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# The 2009 Revision to the PhRMA Code on Interactions with Healthcare Professionals: Challenges and Opportunities for the Pharmaceutical Industry in the Age of Compliance

HOWARD L. DORFMAN\*

## INTRODUCTION

The interaction between pharmaceutical manufacturers and healthcare professionals has been under increased scrutiny for some period of time. Most of the attention has taken a decidedly negative view of those interactions with criticism regarding the adverse impact on the integrity of therapeutic decision making coming from such entities as Congress, the Office of Inspector General of the Department of Health and Human Services (the OIG), the Department of Justice, state attorneys general, and leaders of academic medicine.<sup>1</sup>

In 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA)<sup>2</sup> introduced the PhRMA Code on Interactions with Healthcare Professionals (the 2002 PhRMA Code).<sup>3</sup> The purpose of the 2002 PhRMA Code was to reinforce the appropriate nature of the interaction with healthcare professionals as

professional exchanges designed to benefit patients and to enhance the practice of medicine. The Code is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.<sup>4</sup>

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1. See Troyen A. Brennan et al., *Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*, 295 *JAMA* 429 (2006), available at <http://www.ohsu.edu/xd/about/services/integrity/coi/gifts/upload/Health-Industry-Practices-That-Crete-Conflicts-of-Interest.pdf>.

2. PhRMA is the trade organization that represents research-based pharmaceutical and biotechnology companies.

3. PHRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF'LS (2002) (superseded 2009), available at <http://www.phrma.org/files/PhRMA%20Code.pdf>.

4. *Id.* at 3.

Although voluntary, the 2002 PhRMA Code was embraced by PhRMA members generally and recognized as representing a significant shift in marketing practices for an industry that had been pilloried for excessive spending on healthcare professionals without any patient benefit. In 2003, the 2002 PhRMA Code was designated as a minimum standard for the pharmaceutical industry's relationships with health care professionals under the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers.<sup>5</sup> Vigilant regarding activities that could be viewed as potentially violative of the Anti-Kickback statute, the OIG recognized the 2002 PhRMA Code as a reflection of best practices for the industry, providing "useful and practical advice" for reviewing the industry's relationships with their customers.<sup>6</sup> While stating that following the 2002 PhRMA Code would not insulate a manufacturer from liability, the OIG did recognize that appropriate conduct would "substantially reduce the risk of fraud and abuse," and establish the type of record of compliance that would "help demonstrate a good faith effort to comply with applicable federal health care program requirements."<sup>7</sup> Following the example set by PhRMA, and responding to the same criticisms expressed by various groups, similar ethical guidelines were issued by the medical technology industry in 2003,<sup>8</sup> by the medical imaging equipment manufacturers in 2004,<sup>9</sup> and most recently by the Advanced Medical Technology Association (AdvaMed), the trade organization representing medical device manufacturers, in December 2008.<sup>10</sup>

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5. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003), available at <http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>.

6. *Id.* at 23,737.

7. *Id.* at 23,737-38.

8. See Kathleen Misovic, AAOS On-Line Service (Dec. 2004), <http://www2.aaos.org/aaos/archives/bulletin/dec04/legal.htm>; see also AAOS CODE OF ETHICS & PROFESSIONALISM FOR ORTHOPAEDIC SURGEONS (2004), available at <http://www.aaos.org/about/papers/ethics/code.asp>.

9. NEMA CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROVIDERS (2004), available at <http://www.nema.org/media/pr/upload/NEMA%20CodeofEthics.FAQ.adopted.pdf>.

10. ADVAMED CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROF'LS (2009), available at <http://www.advamed.org/MemberPortal/About/code/> (follow "Code of Ethics Revised & Restated Download" hyperlink). The revised and expanded Code tightens the guidance from the original 2005 Code, adds new provisions addressing industry practices such as royalty arrangements, and establishes a certification process to foster compliance with the Code. Although sharing many of the guidelines of the 2009 PhRMA Code revision, the AdvaMed Code addresses certain types of interactions with healthcare professionals that are more prevalent in the medical

Yet, notwithstanding the issuance of the various codes addressing ethical standards in interactions with the healthcare practitioners, criticism of industry conduct as creating an environment where excesses impacted the healthcare professional's clinical judgment continued. Troyen Brennan's article characterized the relationship between healthcare practitioners and the pharmaceutical industry as a "conflict of interest between the physicians' commitment to patient care and the desire of pharmaceutical companies and their representatives to sell their products."<sup>11</sup> The authors argued for nothing less than a total ban, or at the very least, severe limits on the providing of any items of value, no matter how low or de minimis, to physicians out of concern that bias might be introduced into the prescribing process.<sup>12</sup> Of greater concern to the industry were congressional hearings and promises of legislation sharply curtailing pharmaceutical marketing activities, as well as continuing investigations and prosecutions of various pharmaceutical manufacturers for illegal marketing practices that gave rise to liability for violation of the False Claims Act, among other federal and state laws.

