UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Pharmaceutical Research and Manufacturers of America,

Plaintiff,

v.

Stuart Williams, et al.,

Defendants.

Case No. 0:20-cv-01497-DSD-DTS

DEFENDANTS' OBJECTIONS TO MAGISTRATE'S ORDERS

Defendants object to the magistrate's February 8, 2024 orders, which sua sponte struck Defendants' defenses and then correspondingly limited discovery. (Docs. 133-34.) The orders are contrary to this Court's prior order and incorrect.[1] Accordingly, Defendants request the Court reject them.

FACTS

PhRMA alleges that Minnesota's Insulin Affordability Act effects unconstitutional takings. (Doc. 1.) Following the Eighth Circuit's remand, PhRMA immediately moved for summary judgment. (Doc. 93.) PhRMA argued that Defendants' anticipated defenses were meritless and discovery was unnecessary. (*E.g.*, Doc. 95 at 21-30.) Defendants responded that the motion was premature and they outlined discovery necessary to their defenses. (Docs. 109-10.) The Court denied PhRMA's motion and prohibited PhRMA from seeking summary judgment before fact discovery is complete. (Doc. 114.)

[1] The parties did not consent to the magistrate making dispositive determinations. (Doc. 119 at 3.)

Despite the Court's order prohibiting summary judgment before fact discovery, PhRMA made the same arguments to the magistrate judge in their rule 26(f) report and in later briefing about a scheduling order. (Docs. 122, 124, 130.) Although no motions were before him, the magistrate sua sponte struck Defendants' defenses from their answer, citing Fed. R. Civ. P. 12(f), and foreclosed discovery on the defenses and other issues. (Doc. 133-34). Based on his legal and factual conclusions, the magistrate then set an expedited three-month period for limited fact discovery. (Doc. 134.)

ARGUMENT

Because the magistrate disposed of Defendants' defenses, de novo review is proper. Fed. R. Civ. P. 72(b)(3); D. Minn. LR 72.2(b); *Strike 3 Holdings, LLC v. Doe*, 330 F.R.D. 552, 554 (D. Minn. 2019) (stating commonsense, not labels, determines whether ruling is dispositive). The Court should reject the magistrate's orders, allow discovery on Defendants' defenses and PhRMA's injunctive-relief claim, and direct the magistrate to extend the discovery deadlines and scope accordingly.

Because disputed legal and factual issues exist, the magistrate's extraordinary step of striking Defendants' licensing-benefit and nuisance defenses and prohibiting related discovery was improper. The magistrate's legal conclusions are erroneous, and he further erred by relieving PhRMA of its burden to prove it is entitled to injunctive relief. The decision is particularly drastic because of this Court's prior order denying summary judgment. (Doc. 114.)

I. THE MAGISTRATE IMPROPERLY STRUCK DEFENDANTS' DEFENSES.

The Court should reject the magistrate's striking of Defendants' defenses. Striking a defense under rule 12(f) is an extreme and disfavored measure that should be invoked only when no fact questions exist, the legal questions are clear and undisputed, and the defenses could not succeed under any set of circumstances. *Stanbury Law Firm v. I.R.S.*, 221 F.3d 1059, 1063 (8th Cir. 2000); *FDIC v. R-C Mktg. & Leasing, Inc.*, 714 F. Supp. 1535, 1541 (D. Minn. 1989). Striking a defense is improper when it "fairly presents a question of law or fact which the court ought to hear." *Lunsford v. United States*, 570 F.2d 221, 229 (8th Cir. 1977).

Here, Defendants' defenses are supported by existing law or a reasonable extension of existing law. (*See* Docs. 66 at 22-34, 110 at 9-15, 129 at 5-10.) And, unlike other cases upholding the striking of defenses, the magistrate cited no cases or statutes clearly foreclosing the defenses. *E.g.*, *United States v. Dico, Inc.*, 266 F.3d 864, 880 (8th Cir. 2001) (controlling law foreclosed defense); *United States v. Winnebago Tribe,* 542 F.2d 1002, 1007 (8th Cir. 1976) (federal statute clearly authorized plaintiff's activities). Rather, the magistrate acknowledged both that the Supreme Court has recognized a licensing-benefit defense to takings claims and that the applicability of a nuisance defense in per se physical takings cases "remains an open question." (Doc. 133 at 15-16 & n.5.)

