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Oregon Bill S.B. 792 is Unconstitutional

Oregon Bill S.B. 792 proposes to penalize pharmaceutical manufacturers that advertise prescription drug products in Oregon without "clearly and conspicuously" disclosing in the advertisement the "wholesale price for the prescription drug paid by pharmacies located in [Oregon]." S.B. 792 defines advertising as communication within the state "by newspaper, radio, television or other print, broadcast or other electronic medium information designed to create public interest in a prescription drug." This bill is legally infirm and is vulnerable to constitutional challenges under well-established judicial doctrine regarding preemption and the dormant commerce clause.

I. Oregon Bill S.B. 792 is preempted by the Federal Food, Drug, and Cosmetic Act (FDCA)

Pursuant to the Supremacy Clause of the US Constitution,[1] state laws may be preempted if Congress expressly so states,[2] if Congress has acted to "occupy the field" in which the state seeks to regulate,[3] or if there is a conflict between state law and federal law. A conflict may exist either if "compliance with both federal and state regulations is a physical impossibility"[4] or if state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[5] Congressional purpose is "the ultimate touchstone of every pre-emption case."[6]

Here, S.B. 792 would be preempted because the bill would present an obstacle to the accomplishment and execution of Congress's purposes and objectives. Congress has vested in the U.S. Food and Drug Administration (FDA) the authority and responsibility to regulate prescription drugs, including the advertising and labeling of prescription drugs.[7] The Federal Food, Drug, and Cosmetic Act (FDCA) plainly states that it is a prohibited act to introduce a misbranded drug into interstate commerce.[8] The FDCA specifies an extensive set of circumstances under which a drug "shall be deemed to be misbranded," including if an advertisement for the drug fails to comply with certain requirements.[9] The FDCA also states that a drug may be misbranded if its labeling or advertising is misleading based on the representations made or suggested therein or based on a failure to reveal material facts.[10]

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[1] U.S. Const. art. IV, cl. 2.
[2] *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008).
[3] *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992).
[4] *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).
[5] *Wyeth v. Levine,* 555 U.S. 555, 563 (2009).
[6] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).
[7] 21 USC 371(a) ("The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary."). Congress deliberately granted authority to regulate prescription drug advertising to FDA rather than any other federal agency. Although most advertising in the United States is regulated by the Federal Trade Commission (FTC), Congress specified in statute that prescription drug advertising will be subject to the FDCA and FDA's regulatory framework, rather than the Federal Trade Commission Act. Accordingly, a memorandum of understanding between FDA and FTC reflects that FDA "has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising. In the absence of express agreement between the two agencies to the contrary, the Food and Drug Administration will exercise primary jurisdiction over all matters regulating the labeling of [ ] drugs." Memorandum of Understanding between the Federal Trade Commission and the Food & Drug Administration, MOU 225-71-8003, *available at* https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm. Over time, Congress has expanded FDA's authority to regulate drug advertising. For example, in 2007, Congress enacted the Food and Drug Administration Amendments Act (FDAAA), which included provisions authorizing FDA to require pre-dissemination review of certain TV advertisements for prescription drugs and specifying civil penalties for false or misleading advertising.
[8] 21 USC 331(a).
[9] 21 USC 352(n).
[10] 21 USC 321(n). 21 USC 352(a) also states that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular.

Given this broad statutory mandate to protect the public from misbranded drugs, the FDA has promulgated an extensive regulatory framework to implement these provisions of the FDCA, including an entire part of its regulations devoted to requirements for prescription drug advertising.[11] These rules govern both the content and format of advertising and are intended, among other things, to ensure that prescription drug advertising is neither false nor misleading and that it is consistent with the drug's FDA-approved labeling. FDA has maintained and amended its prescription drug advertising regulations for over half a century.[12] FDA also has issued guidance documents that articulate the agency's current thinking and approach regarding various topics in prescription drug advertising.[13] FDA generally requires prescription drug advertising to be submitted to the agency on Form FDA 2253 at the time of first use,[14] and the agency has issued enforcement letters citing advertisements that it views as violating the advertising regulations and the misbranding provisions of the FDCA.

