March 6, 2023

Representative Zack Stephenson, Chair
House Committee on Commerce Finance and Policy
100 Rev. Dr. Martin Luther King Jr. Boulevard
State Office Building, Room 509
St. Paul, MN 55155-1232

Dear Chairman Stephenson:

Thank you for the opportunity to submit testimony in opposition to HF 1000, related to reporting requirements for manufacturers of products containing PFAS, and a ban on sale in 2032, unless amended to exempt animal health products. The Animal Health Institute (AHI) is the national trade association representing the companies that make the animal medicines, vaccines and parasiticides that keep animals and humans healthy.

AHI members develop, manufacture, and distribute a range of animal health products, including pharmaceuticals, biologics (including vaccines), flea and tick preventatives, and medical devices (including diagnostics), to veterinarians, pet owners, and food animal livestock owners. Based on HF 1000's broad definition of "PFAS" as "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom", certain animal health products from each of these categories contain PFAS either as an active ingredient (AI) or an essential, functional component of product packaging.

No current alternatives to PFAS are available for these products, making the use of PFAS unavoidable. For example, some active ingredients approved by the U.S. Food and Drug Administration (FDA) and U.S. Environmental Protection Agency (EPA) are fluorinated molecules that are administered in animals, either orally or topically. Other veterinary products contain fluorinated molecules as essential, functional components of their administering components (e.g., vaccine syringes) that are federally evaluated and approved together with the health product.

Unlike human drugs and medical devices (including diagnostics), which are all regulated by FDA, our members' animal health products are overseen and regulated by three distinct federal agencies:

- Small molecule pharmaceuticals and medical devices (including diagnostics) at FDA under the FFDCA.
- Biologics (including vaccines and certain diagnostic kits) at the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA) under the VSTA; and
- Flea and tick preventatives administered topically (including via collars) at EPA under FIFRA.

While regulatory responsibility is divided among the above agencies, animal health products are all subject to intense federal oversight and regulatory frameworks focusing on product safety.
The broad definition of PFAS used in HF 1000 is based purely on chemical structure and nomenclature, without any consideration of risk data. The PFAS definition in HF 1000 encompasses thousands of

different chemical combinations that, depending on concentrations, end-use, and a variety of other factors, may not be harmful to human health or the environment and may have beneficial uses (e.g., medicinal uses) that greatly outweigh potential harms. Simply being categorized as PFAS does not equate to being harmful. For some diseases or conditions, active molecules that contain a limited number of fluorine atoms deliver superior treatment efficacy or provide the only treatment option.

HF 1000 requires that companies include in their notification to the state the amount of each of the PFAS, identified by its Chemical Abstracts Service Registry number, in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes by the commissioner. Collecting this analytical information from manufacturers and suppliers is both time and labor intensive. The type of analytical testing required to obtain the information is not readily available and would impose significant costs and disruptions to an already-strained product supply chain. This is assuming such analytical information can even be obtained within a reasonable degree of certainty. In fact, EPA is still in the process of developing and validating analytical methods for wastewater, groundwater, certain PFAS in drinking water, and other environmental media.

The only other state with a requirement like the one proposed in HF 1000, Maine, is currently grappling with how to implement its law through regulations. The Maine Department of Environmental Protection has expressed concerns that the law will result in duplicate reporting of PFAS and fail to provide DEP with an accurate assessment of the amount of PFAS entering the state. Other states have recognized the importance of all these products and exempted them from legislation regarding similar reporting requirements for products containing PFAS, including California and Colorado.

The companies that produce these medications are dedicated to keeping them accessible and affordable. For these reasons, we ask that animal health products not be subject to the requirements of this bill and offer this possible exemption language:

“Drugs, biologics, parasiticides, medical devices, or diagnostics used to treat, or administered to, animals under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), by the United States Department of Agriculture under the federal Virus-Serum-Toxin Act (21 U.S.C. Sec. 151 et seq.), or by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).”

We urge you to amend HF 1000 with exemption language for animal health products. Thank you for your consideration.

Sincerely,

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