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Conference Highlight

The New PhRMA Code and Beyond

Federal & State Laws are Eclipsing Self-Regulation

Author: Vincent DeChellis

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Published by:
VirSci Corporation
PO Box 760
Newtown, PA 18940
infovirsci@virsci.com

It is fair to say that there is a lot going on in the drug industry these days including economic pres-sures, sales force downsizing, M&As, pipeline problems, and a host of other issues. But edging up on the list of growing concerns are the laws regulating drug industry interactions with health-care professionals.

In a recent ExL Pharma conference that took place at the end of March, industry leaders from pharma and the vendor community reviewed the impact on "Marketing and Sales Under the Revised PhRMA Code".

In the national debate that is about to unfold re-garding healthcare, the conduct of the pharma-ceutical, biotech and device industries will un-doubtedly come under review calling in question industry practices and ethics. This process will likely continue to stir public sentiment against the industry unless efforts are put in place to stem the tide.

The new PhRMA Code that went into effect in January is a reflection of PhRMA's response to ongoing pressures and their attempt to bring about industry reform.

The Code also was designed to serve as an industry promotional compass; a set of guidelines that point the way to magnetic north regarding promotional practices and conduct with healthcare professionals.

Recently PhRMA extended the code by banning lavish entertainment of clinical trial investigators, among other changes (see box, pg 2).

New Regulations and State Laws

Unfortunately the current efforts by PhRMA to self-regulate marketing practices through the Code have fallen short as even stricter industry require-ments and expectations have moved beyond the PhRMA Code. New or pending federal and state laws have already eclipsed the Code requiring more restrictions, reporting and transparency with penalties for noncompliance.

At the federal level, the Physician Payments Sun-shine Act of 2009, is a national law that could potentially require all pharma and biotech com-panies to report payments to healthcare profes-sionals of more than $100; it is currently pending Congressional approval (see box, pg 5).

The Massachusetts Public Health Council just pas-sed new rules for both pharma and medical device companies making Massachusetts the state with the most comprehensive marketing and disclosure requirements.

The new Massachusetts ruling will go in effect on July 1, 2009. Companies will then have one year to put their reports in order so they can be posted to a state Web site for public record. Massachusetts is the eighth state to enact regulations. The District of Columbia currently calls for representatives to be licensed setting job and continuing education requirements to qualify for licensure.

A Number of Concerns

So is there reason to worry? It is too soon to tell but the tone was serious and the message was that companies need to get on track with efforts to comply with the new regulations. Trends show that the OIG and state attorneys general have pushed even stronger enforcement of current industry regulations so it is unlikely that these new regu-lations will go ignored.

With new legal and regulatory issues looming it was not surprising that one full day of the two-day conference focused on enforcement and liability issues. Attendees from both the industry and vendor side of the business pondered the business implications and speculated on what the new pro-motional environment will look like.

Concerns were voiced about systems require-ments, implementation, and training. One concern that stood out was the need to mobilize individual company resources to address the growing list of requirements and deadlines created by the new regulations. Presenters, tasked by their organiz-ations on the issue, spoke about the overwhelming scope of their projects and the challenges ahead.

Compliance Issues

Roundtable discussions focused on enterprise wide communication and training initiatives as attendees offered valuable insights for organizing and managing company compliance efforts.

Compliance officers throughout the industry will be faced with setting new promotional standards and utilizing systems designed to track aggregate promotional spend, assess fair market value and track other metrics designed to satisfy individual state and federal requirements.

A few of the many questions discussed were:

- Is the PhRMA Code really voluntary?
- What about all the companies that have not signed on to the PhRMA Code?
- When will it be a level playing field among manufacturers?

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PhRMA Issues Revised Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results: Promises to Provide Results Summaries Even if Sponsor Discontinues Drug Development

By Jamie K. Wolszon & Anne Marie Murphy
(Source: FDA Law Blog; http://bit.ly/t7BZv)

On April 20th, the Pharmaceutical Research and Manufacturers of America ("PhRMA") issued a revised "Principles on Conduct of Clinical Trials and Communication of Clinical Trials Results." The revision outlines, among other things, the trade group's Principles on the appropriate conduct of clinical research, registration of clinical trials on a public website, and disclosure of study result summaries.

PhRMA released the revised measures on the same day it testified at a public meeting on issues that the National Institutes of Health will consider as it develops regulations to expand the clinical trial registry and results data bank in accordance with the FDA Amendments Act of 2007 ("FDAAA") Title VIII. We previously reported on the meeting.

PhRMA first issued its Principles in 2002, and issued revisions in 2004. The Principles address issues including: protecting research participants; conduct of clinical trials; ensuring objectivity in research; and providing information about clinical trials. The revised voluntary code takes effect on October 1, 2009.

Some of the more significant provisions of the Principles are as follows:

Registration of Clinical Trials. PhRMA advises member companies to register on a public database timely summary information about all clinical trials that study products in patients. PhRMA defines timely as 21 days of enrollment of the first patient in the clinical trial.

