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Submitted via Email to rulecomments.dep@maine.gov

Melanie Loyzim
Commissioner, Maine Department of Environmental Protection
17 State House Station
Augusta, ME 04333-0017

Re: Comments to Maine DEP's Draft Regulations Regarding PFAS-Containing Products

Dear Commissioner Loyzim:

The PFAS Pharmaceutical Working Group ("PPWG") is a group of manufacturers and distributors of drugs, biologics, animal drugs, medical devices, pesticides, and pesticide devices. PPWG appreciates the opportunity to provide comments on the Maine Department of Environmental Protection ("DEP") proposed regulations implementing 38 M.R.S. § 1614 ("Section 1614"). The purpose of these comments is to assist DEP in determining which products are exempt from that statute's notification requirement and pending material restriction. PPWG's comments also address the express and implied preemption of these statutory requirements by federal law with regard to certain of the products they manufacture and distribute.

I. INTRODUCTION

Unless a manufacturer is granted an extension, Section 1614 requires, by January 1, 2023, written notification to DEP regarding "a product for sale in the State that contains intentionally added PFAS." 38 M.R.S. § 1614(2)(A). (On November 9, 2022, DEP granted PPWG's members an extension—the new deadline will be six months after the effective date of the Department's final rule implementing the law.) Additionally, by January 1, 2030, absent an exemption, "a person may not sell, offer for sale or distribute for sale in this State any product that contains intentionally added PFAS." 38 M.R.S. § 1614(5)(D). Application of the ban, in particular, to PPWG's members' products would impose a significant and unreasonable burden on those companies' abilities to serve patients and customers in the State of Maine, and could potentially result in the withdrawal of certain products entirely from the market, to the detriment of the public health.

PPWG appreciates the opportunity to engage DEP on these important issues. During the past few months, DEP has offered preliminary comments and non-binding written statements regarding the scope of exemptions under Section 1614(4), and on February 14, 2023, posted its

proposed regulations to implement Section 1614 for public comment. See Chapter 90 Draft, https://www.maine.gov/tools/whatsnew/attach.php?id=10415809&an=2 ("Posting Draft"). DEP has emphasized that its preliminary interpretations of these exemptions may change and has invited public input. As described below, PPWG is of the view that its members' federally regulated products are exempt under Section 1614.

Section 1614 states that a "product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority" is "exempt" from "this section," including both the notification requirement and material restriction. 38 M.R.S. § 1614(4)(A). The Posting Draft clarifies that DEP "will treat as exempt products where an applicable federal law . . . explicitly preempts parts of this program" and "any products where an applicable opinion from a court having jurisdiction in Maine finds that preemption of parts of this program is implied." Posting Draft § 4(A)(1), Note. DEP also asserts that it "does not have the authority to independently make a finding of law or accept an assertion that implied preemption exists" in the absence of an applicable court finding. *Id.*

The U.S. Food and Drug Administration ("FDA") regulates virtually all aspects of drug, biologic, animal drug, and medical device specifications, manufacturing, and distribution under the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301 et seq., the Public Health Service Act ("PHSA"), 42 U.S.C. §§ 201 et seq., and their implementing regulations, 21 C.F.R. pts. 200–680, 800–98. PPWG therefore contends that Section 1614's requirements are implicitly preempted—and in the case of certain medical devices, also explicitly preempted—with regard to its members' federally regulated products and their packaging. PPWG also contends that DEP is not only permitted but is in fact required to make legal determinations regarding the scope of its regulatory and enforcement authorities when promulgating regulations to implement Section 1614.

Separately, Section 1614 states that products "subject to Title 32, chapter 26-A or 26-B" are also exempt from "this section." 38 M.R.S. § 1614(4)(B); *see also* Posting Draft §§ 4.A(2) (exempting products "subject to Title 32, §26-A, *Reduction of Toxics in Packaging*"), 4.A(3) (exempting products "subject to Title 32, §26-B, *Toxic Chemicals in Food Packaging*"). Implementing these provisions, the Posting Draft would explicitly exempt from Section 1614 "all packing, packing components and food packaging as defined in 32 M.R.S. § 1732." Posting Draft §§ 4.A(2)–(3), Note. This exemption would apply only when such items are "actually used as packaging, packing components, or food packing, intended for marketing, handling, or protection of products," *id.*, while "packages, packaging components, and food packaging . . . when sold individually or in bulk and not used in marketing, handling, or protecting a product" are included under the definition of "products" subject to Section 1614's requirements, *id.* at § 2(R). PPWG agrees with DEP's interpretation of Section 1614 in the Posting Draft as it relates to packaging: PPWG members' product packaging is exempt both from the Section 1614 notification requirement and pending material restriction.

PPWG submits these comments to inform DEP of the ways in which federal law clearly "governs the presence of PFAS" in their products and their respective packaging, thus exempting them from Section 1614's requirements, and additionally preempts application of those requirements to those same products and packaging. PPWG's comments then address and support DEP's construction of the phrase "subject to" in Section 1614(4)(B), and show that all

packaging is exempt from the Section 1614 notification requirement and pending material restriction.

These comments continue in five sections. Section II summarizes the federal regulatory schemes that apply to drugs, biologics, animal drugs, medical devices, and their packaging, and explains why, because federal law "governs" and "controls" the presence of PFAS in such products and their packaging, those products and their packaging are exempt from the requirements of Section 1614 under the language of Section 1614(4)(A). Section III then provides an overview of federal preemption doctrine and explains why the State is preempted by federal law from requiring state notification regarding or banning the sales of such products or their packaging, regardless of the language of Section 1614(4). Section IV then explains why DEP not only can but is obligated to make a legal determination regarding the scope of its regulatory and enforcement authorities when implementing Section 1614, even if no directly applicable case law is available. Finally, Section V affirms DEP's interpretation of Section 1614(4)(B) to exempt all product packaging from the notification requirement and pending material restriction.