Thereafter, PhRMA issued a revised code on interactions with healthcare practitioners in July 2008, which took effect in January 2009 (the 2009 PhRMA Code).<sup>13</sup> While the original 2002 PhRMA Code represented a significant shift in pharmaceutical industry marketing practices and ended what had been viewed as some of the more egregious sales and marketing excesses, the 2009 PhRMA Code revisions have been described as more narrowly constructed and represent a targeted guidance in response to specific criticisms. The revisions generally reflect current industry "best practices" and take into account many of the government-imposed changes in marketing processes that have marked an evolution in the compliance environment since 2002. Several key changes are being introduced in the 2009 PhRMA Code that will have significant impact on the marketing and sales practices now in effect for many pharmaceutical manufacturers. Specific areas that are affected by the revisions relate to the providing of meals by field sales representatives, reminder and practice-related items, and entertainment of healthcare professionals. Of greater significance for the members of the pharmaceutical industry is

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device industry, such as reimbursement support and providing products free of charge for evaluation and demonstration purposes.

11. Brennan et al., *supra* note 1, at 429.

12. *Id.* at 431-32.

13. PHRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF'LS (2009), available at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.

the fact that compliance with the 2009 PhRMA Code requires a thorough review of internal policies relating to the medical education function, the retention and payment of consultants and speakers, and the handling of physician prescribing data within individual companies.

This Article will describe the basic tenets of the 2009 PhRMA Code, how the 2009 PhRMA Code has been relied upon by at least one state in crafting its own response to the industry-healthcare professional debate, and it will conclude with a brief overview of pending activity apart from the self-policing guidance of the 2009 PhRMA Code with an outlook on the future of the compliance debate.

## I. THE REVISED PhRMA CODE

### A. *Informational Presentations and Meals*

Historically, a standard method by which pharmaceutical company sales representatives would interact with healthcare professionals was by providing a meal as a means of facilitating an informational presentation. The 2002 PhRMA Code permitted manufacturers to offer healthcare professionals the occasional modest meal solely to facilitate a presentation or discussion with industry representatives and others speaking on behalf of the company, but only where the venue was conducive to informational communication.<sup>14</sup> There was no other limitation as to location.

The revised, 2009 PhRMA Code allows the modest meal while making a scientific or clinical information presentation to healthcare professionals and their staff.<sup>15</sup> However, that modest and occasional meal “offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings.”<sup>16</sup> It does not eliminate the out-of-office or out-of-hospital meal entirely as a means of facilitating a speaker program.

Reading the remainder of the 2009 PhRMA Code and the accompanying question and answer section provides clarification regarding distinctions between the types of pharmaceutical employees in the context of permitted or prohibited activities. For example, Question 12 indicates that if the pharmaceutical company personnel hosting a business discussion are home-office based and not field sales, an out-

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14. PhRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF'LS 7 (2002) (superseded 2009), available at <http://www.phrma.org/files/PhRMA%20Code.pdf>.

15. PhRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF'LS 4 (2009).

16. *Id.*

of-office or hospital setting for the meal is permitted.<sup>17</sup> The explanation does not specifically address non-sales field personnel—such as Medical Science Liaisons or similar field based medical staff—which, presumably, would be permitted to provide out-of-office meals.<sup>18</sup> By refusing to utilize the more descriptive language used in other sections of the 2009 PhRMA Code,<sup>19</sup> it is reasonable to conclude that the drafters created certain distinctions as to appropriate conduct based on the company roles played by pharmaceutical manufacturer personnel.

