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VIA E-MAIL AND FEDERAL EXPRESS

Attn: Karen Winkel
Oregon Department of Consumer and Business Services
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Re: Comment on Oregon HB 4005 Notice of Proposed Rulemaking

Dear Ms. Winkel,

Thank you for providing stakeholders the opportunity to comment on the Oregon HB 4005 Notice of Proposed Rulemaking (the "Regulations") proposed by the Oregon Department of Consumer and Business Services (the "Department"). Pfizer Inc. ("Pfizer") is commenting on both the timing and the contents of the reports under Oregon HB 4005 (the "Statute"). Further, Pfizer has very serious concerns that the Regulations, as currently drafted, are unlawful and would provide inadequate protection of trade secrets.

I. Protections of Trade Secret Information Should Be Bolstered

The Statute seeks to require manufacturers to report detailed information about the costs and profits associated with specific drugs.¹ Much of this information constitutes critical trade secrets for any manufacturer. Further, the Statute and the Regulations state that the Department will publicly post information manufacturers report to the Department unless the Department, or the director, determines that such information is a trade secret.²

Disclosure of trade secret information would destroy a manufacturer's property interest in its trade secrets, undermine competition and innovation, and result in a significant, detrimental economic impact. While the Regulations make some effort to provide manufacturers an avenue to seek protection for its trade secrets, the Regulations fail to adequately protect manufacturer trade secrets and prevent the unlawful disclosure of such trade secrets.

A. Requests for Trade Secret Process Does Not Provide Adequate Opportunity for Judicial Review

Section 836-200-0540 of the Regulations articulates a process for manufacturers to request certain information it reports to the Department be exempt from public disclosure as a trade secret. Pfizer appreciates the Department's acknowledgement of the importance of the

¹ See, e.g. OR HB 4005 §(2)(3) (requiring manufacturers report, amongst other things, the "direct costs incurred by the manufacturer" to manufacture, market, and distribute specific prescription drugs).

² See OR HB 4005 §(2)(9). See also Sections 836-200-0540 and 836-200-0545 of the Regulations.

development of procedures for the identification of trade secret information and trade secret claims. Pfizer is concerned, however, that the Regulations do not provide adequate opportunity for judicial review of a decision by the Department to publicly disclose information that a manufacturer has designated as a trade secret.

For such review to be meaningful, the manufacturer must receive notice sufficiently in advance of intended publication, and the review must be fully adjudicated on the merits, before being rendered moot by a public disclosure. As presently proposed, the Regulations provide only 15 days for appeal to the director, 21 days from the director's decision to publicly disclose, and no express provision for a manufacturer to seek independent judicial review.³ The compressed timelines and lack of clarity as to whether information will be disclosed during litigation may compel manufacturers to seek temporary restraining orders at the outset of such litigation. These kind of accelerated proceedings would unnecessarily increase the burden on the courts, manufacturers, and the Department itself.

Pfizer encourages the Department to modify the Regulations to specify that the Department will not disclose designated trade secret information upon a timely-filed request for judicial review. Pfizer proposes adding the following language to Section 836-200-0545(5) of the Regulations:

If, within 60 days of the director's decision to disclose information designated as a trade secret, a manufacturer commences an action in a court of competent jurisdiction to enjoin the Department from disclosing such information, the Department will not disclose the information until final resolution of the action, including any appeals.

A meaningful opportunity for judicial review is especially important given that there may be important legal questions to resolve regarding the scope of the Regulations. For example, the requirements for written justification of claims of trade secret protection appear to be significantly more onerous and burdensome than needed to establish trade secret status under ORS § 646.461, the federal Defend Trade Secrets Act, 18 U.S.C. § 1839(3) (the "DTSA"), or other states' laws, which are implicated by the Statute and the Regulations.

Section (4) of ORS § 646.461 provides:

'Trade secret' means information, including a drawing, cost data, customer list, formula, pattern, compilation, program, device, method, technique or process that: (a) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and (b) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

³ See Section 836-200-0540 of the Regulations.

By contrast, section 836-200-0540 of the Regulations contains additional requirements such as: “The information is known only to certain individuals within the manufacturer’s organization” and “[t]he public interest does not require disclosure of the information.” Similar discrepancies exist between the Regulations and the DTSA and the laws of other states. To address these conflicts, Pfizer proposes that the trade secret justification requirements listed in Regulations 836-200-0540(1)(b) be harmonized with those of ORS § 646.461.