II. FDA GOVERNS AND CONTROLS THE PRESENCE OF PFAS IN REGULATED PRODUCTS AND THEIR PACKAGING, THEREBY EXEMPTING THEM FROM SECTION 1614

A. Drugs for Human Use

In enacting the FFDCA, Congress charged the FDA with "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). Congress then required the FDA to "protect the public health" by making sure that "drugs are safe and effective." *Id.* § 393(b)(2)(B).[1]

FDA's primary means of carrying out its mission to ensure drug safety is through the pre-market evaluation of new and generic drugs (including, but not limited to, biological products regulated as drugs), as well as its stringent requirements for non-prescription ("over-the-counter" or "OTC") drugs. Drug manufacturers may not sell or distribute any drug in interstate commerce without FDA approval, which hinges on the agency's determination that a drug is both effective and "safe for use," and such determination requires that FDA review and consider all "components" of a drug product and its manufacture and packaging. 21 U.S.C. §§ 355(a), 355(d), 355(j), 355h; 42 U.S.C. §§ 262(a), 262(k). Additionally, a drug shall be deemed "adulterated"—and thus illegal for distribution or sale—"if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health." 21 U.S.C. § 351(a)(3).

[1] The FFDCA defines "drugs" as including "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1). This section specifically discusses drugs intended for human use, as FDA regulates animal drugs separately from human drugs. Federal preemption of state regulation of animal drugs is discussed in section II.C below.

FDA-approved drug products (including, but not limited to, prescription and OTC drugs and biological products) and their packaging are therefore "exempt" from Maine's product notification requirement and material restriction under section 1614 because federal law "governs the presence of PFAS" in such products. 38 M.R.S. § 1614(4)(A). Through the New Drug Application (new traditional drugs), Abbreviated New Drug Application (generic drugs), Biologics License Application (biologic drugs and biosimilars), and OTC monograph (OTC drugs) approval pathways, the FDA considers and makes its safety determination in light of detailed information from the manufacturer regarding all drug product components.

Under the FFDCA and its underlying regulations, the FDA collects information regarding "drug substances," "drug products," and drug product "components." "Drug substance" refers specifically to "an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body." 21 C.F.R. § 314.3. More broadly, a "drug product" is "a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." *Id.* A "component" is defined still more broadly, and includes "any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product." *Id.* As described below, FDA considers detailed information regarding all components of a drug product in order to make its safety determination with respect to a particular drug. This federal oversight and control over the exact composition of drug products necessarily includes any PFAS that may be present in those products.

1. FDA Regulation of New and Generic Drugs

FDA approval of a new brand-name small molecule drug can be secured only through the New Drug Application ("NDA") process, which the Supreme Court has described as "onerous and lengthy." 21 U.S.C. § 355(b); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476–77 (2013) (noting that a "typical NDA spans thousands of pages and is based on clinical trials conducted over several years"). An NDA is a 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 obtained or otherwise received by the applicant from any source," 21 C.F.R. §§ 314.50(d)(2), 314.50(d)(5)(iv), and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling," 21 C.F.R. §§ 314.50(d)(5)(viii), 314.50(c)(2)(ix). Additionally, the NDA must include a "section describing the composition, manufacture, and specification of the drug substance and the drug product," including:

- "A full description of the drug substance including its physical and chemical characteristics and stability" and "the process controls used during manufacture and packaging"; and

- "A list of all components used in the manufacture of the drug product (regardless of whether they appear in the drug product) and a statement of the composition of the drug product," "the specifications for each component," and "a description of the manufacturing and packaging procedures and in-process controls for the drug product."

21 C.F.R. § 314.50(d)(1). In other words, all substances used in a drug product or its manufacture or packaging are disclosed to FDA as part of the NDA package and approved for use by the FDA with the NDA approval.

The FDA may approve an NDA *only* if, in addition to finding substantial evidence of effectiveness, it determines that the drug product in question is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d). In order for the FDA to consider a drug safe, the drug's "probable therapeutic benefits must outweigh its risk of harm." *Bartlett*, 570 U.S. at 476. Therefore, in approving a new drug, FDA must consider and account for the potential risks posed by any and all substances used as ingredients in the drug product or its manufacture or packaging. The NDA process therefore "governs the presence of PFAS" in brand-name drug products, as it does for the presence of any other substance in those products.

By contrast, generic drug products—those chemically identical and therapeutically equivalent to an already approved drug—are approved through the Abbreviated New Drug Application ("ANDA") process prior to their distribution or sale. 21 U.S.C. § 355(j). This process is "abbreviated" in that the generic drug manufacturer does not need to repeat all of the clinical testing required to support an NDA, as long as the generic drug product is "the same as" an approved drug product, meaning that it is "identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use." 21 C.F.R. § 314.92(a)(1). A generic drug product must also be shown to be "bioequivalent to the reference listed drug," 21 C.F.R. § 314.94(a)(7)(i), meaning that there is no "significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study," 21 C.F.R. § 314.3. Nevertheless, the manufacturer must still provide to FDA all of the "information required under § 314.50(d)(1)" for a new drug regarding the components used in or in the manufacture or packaging of the proposed generic drug. 21 C.F.R. § 314.94(a)(9)(i). The manufacturer must also "identify and characterize the inactive ingredients in the proposed drug product and provide information demonstrating that such inactive ingredients do not affect the safety or efficacy of the proposed drug product." 21 C.F.R. § 314.94(a)(9)(ii). In other words, in its assessment of a proposed generic drug product's safety, the FDA must consider and account for all of the same information regarding the products' components as it does for a new drug in the NDA process.

