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October 22, 2025

Submitted via email to pamela.jones@env.nm.gov

Phoebe Suina
Chair
New Mexico Environmental Improvement Board (EIB)
1190 St. Francis Drive, Suite N4050
Santa Fe, NM 87505

Re: PPWG Response to *Petition for Regulatory Change to Adopt 20.13.2 NMAC and Request for Hearing* (EIB 25-61)

Dear Chair Suina:

The PFAS Pharmaceutical Working Group (PPWG) is a group of manufacturers and distributors of drugs, medical devices, biologics, and animal health products. PPWG appreciates the opportunity to provide these comments in response to the New Mexico Environment Department (NMED) *Petition for Regulatory Change to Adopt 20.13.2 NMAC and Request for Hearing* (EIB 25-61). This petition regards a proposed rule to implement HB 212 regulating intentionally added per- and poly-fluoroalkyl substances (PFAS) in products, including the material restriction, reporting, labeling, and product testing provisions of that law.

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, the product labeling provisions of proposed 20.13.2 NMAC have serious problems. On October 7, 2025, PPWG submitted preliminary comments to NMED focused on the deficient labeling provisions of the proposal, and NMED has met with PPWG to discuss the group's concerns. The comments in this letter to EIB are in addition to PPWG's concurrent advocacy with NMED and are focused on providing a recommendation for EIB action on the petition at the Board's upcoming October 24, 2025 public meeting. Specifically, PPWG requests that EIB deny NMED's petition at this upcoming meeting so that NMED can correct the fatal deficiencies with the proposed labeling provisions before proceeding further.

Granting this petition prematurely would be inefficient and waste resources from all stakeholders involved as the proceeding would inevitably focus on the labeling provisions of the proposed rule that are facially and fundamentally flawed. Fruitful and necessary public consultation on the aspects of the proposed rule other than labeling – including the restriction, reporting, and testing provisions – would be eclipsed by discussion on the defective product labeling provisions. EIB should avoid this result.

PPWG therefore respectfully requests that EIB deny the petition so that NMED can proactively address the fatal aspects of proposed 20.13.2 NMAC as currently drafted. One efficient outcome of this denial is that NMED could remove the labeling provisions from the proposal and re-submit that revised proposal soon afterwards. This process will help ensure that the reporting and restriction portions of the rule (with statutory compliance deadlines upcoming in 2027) will be finalized on schedule. In contrast, HB 212 specifies that EIB has the discretion of whether or not to promulgate labeling rules, and labeling does not need to be implemented by a specific date.

I. **A Categorical Labeling Exemption For Drugs, Medical Devices, Veterinary Products, and For These Products' Packaging, is Necessary**.

NMED's petition suffers from a critical omission: NMED's proposed rule provides no categorical exemption from labeling for drugs, medical devices, veterinary products, or their packaging. Both applicable law and sound regulatory practice necessitate such an exemption – not only as a matter of statutory construction, but also to avoid federal preemption conflicts and as a matter of sound policy.

A. Statutory Authority: EIB Has The Obligation To Create Necessary Labeling Exemptions.

There is no bar in HB 212 against EIB enacting a rule that exempts certain product categories from labeling when appropriate. To the contrary, EIB must consider the "technical practicality, necessity for and economic reasonableness" of its rulemaking actions.[1] Application of these factors makes clear that a categorical exemption for drugs, medical devices, veterinary products, and their packaging is not optional but is instead essential to avoid federal preemption conflicts and serious policy harms, as explained in subsections B and C below.

B. Federal Preemption: Imposing Labeling On This Industry's Products Would Conflict With Federal Law.

(i) *Principles of Federal Preemption*.

The Supremacy Clause of the U.S. Constitution provides that federal law "shall be the supreme Law of the Land."[2] This clause gives Congress the power to preempt state law, such that "state law that conflicts with federal law is without effect."[3] "[T]he purpose of Congress is the ultimate touchstone of preemption analysis."[4]

"In general, there are three different types of preemption – express, conflict, and field."[5] "Express preemption occurs when congressional intent to preempt state law is made explicit in the language of a federal statute."[6] By contrast, "[c]onflict preemption takes place when state law imposes a duty that is 'inconsistent—i.e., in conflict—with federal law.'"[7] Conflict preemption is itself divided

