Your Generics & Biosimilars Industry

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Dear Ms. Spillane and Ms. Miller:

This letter supplements our April 7, 2022, letter to Governor Pritzker and expands upon the significant constitutional and legal vulnerabilities of HB 1780, the "Drug Take-Back Act." This bill is unconstitutional and highly vulnerable to a legal challenge whose defense would be borne by the taxpayers of Illinois. While AAM supports the proper disposal of unused medications, the drug take-back program that would be established in HB 1780 is flawed.

The Association for Accessible Medicines (AAM) is the leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines.

AAM respectfully requests a veto of HB 1780, the "Drug Take-Back Act," in its current form. As passed, HB 1780 requires manufacturers of drugs that are "sold or offered for sale in Illinois" to establish a take-back program for unused, unwanted, and expired medications, principally by paying law enforcement or DEA-authorized entities to do the collecting and disposing. It further obligates covered manufacturers to "pay all administrative and operational costs associated with establishing and implementing the drug take-back program in which it participates," and it bars manufacturers from "increas[ing] the cost of covered drugs to recoup the costs of a drug take-back program."

AAM recognizes the need to dispose of unused, unwanted, and expired medications safely and in an environmentally appropriate way. AAM supports efforts to promote sustainable and safety-enhancing drug take-back programs. Indeed, AAM and its members have supported, and

continue to support, innovative and wide-reaching programs like MyOldMeds.com and the DEA's National Prescription Drug Take Back Day.

As enacted, however, **HB 1780 is unconstitutional**. The bill's anti-pass-through provision applies in-state consequences to out-of-state prices and thus regulates prices charged outside of Illinois, in violation of the Commerce Clause. Indeed, a federal court recently declared an almost-identical anti-pass-through provision to be unconstitutional under the dormant Commerce Clause, and the State of New York was required to pay for the defense and reasonable attorney's fees of the plaintiff, our association. HB 1780 also requires competitors to engage in anti-competitive associations, in direct contravention of the federal patent laws and in violation of the Supremacy Clause and preemption principles. And it compels private enterprises to enter government-backed associations and engage in legislatively-prescribed speech, in violation of the First Amendment. We discuss these constitutional infirmities in detail below.

RELEVANT BACKGROUND

AAM previously requested that Governor Pritzker veto HB 1780. As AAM explained in its April 7 letter, HB 1780 suffers from a number of policy problems. The bill fails to require that brand-name drug companies pay their fair share of the take-back expenses it imposes; it is redundant, as Illinois already has a robust statewide drug collection infrastructure that works; it targets small manufacturers instead of Fortune 10 companies; and it threatens the savings Illinois patients currently receive from generic medicines.

We do not belabor those points here. Instead, we focus on the constitutional problems with the bill.

Under HB 1780, any manufacturer of a drug sold in Illinois must "establish, fund, and implement a drug take-back program independently or as part of a group of covered manufacturers." § 15. These take-back programs in turn fund and provide coordination for various independent "authorized collectors," namely law enforcement agencies and entities authorized to collect and dispose of drugs by the U.S. Drug Enforcement Administration, with responsibility shifting to the manufacturers to safely dispose of the drugs once collected. § 25. Take-back programs must work with any collector who demands to participate—at, it appears, whatever price that collector demands. § 25(b). And although manufacturers may propose to engage in a drug collection program on their own, the Illinois EPA has the authority "to ensure the proposals are coordinated to achieve" an effective and efficient statewide program. § 35(a). The bill also declares the intent "to exempt from State antitrust laws, and provide immunity through the state action doctrine from federal antitrust laws, activities that are undertaken pursuant to this Act that might otherwise be constrained by such laws." § 70.

In addition to running the drug take-back program, manufacturers must promote it using, among other things, "a single toll-free number and website and similar education, outreach, and promotional materials." § 45. (We refer to § 45 hereafter as the "promotion provision.") The contents of the materials are also set out in detail, requiring manufacturers to "discourag[e] residents from disposing of drugs in household waste, sewers, or septic systems," "promot[e] the

use of the drug take-back program so that where and how to return covered drugs is readily understandable to residents," and do so using "plain language and explanatory images to make collection services and discouraged disposal practices readily understandable by residents, including residents with limited English proficiency." § 45(2), (3), (5). Some promotion is banned, too: "Promotional materials … may not be used to promote in-home disposal products of any kind, including, but not limited to, in-home disposal products of authorized collectors participating in a drug take-back program." § 45(6). Finally, the bill obligates manufacturers to directly fund the take-back programs they are being forced to establish (although precisely from where the funding will come is a mystery). To that end, the bill provides:

> A manufacturer program operator, covered manufacturer, authorized collector, or other person may not charge:
>
> > (1) a specific point-of-sale fee to consumers to recoup the costs of a drug take-back program;
> >
> > (2) a specific point-of-collection fee at the time covered drugs are collected from a person; or
> >
> > (3) an increase in the cost of covered drugs to recoup the costs of a drug take-back program.

