IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

Pharmaceutical Research and Manufacturers of America, Plaintiff, v. Stuart Williams, Stacey Jassey, Mary Phipps, Andrew Behm, James Bialke, Amy Paradis, Rabih Nahas, Samantha Schirmer, and Kendra Metz, in their official capacity as members of the Minnesota Board of Pharmacy, Defendants.	Case No. 20-cv-1497-DSD-DTS **PLAINTIFF'S RESPONSE TO DEFENDANTS' OBJECTIONS TO MAGISTRATE'S ORDERS**

INTRODUCTION

PhRMA brought this suit over three years ago seeking a declaration that Minnesota's Alec Smith Insulin Affordability Act (the "Act") causes unconstitutional *per se* physical takings of its members' personal property and an injunction barring further enforcement of the Act. The Act requires manufacturers of insulin products to give those products away for free to certain Minnesota residents without any compensation. PhRMA's position is that the Act violates the Takings Clause, as it effects a repetitive series of *per se* takings by depriving manufacturers of the entire bundle of rights in the insulin they must give away—"the rights to possess, use and dispose of" that property. *Horne v. Dep't of Agric.*, 576 U.S. 350, 360 (2015) (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982)). Defendants' position is that the Act does *not* violate the Takings Clause. That is the question at the heart of this litigation.

Despite that straightforward and narrow legal question, Defendants request nearly *two years* of expert and factual discovery on *44* separate topics. Defendants claim that many of these topics relate to their defenses that the Act is not a taking but rather is a permissible licensing condition or an abatement of a supposed nuisance, or to their argument that the Act should not be enjoined even if it is a taking. But as the Magistrate Judge recognized, those defenses and arguments fail as a matter of law under established takings jurisprudence. The Magistrate Judge thus acted well within his discretion in refusing to allow Defendants to delay the resolution of this case with extensive and burdensome discovery on legally irrelevant issues. The Magistrate Judge's well-reasoned order should be adopted by this Court.

ARGUMENT

I. The Court Should Not Revive Defendants' "Licensing" and "Nuisance" Defenses

The court should reject Defendants' attempt to reinstate their licensing and nuisances defenses. Rule 12(f) permits the court to "strike from a pleading … any … immaterial … [or] impertinent … matter." Fed. R. Civ. P. 12(f). Contrary to Defendants' objections, ECF No. 139 at 2, 3, "[t]he court may act (1) *on its own*" in exercising this power, Fed. R. Civ. P. 12(f) (emphasis added). Although striking a defense is generally disfavored, the Magistrate Judge correctly recognized that striking a defense is appropriate where, as here, the defense is legally invalid and allowing it to remain in the case "'would significantly affect the scope of discovery.'" ECF No. 133 at 13 (quoting *WM Cap. Mgmt., Inc. v. Stejksal*, No. 15 C 8105, 2016 WL 6037851, at *1 (N.D. Ill. Oct. 14, 2016)).

Defendants do not dispute the Magistrate Judge's finding that discovery on these defenses would "substantially expand[] the scope of discovery." ECF No. 133 at 21; *see also id.* at 23-24. So the only question is whether the Magistrate Judge erred in holding that the defenses fail as a matter of law. *See* ECF No. 139 at 2. But as explained below, the Magistrate Judge's legal conclusions are correct. That being the case, the Magistrate Judge did not abuse his discretion in barring burdensome discovery into invalid defenses to "streamline the ultimate resolution of the action." *Daigle v. Ford Motor Co.*, 713 F. Supp. 2d 822, 830 (D. Minn. 2010); *see also, e.g.*, *Heller Fin., Inc. v. Midwhey Powder Co., Inc.*, 883 F.2d 1286, 1294 (7th Cir. 1989) (where "motions to strike remove unnecessary clutter from the case, they serve to expedite, not delay").