Once a small molecule drug—whether brand-name or generic—is approved, its manufacturer is prohibited from making any "major changes" to the product without FDA approval. 21 C.F.R. §§ 314.70(b)(1), (3). "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." 21 C.F.R. § 314.70(b)(1). Examples of such changes that require FDA approval include "changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients," as well as any "[c]hanges in a drug product container closure system that controls the drug product delivered to a patient or changes in the type (e.g., glass to high density polyethylene (HDPE), HDPE to polyvinyl chloride, vial to syringe) or composition (e.g., one HDPE resin to another HDPE resin) of a packaging component that may affect the impurity

profile of the drug product." 21 C.F.R. §§ 314.70(b)(2)(i), (vi). Therefore, a drug manufacturer often may not alter an approved drug product's formulation or the formulation of its packaging without FDA's further approval. Federal law thus "governs the presence of PFAS" in drug products and their packaging.

2. FDA Regulation of Biological Products

Biological products, or biologics, are drugs made from living organisms. Specifically, a "biological product" is defined as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i)(1); 21 C.F.R. § 600.3(h). Compared with conventional drugs, biologics tend to be relatively large and complex molecules, and may be composed of proteins, amino acids, carbohydrates, or nucleic acids. Biologics may also be cells or tissues used in transplantation. Biologics thus include vaccines, growth factors, immune modulators, monoclonal antibodies, and other products derived from human blood and plasma. There is also a category of biologics called "biosimilars," which are "highly similar" to a brand-name biologic, "notwithstanding minor differences in clinically inactive components," and for which "there are no clinically meaningful differences . . . in terms of the safety, purity, and potency." 42 U.S.C. § 262(i)(2).[2] The FDA regulates biological products under both the FFDCA, 21 U.S.C. § 321(g)(1) (all biological products fall within the statutory definition of "drugs"), and the Public Health Service Act ("PHSA"), 42 U.S.C. § 201 et seq. *See* 42 U.S.C. § 262(j) (stating that the FFDCA "applies to a biological product subject to regulation under this section," except for the purposes of pre-market approval, as discussed below).

Similar to its regulation of conventional small molecule drugs, the FDA regulates originator biologics and biosimilars with such broad control that federal law "governs the presence of PFAS" in such products and their packaging. Under the PHSA, all originator biologics and biosimilars are subject to pre-market approval ("licensing") following the submission of a Biologics License Application ("BLA"). 42 U.S.C. §§ 262(a)(1)(A) (originator biologics), 262(k) (biosimilars).[3] Analogously to its role in the NDA process for new drugs, the FDA may only approve a BLA and issue a license for the proposed biological product if it determines that the product is "safe, pure, and potent" and "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C). Substantially similar requirements apply to BLAs for biosimilars. 42 U.S.C. § 262(k)(2)(A)(i). Therefore, as for conventional drugs, FDA's approval and licensure of a biological product requires that the agency determine that the product is safe for its intended uses.

Because they are made from living organisms and not chemically synthesized, originator biologics and biosimilars are unlikely to contain PFAS. However, as for conventional drugs, PFAS may be used in the container closures, delivery devices (medical devices), or packaging of

[2] Unlike a generic drug, which generally must be an exact copy of an approved brand-name drug, a biosimilar must be "highly similar" to, and have no clinically meaningful differences from, its reference biologic.

[3] Biological products intended for use in animals are separately regulated as veterinary products by the U.S. Department of Agriculture's Animal Health Inspection Service rather than the FDA. 21 U.S.C. § 151; 21 C.F.R. § 510.4.

some biological products, including ampoules, vials, cartridges, syringes, and autoinjectors. The same CGMP requirements for drug packaging explicitly apply to the packaging of biological products, and FDA therefore has identical control over the components of such packaging as it does for conventional drugs. 21 C.F.R. § 210.2(a).

Therefore, as for conventional drugs, federal law comprehensively controls the component substances and parts of biological products and their packaging licensed for distribution and sale in the United States. Federal law therefore "governs the presence of PFAS" in or used in the manufacture or packaging of originator biologics and biosimilars, and those products therefore are "exempt from" the requirements of Section 1614, including without limitation both Maine's product notification requirement and its subsequent ban on sales or distribution for products that contain "intentionally added PFAS." 38 M.R.S. § 1614(4).

3. FDA Regulation of Non-Prescription Drugs

To market a non-prescription ("over-the-counter," or "OTC") drug in the United States, a manufacturer may choose to go through the NDA process, but may instead use the FDA's OTC drug monograph process, if available for the contemplated class of drug. A "monograph" is an administrative order that "establishes conditions, such as active ingredients, uses (indications), doses, routes of administration, labeling, and testing, under which an OTC drug in a given therapeutic category (e.g., sunscreen, antacid) is generally recognized as safe and effective (GRASE) for its intended use." U.S. FDA, *OTC Drug Review Process | OTC Drug Monographs*, https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs (last updated June 28, 2022); 21 U.S.C. § 355h; 21 C.F.R. § 330.1.[4]

While both the NDA and monograph processes involve safety determinations by FDA, a primary difference between them is that NDA approval permits the marketing of a specific, finished drug product, whereas the OTC drug monograph process focuses on the safety and effectiveness of certain active ingredients within a drug category. If an OTC drug product complies with a monograph (compliance is assessed during FDA's inspection process), it does not need FDA's specific approval prior to marketing because the agency has already determined that the drug product is GRASE. 21 U.S.C. § 355h(a).

Despite the monograph process' primary focus on active ingredients, OTC drugs can only be GRASE if they meet various safety conditions related to their other components. These include requirements that an OTC drug product "contains only suitable inactive ingredients which are safe in the amounts administered." 21 C.F.R. § 330.1(e). If manufactured and packaged in compliance with a monograph, an OTC drug product is deemed safe under federal law, including, but not limited to, with respect to all components of that drug product and packaging.

[4] Prior to the enactment of the CARES Act, P.L. 116-136, on March 27, 2020, monographs were rules promulgated through notice and comment. *See generally* Cong. Res. Serv., R46985, *FDA Regulation of Over-the-Counter (OTC) Drugs: Overview and Issues for Congress* (Dec. 2021), https://sgp.fas.org/crs/misc/R46985.pdf.

