Testimony of

Mr. Ron Phillips, on behalf of the Animal Health Institute

On HB 36, Environment – Packaging, Containers and Paper Products – Producer Responsibility

Committee on Environment and Transportation and
Committee on Economic Matters

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Mr. Chairman and members of the Committee, my name is Ron Phillips and I am here today on behalf of the Animal Health Institute. AHI is the U.S. trade association for research-based manufacturers of animal health products – the medicines that keep pets and livestock healthy. Our members are sponsors for a majority of the pioneer animals drugs approved by FDA and used by veterinarians and producers in Maryland. As such, we have a tremendous interest in the proposed legislation.

The animal health industry is committed to improved sustainability in all facets of the supply chain, including the packaging used to deliver safe products to customers. Many companies have already made changes to reduce unnecessary packing waste, including replacing styrofoam packing needed to keep vaccines cold with reusable coolers.

Sustainability is one factor among many that animal health companies must consider in the packaging equation. Medical products for animals are required to be sterile or enclosed in packaging with tamper-resistant seals to protect public health. Other factors that must be considered include:

- protection against all adverse external influences that can alter the properties of the product, e.g., moisture, light, oxygen, and temperature variations;
- protection against biological contamination;
- protection against physical damage;
- ability to carry the correct information and identification of the product;
- ability to ensure these requirements are met throughout the whole of the intended shelf-life of the product.

Additionally, depending on the requirements from the governing federal agency, products may be labeled with specific instructions on disposal.

The kind of packaging and the materials used must be chosen in such a way that the packaging itself does not chemically interact with the product through leaching or absorption. Conversely, the packaging must not allow the product to have an adverse effect on the packaging, changing its properties or affecting its protective function.

Animal health products are licensed by three different federal agencies, each with their own unique packaging standards and requirements.

1. Drugs approved by the Food and Drug Administration under the Food, Drug and Cosmetic Act. Sponsors must specify for the agency the materials of construction and packaging used for each product and provide data showing those factors will maintain stability of the product over its shelf life. Consequently, each product has its own unique approved packaging. Changes to product packaging take months of development followed by FDA review and approval.

2. Vaccines and biologics are approved by the US Department of Agriculture under the Virus, Serum, Toxins Act. Manufacturers are required to ensure packaging maintains the integrity of the vaccine, so temperature is a major consideration. Packaging must also accommodate detailed USDA labeling requirements.

3. Flea and tick prevention products are approved by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act. FIFRA §25(c)(3) authorizes EPA to establish standards with respect to the package, container, or wrapping in which a pesticide or device is enclosed to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated under FIFRA. Additionally, §25(c)(3) requires EPA's CRP standards to be consistent with those established under the Poison Prevention Packaging Act of 1970.

In order for animal health companies to maintain product safety and stability while increasing the sustainability of packaging, we ask that animal health products not be subject to the requirements of this bill and offer this possible exemption language:

For purposes of this chapter/section, the following products shall not be considered covered products:

(1) Drugs, medical devices, biologics, or diagnostics approved or authorized by the Food and Drug Administration or United States Department of Agriculture for use in animals;
(2) Veterinary pesticide products approved by the Environmental Protection Agency for use in animals.
(3) Medical products for animals required to be sterile or enclosed in packaging with tamper-resistant seals to protect public health.

We appreciate the opportunity to testify today and would be happy to answer any questions.