### B. *Prohibition on Entertainment and Recreation*

The 2002 PhRMA Code permitted entertainment in the context of consultant meetings or speaker training sessions, provided that such entertainment and recreation were clearly subordinate both in time and emphasis to the business agenda of the meeting.<sup>20</sup> The 2009 PhRMA Code eliminates entertainment entirely in these contexts.<sup>21</sup> For the first time, companies are prohibited from providing entertainment or recreation from any interactions with healthcare professionals. The prohibition applies regardless of the relative value of the activity or whether it is secondary to the consultant or educational purpose of the meeting.<sup>22</sup>

### C. *Support for Continuing Medical Education*

The importance of defining the appropriate role for the pharmaceutical industry in relation to support for Continuing Medical Education (CME) is reflected in the 2009 PhRMA Code. Unlike the 2002 PhRMA Code, the CME section is now independent of other code provisions. New requirements are consistent with several of the recommendations found in the OIG Compliance Guidelines for Pharmaceutical Manufacturers and reflect guidelines issued by the Accreditation Council for Continuing Medical Education (ACCME).

The CME provisions track the general philosophy found throughout the 2009 PhRMA Code in stressing the need for the industry to

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17. *Id.* at 23.

18. *Id.*

19. Examples of such descriptive language found in other places in the 2009 PhRMA Code include phrases such as “company representatives,” “industry representatives,” and all company “representatives who visit healthcare professionals.” *Id.* at 4, 14.

20. PHRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF’LS 11 (2002) (superseded 2009), available at <http://www.phrma.org/files/PhRMA%20Code.pdf>.

21. PHRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF’LS 13 (2009).

22. *Id.* at 5.

distance the sales and marketing functions from purely educational endeavors, critical to the independence of developers of CME materials. As the 2009 PhRMA Code suggests, support for CME is intended to educate healthcare professionals on a full range of treatment options, not as a means of promoting a particular therapeutic option.<sup>23</sup> To accomplish this goal, pharmaceutical companies are to separate the CME grant review process from involvement of sales and marketing personnel and to follow ACCME or other accrediting entity standards.<sup>24</sup> Companies are no longer permitted, as they were under the 2002 PhRMA Code, to provide meals or receptions directly at CME events.<sup>25</sup> Instead, companies are allowed to provide funding to the CME provider for meals to all attendees.<sup>26</sup>

A significant change in the Code relates to the ability of a pharmaceutical manufacturer to provide guidance to the CME provider in the development of CME programs. The 2009 PhRMA Code states that manufacturers are no longer permitted to provide guidance regarding potential speakers or content even if an unsolicited request is received from the CME provider.<sup>27</sup> These guidelines, which speak of near absolute separation between industry and CME providers, would likewise suggest that the practice of allowing company medical personnel to review CME materials in advance for factual accuracy is now highly suspect, notwithstanding the potential impact on product liability exposure for those companies that have provided support for a CME program that is thereafter alleged to have provided inaccurate information regarding the sponsor's drug. However, it appears that a company may establish a Request for Proposals concept as part of the decision making process regarding which CME areas to fund.<sup>28</sup>

#### D. Consultants

The "Consultants" Section of the 2009 PhRMA Code begins by reiterating the general principles stated in the 2002 PhRMA Code. It proceeds by enunciating the very basic standards for establishment of consulting arrangements between manufacturers and healthcare professionals and then lists factors that support the existence of bona fide consultant engagements.<sup>29</sup> A justification is now included—"use [of

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23. *Id.* at 6.

24. *Id.*

25. *Id.* at 28.

26. *Id.*

27. *Id.*

28. *Id.* at 29.

29. *Id.* at 7-9.

expert] advice . . . to ensure that . . . medicines . . . are meeting the needs of patients”<sup>30</sup>—which reprises a consistent theme relating to patient interests that is stressed throughout the revised code. The 2009 PhRMA Code also contains several additional details regarding the consultant arrangement, such as the existence of a written contract and the identification of a need for the services to be provided. The company should likewise be prepared to justify the need for the number of consultants being retained.<sup>31</sup>

Expanding the criteria to be utilized in the selection of consultants, the 2009 PhRMA Code states that the decision regarding the selection or retention of healthcare professionals as consultants should be based on “defined criteria such as general medical expertise and reputation” and paid based on an undefined “fair market value.”<sup>32</sup> Additionally, resorts are expressly deemed inappropriate locations for consultant meetings.<sup>33</sup>

The 2009 PhRMA Code suggests new responsibilities for the pharmaceutical manufacturers regarding the use of consultants apart from the now common concern regarding appropriate recompense and venues. The language as to “selection or retention” in the Code suggests a need to monitor consultants and document the extent to which their services will be required beyond the term fixed by contract.<sup>34</sup> As will be discussed further, the need to maintain records of payments to consultant healthcare professionals is not only implicitly suggested by the 2009 PhRMA Code but required in an increasing number of states.