4. FDA Regulation of Drug Packaging

Finally, in addition to its safety review and determination with regard to drug products, FDA also closely controls the packaging of those products. The FFDCA explicitly prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated," 21 U.S.C. § 331(a), and a drug is by definition adulterated "if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health," 21 U.S.C. § 351(a)(3). More specifically, an NDA or ANDA must include "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of" the subject drug. 21 U.S.C. § 355(b)(1)(A)(iv).

But the FDA's oversight over drug packaging goes still deeper: all drugs marketed in the United States must be packaged according to the Current Good Manufacturing Practices ("CGMP") defined in 21 C.F.R. pts. 210 and 211. Failure to comply with the minimum CGMP standards for drug packaging "shall render such drug to be adulterated." 21 C.F.R. § 210.1(b). With respect to packaging and packing components, FDA's regulations recognize that drug packaging is important to maintaining drug quality. The CGMP regulations are clear that a drug's packaging must "not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug." 21 C.F.R. § 211.94(a). It is thus prohibited by federal regulation for drug packaging to incorporate any substance that might negatively affect a drug's safety.

In sum, federal law comprehensively governs and controls the component substances and parts of all drug products and packaging approved for distribution and sale in the United States. Federal law therefore "governs the presence of PFAS" (and any other substances) in or used in the manufacture or packaging of new and OTC drug products. Such products are therefore "exempt from" the requirements of Section 1614, including without limitation both Maine's product notification requirement pending material restriction. 38 M.R.S. § 1614(4).

B. Animal Drugs

Animal drugs include "any drug intended for use for animals other than man, including any drug intended for use in animal feed," and the FDA regulates them—and controls their component parts—analogously to how it regulates human drugs. 21 U.S.C. § 321(v). Animal drug products and their packaging are therefore exempt from the requirements of Section 1614.

Like human drugs, animal drugs must generally be approved by the FDA prior to marketing through a New Animal Drug Application ("NADA") or an Abbreviated New Animal Drug Application ("ANADA") for generic animal drugs. The FDA may approve a NADA or ANADA only upon a determination that the proposed animal drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. §§ 360b(d), (n); 21 C.F.R. § 514.111(a). And as for 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." 21 U.S.C. §§ 360b(b)(1), (n)(1)(G). In other words, all substances used in a new or generic animal drug

product or its manufacture or packaging are disclosed to FDA as part of every NADA or ANADA package.

Additionally, and also as for human drugs, an animal drug manufacturer may not make "any change in the drug, 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 as these factors may relate to the safety or effectiveness of the drug" without FDA's prior approval. 21 C.F.R. § 514.8(b)(2)(i). Such changes include any "[c]hanges in a drug product container closure system that controls the drug delivered to the animal or changes in the type or composition of a packaging component that may affect the impurity profile of the drug product." 21 C.F.R. § 514.8(b)(2)(ii)(E). Therefore, an animal drug manufacturer generally may not alter an approved animal drug product's formulation or the formulation of its packaging without FDA's further approval.

The FFDCA creates two additional (minor) pathways to market for animal drugs, both of which involve FDA oversight of the drugs' components, manufacturing, and packaging. A new animal drug may be conditionally approved for one year if it is "intended for a minor use or a minor species" or "is intended to treat a serious or life-threatening disease or condition or addresses an unmet animal or human health need," but has only a "reasonable expectation of effectiveness." 21 U.S.C. §§ 360ccc(a)(1)(A), (a)(2)(B).[5] However, new animal drugs for which conditional approval is sought "are subject to the same safety standards that would be applied to new animal drugs," and must be properly manufactured. 21 U.S.C. §§ 360ccc(a)(1)(C)–(D).

Separately, drugs listed on FDA's Index of Legally Marketed Unapproved New Animal Drugs for Minor Species are unapproved but have legal marketing status for specific uses in certain species. 21 U.S.C. § 360ccc-1. To be eligible for indexing, a drug must be intended "for use in a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals," or "for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with" the same standards applied to new animal drugs. 21 U.S.C. § 360ccc-1(a)(1). And as for other animal drugs, an application to index an animal drug must include "information regarding the components and composition of the new animal drug" and "a description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such new animal drug." 21 U.S.C. § 360ccc-1(c)(1)(C)–(D).

In short, as it does for human drugs, the FDA closely oversees the composition of animal drugs and their manufacture and packaging. Federal law thus "governs the presence of PFAS"—as it governs the presence of all components—in animal drug products so as to exempt those products and their packaging from the requirements of Section 1614.

[5] Only four animal drugs currently appear to be conditionally approved. 21 C.F.R. §§ 516.812–2980.

C. Medical Devices

The FDA began regulating medical devices in 1976, when Congress enacted the Medical Device Amendments to the FFDCA, Pub. L. No. 94-295, 90 Stat. 539 (1976).[6] The Amendments were intended to provide a "reasonable assurance of the safety and effectiveness" of medical devices intended for use in humans. 21 U.S.C. § 360c(a)(1)(A)(i). Because the FDA strictly controls the composition and packaging of medical devices, federal law "governs the presence of PFAS" in such products, which are therefore exempt from the requirements of Section 1614.

The FDA classifies medical devices into three classes based on their risk profiles, and regulates those classes separately. Class I devices, such as bandages and toothbrushes, are considered low to moderate risk, such that "general controls" are "sufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A)(i). General controls apply to all medical devices and include prohibitions on adulteration and misbranding, a requirement that device producers register with the FDA, and various recordkeeping and reporting requirements. 21 U.S.C. §§ 351, 352, 360, 360i. As for drugs, devices may not "consist[] in whole or in part of any filthy, putrid, or decomposed substance," nor may their containers be "composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health." 21 U.S.C. §§ 351(a)(1), (3). While the FDA does not specifically evaluate the component parts of Class I devices prior to their distribution or sale, such devices and their packaging may not include any substance that would render them adulterated.