B. Other Trade Secrets Manufacturers May Report Pursuant to the Regulations Are Unprotected

The Regulations require manufacturers to provide the Department with additional information, some of which is highly likely to constitute a trade secret. Notably, Sections 836-200-0535 and 836-200-0525 of the Regulations require manufacturers to provide the Department with an explanation of why any information the Department requests is unavailable to the manufacturer, a description of the missing information, and the circumstances contributing to the manufacturer’s inability to provide the information. Such explanations necessarily implicate a manufacturer’s confidential business strategies and internal processes. As such, this information raises concerning trade secret issues.

The Regulations and the Statute do not currently provide any trade secret protection for additional information a manufacturer reports pursuant to the Regulations. Further, trade secret disclosures mandated by certain statutes in other states often contain statutory language that indicates the information reported to the government is confidential and not subject to public disclosure. For example, Vermont’s drug price transparency law, 18 V.S.A. §4635, provides the following protections for manufacturers:

Information provided to the Office of the Attorney General . . . is exempt from public inspection and copying under the Public Records Act and shall not be released in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the information

18 V.S.A. § 4635(e).

This failing in the Regulations creates a conflict in the Oregon regime, as compared to other states’ laws. Accordingly, Pfizer suggests the Department add to Section 836-200-0525 of the Regulations a bullet (6) that reads as follows:

Information manufacturers provide pursuant to this section is exempt from public inspection or copying under O.R.S. § 192.311, *et. seq.*, and shall not be released in a manner that is likely to compromise the financial, competitive, other confidential, and/or proprietary nature of the information.

II. Key Terms Related to Reporting Elements Are Undefined

While the Statute requires manufacturers to report to the Department specific cost and profit information for individual drugs, the Statute and the Regulations fail to define key terms, making the regime one that is void for vagueness.⁴

For instance, neither the Regulations nor the Statute define “specialty drug.” However, the Regulations make numerous references to a “new specialty drug report.”⁵ While “specialty drug” is not defined, the Regulations define “new prescription drug” in Section 836-200-0505(6). Additionally, for instance, the current draft of Section 836-200-0555(2) is unclear about the number of additional assessments levied against a manufacturer. Notably, the language is ambiguous as to whether the additional assessment is due each time a manufacturer files a report under the Statute or whether the additional assessment is due each time a manufacturer files more than one report under the Statute.

III. Threshold for Reporting Drug Price Increases Should be Limited in CY 2018

Section 836-200-0515(1) of the Regulations indicates that, for the initial reporting period, manufacturers need to report to the Department about drugs for which the “price at any point in 2018 was \$100 or more . . . and there was a net yearly increase of 10 percent or more in the price of the prescription drug . . . during 2018.” However, the Statute has an effective date of March 12, 2018, and an operative date of January 1, 2019.⁶ Requiring manufacturers to report on price increases that occurred prior to the enactment of the Statute constitutes statutory retroactivity and violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution and Oregon law.

The Supreme Court has long held there is a general presumption against statutory retroactivity.⁷ A statute operates retroactively if it attaches new legal consequences to conduct occurring before its effective date.⁸ Courts have declined to give retroactive effect to statutes that burden private rights unless Congress made its intent clear.⁹ In evaluating intent, Oregon courts have similarly noted that the lack of an express retroactivity clause in a statute is important, “because such clauses are commonplace and easy to draft in concept as well as in practice.”¹⁰ The Statute does not contain a retroactivity clause.¹¹

⁴ See *United States v. Williams*, 553 U.S. 285, 304 (2008) (“a statute which . . . requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law . . .”).

⁵ See, e.g., Section 836-200-0510(3) of the Regulations.

⁶ OR HB 4005 §§ 13 and 15.

⁷ *Landgraf v. USI Film Products*, 511 U.S. 244, 273 (1994) (“As a general rule there, is a presumption against statutory retroactivity.”).

⁸ *Id.* at 270 (“ . . . the court must ask whether the new provision attaches new legal consequences to events completed before [the statute’s] enactment.”).

⁹ *Id.*; see also *Walleri v. Federal Home Loan Bank of Seattle*, 965 F. Supp. 1459, 1465 (D. Or. 1997) (stating “clear congressional intent is required before a statute will be applied retroactively”).