#### *E. Speaker Programs and Speaker Training Meetings*

The concept of the speaker bureau—the retention and training of healthcare providers to speak at various venues on behalf of a pharmaceutical company’s products within label—has come under scrutiny and criticism from various sources for a wide range of reasons. These reasons include: the excessive payments made to the speakers as a reward for past prescribing activity or as an inducement for future prescribing,<sup>35</sup> and the possibility of disseminating off-label information

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30. *Id.* at 7.

31. *Id.* at 8-9.

32. *Id.* at 7-8.

33. *Id.* at 8.

34. *Id.* at 7.

35. Excessive payments made to speakers could be a violation of the Anti-Kickback statute.



under the guise of an in-label presentation.<sup>36</sup> While the 2009 PhRMA Code allows for the retention of a healthcare professional as a paid speaker, speaker programs are afforded separate discussion from consultant activities.<sup>37</sup> New restrictions are imposed by the 2009 PhRMA Code that will require careful review of existing internal policies and procedures.

The revisions found in the 2009 PhRMA Code incorporate additional compliance concepts regarding the retaining and training of speakers that have become ubiquitous in most company compliance programs since the release of the 2002 PhRMA Code. These additional compliance concepts reflect the OIG Guidance as well as a number of Corporate Integrity Agreements (CIA). The 2009 PhRMA Code confirms that speaker programs are promotional in nature, and that companies should take care to establish a distinction between such engagements and CME activities.<sup>38</sup> To assist in clarifying the distinction between such speaking engagements and CME activities, the Code repeats a number of the requirements suggested for consultant engagements, and requires the establishment of a need for the speaker's services and the relevant expertise of the speaker. By way of example, and specifically responding to the concerns raised, the 2009 PhRMA Code specifies that any healthcare professional engaged to undertake external promotional activities is deemed a speaker who should clearly identify that they are speaking on behalf of the manufacturer and that the information they present is consistent with current labeling and applicable FDA guidance.<sup>39</sup>

In addition to the responsibilities on the speakers, new requirements are imposed on the retaining companies, several of which will no doubt require a careful review of existing compliance policies and procedures. Pharmaceutical manufacturers must develop and implement policies that address the appropriate use of speakers and establish the appropriate number of speaking engagements for any particular speaker over time.<sup>40</sup> Speakers must undergo training regarding the company's products to understand the approved product labeling and FDA regulatory requirements.

Of particular note are two new requirements. The pharmaceutical company is responsible for the active monitoring of its speaker pro-

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36. Such a situation could violate the Federal False Claims Act and the Federal Food, Drug and Cosmetic Act.

37. PhRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF'LS 9 (2009).

38. *Id.* at 10.

39. *Id.* at 9.

40. *Id.* at 10.

grams to verify compliance with all applicable FDA regulations.<sup>41</sup> In addition, each manufacturer is encouraged to “cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking engagements.”<sup>42</sup> No fixed cap amount is provided by the 2009 PhRMA Code, leaving the decision regarding establishing a reasonable limit to the judgment of the company. However, timely access to the pertinent information throughout the organization to permit an accurate assessment of compensation paid to any particular speaker may provide challenges for some companies.

The significance of the revision in the 2009 PhRMA Code regarding the need to actively monitor speaker compliance with FDA regulations cannot be overstated as it relates to the ongoing debate regarding the proper role of a pharmaceutical company in the dissemination of truthful and non-misleading medical information to healthcare professionals. The OIG and various state attorneys general have aggressively investigated pharmaceutical industry marketing practices for activities that they believe constitute promotion of products beyond the scope of the FDA-approved labeling. If such “off label” promotion is suspected, prosecution for violation of the Food, Drug and Cosmetic Act, as well as of both federal and state False Claims Acts, have been maintained. This provision of the 2009 PhRMA Code suggests an attempt to proactively address this issue as relating to presentations by members of a company’s speaker bureau to be sure speakers are responding to unsolicited inquiries for medical information outside approved labeling appropriately.<sup>43</sup>

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41. *Id.*

42. *Id.*

43. On Monday, January 12, 2009, the U.S. Food and Drug Administration (FDA) made available a final guidance on industry dissemination of medical or scientific journal articles and referenced publications that discuss unapproved uses—or “off-label” uses—of FDA-approved or cleared drugs, biologics, and medical devices. The long-awaited final guidance recognizes the public health and policy justification supporting the dissemination of truthful and non-misleading information on off-label uses. The final guidance permits manufacturers, including their sales representatives, to disseminate off-label information about their products if such information is in the form of appropriate (e.g., peer-reviewed and unedited) medical journal articles. See Matthew Arnold, *FDA OKs Distribution of Journal Articles on Off-Label Uses*, MED. MARKETING & MEDIA, Jan. 12, 2009, <http://www.mmm-online.com/FDA-OKs-distribution-of-journal-articles-on-off-label-uses/article/123914/>.