§ 55(c). We refer to § 55(c) hereafter as the "anti-pass-through provision" or the "pass-through prohibition."

Noncompliance with the pass-through prohibition, or any of the above requirements, comes with severe penalties. Under § 65(b), "any person who violates any provision of this Act is liable for a civil penalty of $7,000 per violation per day," recoverable by the Illinois EPA, Attorney General, or the State's Attorney of any county. In other words, if a manufacturer is found to have increased the price of a drug even one cent to "recoup the costs of a drug take-back program," § 55(c)(1), it will be liable for $7,000 in fees per drug sold every day that drug was sold. Meanwhile, any person who makes a "false, fictitious, or fraudulent material statement" "related to or required by this Act or any rule adopted under [it]" is guilty of "a Class 4 felony." § 65(f).

LEGAL ISSUES

I. HB 1780 VIOLATES THE DORMANT COMMERCE CLAUSE.

The United States Constitution provides that "Congress shall have [the] Power … To regulate commerce … among the several States." Art. I, § 8, cl. 3. This "negative command, known as the dormant Commerce Clause," prohibits States from legislating in ways that regulate or discriminate against interstate commerce. Oklahoma Tax Comm'n v. Jefferson Lines, Inc., 514 U.S. 175, 179 (1995). A state law that "regulat[es] commerce occurring wholly outside [the State's] borders" is "virtually per se invalid under the Commerce Clause," even if the transactions that a State wants to regulate "ha[ve] effects within the State." Healy v. Beer Inst., Inc., 491 U.S. 324, 332 (1989); Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573, 579

(1986). That is true, moreover, even if the state law's extraterritorial reach is not plain from the face of the statute and arises only from "its practical effect and design." See C & A Carbone, Inc. v. Town of Clarkstown, 511 U.S. 383, 394 (1994) (invalidating ordinance that did not "regulate interstate commerce" "in explicit terms" but "nonetheless" did so "by its practical effect and design").

Consistent with this virtually per se rule, there is "a long line of cases" both in and out of the Seventh Circuit "holding that states violate the Commerce Clause by regulating or controlling commerce occurring wholly outside their own borders." Dean Foods Co. v. Brancel, 187 F.3d 609, 615 (7th Cir. 1999); see, e.g., Legato Vapors, LLC v. Cook, 847 F.3d 825, 833 (7th Cir. 2017) (invalidating Indiana law that required "commercial relationships between out-of-state manufacturers and their [out-of-state] employees and contractors" to be conducted consistent with Indiana law if the manufacturers sold products in Indiana); Midwest Title Loans, Inc. v. Mills, 593 F.3d 660, 661-62 (7th Cir. 2010) (invalidating Indiana law regulating title loans as applied to loans executed in Illinois); Nat'l Solid Wastes Mgmt. Ass'n v. Meyer, 63 F.3d 652, 657-58 (7th Cir. 1995) (invalidating Wisconsin statute under which "both in-state and out-of-state waste generators are barred from dumping listed materials in Wisconsin landfills unless they reside in a community that has adopted an 'effective recycling program,'" because it "essentially controls the conduct of those engaged in commerce occurring wholly outside the State of Wisconsin"); see also In re Brand Name Prescription Drugs Antitrust Litig., 123 F.3d 599, 613 (7th Cir. 1997) ("A state cannot regulate sales that take place wholly outside it.").[1]

HB 1780 violates this bedrock rule of constitutional law. It attaches penalties of $7,000 per incident, per day, for any "increase in the cost of covered drugs to recoup the costs of a drug take-back program." §§ 55(c)(3), 65(b). These provisions are not, by their terms, limited to covered manufacturers shifting the cost of the take-back program onto purchasers in Illinois. Nor are they limited to transactions that take place in Illinois. Rather, under the plain terms of the bill, a Georgia-based generic drug manufacturer whose covered drugs are sold in Illinois would be in violation of Illinois law, and subject to extensive penalties, if it raised the prices it charged its New York-based wholesale distributor in an effort to account for the increased costs of the take-back program. In other words, the bill would impose substantial legal consequences based on the terms of out-of-state transactions. Indeed, the only way for a covered manufacturer not to be subject to the penalties set forth in the bill would be to refrain from "increas[ing] the cost of

