PFAS Pharmaceutical Working Group (Ryan Carra)

On behalf of the PFAS Pharmaceutical Working Group, please see attached preliminary comments on the PFAS labeling requirements NMED announced during a webinar on September 25, 2025.

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Submitted via NMED's Public Commenting Portal and Email

James Kenney
Cabinet Secretary
New Mexico Environment Department (NMED)
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Re: PPWG Preliminary Comments on PFAS Labeling Proposal under HB 212

Dear Secretary Kenney:

The PFAS Pharmaceutical Working Group (PPWG) is a group of manufacturers and distributors of drugs, biologics, animal drugs, and medical devices. PPWG appreciates the opportunity to provide these comments on NMED's planned PFAS labeling requirements pursuant to HB 212 as presented during a recent NMED webinar.[1] PPWG's members are committed to environmental stewardship and agree that action on certain materials in products can be appropriate when risk-based, science-driven, not misleading to consumers, protective of critical products, realistic in implementation, and consistent with applicable law. Unfortunately, NMED's planned PFAS labeling requirements are problematic in several respects. PPWG therefore urges NMED to hold off on further action for this rulemaking and instead consider PPWG's concerns before proceeding.

These comments are preliminary, high-level, and offered as a means to frame more detailed discussion PPWG aims to have with NMED through a future meeting and in further advocacy if the rulemaking progresses. PPWG may also flag additional concerns once the proposed rule is made public, including on the non-labeling aspects of HB 212 as implemented in the rule.

I. Drugs, Medical Devices, Veterinary Products, and the Packaging for These Products Should Be Categorically Exempt from Labeling.

NMED's webinar indicates that all products containing intentionally added PFAS would need to be labeled by January 1, 2027. This scope would even encompass products expressly exempt from HB 212's restriction and reporting requirement, including drugs, medical devices, veterinary products, and the packaging for these items. Manufacturers of products subject to these exemptions would be able to *request* a labeling exemption, but only if those manufacturers can demonstrate that consumers will not come into direct contact with the PFAS in the product. This request process is unduly limited and inappropriate as applied to drugs, medical devices,

[1] NMED, Overview of Product Labeling (Sept. 25, 2025).

veterinary products, and the packaging for these items. Instead, these products should be categorically exempt from labeling for several reasons, including:

a. *Statutory Authority*. There is no bar in HB 212 against the Environmental Improvement Board (EIB) enacting a rule that exempts certain product categories from labeling when appropriate. Instead, the opposite is true: EIB must consider the "technical practicality, necessity for and economic reasonableness" of its rulemaking actions. N.M. St. § 74-1-9(B). These considerations necessitate a labeling exemption for this industry's products.

b. *Federal Preemption*. Federal law – including the Federal Food, Drug, and Cosmetic Act – governs the labeling of this industry's products and packaging. Imposing a PFAS labeling requirement on drugs, medical devices, and veterinary products, including their packaging, risks upsetting the federal state-balance and could open up the resulting rule to challenges that are not only costly to New Mexico but would also leave manufacturers in a prolonged compliance gray area.

   Although NMED noted in the webinar slides that labeling does not apply where federally preempted, this general disclaimer conflicts with another slide noting specifically that medical products would be eligible to request a labeling exemption. For drugs, medical devices, veterinary products, and the packaging for these items, preemption is not a question that needs to be handled case-by-case under this general preemption disclaimer. Instead, a categorical exemption for these products is the appropriate approach.

c. *Policy Objectives*. For instance, the U.S. Food and Drug Administration determines in its approval processes that drugs and medical devices have favorable benefit-risk profiles. A PFAS labeling requirement for these products would be inconsistent with this determination and risk confusion that may cause consumers to forego use of critical healthcare products without a scientific basis for doing so.

II. **The Labeling Obligations Require Adjustments To Be Workable and Legally Sound**.

Even with the exemption recommended above, certain guardrails are necessary to help ensure the practicability and legal viability of any labeling program – even one that excludes drugs, medical devices, veterinary products, and their packaging. Key guardrails include:

a. *Later Compliance Deadline*. HB 212 does not require the labeling requirement to come into effect on a certain date. Instead, that date must be far enough into the future to be of technical practicality. The currently envisioned January 1, 2027 compliance date is unrealistic, especially for complex products and given that the rule is not expected to be finalized until July 2026.

b. *Exemptions for Lower-Risk PFAS*. These exemptions, such as for certain fluoropolymers, are crucial to avoid misleading consumers into believing these substances pose the same risks to human health and the environment as other PFAS.

c. *Exemptions for Industrial and Professional Use-Only Products*. The presumed intent behind labeling is to inform consumer purchasing choice, which does not apply for

industrial and professional use-only products. Furthermore, exposure to chemicals in these products is mitigated by workplace controls such as personal protective equipment.

d. *Due Diligence Standard*. HB 212 does not require the labeling obligation to follow a strict liability framework, and for good reason. NMED should incorporate the "known to or reasonably ascertainable by" due diligence standard used by other regulators to ensure compliance expectations are set to a reasonable level.

e. *De Minimis Threshold*. Without a de minimis concentration threshold above which labeling is triggered, the labeling scheme will portray trace-level PFAS the same as high-concentration PFAS. This portrayal goes against the basic tenant of chemical risk management that risk is a function of hazard and exposure.

f. *Constitutional Concerns*. Federal courts have invalidated chemical labeling requirements under the First Amendment's protection against compelled commercial speech. This case law makes clear that such disclosures must generally be limited to "purely factual and uncontroversial" information.[2] The broad PFAS labeling language NMED has planned could invite constitutional challenges that delay rule implementation, force costly labeling revisions, and undermine consumer confidence in the program.

g. *Clear Process for Granting Exemptions*. NMED must establish a clear, transparent process for granting labeling exemptions that includes firm deadlines for NMED decisions on exemption requests and a mechanism for manufacturers to appeal denials.

h. *Requirement to Only Label Packaging*. Where a physical label is to be provided, the label should only be required to be on the product packaging as opposed to on the product itself. Packaging is the primary point of consumer interaction, whereas affixing labels to products can be impractical or even impossible in some scenarios.

III. **Next Steps**.

PPWG's members share NMED's goal of protecting human health and the environment. To realize this goal under HB 212, it is essential that the labeling program be consistent with federal law, be grounded in scientific evidence, foster practical implementation, and avoid consumer confusion. NMED should therefore address the concerns outlined in these comments now rather than advancing the labeling proposal in the current form as described in the webinar. Taking the time to incorporate necessary guardrails at the outset will help ensure a durable regulatory framework. By contrast, moving forward with the rulemaking prematurely could require costly revisions down the road, delay implementation, and jeopardize consumer trust in the labeling program.

PPWG welcomes continued engagement with NMED and looks forward to discussing these topics in more detail in a meeting and throughout the rulemaking process.

[2] *National Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263 (9th Cir. 2023).

Sincerely,

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