#### F. Prohibition of Non-Educational and Practice Related Items

The 2009 PhRMA Code effectively eliminates the category of “practice-related gifts” of nominal value imprinted with the company’s name or logo as appropriate for distribution to healthcare professionals and their staff.<sup>44</sup> This includes such classic giveaway items as pens, mugs, notepads, or other such reminder pieces.<sup>45</sup> Instead, the 2009 PhRMA Code redefines “educational items” that are permissible as “items designed primarily for the education of patients or healthcare professionals if the items are not of substantial value (\$100 or less) and do not have value to the healthcare professional outside of his or her professional responsibilities.”<sup>46</sup> This revision keeps in line with the stated 2009 PhRMA Code’s objective of establishing the industry-healthcare practitioner relationship as based on education to the physician and benefit to the patient. Permissible items, however, must be offered only on an occasional basis and be permitted by law.<sup>47</sup> Pens and mugs and similar pieces do not “advance disease or treatment education,” and therefore they are banished from the marketing armamentarium.<sup>48</sup>

These newly articulated restrictions do not appear to require that a gift provided to a healthcare professional have no independent value, only that the item have no independent value to the healthcare professional outside of the professional’s practice. Similarly, it does not appear that the prohibition on “practice related items” means that an educational item cannot have value to the healthcare professional’s practice. Such an interpretation runs counter to other sections of the 2009 PhRMA Code.<sup>49</sup> Therefore, items that have value in relation to a medical practice, such as an anatomical model or a patient tracking form, are clearly permissible and specifically addressed in the 2009 PhRMA Code as educational items with no value to the healthcare practitioner outside of the practice and do not represent prohibited “practice related items.”

#### G. Prescriber Data

Another long-standing and recurring criticism of the pharmaceutical industry is addressed in the 2009 PhRMA Code’s section pertaining to the access by companies of data relating to prescribing activities

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44. PhRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF’LS 11 (2009).

45. *Id.*

46. *Id.* at 12.

47. *Id.*

48. *Id.* at 18.

49. *See generally id.*

of healthcare professionals. Criticism of access to and use of healthcare practitioner prescribing data by pharmaceutical companies, particularly by their field-based sales force, had grown since the 2002 PhRMA Code was released without any reference to this issue.<sup>50</sup> The 2009 PhRMA Code advises companies to use non-patient identifiable prescribing data responsibly and further requires the development of company policies regarding the appropriate use of such data.<sup>51</sup> Companies are further urged to respect and abide by the wishes of any healthcare professional who requests an opportunity to opt-out of any process that provides his or her data to sales representatives; to educate company “employees and agents” regarding company policies; and to establish disciplinary procedures for misuse of such data.<sup>52</sup>

Once again, the 2009 PhRMA Code is responding to an ongoing source of criticism of the pharmaceutical industry. Beginning in the early 1990s, electronic records of prescription activity from retail pharmacies and related sources were linked with physician prescribing information and sold to pharmaceutical manufacturers. This practice soon came under fire from a number of physicians, particularly when healthcare professionals were confronted by sales representatives with knowledge of their exact prescribing habits.<sup>53</sup> The 2009 PhRMA Code tracks the provisions of the Prescribing Data Restriction Program (the PDRP)<sup>54</sup> adopted by the American Medical Association in 2006. The PDRP formalized the process for allowing physicians to restrict prescribing information from release to pharmaceutical company representatives, established an “opt-out” mechanism, and limited access of sales personnel (including managers) to specific data.<sup>55</sup> The data in question includes prescription counts and volume, “change indicators,” and other non-physician specific information.

The 2009 PhRMA Code was too late to forestall state action. On June 30, 2006, the New Hampshire legislature unanimously passed the Prescription Confidentiality Act, which effectively prohibited the trans-

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50. PHRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF'LS (2002) (superseded 2009), available at <http://www.phrma.org/files/PhRMA%20Code.pdf>.

51. PHRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF'LS 13 (2009).

52. *Id.*

53. Stephanie Saul, *Doctors Object to Gathering of Drug Data*, N.Y. TIMES, May 4, 2006, available at <http://www.nytimes.com/2006/05/04/business/04prescribe.html>. See also Robert Steinbrook, *For Sale: Physicians' Prescribing Data*, 354 NEW ENG. J. MED. 2745 (2006), available at <http://content.nejm.org/cgi/content/full/354/26/2745>.