[1] See also, e.g., Sam Francis Found. v. Christies, Inc., 784 F.3d 1320, 1321-24 (9th Cir. 2015) (en banc) (invalidating California law that required sellers to pay a 5% premium into an artists' fund, but which applied to out-of-State transactions only when "the seller resides in California," with respect to all "sales outside the State"); Am. Beverage Ass'n v. Snyder, 735 F.3d 362, 366-76 (6th Cir. 2013) (invalidating Michigan law that imposes "unique-to-Michigan mark designation," even though it "does not discriminate against interstate commerce," because it "allows Michigan to dictate where the product can be sold" and thus "control[s] conduct beyond the State of Michigan"); Am. Booksellers Found. v. Dean, 342 F.3d 96, 99-104 (2d Cir. 2003) (invalidating Vermont law that prohibited distribution of explicit materials to minors because it regulated what people could distribute in other States and thus "'projected … into other States, and directly regulated commerce therein'" (citation omitted)); Am. Civil Liberties Union v. Johnson, 194 F.3d 1149, 1161 (10th Cir. 1999) (invalidating New Mexico law that "attempt[ed] to regulate interstate conduct occurring outside New Mexico's borders").

covered drugs" to recover the cost of the take-back program in any way, to anyone, anywhere. By so "requir[ing] out-of-state commerce to be conducted according to in-state terms," Cotto Waxo Co. v. Williams, 46 F.3d 790, 794 (8th Cir. 1995), the bill violates the Commerce Clause.[2]

To be sure, the bill applies only to manufacturers whose covered drugs are sold in Illinois. But the fact that a particular prescription drug winds up being sold in Illinois does not and cannot vest the state with regulatory power over upstream, out-of-state sales. That is not up for debate. The Supreme Court has long held that the fact that a law "is addressed only to sales" in the state "is irrelevant if the 'practical effect' … is to control … prices in other States." Brown-Forman, 476 U.S. at 583.

For example, in the Baldwin case, a Vermont creamery sold milk wholesale to a New York milk dealer at a price a New York statute deemed too low. 294 U.S. at 518. Because it applied only to milk resold in New York, the statute "could be defined as a regulation of sales within New York." Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc., 492 F.3d 484, 491 (4th Cir. 2007) (discussing Baldwin). Yet "the rule against extraterritorial application of state law is not a technicality to be so readily evaded." Id. Even though the statute "applied only to milk that would eventually be sold to New York consumers," id., it still could not apply to the transaction at issue, which "[b]y concession" took place in Vermont, Baldwin, 294 U.S. at 518, because under the Commerce Clause, "New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there," id. at 521. Such is the case here—whether the product is milk or covered drugs, or the other state is Vermont or Maryland.

The Seventh Circuit has made the point in unmistakable language: Despite "two hundred years of Commerce Clause precedents to draw from," "no authority" supports upholding a state law that purports to "govern[] the … commercial relationships between out-of-state manufacturers and their" out-of-state counterparts. Legato Vapors, 847 F.3d at 833. Time and again, the Supreme Court has explained that "whether or not the commerce has effects within the State," the Constitution "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders." Healy, 491 U.S. at 336 (quoting Edgar v. MITE Corp., 457 U.S. 624, 642-43 (1982) (plurality opinion)). The bill's anti-pass-through provision runs afoul of that core limitation on state authority. See generally Ass'n for Accessible Medicines v. Frosh, 887 F.3d 664, 671 (4th Cir. 2018) (applying these principles to strike down pharmaceutical price regulations that regulated out-of-state, upstream sales).

