

Ryan Carra

Please see enclosed comments of the PFAS Pharmaceutical Working Group.

Ryan Carra
Beveridge & Diamond, PC
1900 N Street NW, Suite 100
Washington, DC 20036
(202)-789-6059
rcarra@bdlaw.com

SUBMITTED VIA NMED'S PUBLIC COMMENTING PORTAL

James Kenney
Cabinet Secretary
New Mexico Environment Department
1190 St. Francis Drive, Suite N4050
Santa Fe, NM 87505
James.kenney@env.nm.gov

Re: PFAS Pharmaceutical Working Group (PPWG) Comments on New Mexico Environment Department Report to the Legislature Pursuant to House Joint Memorial 3

Dear Secretary Kenney:

The PFAS Pharmaceutical Working Group (PPWG) is a group of manufacturers and distributors of drugs, medical devices, biologics, and animal health products. PPWG's members are committed to environmental stewardship and believe that action on certain materials can be appropriate when it is risk-based, science-driven, and consistent with applicable law. PPWG appreciates the opportunity to provide comments in advance of the New Mexico Environment Department's (NMED's) upcoming report to the Legislature, pursuant to House Joint Memorial 3 (HJM3).¹ HJM3 directs NMED to recommend whether the statutory exemptions in the Per- and Poly-Fluoroalkyl Substances (PFAS) Protection Act should be continued, modified, or removed.

The statute contains the following exemption that covers drugs, medical devices, and their packaging:

medical devices or drugs and the packaging of the medical devices or drugs that are regulated by the United States food and drug administration, including prosthetic and orthotic devices.²

The statute also contains the following exemption that covers veterinary products and their packaging:

a veterinary product and its packaging intended for use in or on animals, including diagnostic equipment or test kits and the veterinary product's components and any

¹ H. J. Mem. 3, 57th Leg., 2d Sess. (N.M. 2026).

² N.M. Stat. Ann. § 74-15-3(A)(3).

product that is a veterinary medical device, drug, biologic or parasiticide or that is otherwise used in a veterinary medical setting or in veterinary medical applications that are regulated by or under the jurisdiction of: (a) the United States food and drug administration; (b) the United States department of agriculture pursuant to the federal Virus-Serum-Toxin Act; or (c) the United States environmental protection agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, except that any such products approved by the United States environmental protection agency pursuant to that law for aerial and land application are not exempt from this section.³

For the reasons set forth below, PPWG respectfully requests that NMED recommend that the above statutory exemptions be retained as enacted. In enacting these exemptions, the Legislature made sound public policy choices in line with other states. Deviating from those choices could not only interfere with public health objectives but could also lead to regulatory uncertainty and even legal challenges. Retaining the exemptions will benefit New Mexico, its citizens, and the regulated community.

I. The Existing Exemptions Support Public Health Objectives.

Removing or modifying the exemptions for drugs, medical devices, veterinary products, and their packaging could mislead consumers into believing that the presence of a substance meeting New Mexico’s broad definition of PFAS renders a product unsafe. This misunderstanding may deter patients, healthcare providers, and others from using lifesaving or health-sustaining medical, pharmaceutical, and animal health products, which would ultimately harm public health.

In this heavily regulated field, many products only enter the market if a federal agency has made an affirmative determination that the product is safe and effective for public health. In many cases, a “learned intermediary”—like a doctor—must then decide whether it is in a specific patient’s best interest to use that product. Regulating these products could degrade patients’ trust in the healthcare system and distract from critical information such as dosage instructions, contraindications, and existing safety warnings. This may cause patients to misuse a product or decide not to use it in spite of medical advice. By exempting these products, the Legislature can help ensure the best possible patient safety and therapeutic outcomes.

II. Drugs, Medical Devices, Veterinary Products, and Their Packaging Are Comprehensively Federally Regulated.

As summarized below, drugs, medical devices, and veterinary products—including their packaging—are already subject to comprehensive federal regulatory frameworks to ensure their safety, efficacy, and quality.

³ N.M. Stat. Ann. § 74-15-3(A)(5).

A. Medical Devices, Drugs, and Their Packaging Are Comprehensively Regulated.

The pharmaceutical industry is one of the most highly regulated industries in the U.S. The U.S. Food and Drug Administration (FDA) regulates medical devices and drugs—including their packaging—throughout their lifecycle under the Federal Food, Drug, and Cosmetic Act (FFDCA). For new drugs, the FFDCA requires an application that includes reporting on whether the drug will be safe and effective, a full list of drug components, and a full description the drug’s manufacture, processing, and packaging, among other requirements.⁴ Similarly, manufacturers of certain medical devices are required to apply for premarket approval, which includes “a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device.”⁵

Federal oversight continues after drugs and medical devices enter the market. For example, FDA updated its website on September 1, 2026, to reiterate that it “reviews and monitors the safety and effectiveness of medical devices, including devices that contain materials from the PFAS . . . chemical family.”⁶ FDA concluded that it is “not aware of any evidence that suggests the fluoropolymer PFAS materials in medical devices have harmful public health effects, and the FDA has determined there is no reason to restrict their use in devices.” FDA further asserted that “[f]luoropolymers have unique properties that are essential for [medical] devices to function” and “[c]urrently no other materials exist that can perform the same critical roles in medical devices.”