54. AM. MED. ASS'N, PDRP: THE CHOICE IS YOURS, available at [http://www.ama-assn.org/ama1/pub/upload/mm/432/pdrp\\_brochure.pdf](http://www.ama-assn.org/ama1/pub/upload/mm/432/pdrp_brochure.pdf) (last visited Mar. 21, 2009).

55. *Id.*

fer of patient or provider identifiable data for most commercial purposes, specifically barring the use of prescriber identifiable data for detailing purposes.<sup>56</sup> The legislature cited privacy concerns on the part of physicians and patients, as well as the opinion that physicians who are detailed by company representatives tend to prescribe innovator (and therefore more costly than generic drugs), thereby increasing the state's prescription reimbursement costs. Data miners such as IMS filed suit in federal court in 2007 challenging the state law on various grounds, particularly claiming the law violated their First Amendment right to commercial free speech.<sup>57</sup> While the district court struck down the law under the three-part *Central Hudson* test,<sup>58</sup> the Court of Appeals for the First Circuit upheld the New Hampshire law.<sup>59</sup>

Other jurisdictions, including Vermont and Maine, have passed legislation similar to the New Hampshire statute.<sup>60</sup> While it is premature to opine as to the eventual outcome of these various state initiatives, it is clear that pharmaceutical companies must be cautious in implementing internal policies that relate in any way to the use by marketing and sales functions of such data. In addition, in light of obligations imposed by jurisdictions such as Massachusetts that appear to exceed those contained in the 2009 PhRMA Code,<sup>61</sup> it would be prudent for companies to develop processes for removing identifiable prescriber data from various in-house commercial applications beyond sales representative access.

#### H. Training and Conduct of Field Representatives

When pharmaceutical company personnel interact with healthcare professionals concerning medical and scientific issues, the "highest ethical standards" should be followed.<sup>62</sup> To further reinforce this concept, companies are required to ensure that all company representatives who visit healthcare professionals (i.e., beyond field-based sales representatives) receive training on the applicable laws, FDA regulations, and industry codes of practice (i.e., the PhRMA Code), as well as

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56. N.H. REV. STAT. ANN. § 318:47-f (2006).

57. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 165 (D.N.H. 2007), *rev'd*, 550 F.3d 42 (1st Cir. 2008).

58. *Id.* at 176 (discussing *Central Hudson Gas & Electric Corp. v. New York*, 447 U.S. 557 (1980), and its application to *IMS Health*).

59. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 45 (1st Cir. 2008).

60. See ME. REV. STAT. ANN. tit. 22, §§ 1711-E, 8713 (2008); VT. STAT. ANN. tit. 18, § 4631 (2008).

61. See *infra* notes 72-76 and accompanying text.

62. PHRMA CODE ON INTERACTIONS WITH HEALTHCARE PROF'Ls (2009), available at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.

training on general scientific and product specific information.<sup>63</sup> More importantly, companies are to assess their representatives periodically to determine that they comply with relevant company policies and take appropriate disciplinary action when representatives fail to comply.<sup>64</sup>

Field-based pharmaceutical sales representatives will have opportunities to utilize their training. Presumably, it will be the responsibility of these representatives to monitor speaker programs to establish compliance with the requirements of discussing current, on-label promotional information. The importance of this function should not be underestimated, particularly given the focus of such entities as the FDA, the OIG, the Department of Justice, and the various state attorneys general in investigating off-label promotion for future prosecution on both the state and federal level.

### *I. Formulary Committee Members*

An example of how the 2009 PhRMA Code responded to criticism of the pharmaceutical sales industry since the adoption of the 2002 PhRMA Code can be seen in the newly introduced section on the need for corporate disclosure relative to interactions with formulary committee members. While the 2002 PhRMA Code is silent regarding the issue of disclosure by healthcare professionals of relationships with industry, the 2009 PhRMA Code states that companies should require healthcare professionals who consult or speak for industry and sit on formulary committees to disclose the existence and nature of their relationship with the company.<sup>65</sup> In this regard, the disclosure requirements should extend for a minimum of two years following the termination of the relationship with the company.<sup>66</sup> However, only if the formulary committee procedures require it would the company-retained members recuse themselves from decisions the committee makes relating to a medicine for which they speak or consult.