The anti-pass-through provision cannot be saved by construing it, consistent with the Illinois Supreme Court's presumption against extraterritoriality, see Dur-Ite Co. v. Indus. Comm'n, 394 Ill. 338, 345 (1946), to reach only those transactions in Illinois in which a manufacturer increased the price of covered drugs. That is because "State regulations affecting interstate commerce, whose purpose or effect is to gain for those within the state an advantage at the expense of those

[2] Indeed, any increase in the price of any generic drug would be vulnerable to civil action under the bill because money is fungible. By definition, a price increase in a generic would offset the cost of a take-back program because it would increase revenues, revenues that would then be tapped in part to pay for the drug offset program, even if the price rise was motivated by, for example, an increase in manufacturing costs.

without," violate the Commerce Clause no less than state laws that directly regulate out-of-state transactions in text or by effect. South Carolina State Highway Dep't v. Barnwell Bros., 303 U.S. 177, 184 n.2 (1938); accord New Energy Co. of Ind. v. Limbach, 486 U.S. 269, 273 (1988); Nat'l Solid Wastes Mgmt. Ass'n v. Meyer, 63 F.3d 652, 657 (7th Cir. 1995). And if the bill's anti-pass-through provision were construed (atextually) to be limited to "pass[ing] on" some portion of the cost of the take-back program to purchasers in Illinois, then the clear "effect" of the provision will be to "gain for those within the state an advantage at the expense of those without" in the form of lower prices. Put another way, the bill's necessary economic effect if it only applied to in-Illinois sales would be to force drug manufacturers to charge residents of other states higher prices to recoup the cost of a program for Illinoisans. Cf., e.g., § 25(k) (limiting drug take-back program operation to Illinois). That necessary and necessarily discriminatory consequence violates the Commerce Clause.[3]

Indeed, a federal court recently declared an almost-identical anti-pass-through provision to be unconstitutional under the dormant Commerce Clause. See Healthcare Distribution All. v. Zucker, 353 F. Supp. 3d 235, 246 (S.D.N.Y. 2018) (striking down New York law forbidding covered manufacturers from "pass[ing] the cost of their ratable share [of the opioid fund payment] to a purchaser, including the ultimate user of the opioid"). That conclusion was so clearly established, moreover, that the state did not even defend it on appeal. Accordingly, to the extent the bill's anti-pass-through provision is (atextually) construed not to apply outside Illinois, or to the extent that the bill's provisions are amended to include an express limitation to Illinois, the bill nonetheless violates the Commerce Clause because it has the practical effect of discriminating against interstate commerce.

It is certainly within the State's powers to adopt a drug take-back program; indeed, AAM enthusiastically supports programs to facilitate the proper disposal of unused medications. But the Constitution does not permit the State to pay for such a program by directly regulating the prices for drugs charged outside Illinois, or impose the costs of its own program on individuals outside Illinois.

II. HB 1780 CONFLICTS WITH FEDERAL ANTITRUST LAW

HB 1780 suffers from a second infirmity stemming from its somewhat complex structure. Although the bill recognizes that the government plays a fundamental role in safe and environmentally appropriate drug disposal, it requires involuntarily-formed, government-approved associations of private manufacturers to connect one set of government services to another. That is a textbook antitrust violation. Indeed, the bill itself recognizes as much, acknowledging in the text that "the activities authorized by this Act require collaboration among covered manufacturers"—anti-competitive collaboration, as the State is ordering manufacturers

[3] Discrimination in violation of the Commerce Clause is not limited to laws that benefit in-state companies while simultaneously denying benefits to out-of-state companies. See, e.g., Oregon Waste Sys., Inc. v. Dep't of Envtl. Quality of State of Oregon, 511 U.S. 93, 101 (1994); Chem. Waste Mgmt. v. Hunt, 504 U.S. 334, 334 n.6 (1992).

to cease competing to provide take-back services (or produce drugs more amenable to safe disposal). § 70.

The State is of course free to exempt whatever combinations it chooses from its state antitrust laws (although it is unclear, as written, whether the bill in fact does this). But it cannot exempt manufacturers from federal antitrust law. To the extent the bill effectively exempts manufacturers from federal antitrust law, it conflicts with federal law and is preempted.

A. HB 1780 does not effectively exempt anyone from the federal antitrust laws

Section 70 of the bill declares that it "intends to … provide immunity through the state action doctrine from federal antitrust laws [for] activities that are undertaken pursuant to this Act that might otherwise be constrained by such laws."[4]

The "state action doctrine" refers to the doctrine set forth by the Supreme Court in Parker v. Brown, 317 U.S. 341 (1943), and its progeny, under which federal "antitrust laws" are construed "to confer immunity on anticompetitive conduct by the States when acting in their sovereign capacity." North Carolina State Bd. of Dental Examiners v. FTC, 574 U.S. 494, 503 (2015); see Parker, 317 U.S. at 351. To invoke the state action doctrine, it is necessary, but not sufficient, for a state to "articulate[] a clear policy to allow the anticompetitive conduct." California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc., 445 U.S. 97, 105 (1980).

