

September 16, 2009

The Honorable Arnold Schwarzenegger
Governor
State of California
State Capitol
Sacramento, CA 95814

Re: Request for Veto on Senate Bill 486

Dear Governor Schwarzenegger:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to respectfully request that you veto Senate Bill 486. The bill would require pharmaceutical and biologic manufacturers to submit a plan to the California Integrated Waste Management Board (CIWMB), or its successor agency, describing how they support the safe collection and proper disposal of home-generated sharps waste devices. Additionally, the bill contains ambiguous language that makes it unclear whether manufacturers of medications that are self-injected at home will ultimately bear the responsibility for funding the disposal of these waste devices.

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.

BIO appreciates and supports the Legislature's intent to reduce the risk to public health through the safe and proper disposal of home-generated sharps waste. We stand ready to work with California to create a workable solution that incorporates all stakeholders and members of the pharmaceutical supply-chain. The vast majority of pharmaceutical and biotechnology manufacturers do not produce the sharps used to administer their products. To this end, companies have varying levels of education and support programs in place to facilitate the proper collection and disposal of these devices. Senate Bill 486 singles out pharmaceutical and biotechnology manufacturers to bear the burden of addressing a problem that properly should not be imposed on one industry. As you indicated last year in your veto message for Assembly Bill 501, the problem of sharps waste disposal requires a solution that must be shared among all stakeholders.

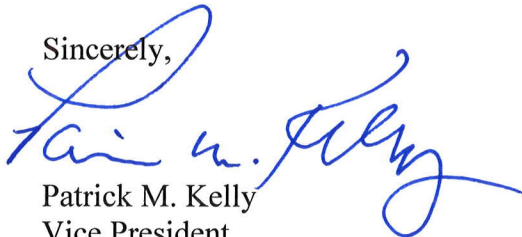
We are also particularly concerned that there is ambiguous language in the bill regarding a manufacturer's role in funding the disposal of home-generated sharps waste. Specifically, in Section 47115.5 the required plan from manufacturers must include a description of how the manufacturer, "provides for the safe collection and proper disposal of the waste devices." Although the bill does not explicitly require companies to provide for the collection and disposal of the waste devices, the mandated plan description coupled with author's indication that this bill is a first step toward developing Extended Producer Responsibility (EPR) Product Stewardship suggests that pharmaceutical manufacturers will ultimately bear the burden of financing collection and disposal.

We support alternatives already in existence to address this problem. For example, several California counties and municipalities have developed successful programs for the safe management of home-generated sharps waste. We believe that the expansion of these programs to include additional supervised collection sites, including physician's offices, pharmacies, hospitals and medical waste facilities could be one of the safest and easiest methods of disposal provided to patients. BIO supports all efforts to educate patients regarding the safe collection and disposal of sharps waste, and we encourage the implementation of programs that provide patients with the most appropriate resources to successfully achieve this goal.

The workable solution to this problem will equally focus on the pharmaceutical industry, device manufacturers, end-users of these devices, waste handlers and others who share responsibility for the proper disposal of home-generated sharps waste. Senate Bill 486 remains silent on interests beyond the pharmaceutical and biotechnology industries.

For the reasons stated above, BIO respectfully requests that you veto Senate Bill 486. Thank you for your consideration of these comments. We welcome the opportunity to further discuss these issues. Please feel free to have your staff contact me at (202) 962-9200 or pkelly@bio.org if you should have any questions or concerns regarding this matter.

Sincerely,



Patrick M. Kelly
Vice President
State Government Relations