Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

JOINT COMMITTEE ON HEALTH CARE FINANCING

March 26, 2009

House Bill 109 – An Act Prohibiting the Use of Health Data for Marketing Purposes
Senate Bill 17 – An Act Relative to Data Mining
Senate Bill 19 – An Act Protecting the Confidentiality of Patient Prescription Records

BIO opposes House Bill 109 and Senate Bills 17 and 19 relating to restrictions on disclosure of prescriber-identifiable prescription data. If passed, these bills would have the unintended consequences of negatively impacting patient safety, access to new innovative therapies, and efforts to research and develop biologic medicines.

BIO is a national trade organization, based in Washington, D.C., representing more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. In Massachusetts we work closely with the Massachusetts Biotechnology Council (MBC), an organization that represents more than 550 biotechnology companies, universities, academic institutions and others dedicated to advancing cutting edge research.

Patient care and safety will be at risk. The Food and Drug Administration (FDA) has promulgated regulations that either require or encourage pharmaceutical manufacturers to make direct contact with prescribing physicians under specific circumstances. If manufacturers are no longer able to access prescriber-identifiable prescribing information, patient care and safety will be at risk.

Under federal rules a manufacturer is responsible for notifying its affected direct accounts about a product recall. FDA guidance encourages manufacturers to provide this information in a timely manner to doctors. Prescriber-identifiable data facilitates this timely notification, minimizing patient risk and adverse events. Additionally, the FDA encourages the use of healthcare practitioner letters or training programs as a way to minimize risk. Without the ability to locate and directly contact physicians who prescribe their products, manufacturers will not be able to take advantage of this critical educational tool. Lastly, manufacturers need to contact prescribing physicians regarding important changes in drug packaging labels. Direct communication with a prescribing physician is necessary for manufacturers to notify physicians regarding significant health hazards.

These restrictions will negatively impact access to new innovative therapies. Although this legislation is aimed at consumer protection and provider privacy interests, enactment of these bills will have the unintended consequences of negatively impacting access to new innovative therapies and efforts to research and develop biologic medicines.

Small biotechnology companies generally do not have the same resources as large pharmaceutical companies to target physicians. Biotech companies rely on prescriber-identifiable data to locate physicians who treat a particular patient population or disease state that could benefit from access to their new treatments. Small biotech companies use prescriber-identifiable data to target their education and outreach activities to physicians who prescribe their products and to physicians whose practices are concentrated in specific analogous specialties (such as oncology or neurology). Such targeted education and outreach activity permits small biotech companies to expand access to and use of specialized medications developed for the treatment of chronic and intractable diseases.

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Since biologic therapies are often administered in the physician's office, it is imperative that biotech companies have a means for contacting physicians in order to provide them with information that furthers clinical knowledge and enhances clinical decision-making. There is no benefit to healthcare providers, and, most importantly patients, in cutting off the free flow of scientific information regarding drug products that can only occur in interactions between biotechnology company representatives and healthcare providers. Enactment of these policies could be detrimental to the well being of patients, as well as to the ability of healthcare professionals to obtain the most current information about important new medicines.

Research and development of biologic medicines is dependent on access to health information. Access to health information, including prescriber-identified data, facilitates high quality research on appropriate treatments using biotechnology therapies. For small biotech companies, access to this information enhances efforts to research and develop new drugs and biologics. Drug development for biologic products is highly specialized. Unlike pill products, biotech products require specialized manufacturing facilities that are often times individually constructed for an individual product. Companies rely on pharmaceutical market studies, often including prescriber-identifiable data, to develop manufacturing capabilities that will meet consumer demand.

Additionally, biotech companies use prescriber-identifiable data to facilitate enrollment in clinical trials. By targeting physicians who have patients in the targeted area of drug development, manufacturers can identify potential research sites and eligible patient populations for participation in trials.

Patient privacy rights are not at issue in this debate. The confidentiality of patient-identifiable prescription data is protected under federal law pursuant to the Health Insurance Portability and Accountability Act of 1996[1] (HIPAA). *Nothing in these state legislative vehicles enhances or further protects patient privacy.*

BIO supports the American Medical Association (AMA) opt-out program. The AMA has instituted a Physician Data Restriction Program (PDRP) to prevent access to physician prescribing information for those physicians who do not want their information shared. Nationwide implementation of the PDRP negates the need for a state-by-state patchwork of legislation to protect the privacy interests of physicians.

These bills will only serve to impede the state's efforts to grow its life sciences industries. This legislation is reactionary and would only serve to harm the state's reputation as a center of excellence for technology development – a reputation that has attracted, grown, and retained so many outstanding research organizations. BIO applauds the commitment the Commonwealth has shown to new technologies and research. House Bill 109 and Senate Bills 17 and 19 could significantly undermine the state's leadership position in the life sciences.

We appreciate the Committee's consideration of our concerns and encourage members to oppose House Bill 109 and Senate Bills 17 and 19.

Respectfully Submitted,

India P.V

India Valentine
Director, State Government Relations

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[1] Public Law 104-191. 45 CFR Parts 160 and 164.