Both general and special controls apply to Class II devices, which are moderate-to-high risk devices such as powered wheelchairs and some pregnancy test kits. A Class II device is one which "cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance." 21 U.S.C. § 360c(a)(1)(B). These "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." *Id.* To the extent that any Class II device's special controls govern the material composition of such a device's components or packaging, federal law "governs the presence of PFAS" in that device or packaging, and those products are thus exempt from the requirements of Section 1614 under the terms of Section 1614(4)(A).

A Class III device is one for which there is insufficient information both to determine that general controls would be sufficient and to establish special controls sufficient to provide a reasonable assurance of the device's safety and effectiveness. 21 U.S.C. § 360c(a)(1)(C)(i). Class III devices usually sustain or support life, are implanted, or present potential unreasonable

[6] A medical device is defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(1).

risk of illness or injury, and include stents, pacemakers, and breast implants. Such devices are subject both to the same general controls as apply to all medical devices, and to the FDA's pre-market approval ("PMA"). Approval may be achieved by submission of a PMA application or by "510(k) notification," including a demonstration that the device is "substantially equivalent" to an already-approved Class III device.

The FDA clearly governs and controls the composition and ingredients of Class III medical devices approved through either of these processes. As part of a PMA application, a device manufacturer must submit a "complete description of: (i) The device, including pictorial representations; (ii) Each of the functional components or ingredients of the device if the device consists of more than one physical component or ingredient; . . . and (v) The methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device . . . ." 21 C.F.R. § 814.20(b)(4). Any PFAS incorporated into the subject device or its packaging would thus be considered by the FDA, and federal law therefore "governs the presence of PFAS" in Class III devices approved for distribution and sale by the FDA.

Additionally, some Class III devices are sold under a pre-market notification and demonstration of "substantial equivalence" to an approved (or "predicate") device. 21 U.S.C. § 360c(f)(1)(A)(ii). A device is "substantially equivalent" to a predicate device if it has "the same intended use" and "the same technological characteristics" as the predicate device, or if it has different technological characteristics, then it "does not raise different questions of safety and effectiveness than the predicate device" and, if requested by the FDA, "appropriate clinical or scientific data . . . demonstrate[] that the device is as safe and effective as a legally marketed device." 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100(b). Accordingly, a 510(k) notification must describe "the significant physical and performance characteristics of the device, such as device design, material used, and physical properties," and a comparison between the subject and predicate devices' "technological characteristics," including their "design, material, chemical composition, [and] energy source." 21 C.F.R. §§ 807.92(a)(4), (6). The FDA reviews each 510(k) notification and subsequently either requests additional information or issues an order declaring whether or not the subject device is substantially equivalent to its approved predicate device. 21 C.F.R. § 807.100(a).

Any question with regard to such devices' safety, including due to their "physical properties" or "chemical composition," would prevent the FDA from determining that a device is substantially equivalent to a predicate with a reasonable assurance of safety. Furthermore, a 510(k)-notified device that has "undergone any significant change or modification that could significantly affect the safety or effectiveness of the device" cannot be marketed without the FDA's approval of a supplementary 510(k) notification, including "appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety . . . of the device." 21 C.F.R. § 807.87(g). In short, though the FDA does not affirmatively approve the chemical composition of medical devices subject to 510(k) notification, the agency only permits their distribution or sale following a review of information regarding that composition, and device manufacturers cannot significantly alter the composition of their devices without further agency permission. Therefore, as for Class III devices subject to pre-market approval, federal law "governs the presence of PFAS" (and other chemical components) in Class III devices subject to pre-market

notification. All Class III devices are therefore exempt from the requirements of Section 1614 under the terms of Section 1614(4)(A).

III. FEDERAL LAW PREEMPTS SECTION 1614 AS APPLIED TO FDA-REGULATED PRODUCTS

A. Principles of Federal Preemption

The Supremacy Clause of the U.S. Constitution provides that federal law "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. This clause gives Congress the power to preempt state law, such that "state law that conflicts with federal law is without effect." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992). "[T]he purpose of Congress is the ultimate touchstone of preemption analysis." *Id.* at 516; *see also Consumer Data Indus. Ass'n v. Frey*, 26 F.4th 1, 5–6 (1st Cir. 2022) ("To illuminate this intent, we start with the text and context of the provision itself.") (quotations omitted).

"In general, there are three different types of preemption – express, conflict, and field." *Consumer Data Indus.*, 26 F.4th at 5 (quotations omitted). "Express preemption occurs when congressional intent to preempt state law is made explicit in the language of a federal statute." *Id.* By contrast, "[c]onflict preemption takes place when state law imposes a duty that is 'inconsistent—*i.e.*, in conflict—with federal law.'" *Id.* (quoting *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1480 (2018)). Conflict preemption is itself divided 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.'" *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).

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." *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) ("Federal law impliedly preempts state law where it is impossible for a private party to comply with both state and federal requirements.") (quotations omitted). 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.'" *Consumer Data Indus.*, 26 F.4th at 5 (quoting *Murphy*, 138 S. Ct. at 1480).

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." *Maine Forest*, 51 F.4th at 6 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). This presumption "does not apply, though, 'when the State regulates in an area where there has been a history of significant federal presence.'" *Id.* (quoting *United States v. Locke*, 529 U.S. 89, 108 (2000)).

DEP's Posting Draft recognizes that products may be exempt from Section 1614's requirements because they are either expressly or implicitly (conflict or field) preempted by federal law, noting that federal preemption "can be expressly written into the enabling statute or implicit where the structure and scope of the federal law reflects the intent to preempt." Posting Draft § 4(A)(1), Note.

Most case law related to the federal preemption of state regulation of FDA-regulated drugs, biologics, animal drugs, or medical devices concerns state labeling or warning requirements for such products, often as imposed through state product liability causes of action. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that 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). As discussed below, the FFDCA, PHSA, and other federal laws implicitly and explicitly preempt application of Maine's PFAS law and regulations to FDA-regulated products and packaging.