A. Defendants' Licensing-Benefit Defense Fails As A Matter Of Law.

The Magistrate Judge correctly rejected Defendants' attempt at framing the Act as a mere condition of licensure. As a matter of law, Minnesota cannot require manufacturers to give free insulin to the State's chosen recipients as a condition of obtaining a license to sell medicines in the State. Because Defendants' licensing defense is legally baseless, it does not support Defendants' sweeping discovery requests.

Defendants' licensing defense is foreclosed by the Supreme Court's decision in *Horne v. Department of Agriculture*. *Horne* held that a government mandate that raisin growers relinquish a portion of their crop as a "'condition' on permission to engage in commerce" is "a per se taking." 576 U.S. at 364-65. The Court recognized that the sale of produce is "certainly subject to reasonable government regulation." *Id.* at 366. But it held that selling produce is "not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection." *Id.*

As the Magistrate Judge correctly recognized, *Horne's* holding is controlling here. ECF No. 133 at 22. Insulin, like raisins, is "private property"—a beneficial product produced by pharmaceutical manufacturers. *Horne*, 576 U.S. at 367. "Any physical taking of [it] for public use must be accompanied by just compensation." *Id.*[1]

Defendants argue that *Horne* is inapplicable because it did not involve a "health and safety regulatory framework" for a product like insulin that "can cause serious harm or death if used incorrectly." ECF No. 139 at 5. In Defendants' view, two other Supreme Court cases—*Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), and *Cedar Point Nursery v. Hassid*, 594 U.S. 139 (2021)—establish that a state may condition a license to sell a dangerous product on a requirement that the

[1] Although not relied on by the Magistrate Judge, *Loretto v. Teleprompter CATV Corp.*, 458 U.S. 419 (1982), also supports the conclusion that the Act is not a valid licensing condition. *Loretto* held that "a landlord's ability to rent his property may not be conditioned on his forfeiting the right to compensation for a physical occupation" of his property. *Id.* at 439 n.17. A contrary holding, the Supreme Court explained, would permit "the government to require a landlord to devote a substantial portion of his building to vending and washing machines" with "no compensation for the deprivation of space," or "to requisition a certain number of apartments as permanent government offices." *Id.* The Takings Clause does not allow property rights to "be so easily manipulated" by the government. *Id.* But that is precisely what the Act does here: it requisitions a portion of the manufacturers' insulin without compensation.

manufacturer give away some of the product at no charge. ECF No. 139 at 4-6. They are mistaken.

Unlike the Minnesota insulin law at issue here, the pesticide licensing law upheld in *Monsanto* did not require manufacturers to give away their products for free. Rather, it required manufacturers to disclose health, safety, and environmental data so the Environmental Protection Agency could determine whether the pesticides could be safely used and how they should be labeled if permitted to enter the market. 467 U.S. at 991-97. Although the data were trade secrets under state law, *id.* at 1003-04, the Supreme Court had long held that the "'right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject'" to the government's police power to require the disclosure of information about products in the market, *id.* at 1008 (quoting *Corn Prods. Refining Co. v. Eddy*, 249 U.S. 427, 431-32 (1919)). Thus, "a voluntary submission of data by an applicant in exchange for the economic advantages of a registration" to sell pesticides "can hardly be called a taking." *Monsanto*, 467 U.S. at 1007-08.

Cedar Point Nursery similarly does not help Defendants—in fact, it *refutes* their position. In *Cedar Point Nursery*, the Supreme Court held that a regulation requiring agricultural employers to allow labor unions on "their property for up to three hours per day, 120 days per year" is a taking. 594 U.S. *Id.* at 139, 143. The Court acknowledged that "government health and safety inspection regimes will generally not constitute takings," so a business license may be conditioned "on allowing access for reasonable health and safety inspections." *Id.* at 161 (citing *Monsanto*, 467 U.S. at 1007). But that principle did not justify the union access regulation because the access did not alleviate any safety risk to workers. *Cedar Point Nursery*, 594 U.S. at 162. Instead, the Court held, the access regulation was a "*per se* physical taking," not a valid license condition, because the ability to use land for a farming business is a "'basic and familiar use[] of property,'" and "not a special benefit that 'the Government may hold hostage, to be ransomed by the waiver of constitutional protection.'" *Id.* (quoting *Horne*, 576 U.S. at 366).

