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Supervisory Official, Office of Legal Policy
U.S. Department of Justice
950 Pennsylvania Avenue NW
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Re: Request for Information on State Laws (Docket No. OLP182) – State PFAS in Products Laws

Dear Mr. Schilling:

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 comments in response to the U.S. Department of Justice (DOJ) request for information on state laws having significant adverse effects on the national economy or significant adverse effects on interstate commerce. In these comments, PPWG aims to inform DOJ about the burdens imposed on the national economy and interstate commerce by certain state laws regulating per- and polyfluoroalkyl substances (PFAS) in products, and in particular Minnesota's PFAS in products law (Minn. St. § 116.943) restricting and requiring reporting on PFAS in all products. PPWG also explains how these laws are preempted as applied to U.S. food and Drug Administration (FDA)-regulated products and these products' packaging.

PPWG's members are committed to both the protection of human health and the environment and to ensuring continued access to the medical, pharmaceutical, and animal health products that society relies on. Members likewise agree that it may be appropriate to phase out the use of certain materials in products – commensurate with risk, guided by science-based decision-making, with guardrails in place to protect access to critical products such as those provided by PPWG's members, on timelines that are realistic, and consistent with existing legal requirements. Unfortunately, Minnesota's PFAS in products law does not fit this description.

The unprecedented scope of Minnesota's law – applying to all products that enter the Minnesota market – effectively imposes a nationwide PFAS restriction and reporting obligation that is not risked-based, imposes requirements with unworkable deadlines, and contains provisions inconsistent with federal law. PFAS have ubiquitous applications and have generally not been regulated in products until very recently, meaning that state-level PFAS in products laws create a fragmented legal landscape and a de facto national standard where companies must often adjust operations to comply with the most restrictive state law – such as Minnesota's law. This type of regulatory patchwork is exactly what federal preemption is designed to prevent.

More specifically, while Minnesota's law exempts FDA-regulated products from the restriction, the law by its text does not necessarily exempt such products from the reporting obligation. The regulator implementing this law (the Minnesota Pollution Control Agency, or MPCA) has likewise taken the position that FDA-regulated products are in scope of reporting. PPWG believes this position is misguided and that the reporting provision as applied to FDA-regulated products and their packaging should be considered preempted by federal law. All restrictions in such state laws as applied to FDA-regulated products and their packaging should similarly be considered preempted. This preemption not only recognizes the existing federal-state balance in the area of FDA-regulated products but also acknowledges that these products with their existing materials have been determined by FDA to have favorable benefit-risk profiles.

As explained in detail below, PPWG recommends that the FDA release guidance affirming this preemptive effect for FDA-regulated products and these products' packaging to help ensure consistent interpretation and enforcement by state regulators and legislatures. In tandem, actions under the Toxic Substances Control Act (TSCA) could help address the burgeoning patchwork of state PFAS in products laws. For instance, TSCA preemption could be adjusted to cover the situation where the U.S. Environmental Protection Agency (EPA) concludes that any individual or groups of PFAS do not present a significant risk. EPA should then consider such a determination, particularly for certain fluoropolymers and other polymeric PFAS where there is clear evidence showing that these categories of PFAS do not pose unreasonable risks to human health or the environment.

I. **The Nationwide Burdensome Impact of State PFAS in Products Laws**.

To date, three states have enacted laws restricting and requiring reporting on PFAS in all products: Maine, Minnesota, and New Mexico.[1] Even more states have enacted laws restricting and/or requiring reporting on PFAS in certain categories of consumer products, such as in cookware, juvenile products, and textile articles.[2] This growing number of state PFAS in products laws has created a regulatory maze imposing substantial and compounding burdens on the national economy and interstate commerce. These state laws vary in scope, definitions, exemptions, and compliance deadlines, fostering a fragmented regulatory landscape that is particularly disruptive to product manufacturers operating across state lines. Manufacturers cannot feasibly reformulate products or reconfigure distribution channels to comply with each state's unique PFAS restrictions and reporting requirements. Instead, companies are often forced to conform entire national product lines to the most restrictive state law – regardless of whether that law reflects national consensus or sound scientific risk assessment.

