

Statement



In Opposition to Connecticut Senate Bill 1049

March 2, 2009

Position: PhRMA opposes Senate Bill 1049 because it would restrict certain biopharmaceutical industry interactions with healthcare providers. Such legislation does not reduce healthcare costs. In fact, restricting these interactions and requiring disclosure of trade secrets could prevent the dissemination of FDA-approved materials and can chill research and development as well as patient access to clinical trials.

States that have had marketing disclosure laws on the books for a few years are not realizing cost savings. For example, in 2008, the West Virginia Legislative Auditor determined that programs implemented to reduce spending on prescription drugs, including marketing disclosure, cost an estimated \$1.1 million dollars in 3 years. The state's savings across programs during that time was an estimated total of \$299,449. Essentially, the state had a negative return on investment of \$800,000.

Economic Benefit Ban and Disclosure of Exceptions

SB 1049 prohibits certain interactions between the biopharmaceutical industry and healthcare providers. The bill prohibits pharmaceutical representatives from providing physicians with educational materials including brochures without drug information that focus on explaining a disease, therapeutic goals, clinical practice guidelines, and additional resources, which are critical for patient safety. The bill also does not appropriately exclude medicine samples for patients. Biopharmaceutical company representatives bring educational materials and samples, which are regulated by the Food and Drug Administration (FDA), to healthcare representatives at lunch to accommodate healthcare providers' busy schedules. SB 1049 bans modest meals provided as a professional courtesy to healthcare providers during these educational sessions. This implies that relationships between physicians and pharmaceutical representatives are improper and that a meal provided during an educational presentation will influence prescribing decisions.

In addition to negatively impacting patient safety, the bill also fails to exclude royalties and licensing fees from the economic benefit ban. These are not marketing expenses, but a research and development expense. Manufacturers enter into royalty arrangements when licensing a compound or entering into a joint development agreement. By not protecting these trade secrets and requiring public disclosure via a website, discovery and collaboration in Connecticut could be negatively impacted.

Disclosing trade secret information about payments made to healthcare providers who conduct research or clinical trials could have a chilling effect on these activities in Connecticut. Research and clinical trials are often considered trade secret activities because disclosure of such elements could give a competitor an advantage in the marketplace. The disclosure and publication requirements could make Connecticut a less than desirable place to host clinical trials (there are currently more than 2,500 clinical trials in the state¹) and other consultant-driven research, as affiliated practitioners may not be comfortable having their names and compensation published on the state's website. This could decrease the number of clinical trials available to patients in Connecticut. Furthermore, many early stage research programs would be excluded from the definition of clinical trials used in the bill.

The bill may also impact research grants and charitable donations. The exceptions to the ban as written may not exclude research grants because there may not be a written contract in place when a grant is issued. As a result, physicians in Connecticut may be prevented from conducting important research that could have significant implications for patient health. The proposal could also prevent funding activities for some charities (e.g., disease

¹ According to the National Institutes of Health (www.clinicaltrials.gov).

management events, 5K walk/runs, charity dinners) and patient organizations when a healthcare provider is a participant (e.g., board member, fund raiser) because not all charities are designated as a 501(c)(3). In addition, pharmaceutical companies cannot provide meals to a healthcare provider engaged in an excepted, non-marketing activity (research or speaker training, meeting with a healthcare consultant, interviewing a healthcare provider for a job).

Federal Health and Human Services (HHS) guidelines make marketing disclosure legislation unnecessary and duplicative.

Pharmaceutical manufacturers are subject to criminal anti-kickback statutes and other criminal and civil provisions, enforced by the U.S. Department of Justice, that govern their relationships with healthcare providers, and the HHS Office of Inspector General (OIG) maintains detailed guidance for pharmaceutical companies designed to deter violations of these federal laws. These marketing guidelines prohibit *quid pro quos* between drug makers and healthcare professionals.

In addition, the pharmaceutical industry issued its own voluntary guidelines ("PhRMA Code") related to communications with healthcare practitioners. A newly revised version of the Code went into effect in January 2009 and is part of an ongoing effort to ensure that pharmaceutical marketing practices comply with the highest ethical standards. The Code is based on the principle that a healthcare professional's care of patients should be based solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

Included in the Code are prohibitions on giving healthcare providers recreational tickets and entertainment events as well as clear guidelines for sponsoring Continuing Medical Education (CME) and contracting with healthcare professionals for consulting services. Efforts to regulate CME could discourage funding of CME activities. For example, some medical societies may run CME programs that do not conform to all ACCME guidelines. CME programs have been recognized as valuable activities that improve the quality of patient care. The prevailing view among the Food and Drug Administration (FDA), the Department of Health and Human Services Office of the Inspector General (OIG), the American Medical Association (AMA), and the Accreditation Council for Continuing Medical Education (ACCME) is that financial support for CME from pharmaceutical manufacturers is not only permissible but desirable.