B. Federal Preemption as Applied to Human and Animal Drugs

Federal law preempts any state law that purports to control or ban the ingredients, components, or packaging of 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 federal preemption analysis 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." 21 U.S.C. § 393(b). As detailed above, 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, its licensing of an originator biologic or biosimilar, and its promulgation of an OTC monograph or indexing of certain minor animal drugs all necessarily require the agency to determine that such product is "safe" for its approved conditions of use.

Federal courts have held that state safety determinations contrary to FDA approval of a drug necessarily interfere with Congress' intent in enacting the FFDCA. Most prominently, the District Court for the District of Massachusetts recently 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. *See Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696 (D. Mass. Apr. 15, 2014). "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." *Id.* at *2. 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." *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 to a license to do so. Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 Mich. St. L. Rev. 1, 32 (2016). The same logic applies to the agency's approval of an ANDA, BLA, NADA, or ANADA. A state may not unilaterally decline to recognize such a federal license. *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").

The Maine legislature enacted Section 1614, and so will prohibit the distribution or sale of all in-scope products that contain PFAS, after it determined that such products necessarily "pose[] a significant threat to the environment of the State and to the health of its citizens." 2021 Me. Legis. Serv. ch. 477 (H.P. 1113) (L.D. 1503). As applied to FDA-approved drug products (including new and generic human drugs, biological products, and animal drugs), this legislative determination runs directly counter to the FDA's own risk analysis and safety determination. "The Constitution does not allow" Maine to "countermand the FDA's determinations" and so "undermine the FDA's ability to make drugs available to promote and protect the public health." *Zogenix*, 2014 WL 1454696 at *2. "Whether a drug may be marketed" is solely the FDA's to decide. *Gross*, 825 F. Supp. 2d at 659. And Maine is additionally prohibited from unilaterally declining to recognize a drug manufacturer's license to sell afforded by FDA's approval of its NDA, ANDA, BLA, NADA, or ANADA. The Section 1614(5) product ban is therefore preempted by federal law as applied to drug products.

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." 21 U.S.C. § 360k(a). At minimum, this provision expressly preempts Section 1614's notification requirement and material restriction as applied to Class III devices subject to the FDA's pre-market approval.

In enacting Section 1614, the Maine legislature found that pre-market notification to DEP, as well as a subsequent ban on all sales, of products that incorporate "intentionally added PFAS" was "immediately necessary for the preservation of the public peace, health and safety."

2021 Me. Legis. Serv. ch. 477 (H.P. 1113) (L.D. 1503). As applied to medical devices, the statute therefore "relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a)(2).

These Maine requirements are also certainly "different 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. *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). Section 1614's notification requirement and material restriction are plainly "different from" and "in addition to" federal controls on device safety and so are expressly preempted.

The FFDCA's express preemption provision preempts state requirements that differ from federal "requirements" related to device safety. The Supreme Court has thus 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. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322–23 (2008). Both Section 1614's notification requirement and material restriction are therefore expressly preempted by federal law as applied to FDA-approved Class III devices.

By contrast, the express preemption provision does not obviously apply to Class III devices permitted following pre-market notification, as the 510(k) process does not impose "requirements" but instead holds devices to a standard of "substantial equivalence" to an approved device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493–94 (1996). Class I and Class II devices may similarly avoid the categorical preemption of state regulations related to device safety.

Nevertheless, Section 1614's material restriction, at least, is implicitly preempted by federal law for <u>all</u> medical devices. As noted above, 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. 21 U.S.C. § 360c(a)(1)(A)(i). 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." *Riegel*, 552 U.S. at 325. Section 1614's material restriction is intended to increase safety without regard for product efficacy. As applied to medical devices, it 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. *Maine Forest Prod. Council*, 51 F.4th at 6. The logic applied to state bans on FDA-approved drugs in *Zogenix* 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." *Zogenix*, 2014 WL 1454696 at *2 (altering "drugs" to "devices"). The Section 1614(5) product ban is therefore preempted by federal law as applied to all medical device products.

IV. DEP MUST DETERMINE THE SCOPE OF ITS REGULATORY AND ENFORCEMENT AUTHORITY IN IMPLEMENTING SECTION 1614

DEP asserts in the Posting Draft, without citation, that it "does not have the authority to independently make a finding of law or accept an assertion that implied preemption exists" unless "an applicable opinion from a court having jurisdiction in Maine finds that preemption of parts of this program is implied." Posting Draft § 4(A)(1), Note. DEP is not only authorized but required to consider the scope of its regulatory and enforcement authorities. DEP should not attempt to apply Section 1614 to FDA-regulated products and their packaging because a court would find such application *ultra vires*.

Section 1614 states that DEP "shall adopt rules to implement this section." 38 M.R.S. § 1614(10). DEP "consists of the Board of Environmental Protection and the Commissioner of the Department," 38 M.R.S. § 341-A(2), and the Maine legislature intended the Board "to provide informed, independent and timely decisions on the interpretation, administration and enforcement of the laws relating to environmental protection," 38 M.R.S. § 341-B. DEP's enabling statute further states that the Department "may adopt . . . reasonable rules . . . necessary for the interpretation, implementation and enforcement of any provision of law that the department is charged with administering as provided in this section." 38 M.R.S. § 341-H. The Supreme Judicial Court has interpreted this text to grant DEP "general rule-making authority" with regard to the statutes within its purview. *Conservation L. Found., Inc. v. Dep't of Env't Prot.*, 823 A.2d 551, 559–60 (Me. 2003). Furthermore, rules promulgated by DEP "are subject to public notice, modification, and judicial review" under the Maine Administrative Procedure Act, which "compensates substantially for the want of precise legislative guidelines" in the determination of the permissible scope of the Department's regulatory authority. *Uliano v. Bd. of Env't Prot.*, 977 A.2d 400, 411–12 (Me. 2009) (internal edits and quotations omitted)[7]; *see also Doane v. Dep't of Health & Hum. Servs.*, 250 A.3d 1101, 1109 (Me. 2021) ("[B]ecause the subject matter of the regulation at issue here concerns public health and safety, a wide amount of rulemaking latitude may be necessary."). Finally, when "preparing and adopting rules," the Maine Administrative Procedure Act requires that DEP "strive to the greatest possible extent" to "consider the goals and objectives for which the rule is being proposed, possible alternatives to achieve the goals and objectives and the estimated impact of the rule." 5 M.R.S. § 8057-A(1).