It can be appropriate to regulate certain discrete chemicals with known and heightened persistence, mobility, and toxicity profiles when present in specified products where the likelihood of exposure and resulting human health and environmental harm is more likely. This evaluation is the basis for risk-based assessment in chemicals regulation, though this evaluation has often been lacking in state PFAS in products laws where "PFAS" is defined structurally to cover tens of thousands of individual substances. These issues are amplified – including at a national scale – for state laws regulating PFAS in all products, which bring in scope all products regardless of actual

[1] 38 M.R.S. § 1614 (Maine); Minn. St. § 116.943 (Minnesota); HB 212 (New Mexico).
[2] *See, e.g.*, California AB 1817; Vermont Act 131.

exposure risk and without due regard for existing legal requirements certain categories of products may be subject to (such as the federal requirements for FDA-regulated products, as discussed further below). Relatedly, states regulating PFAS in all products have consistently, and significantly, underappreciated the burden that will be imposed on manufacturers, importers, and other supply chain actors across the country and the world to collect information about the substances embedded in complex manufactured items, let alone transition away from those uses. Struggles in Maine and Minnesota, along with the resulting structure of New Mexico's law, have demonstrated these challenges. In each case, an overly ambitious legislative framework was quickly identified as unworkable, leaving regulators struggling to adapt and companies in prolonged states of uncertainty.

Maine first adopted a law in 2021 that would have required product manufacturers to notify the Maine Department of Environmental Protection (Maine DEP), by January 1, 2023, about the presence of intentionally added PFAS in any products.[3] That original law also restricted the sale of all products containing intentionally added PFAS in the state starting January 1, 2030. The Maine Legislature vastly underestimated the level of effort and time it would take for industries around the country to comply. Maine DEP granted requests from thousands of manufacturers across different industries to extend the reporting deadline,[4] and the law has now been amended *twice* to make it more workable. The most recent amendment (L.D. 1537), enacted in April 2024, was in response to advocacy from Maine DEP itself demonstrating that implementation of the original law was infeasible. For instance, an October 2, 2023 presentation from Maine DEP to the Maine Legislature lists the challenges the department was experiencing in implementing the original law, including the scope of products and range of chemicals subject the reporting.[5] Maine's law now contains a narrowed and delayed reporting requirement, a delayed material restriction applicable to all products, and several new exemptions – including exemptions for medical, pharmaceutical, and animal health products, and for the equipment used to manufacture these products. New Mexico later enacted a PFAS in products law[6] that is structured similarly to Maine's amended law with more expansive exemptions, presumably as a lesson learned on the potential disruptive nationwide impacts from state PFAS in products laws.

In 2023, Minnesota adopted a PFAS in products law akin to Maine's original statute.[7] Two key provisions of Minnesota's law are that all products containing intentionally added PFAS must be reported to the state by January 1, 2026 and all such products are restricted starting January 1, 2032. Minnesota's law contains only minimal exemptions, and while the law contains an exemption for FDA-regulated products, that exemption by its text applies to the material restriction

[3] 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).
[4] Maine DEP, List of Manufacturers with an Approved Extension Request of the January 1, 2023 PFAS in Products Reporting Deadline (Aug. 14, 2023), https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/Approved-manufacturers.pdf.
[5] Maine DEP, Regulatory Update: PFAS in Products Law at slide 12, in the October 2, 2023 Meeting Materials for the Maine Legislature Joint Standing Committee on Environment and Natural Resources, https://legislature.maine.gov/doc/10288.
[6] New Mexico HB 212 (enacted Apr. 8, 2025).
[7] Minn. St. § 116.943 (effective July 1, 2023).

and not necessarily to the reporting requirement. The MPCA has also taken the position, contrary to PPWG's advocacy, that FDA-regulated products are in scope of reporting.[8]