[1] N.M. St. § 74-1-9(B).
[2] U.S. Const. art. VI, cl. 2.
[3] *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992).
[4] *Id*. at 516; *see also Consumer Data Indus. Ass'n v. Frey*, 26 F.4th 1, 5–6 (1st Cir. 2022).
[5] *Consumer Data Indus.*, 26 F.4th at 5 (quotations omitted).
[6] *Id*.
[7] *Id*. (quoting *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1480 (2018)).

into two types: obstacle preemption and impossibility preemption. "Obstacle preemption is implicated when 'the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' . . . 'What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects.'"[8]

Impossibility preemption arises from a more direct conflict of federal and state laws, "where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce."[9] Finally, "[f]ield preemption comes about when federal law occupies a field of regulation 'so comprehensively that it has left no room for supplementary state legislation.'"[10]

Federal courts generally begin their preemption analysis "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[11] This presumption "does not apply, though, 'when the State regulates in an area where there has been a history of significant federal presence.'"[12] Furthermore, most case law related to the federal preemption of state regulation of healthcare products concerns state labeling or warning requirements for such products, often as imposed through state product liability causes of action.[13] As discussed below, the Federal Food, Drug, and Cosmetic Act (FFDCA) – along with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Virus-Serum-Toxin Act (VSTA) for certain veterinary products – would implicitly (and, in several cases, explicitly) preempt application of NMED's proposed labeling requirements to drugs, medical devices, veterinary products, and these products' packaging.

(ii) *Federal Preemption As Applied to Human and Animal Drugs*.

Both human and animal drugs are regulated by the FDA pursuant to the FFDCA. This statute explicitly preempts state-level labeling requirements as applied to over-the-counter (OTC) drugs. Specifically, 21 U.S.C. § 379r forbids states from enforcing laws relating to OTC drugs that are "different from or in addition to, or that [are] otherwise not identical with, a requirement under" the FFDCA. This statutory provision also notes that "a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug."

Courts have interpreted this express preemption provision broadly by holding that "[in] a nutshell, a plaintiff's claim [under a state failure-to-warn law] is preempted if a judgment ruling in favor of the plaintiff would compel the defendant to add labeling to its product that the FDCA does not require."[14] Furthermore, "[i]n the context of OTC drugs, the FDCA expressly preempts state law

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[8] *Maine Forest Prod. Council v. Cormier*, 51 F.4th 1, 6 (1st Cir. 2022) (quoting *Arizona v. United States*, 567 U.S. 387, 399 (2012), and *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000), respectively).
[9] *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963); *see also In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 40 (1st Cir. 2015).
[10] *Consumer Data Indus.*, 26 F.4th at 5 (quoting *Murphy*, 138 S. Ct. at 1480).
[11] *Maine Forest*, 51 F.4th at 6 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).
[12] *Id*. (quoting *United States v. Locke*, 529 U.S. 89, 108 (2000)).
[13] *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555 (2009); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472 (2013).
[14] *Gibson et al., v. Perrigo Co., et al.*, No. 25-CV-348, 2025 WL 2807671, at *5 (N.D. Ill. Oct. 2, 2025) (citing *Bell v. Publix Super Markets, Inc.*, 982 F.3d 468, 484 (7th Cir. 2020)).

labeling requirements that are 'different from,' 'addition[al] to,' or 'otherwise not identical with' federal labeling requirements . . . The standard, in other words, is not whether a state law actively undermines federal law. It is whether state law diverges from federal law *at all*."[15] There is therefore no question that NMED's proposed PFAS labeling requirement would be expressly preempted as applied to OTC drugs.

NMED's proposed PFAS labeling requirement would also be impliedly preempted as applied to <u>all</u> drugs and these drugs' packaging. For instance, the U.S. Supreme Court has found implied impossibility preemption of a state tort failure-to-warn action as applied to generic prescription drugs, since labeling of the generic must be the same as labeling for the brand-name drug.[16] Furthermore, the Supreme Court of California has found implied obstacle preemption of a Proposition 65 warning label as applied to nicotine replacement therapy (NRT) products given established FDA policy "reflect[ing] the concern that Proposition 65 warnings on product labels might lead pregnant women to believe that NRT products were as dangerous as smoking, or nearly so, and thus discourage the women from stopping smoking."[17]

This reasoning applies directly in the context of NMED's proposed PFAS labeling requirement. Under the FFDCA, "a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label[ing] is accurate and adequate . . . Meeting those requirements involves costly and lengthy clinical testing . . . A new drug application (NDA) will be refused if the FDA determines that the labeling is false or misleading in any particular, if the application contains an untrue statement of a material fact, or if the proposed labeling does not comply with ... [applicable] regulations."[18] Likewise, drug manufacturers only have a limited ability to change drug labels without prior FDA-approval under FDA's "changes being effected" (CBE) regulation.[19] However, even under CBE, drug manufacturers must notify FDA of the labeling modification and that federal agency has ultimate authority to approve or reject the change.[20] This complex federal labeling process would be undermined by the imposition of a state-level PFAS label on drug products without FDA approval. And courts considering the issue have reasoned that state labeling requirements could have the deleterious effect of discouraging consumers from using critical drug products that may save or improve their lives.

