

## Amendment Connecticut General Assembly Bill 5653

Submitted by the Pharmaceutical Research and Manufacturers of America

(PhRMA)

### An Act Concerning Chemicals of High Concern for Children

Add to definition of "Priority Chemical" in Section 1(2)

(2) "Priority chemical" means a chemical identified by the Commissioner of Public Health that is known, on the basis of credible scientific evidence, to: (A) Harm the normal development of a fetus or child or cause other developmental toxicity; (B) cause cancer, genetic damage or reproductive harm; (C) disrupt the endocrine system; (D) damage the nervous system, immune system or organs or cause other systemic toxicity; (E) be persistent, bioaccumulative and toxic; or (F) be very persistent and very bioaccumulative. **This will not apply to substances present in, or used in the production or packaging of, any drug, intended for use in humans or animals, as such term is defined in 21 USC 321, that is manufactured or distributed consistent with the requirements of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.**

#### Rationale:

All materials used as ingredients in or in the production of medicines, or the packaging of medicines, whether intended for use by humans or animals are severely scrutinized by the United States Food and Drug Administration, which reviews both their safety and their effectiveness. The FDA is responsible for assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, foods, cosmetics, and radiation-emitting products. All prescription drug products, including the packaging, for children have been reviewed by the FDA. Because the FDA governs prescription medicines and packaging and requires pharmaceutical companies to provide much information about the safety and effectiveness of both a drug and its packaging (e.g., feasibility studies are required for packaging), additional recommendations for prescription medication are unnecessary.