The MPCA has proposed a rule to implement the law's reporting requirement, though that rule has not yet been finalized.[9] Given the upcoming January 1, 2026 reporting deadline in the statute and the fact that a reporting platform has not yet been released, the MPCA recently extended this deadline by 6 months to July 1, 2026.[10] The MPCA's Statement of Need in Reasonableness for the proposed rule estimates that approximately 5,000-10,000 manufacturers may need to report[11], and it seems likely that the majority of these manufacturers are based outside of Minnesota. Furthermore, a Minnesota administrative law judge released a report on August 28, 2025 disapproving the proposed rule on various grounds, and the state's interim chief administrative law judge concurred with this disapproval.[12] Specifically, the judge determined that the MPCA failed to adequately consider the impact of the rule in relation to federal PFAS reporting requirements under TSCA and that the agency exceeded its statutory authority in several areas of the proposed rule. The failure of the MPCA to address federal requirements under TSCA underpins the nationwide implications of Minnesota's law. The findings that the MPCA exceeded its authority also point to a risk of regulatory overreach when it comes to state PFAS in products laws like that found in Minnesota.

At present, Minnesota's law is the most far-reaching of the state PFAS in products laws. Minnesota's law therefore functions as a de facto national standard, compelling companies across the country to adjust their products and operations to align with the law's requirements. The burden of this effort is magnified by the fact that the MPCA is struggling to implement the law in a timely and efficient manner. Also, the law does not contain sufficient exemptions for products that are federally regulated – and, indeed, are often subject to rigorous federal agency evaluation and approval prior to marketing – and which are critical to the national economy, such as medical, pharmaceutical, and animal health products. Minnesota's law also does not provide sufficient protections for items in the supply chains of FDA-regulated products that may not by themselves be FDA-regulated but nevertheless affect the availability, efficacy, quality, reliability, price, or safety of FDA-regulated products. For instance, if the PFAS content of certain gaskets, pipes, and other equipment is restricted generally at the supplier level, this restriction could impact the availability and price of what is supplied to medical, pharmaceutical, and animal health product manufacturers regardless of whether these manufacturers' end products are exempt from the restriction. Minnesota's law does not provide adequate protections for supply chains, let alone for the FDA-regulated end products that these supply chains make possible.

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[8] *See, e.g.*, MPCA Q&A on PFAS Rule Development (Sept. 2024) (stating that "medical products are not exempt from reporting"), https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-00.pdf.
[9] MPCA, Proposed PFAS Reporting and Reporting Fees Rule, https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-06.pdf.
[10] MPCA, Reporting PFAS in products, https://www.pca.state.mn.us/air-water-land-climate/reporting-pfas-in-products.
[11] MPCA, Statement of Need and Reasonableness at pg. 41 (Apr. 2025), https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-07.pdf.
[12] Order of Interim Chief Administrative Law Judge Timothy O'Malley and Report of Administrative Law Judge Jim Mortenson, Minn. Office of Admin. Hearings, Proposed PFAS Reporting Rule (Aug. 28, 2025), https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-07l.pdf.

II. Application of State PFAS in Products Laws to FDA-Regulated Products and Their Packaging is Preempted.

a. These Products Undergo Safety Review and Reporting Processes at the Federal Level and FDA Has Determined that These Products Have Favorable Benefit-Risk Profiles.

The medical, pharmaceutical, and animal health product manufacturing industry is one of the most highly regulated industries in the United States. The industry's products do not enter the market without first undergoing intense federal agency review to evaluate product safety and efficacy. Regulated products include, but are not necessarily limited to, drugs, biologics, medical devices, combination products, animal drugs, and animal devices. Core federal statutes that these products are subject to include the FFDCA, the Public Health Services Act, and the Virus-Serum-Toxin Act.[13]