That reasoning is controlling here. The Act's requirement to provide free insulin has absolutely nothing to do with Defendants' professed safety concern that "insulin can cause serious harm or death if used incorrectly." ECF No. 139 at 5. The Act does not restrict the use of insulin by Minnesota residents; it compels manufacturers to give away insulin specifically so Minnesota residents *can use* the insulin. Under *Horne* and *Cedar Park Nursery*, that is not a condition the State can impose in exchange for the "benefit" of selling a legal product. *Horne*, 576 U.S. at 366.[2] Therefore, Defendants' "license defense is not legally applicable to this

[2] Defendants make a passing reference to *Southeast Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448 (8th Cir. 2016), but that case does not support their licensing defense. ECF No. 139 at 5. The Eighth Circuit held that there was no taking when the government required a hospice provider to repay Medicare reimbursements that exceeded the Medicare reimbursement cap. But the provider voluntarily chose to

litigation," and the Magistrate Judge acted well within his discretion in denying discovery about it. ECF No. 133 at 23-24.

B. Defendants' Nuisance Defense Fails As A Matter Of Law.

The Magistrate Judge also properly concluded that Defendants' nuisance defense is legally invalid and so cannot support Defendants' position on discovery. The Act's requirement that manufacturers give free insulin to Minnesota residents cannot, as a matter of law, be characterized as an "abatement" of the "nuisance" that Defendants allege the manufacturers created.

As the Magistrate Judge explained, Defendants do "not allege that *insulin itself* is in any way a nuisance or that its distribution unreasonably endangers public health." ECF No. 133 at 17 (emphasis added). Thus, this is not a case in which Minnesota is confiscating private property that is inherently noxious or harmful, such as adulterated drugs or diseased trees. *Cf. Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1022 (1992) (citing the "order to destroy diseased cedar trees to prevent infection of nearby orchards" upheld in *Miller v. Schoene*, 276 U.S. 272 (1928), as an example of a case in which the "public nuisance[]" defense applies).

participate in Medicare in exchange for government reimbursement at a level set by the government. 815 F.3d at 450. And the court distinguished the voluntary participation in a government benefits program from voluntary participation in the market, which "'cannot reasonably be characterized as part of a similar voluntary exchange.'" *Id*. (*quoting Horne*, 576 U.S. at 366).

Indeed, "the Act itself makes clear that widespread availability of insulin is unqualifiedly a public benefit, not a nuisance." ECF No. 133 at 17. Defendants try to sidestep that fact by arguing that supposed "monopolistic pricing practices" by insulin manufacturers created "an insulin affordability crisis" that is a public nuisance that Minnesota may abate by requiring manufacturers to give away free insulin. *Id.*; *see also* ECF No. 139 at 8-10. That theory cannot prevail as a matter of law.

As an initial matter, Defendants have not cited any case holding that the pricing of a *lawful* product can be a nuisance under Minnesota law. *See* ECF No. 133 at 18-19. Their attempt at predicating sweeping discovery on this theory is thus totally unsupported. But even if there were any precedent for this novel theory, the Magistrate Judge properly held that it would not be a valid defense to PhRMA's taking challenge because "the Act does not purport to set a limit on (or otherwise regulate) the price manufacturers may charge Minnesota residents to abate the nuisance of unaffordability. Rather, it takes the manufacturers' property and gives it away free of charge to certain Minnesota residents." *Id.* at 18. That taking cannot be justified as an abatement of the "nuisance of unaffordability" because it goes beyond prohibiting the supposedly harmful pricing behavior and entirely deprives the manufacturers of their insulin. As the Magistrate Judge explained, Defendants have failed to cite a single case applying the nuisance defense to allow such an uncompensated *per se* physical taking of private property. *Id.*