With respect to price information specifically, FDA has concluded that cost information is not the type of information that manufacturers must include in drug advertising.[15] Moreover, in certain contexts FDA has found that presentations of price and cost information in advertising and promotional labeling can be misleading, and the agency currently is conducting research to understand the impact on consumers' perceptions of a drug when price or cost information is included in advertising.[16] The potential for cost or economic information to be misleading is also reflected in a provision of the FDCA that establishes a safe harbor for promotion of health care economic information (HCEI). Congress limited this safe harbor to allow proactive dissemination of HCEI to specific, sophisticated audiences—rather than health care professionals or consumers more generally—because of the potential for HCEI to be misunderstood by those without the requisite expertise to interpret it.[17] Thus, both Congress and FDA have recognized that price and cost information has the potential to be misleading when it is incorporated in drug advertising and promotional labeling.

In short, FDA has determined that cost and price information is not required to be included in advertising, and in some instances both Congress and the agency have found that inclusion of such information can be misleading. As the Supreme Court held in *Geier v. American Honda Motor Company*, state law that affects a federal regulatory scheme by adding requirements that a federal agency has decided not to require is preempted as an obstacle to Congressional objectives.[18,19] By requiring clear and conspicuous disclosure of wholesale prices paid by pharmacies in Oregon, S.B. 792 would intrude on a framework meticulously developed by FDA to carry out Congress' intent for FDA to guard against prescription drug misbranding, and thus would be vulnerable to invalidation under well-established preemption principles.

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[11] 21 CFR Part 202.
[12] *See* Proposed Regulations Regarding Drugs, 28 FR 1447 (Feb. 14, 1963) (proposed rule introducing prescription drug advertising regulations).
[13] *See, e.g.,* Draft Guidance, Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs (2015); Draft Guidance, Direct-to-Consumer Television Advertisements—FDAAA DTC Television Ad Pre-Dissemination Review Program (2012); Final Guidance, Consumer-Directed Broadcast Advertisements (1999); Final Guidance, Consumer-Directed Broadcast Advertisements Questions and Answers (1999), *available at* https://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/guidances/ucm064956.htm.
[14] 21 CFR 314.81(b)(3)(i).
[15] *See, e.g.*, Prescription Drug Advertising: Questions and Answers, available at https://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm076768.htm (explaining that cost is an example of information that prescription drug advertising is not required to tell consumers).
[16] *See, e.g.*, Agency Information Collection Activities; Proposed Collection; Comment Request; Market Claims in Direct-to-Consumer Prescription Drug Print Ads, 80 FR 42823 (July 20, 2015) (describing an FDA research project that is examining whether product-related cues that are not part of the product [e.g., price and brand name] may affect consumer beliefs about product efficacy).
[17] 21 USC 352(a). In the report accompanying the initial enactment of this statutory safe harbor, Congress noted that "the [health care economic information safe harbor] is limited to analyses provided to such entities because such entities are constituted to consider this type of information through a deliberative process and are expected to have the appropriate range of expertise to interpret health care economic information presented to them ... and to distinguish facts from assumptions." H.R. Rep. No. 105-310 at 65 (1997).
[18] 529 U.S. 861, 881 (2000). Upon considering the history of a federal regulation that set safety requirements for automobiles, which included various seatbelt and airbag requirements, but not a specific requirement that cars include a driver's side airbag, the Court held that District of Columbia tort law could not be used to impose a duty that manufacturers include a driver's side airbag. *Id.* at 877-83.
[19] Even in *Wyeth v. Levine*, in which the Court rejected FDA's conclusion that its labeling regulations preempted state tort law, the Court considered "[the] agency's explanation of how state law affects the regulatory scheme" as part of its analysis. 555 U.S. 555, 576 (2009).

II. Oregon Bill S.B. 792 Violates the Dormant Commerce Clause

The Commerce Clause of the U.S. Constitution expressly grants Congress the power to regulate commerce "among the several states."[20] Implicitly, this clause also restrains state power when it reaches beyond its borders to regulate interstate commercial activity. This implicit restraint on state power is referred to as the dormant commerce clause.