Medical, pharmaceutical, and animal health products are also subject to stringent federal regulations that implement the above statutes, such as from FDA's pre-market approval (PMA) requirements for certain medical devices and the agency's Current Good Manufacturing Practice (CGMP) regulations.[14] Through the New Drug Application (NDA, for new traditional drugs), Abbreviated New Drug Application (ANDA, for generic drugs), Biological License Application (BLA, for biologic drugs and biosimilars), and over-the-counter (OTC) monograph (for OTC drugs) approval pathways, FDA considers and makes the agency's safety determinations in light of detailed information from the manufacturer regarding all drug product components. For instance, an NDA is a lengthy compilation of materials that must include, among other information, "any . . . data or information relevant to an evaluation of the safety and effectiveness of the drug product."[15]

Approval pathways are likewise available for animal drugs in the form of New Animal Drug Applications (NADAs) and Abbreviated New Animal Drug Applications (ANADAs). Like with human drug applications, animal drug applications must include extensive information on the components of the proposed product, including "a full list of the articles used as components of such drug," "a full statement of the composition of such drug," and "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug."[16]

Medical devices are also regulated strictly under federal law. The FDA began regulating medical devices in 1976, when Congress enacted the Medical Device Amendments to the FFDCA.[17] The FDA categorizes medical devices into three classes based on their risk profiles, and the agency regulates those classes separately. Class I devices, such as bandages and toothbrushes, are subject to "general controls," which include prohibitions on adulteration and misbranding, a requirement that the device producers register with the FDA, and various recordkeeping and reporting requirements.[18] Class II devices, such as powered wheelchairs and some pregnancy test

[13] 21 U.S.C. § 301 et seq. (FFDCA); 42 U.S.C. § 201 et seq. (Public Health Services Act); 21 U.S.C. § 151 et seq. (Virus-Serum-Toxin Act).
[14] 21 C.F.R. § 814 (PMA requirements); *id*. § 210 et seq. (CGMP regulations).
[15] *Id*. § 314.50(d)(5)(iv).
[16] 21 U.S.C. §§ 360b(b)(1), (n)(1)(G).
[17] Pub. L. No. 94-295, 90 Stat. 539 (1976).
[18] 21 U.S.C. §§ 351, 352, 360, 360i.

kits, are subject to both general and special controls. Special controls are usually device-specific and may include "the promulgation of performance standards . . . and other appropriate actions as the Secretary deems necessary to provide such assurance."[19]

Class III devices usually sustain or support life, are implanted, or present potentially unreasonable risk of illness or injury, and include stents, pacemakers, and breast implants. Such devices are subject to general controls and to the FDA's PMA process. Approval may be achieved by submission of a PMA application or by a "510(k) notification," including a demonstration that the device is "substantially equivalent" to an already-approved Class III device.[20] A PMA must include an intensive collection of materials and descriptions, including a "a complete description of . . . [e]ach of the functional components or ingredients of the device if the device consists of more than one physical component or ingredient."[21]

Like the products themselves, the packaging for medical, pharmaceutical, and animal health products is already highly regulated under federal law because packaging is often critical to appropriate product administration and preservation of drug and device quality. For instance, once a small molecule drug—whether brand-name or generic—is approved by FDA, its manufacturer is prohibited from making any "major changes" to the product without FDA approval.[22] "Major changes" include "any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product."[23] Examples of such changes that require FDA approval include "[c]hanges in a drug product container closure system that controls the drug product delivered to a patient or changes in the type . . . or composition . . . . of a packaging component that may affect the impurity profile of the drug product."[24] Therefore, a drug manufacturer often may not alter the formulation of a drug product's packaging without FDA's further approval.

This federal oversight and control over the exact composition of medical, pharmaceutical, and animal health products and these products' packaging necessarily includes any PFAS that may be present in these items in terms of human health implications. Medical, pharmaceutical, and animal health products that have been authorized for marketing, and continue to be monitored under, these rigorous approval or clearance processes have been deemed to have a favorable safety and effectiveness profile by the federal government for their intended uses. State PFAS in products laws that do not fully exempt these products risks compromising the federal process and depriving patients of life-enhancing and life-saving medical treatments. This risk underpins the importance of federal preemption in this area.