And for good reason. A new confiscatory law or regulation can fall within the nuisance defense to the Takings Clause only if it imposes restrictions that are in the "background principles of the State's law of property and nuisance." *Lucas*, 505 U.S. at 1029. The law's "effect must, in other words, do no more than duplicate the result that could have been achieved in the courts" to "abate nuisances that affect the public generally." *Id.* When a public nuisance is caused by a property owner's *use* of property that is not itself "inherently noxious or dangerous," as Defendants allege PhRMA's members are doing here (ECF No. 139 at 8), the court abates the nuisance by "enjoin[ing] a property owner from activities" that create the public nuisance, *Lucas*, 505 U.S. at 1022.

That is also how Minnesota courts abate public nuisances in the cases on which Defendants rely. *See State ex rel. Goff v. O'Neil*, 286 N.W. 316, 318 (Minn. 1939) ("action for an injunction enjoining defendant from conducting a business wherein the usury law is invariably violated"); *Meagher v. Kessler*, 179 N.W. 732, 734 (Minn. 1920) (when operation of a funeral home in a residential district "impairs the enjoyment of homes in the neighborhood," the "carrying on of such business, in such a locality, becomes nuisance, and may be enjoined"); *see also State v. Juul Labs, Inc*. No. 27-cv-19-1988, 2023 WL 2586110 at *13 (Minn. Dist. Ct. Mar. 13, 2023 ("The Minnesota legislature, through Minn. Stat. § 617.81, has authorized courts to grant an injunction to abate a nuisance based on a finding of [public] nuisance under section 609.74."). None of these cases even suggest, much less hold, that a court could abate a harmful use of property by ordering the owner to give the property away at no charge to someone else.

Nor could a Minnesota court so hold. The Supreme Court has explained that a law abating a nuisance is not a taking because it "does not disturb the owner in the control or use of his property for lawful purposes, nor restrict his right to dispose of it, but is only a declaration by the State that its use by any one, for certain forbidden purposes, is prejudicial to the public interests." *Mugler v. Kansas*, 123 U.S. 623, 669 (1887). But here, the Act does not restrict a forbidden use of insulin; it deprives manufacturers of the right to control, use, or dispose of insulin for lawful purposes. Because Defendants' nuisance defense "is not legally applicable in this case and would prejudice PhRMA by substantially expanding the scope of discovery," the Magistrate Judge acted well within his discretion in denying discovery about it. ECF No. 133 at 21.

II. The Magistrate Judge Did Not Abuse His Discretion In Denying Defendants' Discovery On The Injunctive Relief Factors

"Where a magistrate judge has carefully examined the proposed discovery, the Court will defer to the magistrate judge's broad discretion . . . to manage and define appropriate discovery unless the Magistrate Judge's determinations were clearly erroneous or contrary to law." *Shukh v. Seagate Tech., LLC*, 295 F.R.D. 228, 238 (D. Minn. 2013) (internal quotation marks omitted). The Magistrate Judge did not clearly err or abuse his discretion denying Defendants' request for "extensive discovery into the harm the Act has caused manufacturers, the harm insulin pricing has caused the public, the manufacturers' insulin sales and pricing practices, and their annual gross and net revenues." ECF No. 133 at 26. That discovery "is not relevant or proportional to the parties' claims or defenses." *Id.*

Defendants argue that this discovery is needed to show that even if the Act is found to effect a taking of the manufacturers' insulin, it should not be enjoined because the "balance of harms" to the public from an injunction outweighs the harm of forcing the manufacturers to comply with an unconstitutional law. ECF No. 139 at 13. They are mistaken.

Defendants suggest that an injunction is not appropriate because the Act serves a public purpose and the taking of insulin from the manufacturers could be remedied with the payment of compensation. *Id.* at 12-13. But that would be true only if "an adequate provision for obtaining just compensation exists." *Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2176 (2019). And here, the Eighth Circuit has already held "that in the specific context of this case, Minnesota's condemnation procedure does *not* afford insulin manufacturers an adequate remedy for the repetitive series of alleged takings under the Act." *PhRMA v. Williams*, 64 F.4th 932, 945 (8th Cir. 2023) (emphasis added).

