

Statement

PhRMA

In Opposition to Connecticut Senate Bill 1046
March 2, 2009

Position: PhRMA respectfully opposes Senate Bill 1046 which would place restrictions on the commercial use of physician prescribing data.

Placing restrictions on the use of prescribing data could result in significant unintended consequences that could adversely impact patient care and safety and hamper manufacturers' ability to alert physicians to important new drug information. This data is critical to the efficient, timely, and targeted dissemination of information to doctors and patients. The data used by manufacturers does not contain patient identifiable information and allows prescription drug manufacturers to carry out federally required drug programs that help safeguard patients, help companies address other patient safety concerns, and can help reduce the cost of prescription drug marketing.

Banning the Commercial Use of Patient Identifiable Information is Unnecessary as it is Protected Under Federal Law

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) bars any unauthorized use of patient identifiable information. Therefore, under federal law, prescriber data cannot include individual patient identifiable information.

Critical Value of Prescriber Data Reinforced by US Congress

The federal regulatory system increasingly depends on pharmaceutical companies to communicate directly with health care providers about how to use medicines safely and effectively. This communication allows drugs with significant benefits, but serious safety risks, to be made available to patients. Without prescriber data, such communication will be less efficient.

The critical nature of prescriber data was recently recognized by Congress in the Food and Drug Administration Amendments Act of 2007 (FDAAA). The FDAAA authorizes the FDA to require Risk Evaluation and Mitigation Strategies (REMS) for certain high risk medicines. These structured, required programs are intended to increase safeguards for patients when FDA believes that extra vigilance is needed.

A REMS can require manufacturers to: ensure that prescribers have specific training, experience or certification; disseminate information about the REMS to health care providers; ensure that a drug is dispensed to patients only "with evidence or other documentation of safe-use conditions, such as laboratory test results" or if "each patient using the drug [is] subject to certain monitoring;" and monitor, evaluate, and improve the implementation of REMS.

Complete access to prescriber data is necessary to train providers and monitor REMS. This is because, most importantly, one cannot predict in advance which drugs will be the subject of a REMS (a safety issue can be identified after FDA approval). Drug manufacturers will need access to prescriber data for compliance so it is important that access to prescriber data is not limited to only when required by federal law.

The importance of REMS is further emphasized by the penalties for non-compliance. Manufacturers will be subject to \$250,000 per violation; \$1 million for all violations adjudicated in a single proceeding; and \$10 million for all violations adjudicated in a single proceeding if the violations continue after written notice from FDA for failing to comply with REMS requirements.

Pharmaceutical Research and Manufacturers of America

PhRMA's Code on Interactions with Healthcare Professionals ("Code") Make the Restrictions in SB 1046 Unnecessary and Duplicative

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. The revised Code provides detailed guidelines for the proper and ethical use of prescriber data that safeguards confidentiality, identifies appropriate disciplinary actions for misuse of the data, and respects physicians' privacy wishes.

Other Patient Safety Concerns

Because pharmaceutical companies generally sell their medicines to wholesalers (who in turn sell to pharmacies), without prescriber data manufacturers do not have direct knowledge of which health care professionals prescribe their medicines. For example, with limited access to prescriber data, it becomes extremely difficult for pharmaceutical companies to conduct targeted and effective drug recalls; identify and report to FDA any adverse events associated with a medicine; and efficiently distribute new drug labeling information such as drug-drug interactions and black box warnings.

Additionally, prescriber data contributes significantly to the acceleration of clinical trials by identifying physicians most likely to have pools of patients eligible for enrollment. Analysis of prescriber data also helps efforts to identify: physicians from whom to solicit information on unmet medical needs (for use in the development of new medicines or new formulations of existing medicines); specific patient populations for targeted sales and marketing of pharmaceuticals; prescribers who are not treating patients optimally (e.g. under-prescribing for high cholesterol); and physicians whose patients could use samples.

Access to Prescriber Data Allows Manufacturers to Focus Outreach Efforts on Providers and Patients

Continued access to prescriber data can help pharmaceutical manufacturers reduce the cost of marketing by preventing expensive, blanket marketing of prescription medicines. Banning the commercial use of this data may hinder the ability of prescription drug manufacturers to effectively target the dissemination of necessary clinical information and drug samples to those physicians most likely to need education on certain prescription and require specific drug samples for their patient populations.

The AMA Prescribing Data Restriction Program ("PDRP") Allows Physicians to Restrict the Use of Their Prescribing Data

The AMA's PDRP provides physicians with an opt-out mechanism to prohibit the release of their prescribing data to pharmaceutical sales representatives. Physicians can also register complaints against companies or individuals who have used prescriber data inappropriately through the PDRP. Physicians may easily opt-out by logging on to www.ama-assn.org/go/prescribingdata or by requesting the restriction via phone, fax, email, or standard mail. Pharmaceutical companies must ensure compliance with the PDRP by processing restriction requests within 90 days.

Prescriber data does not contain patient identifiable information, allows prescription drug manufacturers to carry out federally required drug programs that help safeguard patients, helps manufacturers address other patient safety concerns, and can help reduce the cost of prescription drug marketing.

For these reasons, PhRMA urges state legislators to oppose SB 1046.