¹⁰ *State ex rel. Juv. Dept. of Multnomah County v. Nicholls*, 97 P.3d 680, 684 (Or. Ct. App. 2004).

¹¹ See *SAIF Corp. v. Wolff*, 952 P.2d 1036, 1037 (Or. Ct. App. 1997) (providing as an example of a retroactivity clause: “Notwithstanding any other provision of law to the contrary, the amendments to . . . this Act apply to all

Under Oregon law, if a statutory provision is substantive in nature, it presumptively applies prospectively only.¹² If the application of a new law will impair existing rights, create new obligations, or impose additional duties with respect to past transactions, it otherwise is substantive in nature and does not apply retroactively unless the legislature expressly provides.¹³

The Regulations, as currently proposed, would clearly impose new duties with respect to transactions already completed, by requiring manufacturers to report to the Department under the Statute based on price increases that occurred prior to the effective date of the Statute. Moreover, the Statute attaches new legal consequences to these transactions by making manufacturers liable for civil penalties if they fail to comply with the Statute.¹⁴

Accordingly, Due Process requires that the Statute be applied only prospectively from its effective date. At a minimum, the Department should revise the Regulations to make clear that only price increases that occurred after the effective date of the Statute contribute toward the calculation of the 10% threshold established in the Section 2(2)(b) of the Statute used to determine what drugs are subject to reporting under the Statute.

IV. Account Generation Requirements Should Be Aligned

Section 836-200-0510 of the Regulations requires reporting manufacturers to create an online account with the Department if they are required to submit a report under the Statute. However, the account generation timelines within Section 836-200-0510 appear inconsistent.

Manufacturers required to submit a new drug report pursuant to Section 2(6) of the Statute must create an online account with the Department “no later than 10 days prior to submitting the report.”¹⁵ However, manufacturers required to submit a price increase report pursuant to Section 2(3) of the Statute must create an online account with the Department by March 15, 2019, for the first reporting period, and by February 15 in subsequent years.¹⁶

The Department should align the account generation requirements for the two reports manufacturers need to submit under the Statute. Accordingly, Pfizer suggests that Section 836-200-0510 be revised to read as follows:

Reporting manufacturers without an online account with the department that are required to file a report under OAR 836-200-0515(1), OAR 836-200-0515(2), or OAR 836-200-0520 must create an online account with the department no later than 10 days prior to submitting the report.

claims or causes of action existing or arising on or after the effective date of this Act, regardless of the date of injury or the date a claim is presented, and this Act is intended to be fully retroactive.”

¹² *Nicholls*, 97 P.3d at 684 (“... if [a statute] is substantive, it presumptively applies prospectively only.”).

¹³ *Id.* at 686.

¹⁴ OR HB 4005 § 3.

¹⁵ Section 836-200-0510(3) of the Regulations.

¹⁶ Section 836-200-0510(1)-(2) of the Regulations.

V. Additional Information Requests Should Be Aligned with the Statute

While the Statute permits the Department to request “supporting documentation or additional information concerning [a manufacturer’s] report”, the Statute expressly limits the Department’s requests to information “concerning the report.”¹⁷ The Regulations attempt to expand the Department’s ability to request additional information from a manufacturer beyond the scope of the Statute. That attempt is without statutory authority and is, as a consequence, void.

Section 836-200-0535(1) of the Regulations purport to allow the director to “submit a written request for supporting documentation or additional information to the manufacturer.” Consistent with the Statute’s express limitation on the Department’s ability to request information from manufacturers, this section of the Regulations should be limited to requests concerning the manufacturer’s report.

Section 836-200-0515(2) of the Regulations also seek to improperly expand the scope of the director’s additional information requests to information that “enable[s] the director to conduct an analysis of factors affecting drug prices for the purposes of providing recommendations to the Legislature . . .” This language seeks to permit the director to secure information from drug manufacturers about drug prices not related to a manufacturer’s report. As such, this language violates the statutory limitation.

* * *

Thank you for providing Pfizer this opportunity to comment on the Regulations and for your attention to this matter.

Sincerely,



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Pfizer Inc.

cc: Amanda Perez, Assistant General Counsel, Pfizer Inc.
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¹⁷ OR HB 4005 § (2)(7)(a).