Under the dormant commerce clause, any state or local action that blatantly discriminates against interstate commerce, or that imposes a burden on interstate commerce that is clearly excessive in relation to the putative local benefits, violates the commerce clause.[21] Normally, where a local measure merely burdens interstate commerce, it is subject to a balancing test that asks whether the burdens imposed on interstate commerce are "clearly excessive in relation to the putative local benefits."[22] However, state statutes that directly regulate commerce beyond the boundaries of a state are *per se* invalid.[23] The dormant commerce clause thereby "protects against inconsistent legislation arising from the projection of one state's regulatory regime into the jurisdiction of another," and does so "even if the extraterritorial reach was unintended by the state legislature."[24]

S.B. 792 runs afoul of the dormant commerce clause in both respects. First, the bill is *per se* invalid because it improperly reaches beyond the state of Oregon and regulates advertising that, by definition, takes place in other states. Pharmaceutical advertising is intrinsically an interstate activity. Prescription drug manufacturers typically advertise to the general public by purchasing an advertisement in a newspaper or magazine with a nation-wide circulation (*e.g.*, USA Today, TIME Magazine), running a broadcast TV advertisement on a national network (*e.g.*, NBC, CBS), or securing advertising placements on Internet sites that are accessible in all states. Even local or regional newspapers are read by out-of-state subscribers, including both on-line and through nationwide delivery services. Therefore, as a practical matter, there is no way for a pharmaceutical manufacturer to comply with S.B. 792 without impacting its advertising in every other state. As noted by one court, "[t]here is no technological or commercially realistic means to black [one state] out of a national advertising market" for pharmaceutical products.[25]

S.B. 792 would force a drug manufacturer to choose between two stark options: (i) run national advertisements that "clearly and conspicuously" bear an Oregon-specific wholesale price that is wholly irrelevant to citizens in the other 49 states, or (ii) forego national advertisements altogether. In either scenario, S.B. 792 will exert a substantial burden on a drug manufacturer's ability to engage in national advertising and essentially will impose Oregon's preference on other states. If other states were to adopt statutes similar to S.B. 792, the burden on drug manufacturers' ability to advertise nationally would be constrained even further.

Moreover, S.B. 792 is unconstitutional even under the *Pike* balancing test applicable to laws that impose an indirect burden on interstate commerce and that do not directly regulate commerce beyond a state's borders. The burdens imposed by the law—including potential additional advertising costs for manufacturers, and the chill on manufacturers' ability to advertise nationally—would not be outweighed by any legitimate benefits. The state interest in S.B. 792 is illusory and perhaps even counterproductive. Presumably, Oregon's goal is to provide consumers with pricing information to allow them to make better-informed decisions about their medical treatment options. Perhaps the state also hopes that price transparency will result in lower costs to consumers and to the healthcare system. But wholesale prices paid by pharmacies are unlikely to be meaningful to consumers who will see these advertisements. Not only are wholesale prices and actual retail prices different, but the actual cost of a prescription drug to the consumer varies significantly based on insurance coverage and other factors. The net cost of prescription drugs to

[20] U.S. Const. Art. I, § 8, cl. 3.
[21] *C & A Carbone, Inc. v. Town of Clarkstown, N.Y.*, 511 U.S. 383, 390 (1994).
[22] *See Pike v. Bruce Church, Inc.,* 397 U.S. 142 (1970).
[23] *See Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989); *Brown–Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, 579 (1986).
[24] *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989).
[25] *Knoll Pharm. Co. v. Sherman,* 57 F.Supp.2d 615, 623 (N.D. Ill. 1999).

the healthcare system also depends on numerous factors, including insurance coverage, rebates and discounts provided by drug manufacturers, and prescribing and utilization patterns determined by health care practitioners. As a result, there is little useful information consumers would gain if advertisements disclosed wholesale prices paid by pharmacies in the state, pursuant to S.B. 792.

In fact, the law may undermine its goal of providing more useful information to consumers. Prescription drug advertising serves important public health objectives, such as increasing awareness about treatable conditions and symptoms, conveying information about available therapies, prompting patients to engage in dialogue with their doctors, and encouraging compliance with physician-prescribed treatment regimens. However, if S.B. 792 has the effect of diminishing manufacturers' ability or willingness to engage in drug advertising, patients could ultimately receive less—rather than more—information about their prescription drug options.

In short, the burden imposed on interstate commerce is excessive in relation to the speculative benefits for Oregon citizens. As a result, S.B. 792 likely would fail the balancing test established in dormant commerce clause jurisprudence.