(iii) *Federal Preemption As Applied to Medical Devices for Humans and Animals*.

As with drugs, medical devices for both humans and animals are regulated by the FDA under the FFDCA. This statute at 21 U.S.C. § 360k(a) expressly preempts application of a state-level PFAS

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[15] *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375 (S.D.N.Y. 2014) (emphasis in original).
[16] *PLIVA, Inc.*, 564 U.S. 604; *see also* 21 U.S.C. § 355(j)(2)(A)(v); §355(j)(4)(G); 21 C.F.R. §§314.94(a)(8), 314.127(a)(7).
[17] *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 929 (2004). The NRT product in question was an OTC drug. Proposition 65 is covered by a savings clause in 21 U.S.C. § 379r, meaning that Proposition 65 is not expressly preempted by the FFDCA for OTC drugs. Nonetheless, the court found obstacle preemption using reasoning that is relevant to all drugs.
[18] *Ctr. for Env't Health v. Perrigo Co.*, 89 Cal. App. 5th 1, 17 (2023) (internal quotations omitted).
[19] 21 C.F.R. §314.70(c).
[20] *See, e.g.*, *Sykes v. Glaxo-SmithKline*, 2007 WL 957337, at *18 (E.D. Pa. Mar. 28, 2007) ("A manufacturer may, under FDA regulations, strengthen a labeling warning, but in practice manufacturers typically consult with FDA before doing so to avoid implementing labeling changes with which the agency ultimately might disagree").

labeling requirement to Class III medical devices.[21] That provision explains that "No State ... may establish or continue in effect any requirement ... which is different from, or in addition to, any requirement applicable under this chapter to the device ... and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." The FDA has interpreted this preemption provision in regulation by acknowledging that "State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the [FFDCA], thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements."[22]

The U.S. Supreme Court has interpreted this express preemption provision to apply to Class III medical devices since these devices are subject to a rigorous pre-market approval (PMA) process which established federal requirements in scope of 21 U.S.C. § 360k(a).[23] Specifically, as explained by another federal court, "Class III devices may enter the market only if the FDA reviews their design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of safety and effectiveness. Manufacturers may not make changes to such devices that would affect safety or effectiveness unless they first seek and obtain permission from the FDA. The PMA includes a review of the device's proposed labeling."[24] With this in mind, the U.S. Supreme Court held that state safety claims against a Class III device were expressly preempted, and it necessarily follows that a state PFAS labeling requirement against Class III devices would likewise be expressly preempted.

And as with drugs, application of a state PFAS labeling requirement is impliedly preempted as applied to all medical devices and these devices' packaging. For instance, while Class I and II devices undergo a more limited pre-market approval process known as the 510(k) process, 510(k) approval requires an applicant to "demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device . . . [and] the 510(k) submission 'shall contain' 'proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use.'"[25] The FDA has also put forward guidance explaining how the PFAS used in medical devices are safe and the agency has currently no reason to restrict their continued use in devices.[26] Using the reasoning of the Supreme Court of California as mentioned above in the context of NRT, application of a state PFAS labeling requirement to devices would conflict with this FDA determination and run counter to FDA's detailed device labeling requirements for all device classes. Accordingly, a state PFAS labeling mandate for medical devices cannot stand under federal law.

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[21] FDA categorizes medical devices into three classes based on their risk profiles, and the agency regulates those classes separately: Class I (such as bandages and toothbrushes), Class II (such as powered wheelchairs and some pregnancy test kits), and Class III (devices that typically sustain or support life, are implanted, or present potentially unreasonable risk of illness or injury, and include stents, pacemakers, and breast implant). *See* FDA, Classify Your Medical Device (updated Feb. 7, 2020).
[22] 21 C.F.R. § 808.1(d).
[23] *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).
[24] *Kelsey v. Alcon Laboratories, Inc.*, 2019 WL 1884225 at *4 (Utah Dist. Ct. Apr. 22, 2019).
[25] *Id*. at *4-5 (quoting 21 C.F.R. § 807.87).
[26] FDA, PFAS in Medical Devices (updated Aug. 6, 2025).

