

Statement



In Opposition to Senate Number 270

February 26, 2010

Position: PhRMA respectfully opposes S 270 because it would onerously regulate relationships between biopharmaceutical companies and healthcare providers. S 270's requirements are not the same as the PhRMA Code on Interactions with Healthcare Providers. Implementing such a proposal could have a chilling effect on these relationships which further biopharmaceutical research and improve patients' lives.

S 270 goes beyond codifying the PhRMA Code on Interactions with Healthcare Providers ("the Code"). Often proponents of marketing restriction legislation, such as S 270, claim that such restrictions reduce healthcare costs. However, restricting certain biopharmaceutical industry interactions with healthcare providers does not reduce health care costs. In fact, restricting these interactions and requiring disclosure of certain payments to healthcare providers could chill research and development as well as patient access to clinical trials.

For example, in 2008, the WV Legislative Auditor determined that programs implemented to reduce spending on prescription drugs, including marketing disclosure, cost an estimated \$1.1 million dollars over 3 years. The state's estimated savings across healthcare programs during that time totaled \$299,449. Essentially, the state had a negative return on investment of \$800,000.

S 270 Could Jeopardize Jobs in Connecticut

The biopharmaceutical industry has a significant impact on the Connecticut economy. In 2006, biopharmaceutical companies supported a total of 53,584 jobs in Connecticut - 10,653 directly in the sector and 42,932 in other sectors. Direct biopharmaceutical wages in Connecticut were estimated to be \$1.2 billion in 2006, resulting in an estimated \$314.7 million in federal taxes and \$54.2 million in state taxes paid by employees. S 270 sends the message to the biopharmaceutical sector that it is unwanted in Connecticut.

The Pharmaceutical Industry Is Already Heavily Regulated

Legislation establishing a "Code of Conduct" between PhRMA members and health care providers is a "solution in search of a problem". Not only has the industry adopted an aggressive code of conduct, but the industry and their relationships with healthcare providers are already heavily regulated by a number of governmental entities. Specifically, the U.S. Department of Justice; U.S. Department of Health and Human Services; the Food and Drug Administration, including the Division of Drug Marketing, Advertising and Communications (DDMAC) already regulate the industry; and the Office of Inspector General has issued guidelines for companies to follow to comply with anti-kickback regulations.

DDMAC reviews promotional materials to ensure that they are truthful, scientifically accurate and consistent with the product's FDA-approved labeling. DDMAC reviewers engage in a wide range of tasks, including providing written comments to pharmaceutical companies on proposed promotional materials 'to ensure clear and unambiguous communication of the law and regulations' on drug promotion; reviewing complaints of alleged violations; initiating enforcement actions; and comparing product labeling and promotional material to ensure that regulatory requirements are consistently and equitably applied.

The PhRMA Code Is Not Conducive to Statutory Codification

The PhRMA Code is a compliance guidance tool that companies use when structuring their compliance programs—it is not meant to be an enforcement tool. As such, the language is not conducive to statutory codification. For example, PhRMA companies have the flexibility to update the Code as business practices change, which does not exist with statutory language. For example, as the practice of healthcare changes, the

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PhRMA Code can be updated to address new concerns. Specifically, the 2008 revision of the PhRMA Code, which took effect January 1, 2009, was updated to address companies' support for Continuing Medical Education (CME) because of changes in the requirements imposed by the national accrediting group, the American Academy for Continuing Medical Education (AACME). Such changes are much more difficult to implement when they require that a state legislature modify statutory language. Incorporating some elements of the Code in Connecticut law prevents pharmaceutical companies from complying with any future modifications of the PhRMA Code, and could create conflicts with future guidance from the Office of the Inspector General of the Department of Health and Human Services.

S 270 Goes Well Beyond the PhRMA Code in Numerous Instances

- **Meals.** The PhRMA Code only addresses meals offered by field sales representatives or their immediate managers and specifies that these should be modest, occasional and limited to in-office or in-hospital settings. This bill would only allow modest meals in the provider's office and would not allow for the flexibility of providing meals in non-marketing settings (e.g., no training sessions, no dinner presentations, no research meetings or job interviews over a meal).
- **Disclosure requirements.** The PhRMA code does not require disclosure. S 270 requires reporting of the value, nature, purpose, and recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50 provided to any covered recipient by a pharmaceutical company in connection with sales and marketing activities.
- **Penalties.** The PhRMA Code does not impose a penalty—pharmaceutical marketing activities are already closely regulated by the federal government.

Potential Impact of Disclosure on Clinical Trials and Research in Connecticut

S 270's disclosure and publication requirements could make Connecticut a less than desirable place to host clinical trials and conduct other consultant-driven research. Affiliated practitioners may not be comfortable having their names and compensation published on the state's web site for other interactions with pharmaceutical companies. This could decrease the number of clinical trials available to patients in Connecticut.

Although the bill exempts payments for clinical trials reported to clinical trials.gov, this does not exempt pre-clinical and Phase I research, which are not reported to the NIH website. Therefore, providers' cooperative research with companies, even for clinical trials, could be chilled because providers may not want to be subjected to the scrutiny that accompanies the disclosure of information, especially when reasonable consulting payments are labeled a "gift".

In addition, the bill could prevent companies from providing research grants to physicians. Conducting an investigator-sponsored clinical trial would arguably not constitute "consideration" for a research grant, and thus the grant would be unlawful. This could prevent physicians in Connecticut from conducting small initial studies that improve medical practice for patients.

According to the National Institutes of Health, there are more than 3,000 clinical trials under way in Connecticut or under the guidance of Connecticut researchers. Although the bill exempts clinical trials payments it does not exempt other legitimate payments that a pharmaceutical company may pay to a provider, such as a payment for serving on a committee to design pre-clinical research or a Phase I study. Given the strong and growing presence of the biopharmaceutical industry in Connecticut, why jeopardize the industry's contribution to our economy.

For these reasons, PhRMA respectfully asks legislators to oppose S 270.