Most case law related to the federal preemption of state laws concerning FDA-regulated drugs, biologics, animal drugs, or medical devices is in the context of state labeling or warning

[19] *Id*. § 360c(a)(1)(B).
[20] *Id*. § 360c(f)(1)(A)(ii).
[21] 21 C.F.R. § 814.20(b)(4).
[22] *Id*. §§ 314.70(b)(1), (3).
[23] *Id*. § 314.70(b)(1).
[24] *Id*. § 314.70(b)(2)(vi).

requirements for such products, often as imposed through state product liability causes of action.[25] As discussed below, the FFDCA and other federal laws either implicitly or explicitly preempt application of state PFAS restrictions and reporting requirements to FDA-regulated products and their packaging.

b. **Federal Preemption as Applied to Human and Animal Drugs.**

Federal law preempts any state law that purports to control or ban FDA-approved drug products (including biological products and animal drugs) because such laws stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. This conclusion is independent of whether the state law contains a preemption clause. The FDA's codified mission statement makes clear that Congress intended the agency to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and "protect the public health by ensuring that . . . human and veterinary drugs are safe and effective."[26] The FFDCA delegates the task of balancing patient safety and drug availability to the FDA through various approval and licensing pathways available for human drugs, human biologics, and animal drugs. FDA's approval of a new or generic human or animal drug, the agency's licensing of an originator biologic or biosimilar, and the agency's promulgation of an OTC monograph or indexing of certain minor animal drugs all require the FDA to determine that such product is "safe" for its approved conditions of use.

Federal courts have held that state determinations contrary to FDA approval of a drug interfere with Congress' intent in enacting the FFDCA. The District Court for the District of Massachusetts has held that Massachusetts could not ban an approved drug or require that it only be sold in a dosage form not yet approved by FDA.[27] "If [a state] were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health. [Such a state law] thus stands in the way of the accomplishment and execution of an important federal objective. The Constitution does not allow it to do so."[28] Similarly, the District Court for the District of Maryland has held (and the Fourth Circuit affirmed) that no state law "could . . . exist" that would "compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce" because "it would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce."[29]

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[25] *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that the FFDCA does not preempt a state cause of action for failure to warn that would require label statements beyond those required or approved by FDA); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (holding that federal law preempts state law imposing a duty to change a generic drug's label when FFDCA prohibits such changes absent FDA approval); *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472 (2013) (holding that federal law preempts state causes of action for design defect when FFDCA prohibits unilateral generic drug label changes to strengthen warnings).

[26] 21 U.S.C. § 393(b).

[27] *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696 (D. Mass. Apr. 15, 2014).

[28] *Id*. at *2.

[29] *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011), *aff'd sub nom. Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014); *see also* Peter H. Schuck, *Multi-Culturalism Redux: Science, Law, and Politics*, 11 Yale L. & Pol'y Rev. 1, 39 (1993) ("For better or for worse, the FDA is the agency that the public has empowered to make authoritative judgments of this kind on its behalf.").

Additionally, the FDA's approval of an NDA amounts not merely to federal permission to market a drug product but a license to do so.[30] The same logic applies to the agency's approval of other application types, such as for ANDAs, BLAs, NADAs, and ANADAs. A state may not unilaterally decline to recognize such a federal license.[31]

The legislative intent behind state PFAS in products laws, as evidenced by the legislative history of Maine's law, is to protect against concerns that PFAS-containing products "pose[] a significant threat to the environment of the State and to the health of its citizens."[32] As applied to FDA-approved drug products and these products' packaging, state regulation of PFAS in these items runs directly counter to the FDA's own risk analysis and safety determination. This conclusion extends to state reporting obligations, such as found in Minnesota's law, which are executed to analyze health and safety information about these products. As explained by federal courts, "[t]he Constitution does not allow" a state to "countermand the FDA's determinations" and so "undermine the FDA's ability to make drugs available to promote the public health."[33] "Whether a drug may be marketed" is solely the FDA's decision to make.[34]

