



ASSEMBLY CONCURRENCE ALERT

AB 501 (SWANSON) PREFILLED SYRINGES FILE ITEM # 36

MYTH #1 – AB 501 adequately addresses the serious problem of medical waste disposal

FACT – AB 501 does not address the full spectrum of issues needed to comprehensively deal with medical sharps disposal. The legislation only covers pre-filled syringes, pre-filled pens, or other pre-filled injection devices. **Some of the devices covered under this bill are not even sold with needles.** However the bill doesn't cover other medical sharps including non pre-filled devices, lancets, and insulin infusion catheters. These other areas include non-prescription use of syringes, such as injectable vitamin supplements. As all medical sharps have the same risk profile, they should be equally included in any legislation. Also, the bill only addresses how to get the sharps out of the hands of the consumer, but not how to handle the waste once it is collected. The appropriate disposal site infrastructure for the hauling and disposal of medical waste, as well as an analysis of how this will be paid for, should be considered as part of an overall comprehensive solution.

FACT – To address the issue of shared-responsibility, the Product Stewardship Institute (PSI), a non-profit organization that helps resolve environmental issues through a shared responsibility approach has brought a large spectrum of stakeholders together to develop a comprehensive approach to the problem of sharps waste disposal. Stakeholders such as state governments from California, Massachusetts, New Hampshire and Iowa, along with product manufacturers, pharmaceutical manufacturers, waste industry leaders (both medical and municipal solid waste) are joining together to determine the most effective way to contain and dispose of sharps waste. The efforts and dialogue lead by PSI will certainly aid California and other states in implementing safe needle disposal and the cost associated with these programs.

MYTH #2 – Creating an additional state requirement will convince non-compliant consumers to safely dispose of these products.

FACT – Beginning September 1, 2008, state law will require consumers to properly dispose of needles, including the products addressed by this legislation. That law places

the burden on the consumer to comply with the law and ensure the safety of their families, neighbors and communities. Hazardous waste sites are currently listed on the California Department of Public Health website. Most, if not all consumers of prescribed products receive information in the product labeling or from their physicians that describes proper disposal. It is counterintuitive to believe that individuals who choose not to comply with that law will alter their behavior because another law is on the books.

MYTH #3 – Companies can easily put in an insert to comply with the requirement to inform consumers about the California law.

FACT – Medical product labeling is heavily regulated by the U.S. Food and Drug Administration (FDA) and is used to convey important product usage directions. This information is submitted at the time of FDA approval and changes to this will require approval by the FDA. The addition of such information on or in the product could be confusing to product users and exceptionally difficult and costly for manufacturers to devise and control. Manufacturers in today's healthcare system are producing products that will be shipped around the world. It is not realistic to think that manufacturers can segment their production and labeling lines to accommodate numerous individual state mandates with out a significant increase in cost that will be passed on to patients.

MYTH #4 – The bill only applies to home-use pre-filled devices.

FACT – While this may have been the intent of the author, the legislation does not recognize the difference between products intended to be injected at home and products intended to be injected in a medical setting. Because this distinction is not clear, many products would be susceptible to the requirements of the bill even though they are not intended to be used at home.

MYTH #5 – Pre-filled syringes are more dangerous to the public than other types of medical sharps.

FACT – While certain medical therapies to treat contagious diseases such as HIV or Hepatitis come in pre-filled devices, the idea that pre-filled devices are more dangerous to the public is false. The most common products, contained in roughly 40% of pre-filled devices, are antithrombotics - Drugs intended to treat thrombosis in the blood-vessels (arteries and veins), mainly classified under 3 types of treatment: platelet aggregation inhibiting drugs, anticoagulants and fibrinolytics (or thrombolytics). Other common uses include vaccines and home-use products for the long-term treatment of chronic diseases such as rheumatoid arthritis, diabetes, psoriasis, multiple sclerosis, Crohn's disease. If public safety is the major concern then all sharps products, which may be used by a person infected with a contagious disease, should be addressed under a comprehensive solution. In addition, this bill does not address unregulated, non-prescription use of needles such as vitamin products that are injected.