## II. IMPLEMENTING AND ADHERENCE TO THE CODE

The 2009 PhRMA Code, like its predecessor, is an articulation of guidance for its members. Antitrust principles prevent an association such as PhRMA from dictating internal policies to its members. Yet, to address the criticisms of the industry, as well as take into account the

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63. *Id.* at 14.

64. *Id.*

65. *Id.* at 31.

66. *Id.*

conduct that gave rise to the several investigations, settlements, and CIAs since 2002, the 2009 PhRMA Code anticipates a certification process for companies to commit to following the provisions by the posting of company “certifications” that policies and processes are in place to foster Code compliance.<sup>67</sup> Further, companies will be encouraged to seek external verification at least once every three years that they, in fact, have such policies and processes in place.<sup>68</sup>

A. *Potential Impact on the Pharmaceutical Industry: Opportunities and Challenges*

The PhRMA activities during the past six years that gave rise to the 2002 PhRMA Code and the 2009 PhRMA Code were certainly not undertaken in a vacuum. Both reflect the state of an industry facing significant criticism and the development of a response to that criticism.

The importance of the 2009 PhRMA Code can be seen by virtue of its being viewed as the most definitive articulation of minimum conduct by which individual members of the pharmaceutical industry will be measured and often judged. We have already noted that the OIG, for example, viewed the 2002 PhRMA Code as a minimum code of conduct for pharmaceutical companies that, while not insulating a manufacturer from liability as a matter of law, would still “substantially reduce the risk of fraud and abuse” and “demonstrate a good faith effort to comply with applicable federal health care program requirements.”<sup>69</sup> We can anticipate a similar articulation of OIG opinion with regard to the 2009 PhRMA Code. However, it is important to note there has been increased OIG activity during the six years following release by PhRMA of the 2002 Code. The increased requirements of the 2009 PhRMA Code bring potential for increased exposure and potential liability for any failure to commit the necessary resources in the review of existing compliance policies and procedures and the development of new ones as required.

The 2009 PhRMA Code is considered by various states to be an important basis for determining appropriate industry conduct as new regulations are adopted that govern interactions between pharmaceutical companies and healthcare providers on the state level. For example, California Health and Safety Code 119402 states that every

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67. *Id.* at 14.

68. *Id.* at 15.

69. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,737 (May 5, 2003), available at <http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>.

pharmaceutical company must adopt a “comprehensive compliance program” that includes policies that are compliant with the PhRMA Code and requires conforming changes within six months of any update or revision of the PhRMA Code.<sup>70</sup> Nevada has likewise adopted regulations that require pharmaceutical and medical device manufacturers to adopt a written marketing code of conduct where adoption of the most recent version of the PhRMA Code would satisfy the Nevada requirements.<sup>71</sup>

Another recent state action in this regard took place on August 10, 2008 when Governor Patrick of Massachusetts signed Senate Bill 2863, “An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care.”<sup>72</sup> As seen in California and Nevada, attention is paid to the guidance offered in the PhRMA Code, as the Massachusetts law requires the Department of Public Health to promulgate regulations that are “no less restrictive” than those contained in the most recent version of the PhRMA Code.<sup>73</sup> Under the Massachusetts statute, effective January 1, 2009, both pharmaceutical and medical device manufacturers selling or marketing in the state have to comply with the Massachusetts Department of Public Health (the DPH) Code of Conduct.<sup>74</sup> The DPH released proposed implementing regulations in December 2008, which included specific requirements similar to, but in some cases more expansive than, those in the PhRMA or AdvaMed codes.<sup>75</sup> The state code requires companies to undertake specific compliance activities (such as training, auditing, and instituting policies for corrective action) and to publicly disclose any payments to HCPs with a value of fifty dollars or more in connection with sales and marketing activities.<sup>76</sup>

The Massachusetts legislation has as much in common with recent OIG enforcement actions as it does with the pharmaceutical and medical device industry codes, and many requirements will look familiar to those companies operating under corporate integrity agreements. For example, in addition to adopting training programs,

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70. CAL. HEALTH & SAFETY CODE § 119402 (West 2006).

71. NEV. REV. STAT. § 639.570 (2008).

72. S. 2863, 2008 Leg. (Mass. 2008).

73. MASS. ANN. LAWS ch. 111N, § 2 (LexisNexis Supp. 2009).

74. *Id.*

75. Press Release, Mass. Dep't of Pub. Health, Massachusetts Proposes Sweeping New Rules Governing Sales and Marketing Tactics of Pharmaceutical and Medical Device Companies (Dec. 10, 2008), available at [http://www.mass.gov/?pageID=eohhs2pressrelease&L=1&L0=Home&sid=Eeohhs2&b=pressrelease&f=081210\\_new\\_regs&csid=Eeohhs2](http://www.mass.gov/?pageID=eohhs2pressrelease&L=1&L0=Home&sid=Eeohhs2&b=pressrelease&f=081210_new_regs&csid=Eeohhs2).

