Montana House Human Services Committee

February 9, 2009

Statement of Opposition to House Bill HB394

Chair Becker and members of the House Human Services Committee, BIO would like to submit our statement, on behalf of our member companies, in opposition to HB394. BIO opposes the proposal relating to restrictions on disclosure of prescriber-identifiable prescription data. If passed, this bill would have the unintended consequences of negatively impacting patient safety, access to new innovative therapies, and efforts to research and develop biologic medicines in the State of Montana.

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.

These restrictions will negatively impact access to new innovative therapies. Small biotechnology companies, that represent the majority of our membership, generally do not have the same resources as large pharmaceutical companies to target physicians. Biotech companies rely on prescriber-identifiable data to locate particular patients in a special 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. HB394 would jeopardize such access by patients to new therapies in Montana.

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 biologicals. 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 patients in the area of drug development, manufacturers can identify potential research sites and eligible patient populations for participation in trials. While the bill claims it does not intend to impact research, the bill as a whole raises many questions that serve to confuse and may have a chilling effect on how research and ultimate therapies from that research may be impacted in the state. We do not think that it is the intent of the bill's proponents to disqualify patients in Montana from participating in critically needed research. Yet at the same time if enough confusion from this bill remains it would be unfortunate if small biomedical companies choose other states to conduct their clinical trials.

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.

Patient care and safety will be at risk. The Food and Drug Administration (FDA) has promulgated regulations that either require or encourage biomedical 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 patients who are prescribed with their products, manufacturers will not be able to take advantage of this critical educational tool.

House Bill HB 394 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 work towards technology development – a reputation that has attracted, grown, and retained some outstanding research entities. BIO applauds the commitment that Montana has shown to new technologies and research. House Bill HB394 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 HB394.