PhRMA defines clinical trials subject to registration as those, including Phase I studies, conducted in patients. Use of the word "patients" is significant as PhRMA's definition excludes most Phase I studies, i.e., those performed in healthy volunteers. In this respect, PhRMA's Principles may be viewed as more comprehensive than the text of the FDAAA provision, which defines an "applicable drug clinical trial," subject to the databank registration requirements, to mean, "a controlled clinical investigation, other than a phase 1 clinical investigation."

PhRMA recommends that sponsors, when registering trials, provide all of the information mandated in FDAAA, even for studies not subject to the new law, "except if providing such information could jeopardize the [product's] intellectual property protection."

Submission of Summary Results. As it did in its prior version, PhRMA promises to disclose summary results of all clinical trials for approved drugs, regardless of the study's outcome. In a major change from its prior version, however, PhRMA also promises to post timely summary results of all clinical trials if the sponsor discontinues development of the drug. PhRMA defines timely as 12 months after the trial ends, 30 days within drug approval or a year after a company discontinues the drug development program.

Conflict of Interest Disclosures for Articles. The revision urges sponsors to encourage physicians and researchers to disclose conflict of interest information when authoring manuscripts to medical journals. Authors that submit a manuscript to a medical journal, according to PhRMA, should disclose "all financial and personal relationships that might bias their work," and explicitly state whether potential conflicts exist. The trade group also recommends that authors identify "individuals who provide writing or other assistance and disclose the funding source for this assistance." Furthermore, authors should describe several aspects of the sponsor's involvement with the study.

Increased Qualifications Needed for Authorship. The revised Principles would make it more difficult to be listed as an author of an article in a medical journal. These more stringent guidelines adhere to the standards of the International Committee of Medical Journal Editors.

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Interpreting the Code

Interpreting the PhRMA Code and reconciling its voluntary nature with mandatory state requirements was a source for confusion. The consensus was that although technically voluntary, we have moved beyond voluntary as interpreted by a panel of attorneys and industry leaders.

If a company is a signatory of the current PhRMA Code, they are indicating that they will adopt that code as their own. Companies who have not signed the PhRMA Code may still follow it or should create their own code and put it in effect.

Attendees were cautioned that they should not sign on to any code if they cannot fully implement the stated commitments. Companies also need to set in motion a plan that moves toward meeting the new state and federal requirements.

Currently, there are 41 companies that have signed the PhRMA Code. It is not known how many com-panies are following the code that have not signed but there are a number of companies that still seem to be operating in a business as usual mode.

Those companies who do nothing will increasingly be at risk of noncompliance and it will be only a matter of time before they are forced to comply. Until such time the playing field will not be level and frustrations with regard to unfair competitive practices will continue.

Need to Educate Physicians

If there was one theme that ran throughout the conference from workshops, general sessions and roundtable discussion groups it was education is needed at all levels.

First and foremost education is needed at the company level from top management down to individual employees. It was stressed repeatedly that ongoing training and documentation needs to be impressed upon all employees. The adoption of leading practice procedures, knowledge of the new regulations and the consequences of noncompliance needs to be infused into the corporate culture.

Next, the medical community needs to be educated to ensure their comprehension of the new code/regulations. It was felt that providers need to understand the implications the new regulations that govern numerous types of interactions, including contractual, between healthcare professionals and the drug industry.

PhRMA Issues Revised Principles (cont'd)

Provision of Study Results to Investigators and Participating Patients. PhRMA directs sponsors to provide all investigators with a full summary of the study results even if an investigator does not contribute to the publication of the study. The trade association offers investigators in a multi-site clinical trial an opportunity to review data for the entire study. The document also supports efforts of investigators to communicate a summary of the trial results to research participants after the study ends.

Sponsor Right to Review. PhRMA also confirms that sponsors have the right to review manuscripts, presentations, or abstracts that result from the sponsor's studies or use the sponsor's data prior to publication or presentation.

Conforming with PhRMA Code on Interactions with Healthcare Professionals. PhRMA Principles also conform to the revised PhRMA Code on Interactions with Healthcare Professionals, effective January 2009. We previously reported on the revised PhRMA Code, a voluntary code that focuses on appropriate industry interactions with healthcare professionals as they relate to the marketing of products. For instance, the Principles discourage: the use of resorts as venues for meetings with clinical investigators and staff; sponsor provision of entertainment or recreational events for clinical investigators and staff; and sponsor payment of honoraria or travel or lodging expenses for those who are not involved in the clinical trial.

It was also stressed that education was perceived as a more credible and safer approach than promotion for supplying physicians with valued content. Although industry supported CME has come under much closer scrutiny and is waning in industry support, clinical information is still highly regarded and believed to be the high road when it comes to promotion.