76. MASS. GEN. LAWS ch. 111N, § 2.



companies are required to conduct annual audits to monitor company compliance and to adopt policies and procedures for investigating instances of noncompliance and reporting such noncompliance to the state authorities.<sup>77</sup> Companies are expected to identify a compliance officer responsible for monitoring activities relating to the DPH Code, certify that it has conducted its annual audit and that all activities are in compliance, and submit a disclosure report annually regarding payments for marketing expenditures for the prior year.<sup>78</sup>

### B. Industry Oversight Outside the Code

The release of the 2009 PhRMA Code does not represent the final statement regarding establishing the appropriate level of interaction between the pharmaceutical industry and healthcare professionals. In addition to legislative initiatives in other states,<sup>79</sup> the federal government is entering the field.

On January 22, 2009, the Physician Payment Sunshine Act of 2009 (the Sunshine Act) was introduced in the United States Senate by Senators Charles Grassley (R-IA) and Herb Kohl (D-WI).<sup>80</sup> The stated purpose of the Sunshine Act is to “provide for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.”<sup>81</sup> Under the bill, these manufacturers would need to publicly disclose payments and gifts made to HCPs in excess of \$100 with penalties for non-compliance running as high as \$1 million.<sup>82</sup> A previous version of the Sunshine Act introduced by Senator Grassley in 2007 had set the disclosure reporting requirement at \$500.<sup>83</sup>

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77. *Id.*

78. *Id.* Certain payments in cash or providing items of value, albeit made to HCPs, are explicitly excluded from the Massachusetts legislation. Such items of value can include: price concessions made in the normal course of business and documented appropriately as per the OIG Safe Harbor; the provision of reimbursement information, unless provided to induce use of a company’s products; and drugs or other support provided through established Patient Assistance Programs that comply with federal anti-kickback statutes.

79. Seven jurisdictions in addition to Massachusetts have state laws that govern activities relative to the marketing of pharmaceuticals, medical devices, or both. As of January 2009, they were California, Maine, Minnesota, Nevada, Vermont, West Virginia, and the District of Columbia.

80. Physician Payment Sunshine Act of 2009, S. 301, 111th Cong.

81. *Id.*

82. *Id.*

83. Physician Payments Sunshine Act of 2007, S. 2029, 110th Cong.

In fact, several pharmaceutical companies, having already been subject to exhaustive investigations by federal and state governmental agencies, have already agreed to list payments made to physicians on a public web site, most notably Pfizer<sup>84</sup> and Eli Lilly.<sup>85</sup> Given the current environment in Congress regarding the relative cost of reimbursing pharmaceuticals under the present reimbursement systems, and the belief that such costs are increased as a result of inappropriate relationships between industry and the HCPs, it is highly likely the bill will pass.

#### CONCLUSION

The implications of the 2009 PhRMA Code for the U.S. pharmaceutical industry are significant. We have already noted how the 2009 PhRMA Code will be considered the minimum standard of conduct by the OIG and by the various states. In this regard, it is critical for the individual companies to review their existing policies and procedures to determine if they meet the new requirements suggested by the revised Code. Even those entities currently operating under a CIA, deferred prosecution, or other compliance-related obligations would need to determine the extent to which the 2009 PhRMA Code requires processes such as external verification. Moreover, as PhRMA has indicated it will direct any complaints as to inappropriate corporate conduct to that company's Chief Compliance Officer (CCO) and will identify on its website those companies that have obtained external verification of its policies and procedures to foster compliance, new grounds for criminal and civil liability may develop. It is safe to state that compliance has become a complex and ongoing issue for the pharmaceutical industry that will continue to dominate the industry's already crowded agenda for years to come.

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84. *Pfizer to Publicly Disclose Payments to U.S. Physicians, Healthcare Professionals and Clinical Investigators*, MED. NEWS TODAY, Feb. 11, 2009, <http://www.medicalnewstoday.com/articles/138525.php>.

85. Posting of Jacob Goldstein to WSJ Health Blog, <http://blogs.wsj.com/health/2008/09/24/eli-lilly-to-disclose-payments-to-doctors/> (Sept. 24, 2008, 9:06 EST).