DEP cannot adopt "informed" or "reasonable rules" for the administration of Section 1614 without "striv[ing] to the greatest possible extent" to understand the legislature's "goals and objectives" in that statute. DEP must therefore consider, and certainly "may accept," a reasonable legal assertion that certain products are exempt from the requirements of Section 1614 under the terms of the statute. The Department may be correct that it cannot make a *final* legal determination with regard to the scope of its authority—any such determination will be "subject to public notice, modification, and judicial review" under the Maine Administrative Procedure Act. Nevertheless, in promulgating rules to implement and enforce Section 1614, DEP should strive to avoid unnecessary litigation by promulgating rules that are "reasonable" in light of the information—including legal arguments—before it. Though no state or federal court

[7] While the *Conservation Law Foundation* and *Uliano* courts interpreted the statutory provision codified at 38 M.R.S. § 341-D(1-B), that statute was repealed in 2011. 2011 Me. Legis. Serv. ch. 304 (S.P. 10) (L.D. 1). The Maine legislature simultaneously recodified substantially the same text at 38 M.R.S. § 341-H. *Id.*

in Maine has yet held that Section 1614 is preempted by federal law with regard to PPWG's members' FDA-regulated products, DEP must consider and administer Section 1614 in light of the legal arguments and judicial holdings presented in these comments and the public record.

V. SECTION 1614 EXEMPTS ALL PACKAGING AND PACKAGING COMPONENTS FROM ITS REQUIREMENTS

Separate from its exemption of products in which federal law "governs the presence of PFAS," Section 1614 also states that products "subject to Title 32, chapter 26-A or 26-B" are exempt from "this section." 38 M.R.S. § 1614(4)(B); *see also* Posting Draft §§ 4.A(2) (exempting products "subject to Title 32, §26-A, *Reduction of Toxics in Packaging*"), 4.A(3) (exempting products "subject to Title 32, §26-B, *Toxic Chemicals in Food Packaging*"). This exemption is not limited to provisions of chapters 26-A or 26-B that govern the presence of PFAS. Therefore, as DEP has recognized in the Posting Draft, the exemption covers all product packaging (including without limitation its components).

A. Overview of Title 32, Chapters 26-A and 26-B

By exempting products "subject to Title 32, chapter 26-A or 26-B" from Section 1614's scope, the Maine legislature has separated DEP's regulatory oversight over materials used in packaging from its oversight over PFAS in products, generally. Chapters 26-A and 26-B of Title 32 of the Maine Revised Statutes ("Chapter 26-A" and "Chapter 26-B," respectively) govern the presence of various chemicals, including but not limited to PFAS, in packaging and packaging waste.

Chapter 26-A, which is entitled "Reduction of Toxics in Packaging," "prohibit[s] the unnecessary addition of certain chemicals, such as lead, mercury, cadmium, hexavalent chromium, PFAS and phthalates, in packaging and packaging components." 32 M.R.S. § 1731. The statute defines a "package" as "a container used in marketing, protecting or handling a product," and "includes a unit package and a shipping container defined by the American Society for Testing and Materials in its annual book of standards as ASTM, D996; a food package; and unsealed receptacles such as carrying cases, crates, cups, pails, rigid foil and other trays, wrappers and wrapping films, bags and tubs." *Id.* at § 1732(4). In turn, the statute defines "packaging component" as "any individual assembled part of a package such as, but not limited to, any interior or exterior blocking, bracing, cushioning, weatherproofing, exterior strapping, coatings, closures, inks and labels." *Id.* at § 1732(5). These definitions broadly encompass all product packaging and containers, including their component parts and substances. With only limited exceptions, the statute applies to "[a]ll packages and packaging components." *Id.* at § 1734.

Chapter 26-A prohibits the sale or promotional use in the State of Maine of any package or packaging component that includes various substances. For instance, packages, packaging components, and packaged products are prohibited if they include any "inks, dyes, pigments, adhesives, stabilizers, coatings or any other additives to which" certain heavy metals have been intentionally introduced." *Id.* at §§ 1733(1), (2). Additionally, food packages are prohibited if they include "inks, dyes, pigments, adhesives, stabilizers, coatings, plasticizers or any other additives to which phthalates have been intentionally introduced," *id.* at § 1733(3-A), and DEP

also "may by rule prohibit [the sale of] food packages to which PFAS have been intentionally introduced," *id.* at § 1733(3-B). Chapter 26-A then states that "[n]o material used to replace lead, cadmium, mercury, hexavalent chromium, phthalates or PFAS in a package or packaging component may be used in a quantity or manner that creates a hazard as great as or greater than the hazard created by the prohibited heavy metal or chemical." *Id.* at § 1733(4).

Separately, Chapter 26-B specifically targets food packaging: it directs DEP to publish and revise a list of up to ten "food contact chemicals of high concern," 32 M.R.S. § 1742, and enables the department to "designate a food contact chemical of high concern as a priority food contact chemical," *id.* at § 1743. The manufacturers and distributors of a priority food contact chemical must then notify DEP in writing of their distribution of food packaging in Maine that contains such chemical substance. 32 M.R.S. § 1744(1).[8] Additionally, DEP's Board of Environmental Protection "may adopt rules prohibiting the manufacture, sale or distribution in the State of a food package containing a priority food contact chemical in an amount greater than a de minimis level" if it determines that "[d]istribution of the food package directly or indirectly exposes consumers to the priority food contact chemical" and "[o]ne or more safer alternatives to the priority food contact chemical are available at a comparable cost." 32 M.R.S. § 1744(1).