And states are additionally prohibited from unilaterally declining a drug manufacturer's license to sell afforded by FDA's approval of the manufacturer's NDA, ANDA, BLA, NADA, or ANADA. State PFAS restrictions and reporting requirements are therefore federally preempted. This conclusion holds because such restrictions would impose a direct barrier to the market for drugs that the FDA has approved for sale because these products and their packaging are safe and effective. Such reporting requirements are preempted because the purpose of reporting is for the regulator to gather and assess the health and safety attributes of drug products, in contradiction to FDA's determination that drugs and their packaging have favorable benefit-risk profiles.

c. **Federal Preemption as Applied to Medical Devices.**

The FFDCA expressly preempts state regulations with regard to medical devices. Specifically, "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."[35] At minimum, this provision expressly preempts state PFAS in products laws as applied to Class III devices subject to the FDA's pre-market approval.

As mentioned above, state PFAS in products laws are enacted for the purported protection of public health and safety. As applied to medical devices, these state laws clearly "relate[] to the safety or effectiveness of the device." The requirements of these state laws are also "different

[30] Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 Mich. St. L. Rev. 1, 32 (2016).
[31] *See Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 210, 240 (1824) (holding that "the laws of New-York . . . have, in their application to this case, come into collision with an act of Congress, and deprived a citizen of a right to which that act entitles him"); *see also Jacobs Wind Elec. Co. v. Fla. Dep't of Transp.*, 919 F.2d 726, 728 (Fed. Cir. 1990) (noting that "a state court is without power to invalidate an issued patent").
[32] 2021 Me. Legis. Serv. ch. 477 (H.P. 1113) (L.D. 1503).
[33] *Zogenix*, 2014 WL 1454696 at *2.
[34] *Gross*, 825 F. Supp. 2d at 659.
[35] 21 U.S.C. § 360k(a).

from" and "in addition to" any imposed on medical devices under federal law. A statutory provision that preempts "different" or "additional" requirements "sweeps widely" and "prevents a State from imposing any additional or different—even if non-conflicting—requirements that fall within the scope of the Act and concern" the regulated topic.[36] State-level restrictions and reporting requirements on PFAS in devices are clearly "different from" and "in addition to" federal controls on device safety and are therefore expressly preempted. Moreover, the Supreme Court has held that state regulation related to the safety of Class III medical devices that have gone through the FDA's pre-market approval process is preempted, as the pre-market approval process imposes numerous "requirements" with regard to such devices.[37] State PFAS in products laws are therefore expressly preempted by federal law as applied to FDA-approved Class III devices.

Moreover, at the very least, any material restriction in a state PFAS in products law is implicitly preempted by federal law for all medical devices. The Medical Device Amendments to the FFDCA were intended to provide, through FDA regulation and oversight, a "reasonable assurance of the safety and effectiveness" of medical devices.[38] The Supreme Court has held that a state regulation that "requires a manufacturer's [medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme."[39] These state PFAS in products restrictions are presumably intended to increase safety without regard for product efficacy. As applied to medical devices, these restrictions therefore "disrupts the federal scheme" and so "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in delegating regulation of medical devices to the FDA.[40]

This logic applied to state bans on FDA-approved drugs in *Zogenix* and thus also applies to medical devices for which the FDA has established general and special controls and issued pre-market approvals or substantial equivalence determinations: a state ban on devices for which the FDA has found "a reasonable assurance of . . . safety" would "undermine the FDA's ability to make [devices] available to promote and protect the public health."[41] Material restrictions in state PFAS in products laws are therefore implicitly preempted by federal law as applied to all medical device products.