Thus, the propriety of injunctive relief turns not on the broad topics on which the Defendants want discovery but on whether (1) the Act's requirement to dispense insulin at no charge is a *per se* physical taking; and (2) one or more of PhRMA's members is being and will continue to be subject to a repetitive series of takings, by being forced repeatedly to give away insulin at no charge. And the Magistrate Judge has permitted Defendants all the discovery needed to resolve those questions. *See* ECF No. 133 at 31 & ECF No. 133-1 (allowing Defendants to take discovery on, *inter alia*, how many applications for free insulin have been submitted and how much insulin has been given away).

Beyond that, the Magistrate Judge properly held that no further discovery into the relative costs and benefits of the Act on the manufacturers compared to members of the public is necessary or appropriate. The "denial of a constitutional right is a cognizable injury and an irreparable harm." *Ng v. Bd. of Regents of Univ. of Minn.*, 64 F.4th 992, 998 (8th Cir. 2023) (citation omitted); *see also Little Rock Fam. Plan. Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1321 (E.D. Ark. 2019) (same). And where a statute is unconstitutional, "the question of harm to the [defendants] and the matter of the public interest drop from the case," because "the public interest will perforce be served by enjoining the enforcement" of an unconstitutional law. *Bank One Utah v. Guttau*, 190 F.3d 844, 847-48 (8th Cir. 1999).

III. The Court Should Not Expand the Scope And Length Of Discovery.

Defendants maintain that, even if this Court affirms the Magistrate Judge's determinations, the Court should "modify the orders to allow" additional discovery on certain topics and extend the schedule for discovery "at least six months." ECF No. 139 at 13-14. But the Magistrate Judge has "broad discretion . . . to manage and define appropriate discovery." *Shukh*, 295 F.R.D. at 238. Defendants cannot show that the Magistrate Judge abused this "broad discretion."

Defendants request "some discovery" on ten topics they claim "relate to standing and PhRMA's affirmative allegations, not the struck defenses." ECF No. 139 at 13. This extra discovery is inappropriate or otherwise unnecessary. Topics 18 to 21, for example, all relate to Defendants' arguments about injunctive relief, which (as explained above) the Magistrate Judge properly found to be irrelevant. *See, e.g.*, Doc. 133-1 at 2. And Defendants have provided no basis for discovery into PhRMA's lobbying and its communications with its members about this litigation (topics 25, 29).

Discovery on Defendants' remaining subjects is overbroad and unduly burdensome. PhRMA's publications and press releases about diabetes or insulin (topic 32) are not relevant to its taking claim. Information about manufacturers' revenue from insulin sales (topic 10) is relevant only to the extent it shows whether PhRMA has standing because its members are covered by the Act, a subject on which the Magistrate Judge did allow discovery (topic 2). The Magistrate Judge also allowed discovery about how the Act's programs work in practice (topic 11) and how much insulin has been requested and given away under the Act (topics 13-16), making a further request for the documents manufacturers used to prepare their annual reports to the Board of Pharmacy (topic 17) duplicative and unduly burdensome. Defendants' request for information about manufacturing costs and insulin prices other than Wholesale Acquisition Cost (topic 12) is also irrelevant and unduly burdensome. The Wholesale Acquisition Cost is the price that triggers application of the Act, Minn. Stat. § 151.74, subdiv. 1(d), and, as explained above, Defendants cannot defend the Act's confiscation of insulin by attempting to show that insulin prices are too high.

Finally, Defendants' undeveloped view that the discovery permitted is "significant" and that third-party discovery will take "at least six months" is no reason to disturb the Magistrate Judge's judgment that three months of fact discovery will be adequate here. ECF No. 139 at 14.

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Respectfully submitted,

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