(iv) *Federal Preemption As Applied To Veterinary Parasiticides and Veterinary Biologics*.

A similar analysis applies for veterinary parasiticides and veterinary biologics. Most topical parasiticides are subject to regulation under FIFRA. FIFRA contains express language to ensure nationwide uniformity on labels: "State[s] shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter."[27] Based on this language, courts have held that state-imposed warnings that go beyond U.S. Environmental Protection Agency-mandated warnings are preempted.[28] Veterinary biologics are regulated under the VSTA. U.S. Department of Agriculture (USDA) regulations promulgated under the VSTA state that: "No person shall apply or affix to or include with, or cause to be applied or affixed to or included with, any carton or final container of a biological product, any label, stamp, mark or statement that is false or misleading in any particular, is not in compliance with the regulations, or is not approved by [USDA's Animal and Plant Health Inspection Service]."[29] USDA has concluded based on the VSTA's statutory text and legislative history that "labeling requirements which are different from or in addition to those in the [USDA] regulations under the Act may not be imposed by the states."[30] Thus, NMED's proposed labeling scheme is preempted as applied to both veterinary parasiticides and veterinary biologics.

(v) *Reliance on a General Preemption Provision For This Industry's Products Is Unsuitable*.

NMED's proposed rule gestures toward federal preemption by including a blanket disclaimer that labeling requirements do not apply where preempted by federal law. But this approach is inadequate for drugs, medical devices, veterinary products, and these products' packaging. As explained above, these product categories are governed by comprehensive federal labeling regimes under the FFDCA, FIFRA, VSTA, and related regulations. A generic statement of preemption leaves manufacturers in a compliance gray zone, forcing them to make case-by-case determinations on whether the state requirement conflicts with federal law. This product-level assessment is inappropriate and inefficient for products in this industry that are clearly subject to federal preemption at a categorical level.

Instead of over-relying on a vague carveout, NMED should add to its proposed rule a categorical labeling exemption for these products and their packaging. This exemption could mirror the language used for the restriction and reporting exemptions in section 4(A)(3) and (5) of HB 212. Incorporation of this labeling exemption would provide clarity, avoid unnecessary litigation risk, and respect the federal-state balance Congress established. Anything less invites confusion, inconsistent enforcement, and potential challenges that could undermine the entire rulemaking effort.

C. <u>Policy: A Labeling Exemption For This Industry's Products Will Support Public Health Objectives</u>.

A categorical labeling exemption for drugs, devices, and veterinary products, as well as for these products' packaging, would advance public health objectives. These products are already subject

[27] 7 U.S.C. § 136v(b).
[28] *See, e.g.*, *Shaffner v. Monsanto Corp.*, 113 F.4th 364 (3d Cir. 2024)
[29] 7 C.F.R. § 112.1(b).
[30] 57 Fed. Reg. 38758, 38759 (Aug. 27, 1992).

to rigorous federal oversight by agencies including the FDA, which evaluates these products' safety, efficacy, and labeling under a comprehensive risk-benefit framework. Requiring PFAS labeling on these products would conflict with FDA determinations and could mislead consumers into believing that the presence of PFAS renders the product unsafe. This misunderstanding may deter patients, healthcare providers, and others from using life-saving or health-sustaining medical, pharmaceutical, and animal health products, which would ultimately harm public health. The labeling scheme proposed by NMED does not account for the unique regulatory and clinical context of these products and could unintentionally erode trust in the healthcare system.

A labeling exemption for this industry's products also helps preserve the clarity and effectiveness of public health communication. Consumers rely on labeling to make informed decisions, particularly when it comes to health-related products. Adding PFAS disclosures to these labels could distract from critical information such as dosage instructions, contraindications, and existing safety warnings. This dilution of essential content may reduce the overall utility of the label and increase the risk of product misuse. By exempting these products from PFAS labeling, EIB can help ensure that drug, device, and animal health product labeling remains focused on the information most relevant to patient safety and therapeutic outcomes.

II. **The Sweeping and Unprecedented Nature Of The Proposed Labeling Scheme Is Inconsistent With The Statute and Legislative Intent**.

