD, Director, Field Operations and Client Management. Dr. Smith has more than 10 years of experience in Medical Affairs in a variety of settings ranging from a small biotech company in southern California to a large multi-national pharmaceutical company based in New Jersey. She has previously served as a MSL at Bristol Myers Squibb, Spectrum Pharmaceuticals, and ImClone Systems. Her therapeutic areas of expertise include colon cancer, lung cancer, lymphoma, bone marrow transplant, myelofibrosis/myeloproliferative neoplasms and other subjects within hematology. In addition to her extensive MSL experience in the field, Dr. Smith has also developed both MSL and sales training programs, organized regional and national advisory boards, and closely collaborated with both in-house commercial and medical strategy colleagues on a number of special projects, including the development of promotional materials as well as reactive materials for the medical team.

Peg Crowley-Nowick, PhD, MBA, Founder and President of Zipher Medical Affairs Co., LLC. Prior to starting Zipher, Dr. Crowley-Nowick was head of Global Oncology Publications and Communications at Bayer Healthcare Pharmaceuticals. In this capacity, she was responsible for strategic communications planning, execution and global product launches. She also had responsibility for all Bayer hematologic oncology products and pipeline oncology agents.

Dr. Crowley-Nowick joined Bayer through the acquisition of Berlex Laboratories where she was Medical Director for Leukine® and responsible for medical strategy and leadership of the medical affairs team accountable for CME, research, publications and liaison activities. She was also the medical monitor supporting pharmacovigilence and regulatory oversight of the Phase IV program. Previously, she served as a MSL and a liaison manager for Berlex gaining valuable field experience.

References

1. Kusnetz N. (2013) *Dollars for Docs: How to Evaluate Drug Payment Data.* Retrieved from http://www.propublica.org/getinvolved/item/dollars-for-docs-how-to-evaluate-drug-payment-data.
2. Agrawal S., et al. (2013) "The Sunshine Act – Effects on Physicians." *New England Journal of Medicine.* 369:2054-7.
3. Sagara E. (2014) *Doctor Payments on the Decline.* Retrieved from http://projects.propublica.org/graphics/d4d-slopegraph.