B. DEP's Posting Draft Correctly Follows the Plain Meaning of Section 1614 to Exempt All Packaging and Packaging Components from its Requirements

Section 1614 explicitly exempts all products "subject to" Chapters 26-A or 26-B from its notification requirement and pending material restriction. 38 M.R.S. § 1614(4)(B). DEP's Posting Draft follows the plain and ordinary meaning of the statute to exempt from Section 1614's requirements "all packing, packing components and food packaging as defined in 32 M.R.S. § 1732." Posting Draft §§ 4.A(2)–(3), Note.[9] PPWG agrees with and supports DEP's implementation of this exemption to Section 1614. As discussed below, all packages and packaging components as defined in 32 M.R.S. §§ 1732(4)–(5) are "subject to Title 32, Chapter 26-A or 26-B," and so are exempt from the requirements of Section 1614. PPWG members' product packaging is therefore exempt both from the Section 1614 notification requirement and pending material restriction.

When examining statutory text, Maine courts "construe [statutory] terms to give effect to the Legislature's intent in enacting the statute." *20 Thames St. LLC v. Ocean State Job Lot of Maine 2017, LLC*, 231 A.3d 426, 428 (Me. 2020) (quotations omitted). To do so, Maine courts will "interpret the statute in the context of the entire statutory scheme, and give the statute's words their plain, common, and ordinary meaning, such as people of common intelligence would usually ascribe to them." *Id.* (quotations and citations omitted). "In doing so, [courts] will avoid

[8] The written notice "must identify the food package, the number of units sold or distributed for sale in the State or nationally, the priority food contact chemical or chemicals contained in the food package, the amount of such chemicals in each unit of the food package and the intended purpose of the chemicals in the food package." 32 M.R.S. § 1744(1).

[9] This exemption applies only when such items are "actually used as packaging, packing components, or food packing, intended for marketing, handling, or protection of products," Posting Draft §§ 4.A(2)–(3), Note, while "packages, packaging components, and food packaging . . . when sold individually or in bulk and not used in marketing, handling, or protecting a product" are included under the definition of "products" subject to Section 1614's requirements, Posting Draft § 2(R).

results that are absurd, inconsistent, unreasonable, or illogical," and "[o]nly if the statute is susceptible of different meanings and therefore ambiguous, will [they] look to extrinsic indicia of legislative intent, such as the legislative history of the statute, to ascertain the Legislature's intent in enacting the statute." *Id.* (quotations and citations omitted).

Like courts in other jurisdictions, Maine courts often turn to dictionaries to understand a term or phrase's "plain, common, and ordinary meaning." No one dictionary appears to be more definitive than another. For example, the Supreme Judicial Court has recently cited to Black's Law Dictionary (11th ed. 2019), *20 Thames*, 231 A.3d at 428; *Portland Pipe Line Corp. v. City of S. Portland*, 240 A.3d 364, 368–69 (Me. 2020); the American Heritage Dictionary of the English Language (5th ed. 2016), *20 Thames*, 231 A.3d at 428; Webster's New World College Dictionary (5th ed. 2016), *id.*; Merriam-Webster's Collegiate Dictionary (11th ed. 2014), *Portland Pipe*, 240 A.3d at 368; Merriam-Webster Online Dictionary, *Jackson Brook Inst., Inc. v. Maine Ins. Guar. Ass'n*, 861 A.2d 652, 657 (Me. 2004); and Webster's Third New International Dictionary (1971), *id.* (superseded by Merriam-Webster's Unabridged Dictionary).

These dictionaries and others define the phrase "subject to" differently, but to substantially the same effect. The following are five such definitions:

- "To expose to the operation of some law or agency; to render liable to be affected," Black's Law Dictionary (11th ed. 2019);

- "Affected by or possibly affected by," Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/subject%20to;

- "Likely to be conditioned, affected, or modified in some indicated way," Merriam-Webster Unabridged Dictionary, https://unabridged.merriam-webster.com/unabridged/subject;

- "Being in a position or in circumstances that place one under the power or authority of another or others," American Heritage Dictionary of the English Language (5th ed. 2022), https://www.ahdictionary.com/word/search.html?q=subject;

- "Likely or prone to be affected by," New Oxford American Dictionary (3d ed. 2015).

All five of the dictionary definitions above make clear that one thing is "subject to" another when that latter thing controls or affects—or even potentially controls or affects—the former.

Chapter 26-A prohibits the sale or promotional use of any "package or packaging component" that incorporates certain heavy metals, and applies to "[a]ll packages and packaging components." 32 M.R.S. §§ 1733(1), 1734. Additionally, food packages may not contain phthalates, and DEP may by rule prohibit their sale if they incorporate PFAS. *Id.* at §§ 1733(3-A), (3-B). Food package manufacturers must also notify DEP if those packages incorporate any designated priority food contact chemical, and DEP may by rule prohibit their sale for incorporating such chemicals. 32 M.R.S. § 1743. All packages and packaging components are thus "exposed to the operation of," "affected by or possibly affected by," and "under the power

or authority of"—and so "subject to"—Chapter 26-A, and some packaging is even subject to Chapters 26-A and 26-B under multiple, overlapping provisions.

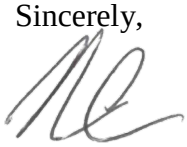
Unlike the statute's exemption for "product[s] for which federal law governs the presence of PFAS in the product in a manner that preempts state authority," the Maine legislature did not limit the packaging exemption to products regulated on account of other regulations on the use or incorporation of PFAS. *Compare id. with* 38 M.R.S. § 1614(4)(A). The legislature therefore intended for DEP to regulate packaging separately from, and not under, Section 1614's general regulation of PFAS in products.

By exempting all "product[s] subject to Title 32, chapter 26-A or 26-B," Section 1614(4)(B) therefore expressly exempts all packaging from its notification requirement and pending material restriction. PPWG commends Maine DEP for its proper implementation of this express exemption in the Posting Draft.

VI. CONCLUSION

PPWG thanks Maine DEP for considering its comments on Posting Draft. If you have any questions, please feel free to contact me.

Sincerely,



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