III. FDA Guidance and Other Federal Actions Can Help Mitigate Concerns with State PFAS in Products Laws.

PPWG has presented the above information about preemption and related issues to the MPCA in public comments on rulemakings to implement the state's PFAS in products law.[42] The MPCA has generally been unresponsive to those concerns, particularly when it comes to preemption given that the agency has taken the position that FDA-regulated products are in scope of reporting under

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[36] *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 459–60 (2012) (interpreting a preemption provision under the Federal Meat Inspection Act nearly identical to the FFDCA's medical device regulation preemption provision).
[37] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322–23 (2008).
[38] 21 U.S.C. § 360c(a)(1)(A)(i).
[39] *Riegel*, 552 U.S. at 325.
[40] *Maine Forest Prod. Council v. Cormier*, 51 F.4th 1, 6 (1st Cir. 2022).
[41] *Zogenix*, 2014 WL 1454696 at *2 (altering "drugs" to "devices").
[42] PPWG, May 2025 Comments to the MPCA, https://tinyurl.com/nkkcp65c; PPWG, Dec. 2024 Comments to the MPCA, https://tinyurl.com/2nz75c8h; PPWG, Mar. 2024 Comments to the MPCA, https://tinyurl.com/97vxk9u9; PPWG, Nov. 2023 Comments to the MPCA, https://tinyurl.com/bdefn5h9.

the statute. This position is contrary to federal preemption and inconsistent with other recent state PFAS in products legislation that is beginning to recognize that comprehensive exemptions for this industry's products are necessary. For instance, as explained above, Maine's amended law exempts from all of its provisions medical, pharmaceutical, and animal health products and equipment used in the manufacture and development of such products. New Mexico's law contains similar exemptions to Maine's.

Even if states were to exempt FDA-regulated products and their packaging in future state PFAS in products laws, this is not a definitive solution and it does not address the outstanding issues with Minnesota's law. FDA guidance[43] affirming that state-level restrictions and reporting requirements as applied to FDA-regulated products and their packaging is preempted would provide much-needed clarity not only to Minnesota, but also to other states that may consider similar legislation in the future. While PPWG believes that the extent of this federal preemption is already clear, affirmative guidance from FDA on this topic will help ensure that the message is actionable.

In tandem with promulgating this guidance, actions under TSCA may also be appropriate. Drugs and devices are excluded from TSCA[44], though certain developments under TSCA could work to address state PFAS in products legislation more broadly. TSCA's preemption provision is nuanced and only applies in certain situations where EPA has evaluated or restricted a chemical under the statute.[45] One potential adjustment to TSCA's preemption provision is that states could be preempted from enacting or enforcing state PFAS in products laws to the extent EPA has concluded that any individual or groups of PFAS do not present a significant risk to human health or the environment. This provision could be narrowly tailored to only apply to PFAS so as to address the immediate and disproportionate regulatory burden that state PFAS in products laws impose on the national economy while preserving TSCA's existing framework for chemical risk assessment and federal-state coordination as brokered through the substantial amendments to TSCA passed in 2016.[46] Relatedly, EPA's authority under TSCA to collect fees in support of TSCA regulatory programs expires on June 22, 2026.[47] Congressional action on TSCA fees will therefore be the subject of upcoming Congressional action, and this effort may present an opportunity to advocate for PFAS to be addressed in TSCA's preemption provision.

If such an adjustment to TSCA's preemption provision is made, EPA should prioritize consideration of such a no-unreasonable-risk determination for certain PFAS, and in particular fluoropolymers and other polymeric PFAS where appropriate. Fluoropolymers are critical components of products in almost every major sector of the economy and there are currently no viable alternatives. Moreover, many fluoropolymers cannot dissolve in water or enter a person's bloodstream and, based on their molecular characteristics, meet the Organisation for Economic Co-operation and Development's criteria for "polymers of low concern".

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[43] The FDA has existing policies and procedures for developing guidance of this nature on issues of statutory interpretation. *See* 21 C.F.R. § 10.115.
[44] 15 U.S.C. § 2602(2)(B)(vi).
[45] *Id*. § 2617.
[46] *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 492 (2016).
[47] 15 U.S.C. § 2625(b)(6).