Section 4(B) of HB 212 states that EIB "*may* . . . adopt rules *to carry out* the provisions of [HB 212], *including* requiring the labeling of products in English and Spanish" (emphasis added). HB 212 is 20 pages long, explaining in detail how the material restriction, reporting, product testing, and enforcement provisions of the law are to be carried out. The law also contains several exemptions from the restriction and from reporting for critical products, including for drugs, medical devices, veterinary products, and these products' packaging.[31] NMED Cabinet Secretary Kenney likewise stated during a recent webinar that product labeling is a "mere mention" in the statute.[32] This statutory framework makes clear that the legislature envisioned labeling to be a focused mechanism, not an expansive requirement that overshadows the law's core provisions restricting and requiring reporting on PFAS in products. Nevertheless, NMED has proposed a sweeping PFAS labeling mandate that would extend to all products – including to products that the legislature explicitly exempted from the law's restriction and from reporting.

Adding to the fact that labeling receives only a passing reference in the statute is the wording of that reference, as quoted above. Specifically, the phrases "to carry out" and "including" confirm that labeling is intended as an implementing measure to complement the core restriction and reporting provisions of the statute, not to override those provisions. And use of the word "may" in section 4(B) makes labeling a discretionary action with no statutory deadline, further signaling that labeling was conceived by the legislature as an optional, supporting measure rather than an expansive, rushed mandate that displaces statutory carveouts such as the exemptions for this industry's products.

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[31] NMED itself underscored that HB 212 "includes important exemptions and enforcement provisions — such medical devices and electronic — where PFAS is essential and does not pose serious harm to those using the products." NMED, PFAS in New Mexico webpage.

[32] NMED, PFAS Protection Act – Labeling Webinar (Sept. 25, 2025) (Secretary Kenney introduction, timestamp 5:33).

Another line of evidence comes from HB 212's counterparts in other states. In 2021, Maine became the first U.S. state to enact a law regulating intentionally added PFAS in all products.[33] Minnesota followed in 2023 with passage of a law similar in scope to Maine's.[34] Maine's original law proved infeasible to implement, and that law has since been amended twice to make implementation more workable. Maine's law now contains a narrowed and delayed reporting requirement, a delayed material restriction applicable to all products, and several new exemptions to all of the law's provisions – including exemptions for medical, pharmaceutical, and animal health products. New Mexico HB 212 was clearly modeled after Maine's amended law, copying many of the provisions of that Maine law word-for-word. Secretary Kenney also gave testimony before the New Mexico Senate earlier this year during which he described HB 212 as a "middle ground" among state PFAS in products legislation.[35] Secretary Kenney likewise gave testimony on HB 212 before the New Mexico House of Representatives where he stated that "we don't need to regulate everything."[36]

The text of section 4(B) and this legislative history matters.[37] Since HB 212 was intended as a "middle ground" and product labeling is just a "mere mention" in the statute, NMED's proposal for an expansive, all-products labeling regime is fundamentally at odds with the text of the statute. Secretary Kenney's own statement that "we don't need to regulate everything" further underscores that the statute was never meant to enable a labeling program applicable to essentially all products sold in New Mexico. EIB cannot transform the brief, permissive reference in section 4(B) into a sweeping mandate that rewrites the statute and disregards the legislature's deliberate balance. This disconnect makes clear that the proposed labeling scheme is so far beyond the legislature's design that granting NMED's petition would only prolong consideration of a proposed rule that cannot withstand legal scrutiny.

III. **The Labeling Scheme As Proposed Presents Serious U.S. Constitutional Concerns**.

The First Amendment of the U.S. Constitution protects against compelled speech in the commercial context. Courts have held that when the government requires businesses to include specific statements on product labels, those statements must generally be limited to "purely factual and noncontroversial information."[38] In determining whether a disclosure meets this standard, courts have emphasized that a technically accurate statement can be considered

[33] 38 M.R.S. § 1614 (L.D. 1503 (enacted July 15, 2021)), later amended by L.D. 217 (enacted June 8, 2023) and L.D. 1537 (enacted Apr. 16, 2024).
[34] Minn. St. § 116.943.
[35] Hearing on HB 212 Before the Senate Conservation Committee (Mar. 18, 2025) (testimony of Secretary Kenney, timestamp 9:54 AM).
[36] Hearing on HB 212 Before the House Energy, Environment & Natural Resources Committee (Feb. 8, 2025) (testimony of Secretary Kenney, timestamp 9:09 AM).
[37] New Mexico courts look primarily to the text of the statute itself to ascertain legislative intent, though contemporaneous documents presented to the legislature and statements of legislators made while legislation is pending can also bear on legislative intent. *See Int'l Chiropractors Ass'n v. New Mexico Bd. of Chiropractic Examiners*, 2014-NMCA-046, ¶ 32, 322 P.3d 1033.
[38] *National Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263 (9th Cir. 2023).

misleading if the statement lacks appropriate context.[39] Similarly, a disclosure may fail the "noncontroversial" requirement if that statement addresses a subject that is the focus of "robust disagreement by reputable scientific sources."[40] Based on these principles, the labeling approach currently under consideration by NMED raises significant constitutional questions.