The PhRMA Code on Interactions with Healthcare Providers notes that financial support for CME is intended to support education on a full range of treatment options and not promote a particular medicine. Accordingly, a company should separate its CME grant-making functions from its sales and marketing departments, should only fund bona fide educational programs, and should provide the CME organizer with funds to distribute and plan the conference without company influence.

For these reasons, PhRMA asks Connecticut legislators to oppose Senate Bill 1049.

PhRMA Code on Interactions with Healthcare Professionals – Signatory Companies

In June 2008, the PhRMA Board of Directors unanimously adopted measures to enhance the PhRMA Code on Interactions with Healthcare Professionals.

The revised, voluntary Code, which took effect Jan. 1, 2009, reaffirms that interactions between pharmaceutical company representatives and healthcare professionals should be focused on informing the healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

Among its changes, the revised Code provides that all companies that interact with healthcare professionals about pharmaceuticals should adopt procedures to assure adherence to the Code. It also states that PhRMA will identify on its website all companies that announce their commitment to abide by the Code and complete (at the appropriate time) an annual certification that they have policies and procedures in place to foster compliance with the Code.

The following is a list of all signatory companies that have announced as of Feb. 24, 2009 that they intend to abide by the Code:

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| Abbott | Johnson & Johnson |
| Amgen Inc. | Eli Lilly and Company |
| Amylin Pharmaceuticals, Inc. | Merck & Co., Inc. |
| Astellas US LLC | Millennium Pharmaceuticals, Inc. |
| AstraZeneca LP | Novartis Pharmaceuticals Corporation |
| Bayer HealthCare Pharmaceuticals | Novo Nordisk Inc. |
| > Biogen Idec | > OSI Pharmaceuticals |
| Boehringer Ingelheim Pharmaceuticals, Inc. | Otsuka America, Inc. |
| Bristol-Myers Squibb Company | Ovation Pharmaceuticals, Inc. |
| Celgene Corporation | Pfizer Inc |
| Cephalon, Inc. | > Proctor & Gamble Pharmaceuticals |
| > Covidien | Purdue Pharma L.P. |
| > Cumberland Pharmaceuticals Inc. | > Regeneron Pharmaceuticals, Inc. |
| > CV Therapeutics, Inc. | sanofi-aventis U.S. |
| Daiichi Sankyo, Inc. | Schering-Plough Corporation |
| > Enzon Pharmaceuticals, Inc. | > Sepracor Inc. |
| Eisai Inc. | > Shire Pharmaceuticals, Inc. |
| EMD Serono | Sigma-Tau Pharmaceuticals, Inc. |
| Endo Pharmaceuticals Inc. | > Solstice Neurosciences, Inc. |
| > Forest Laboratories, Inc. | > Solvay Pharmaceuticals, Inc. |
| Genzyme Corporation | Takeda Pharmaceuticals North America, Inc. |
| GlaxoSmithKline | Wyeth |
| Hoffman-La Roche Inc. | |

> = Companies that are not Members of PhRMA and comply with the PhRMA Code.

PhRMA Member Companies adhere to "Code on Interactions with Healthcare Professionals" (The following are just some highlights of acts prohibited and allowed)

- The new PhRMA Code of Conduct took effect on January 1, 2009. As part of PhRMA's ongoing effort to ensure marketing practices comply with the highest ethical standards, PhRMA revised and strengthened its Code.
- The Code does not allow companies to give health care professionals items such as coffee mugs, pens, notepads, etc.
- The Code does not allow sales representatives to host restaurant meals. It does allow modest meals in a physician's office or hospital when accompanied by an informational presentation.
- Recreational or entertainment events such as tickets to baseball games, football games, basketball games, airline tickets, and free vacations are prohibited. Also prohibited are golf outings locally or nationally.
- The Code does not allow meeting venues at resorts.
- The Code does allow educational items with a value of less than \$100 such as an anatomical model, research textbook, and pamphlets.
- The Code allows representatives to provide a modest meal in a physician's office or hospital when accompanied by an educational briefing.
- The Code allows payment for speaking and consulting arrangements based on fair market value, with increased disclosure of relationships.
- The Code requires training and monitoring of sales representatives to maintain the highest ethical standards.
- Requires Company CEOs and Compliance Officers to certify annually that they have policies and procedures in place to foster compliance with the Code.