B. Veterinary Products and Their Packaging Are Comprehensively Regulated.

Animal health products are also stringently regulated. The New Mexico Legislature acknowledged as much by exempting veterinary products that are regulated under the FFDCA, the U.S. Department of Agriculture’s (USDA’s) Virus-Serum-Toxin Act (VSTA), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) at N.M. Stat. Ann. § 74-15-3(A)(5).

The FFDCA regulates new animal drugs, including their approval, composition, labeling, packaging, and manufacturing.⁷ VSTA separately regulates the production, packaging, and labeling of veterinary biologics to ensure purity, safety, potency, and efficacy.⁸ FIFRA governs the registration, labeling, and packaging of veterinary products directed at external animal pests, such as EPA-regulated flea and tick products. These pesticides undergo human health and ecological risk assessments prior to registration to evaluate potential impacts on wildlife and water quality, among other considerations.⁹

⁴ 21 U.S.C. § 355(b).

⁵ 21 U.S.C. § 360e(c).

⁶ U.S. Food & Drug Admin., *PFAS in Medical Devices: What You Need to Know*, (Sept. 1, 2026), <https://www.fda.gov/medical-devices/products-and-medical-procedures/pfas-medical-devices-what-you-need-know>.

⁷ 21 U.S.C. §§ 360b(b)(1), (n)(1)(G).

⁸ 9 C.F.R. pt. 112; 9 C.F.R. §§ 102.3(b), 114.9(c).

⁹ U.S. Env’t Prot. Agency, *Pesticide Registration Process* (last updated Oct. 30, 2025), <https://www.epa.gov/pesticide-registration/about-pesticide-registration>.

III. The Existing Exemptions Avoid Preemption Concerns and Regulatory Uncertainty.

Given the federal frameworks described above, removing or modifying the exemptions for drugs, medical devices, veterinary products, and their packaging would raise serious federal preemption concerns. Under conflict preemption, a state law can be preempted when it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”¹⁰ State labeling requirements of medical and pharmaceutical products (and their packaging) may be expressly preempted¹¹ and state reporting requirements could raise obstacle-preemption concerns by adding an additional state regulatory layer to federal regulatory requirements. Potential express and obstacle preemption concerns are also present for veterinary products.¹²

Removing or modifying the existing exemptions could lead to regulatory uncertainty and potentially to legal challenges. Either would be an unfavorable outcome for both the state and the regulated community.

IV. New Mexico’s Exemptions Are Consistent with Other State PFAS Laws.

New Mexico is one of several states that made the sound policy decision to exempt drugs, medical devices, veterinary products, and their packaging from PFAS laws. For example, Maine’s PFAS law contains a blanket exemption for FDA-regulated products, including drugs and medical devices.¹³ Similarly, Colorado, Connecticut, Minnesota, and New Hampshire PFAS in products laws include exemptions for federally-regulated medical devices, drugs, and their packaging.¹⁴

Other states have similarly exempted veterinary products and their packaging from PFAS laws. For example, Maine expressly exempts veterinary products regulated under the FFDCA, VSTA, and FIFRA.¹⁵ Colorado’s PFAS in products law exempts veterinary pesticides, parasiticides, biologics, diagnostics, and the packaging of these products.¹⁶ These states, like New Mexico, recognized the

¹⁰ *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

¹¹ See 21 U.S.C. § 379r(a) (providing that a state may not establish or continue in effect an OTC drug requirement that is “different from or in addition to, or that is otherwise not identical with” a requirement under the FFDCA); *id.* § 379r(c)(2); 21 U.S.C. § 360k(a) (prohibiting states from imposing certain requirements on medical devices that are “different from, or in addition to” applicable federal requirements).

¹² See, e.g., 7 U.S.C. § 136v(b) (“[a] State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.”); *Symens v. SmithKline Beecham Corp.*, 152 F.3d 1050, 1054 (8th Cir. 1998) (holding that APHIS validly preempted state laws); *Monsanto Co. v. Durnell*, 146 S. Ct. 2001, 2013 (2026) (“FIFRA demands ‘[u]niformity’ and expressly preempts state labeling requirements that are “in addition to” or “different from” federal labeling requirements.”).

¹³ 38 M.R.S. § 1614(4)(B), (E).

¹⁴ Colo. Rev. Stat. § 25-15-603(20)(c); Conn. Gen. Stat. § 22a-903c(j); Minn. Stat. § 116.943, subd. 8(b); N.H. Rev. Stat. § 149-M:64(II)(a)(3).

¹⁵ 38 M.R.S. § 1614(4)(F).

¹⁶ Colo. Rev. Stat. § 25-15-603(20)(c).

need to specifically exempt federally regulated veterinary products from state PFAS in products laws.

V. Conclusion.

For the above reasons, PPWG respectfully requests that NMED recommend in its report that the New Mexico Legislature retain the exemptions at N.M. Stat. Ann. § 74-15-3(A)(3), (5). PPWG appreciates the opportunity to provide these comments and welcomes further discussion as NMED develops its report to the Legislature.

Sincerely,

Ryan Carra
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