Section 70 likely satisfies that criterion. However, that is not enough to come within the Supreme Court's state action doctrine. Rather, "a state law or regulatory scheme cannot be the basis for antitrust immunity unless … the State provides active supervision of the anticompetitive conduct." Dental Examiners, 574 U.S. at 503 (emphasis added).

This active-supervision prong requires that "state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy." Patrick v. Burget, 486 U.S. 94, 101 (1988). Mere state endorsement of a private association is not enough: "State agencies controlled by active market participants, who possess singularly strong private interests, pose the very risk of self-dealing Midcal's supervision requirement was created to address." Dental Examiners, 574 U.S. at 510.

As written, the bill does not satisfy that requirement to come within the doctrine. Here, although the Illinois EPA has a role in approving the take-back program, manufacturers must submit to it, § 35(a), the Illinois EPA is obligated to approve the program if it meets the statutory requirements, § 35(b), after which state enforcement is limited to post-hoc civil actions initiated by the Illinois EPA, Attorney General, or State's Attorney, § 65.

This is exactly the kind of hands-off endorsement of private associations the Supreme Court held to be outside the state action doctrine in Dental Examiners. There, the Court identified three

[4] Although this section ostensibly declares a legislative intent only to invoke the doctrine and does not by its terms invoke the doctrine per se, AAM proceeds on the assumption that this section would have the effect of affirmatively employing the state's powers in this area, insofar as they exist.

"constant requirements of active supervision: the supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it; the supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy; and the mere potential for state supervision is not an adequate substitute for a decision by the State." 574 U.S. at 515.

HB 1780 satisfies none of these criteria: Only compliance with the program's requirements is reviewed by the agency, § 35(a); the agency "shall" certify plans, rather than have the power to veto them, § 35(b); and after the initial grant of approval, state supervision recedes to the realm of potentiality, § 65. "The national policy in favor of competition cannot be thwarted by casting such a gauzy cloak of state involvement" over what is otherwise violative of the antitrust laws. Midcal, 445 U.S. at 106. Accordingly, a court likely would hold that HB 1780 does not effectively exempt covered manufacturers from federal antitrust laws.

B. HB 1780 is conflict preempted

Section 1 of the Sherman Act provides that [e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce … is declared to be illegal." 15 U.S.C. § 1. A state statute is preempted to the extent it is in "irreconcilable" with Section 1 and the federal antitrust regulatory scheme. Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982). This occurs when a state statute "mandates or authorizes conduct that necessarily constitutes a violation of the antitrust laws in all cases, or if it places irresistible pressure on a private party" to violate those laws. Fisher v. City of Berkeley, 475 U.S. 260, 265 (1986) (cleaned up).

Here, the text of HB 1780 admits that the "activities authorized by this Act require collaboration among covered manufacturers and among authorized collectors." § 70. And that is quite the understatement. The thrust of the bill is essentially to compel, through withholding of approval under § 35(a), the creation of a single monopoly drug take-back program, under threat of fine. This arrangement plainly will provide "irresistible pressure" to violate antitrust laws in obvious ways: dividing markets (such that the program efficiently meets the one-per-county requirements of § 25(j)), fixing prices (paid to collectors, among other things, under § 25(a)), and, through the ban on promoting in-home disposal of drugs, using their collective monopoly over drug manufacturing and distribution, as well as the take-back program, to completely eliminate a modality of excess drug distribution. See generally Freedom Holdings, Inc. v. Spitzer, 357 F.3d 205, 222 (2d Cir. 2004) (invalidating master settlement agreement in part on antitrust preemption grounds).

III. HB 1780'S PROMOTION PROVISION VIOLATES THE FIRST AMENDMENT

HB 1780 suffers from a third infirmity: By forcing all manufacturers to promote the take-back program therein established—and only the take-back program therein established—it both restricts and compels commercial speech in violation of the First Amendment.[5]

Commercial speech is protected under the First Amendment because it serves both the speaker's commercial interests and the public's interest in making informed commercial decisions. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 561-62 (1980) ("Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information."). "[P]eople will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them." Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976).

A prohibition on commercial speech is generally reviewed under the intermediate scrutiny standard, see Cent. Hudson, 447 U.S. at 566, while a more lenient rational basis test applies where a commercial speaker is required to make certain disclosures in the context of potentially misleading speech, see Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 651 (1985). But "when a State entirely prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous review that the First Amendment generally demands." 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 501 (1996).