Regulators and legislatures in several jurisdictions are beginning to recognize the importance and low-risk profile of fluoropolymers, including the FDA which recently released guidance explaining why the use of fluoropolymers in medical devices is essential and safe.[48] Other examples include New Mexico's PFAS in products law that contains an exemption for fluoropolymers, the EU's PFAS restriction proposal which includes several derogations for fluoropolymers in certain products, and Canada's proposed PFAS risk management approach that excludes fluoropolymers from its scope.[49] In concert with considering a no-unreasonable-risk determination for fluoropolymers, EPA should consider similar determinations for polymeric PFAS more broadly. Many polymeric PFAS are comprised of large molecules that are less reactive and not as easily absorbed by humans, wildlife, and environmental media as compared to non-polymeric PFAS. No-unreasonable-risk determinations for certain polymeric PFAS may therefore be appropriate, which would in turn prevent states from unnecessarily regulating these substances in state PFAS in products laws.

In addition, there may be other potential federal actions to address state PFAS in products laws that DOJ may want to consider. For instance, while Minnesota's law restricts PFAS in all products starting in 2032, certain categories of consumer products (including cookware) are subject to an earlier restriction under the law that came into effect on January 1, 2025. A recent case in the U.S. District Court for the District of Minnesota challenged the law's 2025 cookware restriction and 2026 reporting obligation, alleging in the complaint that the law was unconstitutional under the Dormant Commerce Clause and First Amendment, and also preempted under the federal Defend Trade Secrets Act.[50] Some of these claims were later dropped, and the District Court subsequently granted the MPCA's motion to dismiss in the case.[51] Even if the federal government is not a plaintiff in future challenges of this kind, DOJ could consider intervening on a plaintiff's behalf or filing an amicus brief in support of the proffered claims.

IV. **It May Be Appropriate for FDA, EPA, and the CPSC to Coordinate and Address State PFAS in Products Laws**.

The last part of DOJ's request for information asked for comments on which federal agency has subject-matter expertise to address concerns with the relevant state law. As mentioned throughout these comments, FDA has the primary authority to address the impact of state PFAS in products laws on medical, pharmaceutical, and animal health products. EPA could also be consulted on issues of how these state PFAS in products laws relate to TSCA, though with the understanding that drugs and medical devices are out of scope of TSCA.

A third federal agency that may be consulted is the Consumer Product Safety Commission (CPSC). Consumer products, as regulated by the CPSC, do not encompass drugs and medical devices.[52]

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[48] FDA, PFAS in Medical Devices (updated Aug. 6, 2025), https://www.fda.gov/medical-devices/products-and-medical-procedures/pfas-medical-devices.

[49] New Mexico HB 212, sec. 3(A)(16); EU PFAS restriction proposal (updated Aug. 20, 2025), *available at* https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas; Canada risk management approach for certain PFAS, excluding fluoropolymers (Mar. 2025), https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/risk-management-approach-per-polyfluoroalkyl-substances.html.

[50] Compl., *Cookware Sustainability All. v. Kessler*, No. 0:2025-cv-00041 (D. Minn. Jan. 6, 2025).

[51] *Cookware Sustainability All.*, 2025 WL 2307591 (D. Minn. 2025).

[52] 15 U.S.C. § 2052(a)(5)(H).

That being said, it may be appropriate to solicit the CPSC's input as a means to address state PFAS in products laws across the board. For instance, in 2023 the CPSC published a request for information on PFAS in consumer products.[53] PPWG understands that several commenters responded to the CPSC's request, cautioning the Commission against unrealistic and unmeasured regulation of PFAS in consumer products. It does not appear that the CPSC has yet taken action in response to that request for information, meaning that CPSC input – in addition to FDA and EPA input – on the topic of state PFAS in products laws may be timely.

V. **Conclusion**.

PPWG thanks DOJ for considering its response to the request for information and welcomes the opportunity to engage with DOJ, FDA, and others to further the recommendations provided above. If you have any questions, please feel free to contact me.

Sincerely,

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[53] 88 Fed. Reg. 64890 (Sept. 20, 2023).