April 10, 2013

TO: Members, Assembly Environmental Safety and Toxics Committee

SUBJECT: AB 403 (Stone): Solid waste: home-generated sharps.
Oppose– As Amended April 8, 2013
Set For Hearing – April 16, 2013

On behalf of the identified organizations we respectfully inform you of our opposition to AB 403 regarding "home generated sharps."

The development, distribution and use of sharps and related medical devices, which provide life-saving medications to patients, is a complex process. This process involves many stakeholders, including medical device manufacturers, wholesalers, distributors, hospitals, medical providers, local governments, public health officials, waste haulers, health care organizations, long-term care facilities, patients, and other beneficiaries. Placing the responsibility for end-of life disposal of sharps solely on any manufacturer as defined in the amended bill places an unfair burden on a single stakeholder and will hamper an important and fast-growing California based industry. Further, a study from the April 3, 2013 Journal of Public Health Advance Access calls into question the need for disposal programs like the one in this bill. During the past twenty years, the number of Americans who self-inject medications has dramatically increased. Despite this, the number of needle-stick injuries, and associated medical costs, remain extremely low. [1]

AB 403 Creates Tremendous Cost Pressures in Healthcare

AB 403 establishes a large, statewide bureaucracy that is fully funded by medical device manufacturers. The program is rigid, specific, and punitive. The bill holds medical device manufacturers responsible for all the Department of Resources Recycling and Recovery's (Department) administrative, operational, and capital costs associated with oversight of this untested program. Per the bill, medical device manufacturers must fully reimburse the Department for all of its expenses to administer and enforce the program. This alone amounts to a sizable tax on device manufacturers. But, to comply with the specific mandates in AB 403, the medical device industry will also have additional costs. These additional cost burdens, as specified by the bill include:

- Developing and administering marketing and educational outreach materials for distribution throughout the supply chain
- Establishment of collection sites throughout the state, located at a minimum of one collection site per every 5,000 people
- Hiring independent auditors to detail and review the stewardship plans' financing methods
- Responsibility for all costs associated with the transport and disposal of collected products
- Administrative penalties of $1,000 per day if the Department finds a company is in violation of the program
- $10k per day penalty if the Department finds the company is in negligent violation

The exorbitant costs imposed on sharps manufacturers will negatively impact the health care delivery system and are not commensurate with the value to patients, particularly when take back programs exist. Also, though the bill suggests otherwise, the financial impact to health systems especially Medi-Cal and patients will prove substantial via increased costs for these vital tools necessary for patient self-care.

AB 403 Allows For Medical Devices to Be Banned

Authority to approve or deny the sale of medical devices is granted today solely to the federal Food and Drug Administration (FDA) based on a device's safety and efficacy to patients. Obtaining FDA marketing clearance can take years, after the many more years already spent in research and development. This bill, however, changes this dynamic, thereby threatening the safety of patients. Under AB 403, the state Department of Resources, Recycling, and Recovery—a non-medical entity—will have new and FDA-like authority to allow or disallow the sale of medical devices containing sharps.

Section 47117 states: "(a) A producer or retailer shall not sell or offer for sale in this state home-generated sharps to a person in this state unless the producer of those home-generated sharps is in compliance with this article."

The willingness of state waste officials to grant the authority for a medical device containing a sharp to be sold or not based on arbitrary and subjective decisions is a dangerous precedent to patient safety. Granting this authority will prevent patients from obtaining vital and necessary medical devices with sharps to manage chronic disease for reasons not related to safety and efficacy of a product. AB 403 could create serious and long-term obstacles to vital medical care and impede patient compliance with their treatments ordered by physicians and medical professionals.

AB 403 Mandated Collection Rates Not Practical

The mandated collection rates established in the bill are wholly impractical, unworkable and fail to recognize existing statute. An example, federal and state health privacy laws protect the identity of patients using medical devices containing sharps. Therefore, manufacturers cannot contact patients to request the return of used sharps. Further, once a product is distributed to a wholesaler or other intermediary, ownership and control of the sharp by a manufacturer is lost. This means a manufacturer cannot force or compel the patient to dispose of the sharp according to the company's wishes. Given this reality it is not practical to penalize, fine and threaten the banning of a product if a patient does not return the sharp. Because the mandated collection rates and severe penalties are impractical and do not recognize the manufacturer does not have control over the patient's actions, we believe AB 403 is infeasible.

CONCLUSION – OPPOSE AB 403

We believe product stewardship programs must include a broad base of stakeholders as opposed to the punitive approach focused on manufacturers established by AB 403. Any equitable, fair and effective program by comparison must involve shared responsibility among all affected parties ranging from end users to waste haulers, health care facilities, all taxpayers and other beneficiaries of these products.

For these reasons, we strongly oppose AB 403