On this standard, at least one subsection of the promotion provision, § 45(6), is unconstitutional. That section provides that "promotional materials prepared and distributed in conjunction with an approved drug take-back program under this Section may not be used to promote in-home disposal products of any kind, including, but not limited to, in-home disposal products of authorized collectors participating in a drug take-back program." **This is a flat ban on the dissemination of truthful, nonmisleading commercial speech about in-home disposal products—including products that could ameliorate, even if not outright satisfy, the purposes of the bill.** "The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." 44 Liquormart, 517 U.S. at 503. Although the State may be able to ban in-home disposal products, "the text of the

[5] It is not at all clear that the speech regulated here is commercial speech. Commercial speech is that which "propos[es] a commercial transaction," Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 456 (1978), or is an "expression related solely to the economic interests of the speaker and its audience," Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 561 (1980). Here, the speech that the bill compels manufacturers to make relates not to their economic interests (e.g., the ways and means they promote their products), but rather to a separate public health and environmental problem that is, at most, an attenuated externality of their commercial activity. If a court were to treat the compelled speech as non-commercial, the provision's unconstitutionality would follow a fortiori. Nonetheless, AAM proceeds on the assumption that a court would deem the speech compelled and restricted here as commercial speech.

First Amendment makes clear that the Constitution presumes that attempts to regulate speech are more dangerous than attempts to regulate conduct." Id. at 512.[6]

As for the remainder of the promotion provision, the requirements go well beyond disclosures incidental to existing advertising, cf. Zauderer, 471 U.S. at 651, and instead compel manufacturers to design and promote, under their own names, full-dress advertising campaign setting forth specific state-approved messages. This is quintessential compelled speech. "Just as the First Amendment may prevent the government from prohibiting speech, the Amendment may prevent the government from compelling individuals to express certain views, or from compelling certain individuals to pay subsidies for speech to which they object." United States v. United Foods, Inc., 533 U.S. 405, 410 (2001) (internal citations omitted). "[T]hat the speech is in aid of a commercial purpose does not deprive respondent of all First Amendment protection." Id.

HB 1780 essentially forces manufacturers to join drug take-back programs, and then produce specific state-mandated messages. It is similar to the scheme in United Foods, where the state sought to compel multiple competing mushroom providers to join a single association to promote mushrooms generally, and where the Supreme Court held that "the statute" was an unconstitutional compulsion of speech to the extent it "does not require group action, save to generate the very speech to which some handlers object." Id. at 415. To be sure, here the speech is connected to the operation of the take-back program. But the bill does not merely require the payment of money to support an association, but rather the creation of an association ex nihilo to promote state-backed speech using the reputation and goodwill of the very manufacturers compelled. Particularly in light of the Supreme Court's recent expansion of the compelled speech doctrine, see, e.g., Janus v. Am. Fed'n of State, Cty., & Mun. Emps., Council 31, 138 S. Ct. 2448, 2465 (2018), it is likely that the compelled speech required here would be subject to strict scrutiny and deemed insufficiently tailored to satisfy that exacting standard.

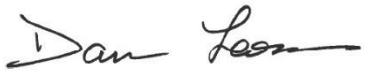
[6] It is no answer to say that, because section 45(6) is limited to "promotional materials prepared and distributed in conjunction with an approved drug take-back program," it does not serve as a broader ban on promoting in-home devices. Section 45 provides no means of demarcating communications that satisfy the statutory requirements and those that do not. Even a disclaimer on a hypothetical mailer or website promoting an in-home disposal device that "this promotion was not part of a covered manufacturer's efforts to satisfy the requirements" would not necessarily suffice, because a manufacturer would always be open to the accusation that the pamphlet was "prepared … in conjunction" with its take-back-only materials.

* * *

For these reasons and more, HB 1780 is unconstitutional and highly vulnerable to a legal challenge whose defense would be borne by the taxpayers of Illinois. While AAM supports the proper disposal of unused medications, the drug take-back program that would be established in HB 1780 is flawed. We respectfully request that the Governor veto HB 1780 in its current form.

If you have any questions, please do not hesitate to contact me or Ashlie Van Meter, AAM's Senior Director for State Affairs.

Best regards,



Dan Leonard
President and CEO

Your Generics & Biosimilars Industry

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