CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

July 31, 2020

Solid Waste Management Program
Department of Ecology
300 Desmond Drive SE
Lacey, WA 98503

Dear Sir or Madam:

On behalf of the Consumer Healthcare Products Association (CHPA), the national trade association representing the leading manufacturers of over-the-counter (OTC) medications, dietary supplements, and consumer medical devices, I'd like to thank you for the opportunity to comment on the plastic packaging study being conducted pursuant to the Washington Plastic Packaging Evaluation and Assessment law.

The consumer healthcare products industry is strongly committed to advancing more sustainable practices and supports the intended goal of minimizing environmental impacts created by plastic packaging in the state of Washington. However, the issue is challenging and it is important to understand the role of packaging for pharmaceuticals and medical devices and the already existing federal regulations governing the industry's packaging approaches, before attempting to mandate changes to current packaging selection. The packaging of these products is very complex and highly regulated by the FDA to ensure the safety, quality, and stability of the products sold.

In other state policy measures to minimize the environmental impact of plastic packaging, no state has thus far included medical devices or medications - nonprescription or otherwise – in their packaging initiatives. Even states that have contemplated legislation have included some form of exclusion for medications and medical devices from packaging requirements in their bills. They have done so after considering the existing regulatory framework for medication packaging, and the role packaging plays in the distribution and ultimate use of medications and devices by consumers.

Medication Packaging

OTC drugs in the United States, much like prescription drugs and medical devices, must meet the Food and Drug Administration's (FDA) extensive standards for safety and effectiveness before they can be introduced in the marketplace for consumer access. For OTC drugs with ingredients introduced since the late 1980s, these extensive standards are identical for OTC and prescription drugs. But even for older OTC active ingredients, FDA has extensively reviewed their safety and effectiveness and has detailed requirements for labeling and tamper-evident packaging. FDA carefully evaluates the use of all OTC medications as their use does not involve the intervention of a healthcare professional, thus requiring a wider margin of safety than

prescription drugs. OTC product labeling and packaging must include Drug Facts information for consumers to properly use the medication. These rules are in place to ensure consumer protection and to maintain medication integrity.

OTC Medications Are Meant to Be Stored

Unlike many other consumer goods, OTC medications are meant to be contained within the original product packaging until the medication is no longer in use and properly disposed. When consumers purchase OTC medications and dietary supplements, they store them in their medicine cabinets, and use them as necessary. Throughout the product's life cycle, the medication or dietary supplement being used by a consumer remains in the package in which it was originally sold. This is critically important because consumers refer to Drug Facts information, including intended uses, dosing information, and any necessary Warnings related to the active drug ingredient. And this packaging must protect the product's stability throughout its expiration date. In some cases, the available space to provide mandated information is limited, thus limiting existing packaging options could hinder the capacity of manufacturers to convey critical safety information to consumers.

Plastic Packaging Helps Prevent Tampering and Child Access

The Poison Prevention Packaging Act, enacted in 1970, is intended to prevent children from exposure to household products, including many drugs and certain cosmetics. The Consumer Product Safety Commission has the authority to require child-resistant packaging and has done so for many drugs. This packaging overwhelmingly involves plastic packaging. Therefore, it would be technologically unfeasible for manufacturers of these items to alter their packaging due to the standards, including testing, they must meet for child-resistant packaging under federal law.

Similarly, under FDA requirements, all ingested OTC drugs must include tamper-evident packaging to help protect consumers against malicious tampering of products. Tamper-evident packaging most frequently involves plastic packaging features which are removed after the consumer brings the product home. In that instance, where the tamper-evident package element could be removed and discarded, it is an essential and federally required aspect of the package and should be exempt from any state regulatory mandate.

Package Changes Are Multi-Year Endeavors

Changes to packaging materials are not undertaken lightly, as they require testing, validation, and stability studies prior to introduction. All of these are subject to FDA's current Good Management Practice (GMP) regulations, which apply to all medical devices, drugs – prescription and OTC. Ultimately, all packaging must remain "suitable" from the perspective of protecting the product, compatibility, and safety. Frequently, multiple iterations of testing are needed to determine package functionality and acceptability to meet these criteria. Steps involved can include:

- Design development
- Prototype tooling
- Industrial scale-up for packaging and validation
- Stability testing
- Regulatory submissions to FDA or CPSC (e.g., for ingredients approved under a new drug application, abbreviated new drug application, or to address child-resistant packaging requirements).

Apart from this timeline, which can exceed 18 months, some materials may not be suitable replacements, requiring additional rounds of testing and design. Furthermore, packaging changes can be extremely expensive, which negatively impacts the affordability of the products that cost a consumer an average of $7-$8 per unit/box.

Covid-19 Considerations

The current Covid-19 pandemic has illustrated the importance of self-care achieved in part by utilizing OTC medications and dietary supplements. Now more than ever, consumers have been empowered to address their health by relying on OTC treatments and limiting unnecessary visits to primary care centers and hospitals. The enhanced reliance on self-care highlights the critical role that packaging of pharmaceuticals and dietary supplements plays in ensuring consumer safety. Packaging for OTC drugs, dietary supplements, and consumer medical devices communicates vital information about the product educating consumers on dosing, directions for use, and any necessary warnings. Any recommended change to existing medication and dietary supplement packaging rules should consider the current public health environment as well as any potential unintended negative consequences associated with mandated changes before moving forward with a particular mandate.

Current Sustainability Efforts

Many manufacturers are demonstrably committed to environmentally responsible operations and already have recycling and sustainability efforts in place, while remaining compliant with federal law. In 2018, Johnson & Johnson's Consumer Health Division signed on as a charter member of the New Plastics Economy Global Commitment. In doing so, Johnson and Johnson Consumer Health has pledged to use more recycled materials in packaging, reduce reliance on single-use model, and ensure that 100% of plastic packaging be reusable, recyclable or compostable by 2025, excluding pharmaceutical/OTC blister packages. [1]This new commitment is the latest in a legacy of company efforts to reduce their footprint through initiatives like Earthwards® approach to sustainable product innovation, inclusion of

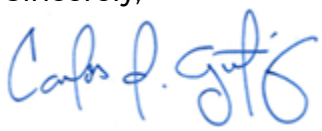
[1] https://www.jnj.com/latest-news/johnson-johnson-consumer-inc-joins-the-new-plastics-economy-global-commitment

How2Recycle® labels on packaging and the Care To Recycle® program, which helps address consumer behavior that has contributed to historically low recycling rates for personal care products. Procter & Gamble (P&G) has a 2020 sustainability goal to reduce packaging by 20% per consumer use. P&G also announced an initiative titled Ambition 2030 which sets a goal for the company to ensure 100% of their packaging will be recyclable or reusable by 2030. Several other large-scale manufacturers have programs in place to accomplish similar sustainability goals.

Packaging for pharmaceuticals, dietary supplements, and medical devices is a very complex and highly regulated space that forces manufacturers to take into account several factors beyond just the aesthetic appeal of the package itself. A federal framework guiding the industry's packaging is already in place, and for decades has served the public interest well. For this reason, we strongly recommend your package recommendations pursuant to the Washington Plastic Packaging Evaluation and Assessment law, exempt pharmaceuticals, medical products and dietary supplements from its scope.

Thank you for taking the time to consider our concerns and feel free to contact me directly with any follow up questions you may have.

Sincerely,



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