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Proposed Physician Payments Sunshine Act of 2009 Introduced in Senate

(Source: Sonnenschein Nath & Rosenthal LLP Health Alert; http://bit.ly/7PkVs)

On Jan. 22, 2009, Senate Finance Committee Ranking Member Chuck Grassley (R-Iowa) introduced S. 301, the Physician Payments Sunshine Act of 2009 ("S. 301"). Senators Herb Kohl (D-Wis.) and Amy Klobuchar (D-Minn.) are original co-sponsors of the bill, which has been referred to the Finance Committee. S. 301 represents the continued efforts of Senators Grassley and Kohl to bring transparency to the financial relationships between physicians and the pharmaceutical and medical device industries. The new bill contains greater and more specific disclosure requirements than the prior version and also incorporates recommendations of the Medicare Payment Advisory Commission related to disclosure.

Background and Purpose

A previous version of the bill was introduced but not adopted in the last Congress. S. 301 proposes an amendment to Title XI of the Social Security Act by adding a new section entitled, "Transparency Reports and Reporting of Physician Ownership or Investment Interests." The bill's purpose is to require disclosure of: (1) payments (or other transfers of value) made to physicians, physician medical practices, or physician group practices by drug and device manufacturers, and (2) physician ownership interests in applicable manufacturers or group purchasing organizations. This chart outlines each section of the bill.

Applicable manufacturers and group purchasing organizations would be required to begin reporting on March 31, 2011 and then on the 90th day of the year each year thereafter; however, the Secretary of the U.S. Department of Health and Human Services ("HHS") is required to establish procedures for submission of required information as early as Nov. 1, 2009.

Payments/Other Transfers of Value

Payments or other transfers of value include: (1) gifts, (2) honoraria, (3) speaking fees, (4) consulting fees, (5) travel, (6) services, (7) dividends, (8) profit distributions, (9) stock or stock option grants, and (10) ownership or investment interests. Exceptions include:

- Any payment or other transfer of value where the aggregate amount does not exceed $100 during the calendar year.
- Product samples not intended to be sold and that are for patient use.
- Educational materials that directly benefit patients or are intended for patient use.
- Loan of a device for a short term trial period (not to exceed 90 days) to permit evaluation by the covered recipient (physician).
- Items or services provided under a contractual warranty, including the replacement of a device, if terms of the warranty are set forth in the purchase or lease agreement.
- A transfer of anything of value when the covered recipient (physician) is a patient and not acting in his or her professional capacity as a physician.
- Discounts (including rebates).
- In-kind items used for the provision of charity care.
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund.

With respect to all payments or transfers of value, S. 301 would require applicable manufacturers to disclose the following information: (1) the name and business address of the physician to which a payment was made, (2) the date of the payment, (3) the value of the payment, and (4) a description of the form (e.g., cash, stock) and nature of the payment (e.g., consulting fee, gift, honorarium). If a payment of value is related to marketing or research, the entity must also disclose the name of the drug to which those payments relate.

The last form of education need is with the public. It was noted that industry public opinion has hit an all time low and perhaps the PhRMA Code and the latest round of legislation can help restore public trust but that will not happen if industry practices are not more visible. Greater transparency and a more professional image will hopefully allow the industry to recapture lost ground.

Impact on Vendor Community

What set this conference apart was the interest and concern shared by both manufacturers and vendors. It was very clear that the new code and added requirements were not just an issue for manufacturers, but one that impacts the suppliers of industry marketing and sales support.

The impact on some segments of the vendor community will be significant and the concerns were palpable. Some vendors were anxious, worrying about their future; others optimistic, hoping to take advantage of a cottage industry that is popping up in hopes of supporting the new requirements.

Whatever the situation, all meeting attendees—manufacturer and vendor alike—were actively engaged throughout the conference.

Plan for What's Ahead

The countdown has already begun and we have little time to put plans and systems in place to meet the new reporting requirements that lie ahead.

Those that feel the New PhRMA Code is just the tip of the iceberg are right. Who knows what will happen when all the promotional information gets posted and is becomes public record.

Over the next weeks and months, more clarity will emerge regarding the PhRMA Code. Without question the evolving regulatory environment will lead to the development of and changes to numerous business plans.

While assessing product and company promotion, industry leaders will need to be more introspective about where they look for answers. Managers should ask themselves whether the company culture has been infused with the principals of the PhRMA Code and if so inspired people to rise to the challenge.

As management teams weigh their options and risks, they should do so with some feeling of optimism. One of the final presentations given at the conference compared European codes to the new PhRMA Code (also see "PhRMA's New Code on Interactions with Healthcare Professionals," PMN Reprint #77-01: http://bit.ly/oqlxq). Attendees were struck by the similarities and encouraged by seeing the levels of innovation and the creativity used to overcome the challenges.

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About the Author

Vincent DeChellis is Principal at NHHS Healthcare Consulting LLC, providing consulting services in the area of Health Information Technology (HIT) and eBusiness for life science companies and vendors. You can reach Vincent at vdechellis@comcast.net