According to the materials presented in NMED's webinar and in the proposed rule, NMED appears to envision that the proposed label for products would include a symbol of an Erlenmeyer flask containing the phrase "! PFAS." For packaging, this symbol would be accompanied by a warning that reads, "CAUTION: Associated with environmental impacts and health effects such as cancer," along with a link to the Department's PFAS webpage. The proposed rule also specifies that, for complex durable goods, the disclaimer would state "This product is made with PFAS or contains component parts made with PFAS. PFAS are a family of chemicals, exposure to which are associated with negative health and environmental effects. For more information on the location of components made with PFAS, review the product's operation and maintenance manual." These disclosure phrases are problematic for several reasons.

First, the phrases imply a uniform level of risk across all PFAS, despite the fact that "PFAS" as defined in HB 212 encompass a vast and chemically diverse group of substances. Only a small subset of these compounds has been studied for adverse effects, and some, such as fluoropolymers, are recognized by the Organisation for Economic Co-operation and Development as presenting low concern for human health. Secretary Kenney acknowledged through testimony on HB 212 that fluoropolymers are "not as risky" as other PFAS.[41] Despite this background, the proposed disclosures treat all PFAS-containing products the same, without regard to concentration, exposure potential, or chemical structure. Second, inclusion of a link to a government webpage that may change over time without manufacturer input further complicates the issue. Although NMED has stated that the label design is not yet final, these constitutional concerns are substantial and warrant careful consideration before additional rulemaking steps are taken.

IV. **NMED Must Consider Other Adjustments To The Labeling Scheme To Ensure The Program Is Workable**.

PPWG's October 7, 2025 comments to NMED recommend several other guardrails to the labeling scheme to help ensure the practicability and legal viability of the program, even if that program 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

[39] See *id*. at 1276 (explaining that "a statement may be literally true but nonetheless misleading and, in that sense, untrue") (quoting *CTIA - The Wireless Ass'n v. City of Berkeley, California*, 928 F.3d 832, 847 (9th Cir. 2019)).
[40] *Id*. at 1277 (quoting *California Chamber of Com. v. Council for Educ. & Rsch. on Toxics*, 29 F.4th 468, 478 (9th Cir. 2022)).
[41] Hearing on HB 212 Before the Senate Conservation Committee (Mar. 8, 2025) (testimony of Secretary Kenney, timestamp 10:28 AM).

unrealistic, especially for complex products and given that NMED does not envision the rule will 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. 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. *Clear Process for Granting Labeling Waivers*. NMED must establish a clear, transparent process for granting labeling waivers that includes firm deadlines for NMED decisions on waiver requests and a mechanism for manufacturers to appeal denials.

G. *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.

V. **Other Non-Labeling Aspects Of the Proposed Rule Should Be Refined**.

As explained above, these comments to EIB focus specifically on the proposed product labeling provisions, which raise immediate and significant legal concerns that warrant denial of NMED's petition. PPWG intends to continue engaging in the rulemaking process and may offer additional input on labeling and other elements of the proposed rule as rulemaking efforts on HB 212 progress.

For instance, one notable non-labeling concern comes from the proposed rule's product testing provision in proposed 20.13.2.14 NMAC. Section 6 of HB 212 expressly exempts from product testing drugs, medical devices, and these products' packaging. This exemption is carried over in proposed 20.13.2.14(A) NMAC, though the introduction to proposed 20.13.2.10 NMAC indicates that the exemptions to 20.13.2.14 NMAC are "limited to medical devices." This limitation must be corrected since it is directly inconsistent with the statute and with proposed 20.13.2.14(A) NMAC.

VI. **Conclusion**.

EIB's denial of the petition will help ensure that, if and when EIB does proceed with rulemaking to implement HB 212, the Board does so on a foundation that promotes constructive stakeholder collaboration and lasting public confidence in the resulting regulatory program. PPWG welcomes continued engagement with EIB and NMED to further the recommendations provided above. If you have any questions, please feel free to contact me.

Sincerely,

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