

September 17, 2026

New Mexico Environment Department
Santa Fe, New Mexico

IPAC Comments Re: Exemptions Under New Mexico's PFAS Protection Act

These comments are submitted on behalf of the International Pharmaceutical Aerosol Consortium (“IPAC”).¹

IPAC strongly endorses the exemption for medical and drug devices in the PFAS Protection Act and urges NMED to retain these exemptions across all three components of the Act—the prohibition on PFAS, the labeling requirements, and the reporting requirements. The Act recognizes that FDA-regulated medical products serve critical patient health needs and are already subject to rigorous federal oversight. As set forth below, the exemptions protect public health and ensure uninterrupted access to essential medical and drug devices, including metered-dose inhalers, across the state.

The following points emphasize why it is essential for the PFAS Protection Act to retain the medical and drug device exemptions.

- Any PFAS used in metered-dose inhalers are essential for life-saving therapies, with no viable substitutes ready to take their place. The burden of respiratory illnesses, including asthma and COPD, is significant. More than 35 million Americans suffer from a chronic lung disease.² In 2023, COPD was the fifth leading cause of death in the United States with 141,733 deaths in total.³ In the United States, 8.6% of adults have asthma.⁴ Those with respiratory illnesses also face secondary burdens, including diminished participation in daily activities, such as school and work, as well as increased risk of hospitalization.⁵ To the extent that the PFAS Protection Act limits the use of the types of PFAS typically used in medical and drug devices, including by

¹IPAC's mission is to ensure that environmental policies relevant to inhaled therapies are patient-centric and appropriately balance both patient care and sustainability objectives. Further information is available at www.ipacinhale.org.

² ALA, 2026, Trends in Lung Diseases: U.S. Data and Statistics. *The American Lung Association*. <https://www.lung.org/research/trends-in-lung-disease>.

³ Weeks and Elgaddal, 2025, Chronic Obstructive Pulmonary Disease in Adults Age 18 and Older: United States, 2023. *National Center for Health Statistics*. <https://dx.doi.org/10.15620/cdc/174596>.

⁴ CDC, 2026, Asthma: National Prevalence and Mortality Figures. *National Center for Health Statistics*. <https://www.cdc.gov/nchs/fastats/asthma.htm>.

⁵ ALA, 2024, Asthma Trends and Burden. *The American Lung Association*. <https://www.lung.org/research/trends-in-lung-disease/asthma-trends-brief/trends-and-burden>

imposing regulatory burdens on its use through labeling and reporting requirements, there is a risk to public health. Alternatives are not currently available for all uses. Each drug and device has unique requirements, and individual components are not readily interchangeable. We are therefore concerned that elimination of this important exemption will lead to drug shortages of essential medicines.

- State regulation of FDA-approved products would disrupt the balance struck with rigorous FDA review and approval of drugs and devices, including metered dose inhalers, and create significant practical challenges through burden on FDA. FDA-approved metered-dose inhalers undergo a multi-disciplinary review involving chemists, toxicologists, pharmacologists, and medical officers under 21 CFR § 201.56 and § 201.57. The FDA approves both the product and its labeling as an integrated unit, ensuring that all relevant risks are accurately disclosed and managed. Imposing state-level PFAS restrictions on these products may disrupt this existing federal oversight framework.
- Mandating additional state-specific PFAS warnings would impose substantial logistical burdens and risks disrupting patient care. Manufacturers cannot feasibly create New Mexico-specific labeling for products distributed nationally, especially for small devices like metered-dose inhalers. Label changes would require FDA review and approval, adding administrative burden (with potential costs), and complicating supply chains. Further, FDA labeling is carefully hierarchized to prioritize essential safety information. Inserting state-mandated PFAS warnings not based on a clear risk-benefit assessment would dilute critical instructions, increase “warning fatigue,” and could undermine patient confidence and adherence. These unintended consequences should be avoided.
- Requiring reporting for medical and drug devices would impose significant administrative burdens/costs with no corresponding public health benefit. The contents of a drug or medical device are well-known to FDA, and the agency will not approve one of these products if the product does not pass the Agency’s benefit-risk assessment related to human health, including evaluation of toxicity. Requiring reporting on products already subject to comprehensive FDA oversight would impose significant administrative burdens on manufacturers without yielding meaningful environmental or public health data.

Conclusion and Recommendation

IPAC respectfully urges NMED to retain the exemptions for medical devices and drug devices across all three components of the PFAS Protection Act—the prohibition on PFAS, the labeling requirements, and the reporting requirements. Retaining these exemptions is essential to protect patient safety, avoid supply chain disruptions for life-saving medicines, and ensure that regulatory resources are directed where they can have the greatest public health impact. Narrowing or eliminating these exemptions would risk patient health without a corresponding environmental or public health benefit, given the rigorous federal oversight to which these products are already subject. IPAC welcomes the opportunity to serve as a resource to NMED as it evaluates the medical device and drug device exemptions.

Sincerely,



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