The magistrate compounded his errors by deciding numerous disputed legal and factual issues when no dispositive motion was before him. Because Defendants' defenses present unresolved, disputed legal and factual questions the Court ought to hear, the magistrate erred in striking them and the Court should reject the rulings.

A. The Magistrate Erred by Striking Defendants' Licensing-Benefit Defense.

The government may require property owners to cede a property right as a condition of receiving a license, without causing a taking. *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 161 (2021); *see also Ruckelhaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984). Despite acknowledging this, the magistrate struck Defendants' licensing-benefit defense. (Doc. 133 at 22-23.) In doing so, the magistrate erroneously concluded that (1) the defense applies only if the licensing benefit was a pre-existing property limitation, (2) selling insulin in Minnesota is a "basic and familiar use of the property" that cannot be conditioned, so manufacturers receive no benefit from a Minnesota license, and (3) failing to comply with the Act cannot result in license revocation, and compliance therefore is not a true condition of licensure. These conclusions are legally and factually wrong.

First, the magistrate erroneously applied the "pre-existing limitation on property" defense as an element of the licensing-benefit defense. It appears the magistrate mistakenly conflated *Cedar Point*'s discussions of the two distinct defenses. *See Cedar Point*, 594 U.S. at 159-61; Doc. 133 at 22-23. Extending this "pre-existing limitation" requirement to the licensing context, however, is not supported by *Cedar Point* or other licensing-benefit takings cases. *See Cedar Point*, 594 U.S. at 159-61; *Ruckelshaus*, 467 U.S. at 1007. Moreover, the Eighth Circuit has rejected takings claims involving changed regulatory obligations. *See, e.g.*, *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 447 (8th Cir. 1984). And for good reason: under the magistrate's conclusion, any new or revised licensing requirement would

effectuate a taking because the change would necessarily depart from pre-existing limitations. This would severely impede governments from engaging in regulatory activity. But even under the magistrate's erroneous standard, the licensing-benefit defense survives as there are pre-existing limitations on insulin sales as discussed below.

Second, the magistrate erroneously determined that Defendants' licensing-benefit defense is invalid because selling insulin is a "basic and familiar use of property" that cannot be conditioned. (ECF 133 at 22.) In reaching this conclusion, the magistrate erroneously relied on *Horne v. Department of Agriculture*, 576 U.S. 350, 366 (2015). *Horne* involved materially different facts: a mandatory agricultural marketing program for raisins. *Horne*, 576 U.S. at 354. It did not address a health and safety regulatory framework applicable to voluntary sales of a highly regulated product like insulin. *See E. Ark. Hospice, Inc. v. Burwell,* 815 F.3d 448, 450 (8th Cir. 2016) (distinguishing *Horne* and *Monsanto*). The magistrate's interpretation expanded *Horne*'s holding beyond its own recognized limits. *Horne* distinguished selling produce from selling potentially hazardous substances, recognizing the obvious difference between seizing agricultural products to preserve market prices, and assuring public health and safety. *Horne*, 576 U.S. at 365-66; *see also Cedar Point*, 594 U.S. at 161 (stating health and safety regimes generally not takings). The Court signaled it would reject a physical-takings claim in the context of conditioning the sale of a potentially dangerous product. *Id*.

Unlike raisins, insulin sales are heavily regulated precisely because insulin can cause serious harm or death if used incorrectly. Unlike the sale of produce, selling insulin in interstate commerce is not a basic and familiar use of insulin. Insulin sales have been

regulated since insulin's discovery in the 1920s. *See* U.S. Drug & Food Administration, 100 Years of Insulin, https://www.fda.gov/about-fda/fda-history-exhibits/100-years-insulin (last visited Feb. 17, 2024). And many states, including Minnesota, require manufacturers to be licensed to sell their drugs in that state. *See* Minn. Stat. § 151.252. Insulin manufacturers voluntarily chose to do business in Minnesota and obtain a license, fully aware of the Act's requirements. They did so because they benefit greatly from a Minnesota license, selling millions of dollars of drugs to Minnesotans annually.

Finally, the magistrate erroneously declared that complying with the Act is not a true condition of licensure because its violation cannot lead to revocation, citing the Act and *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232-33 (D.C. Cir. 2023). (Doc. 133 at 23.) The magistrate mentioned the penalties contained within the Act, incorrectly assuming that was the extent of the Board's authority. But the magistrate failed to consider the Board of Pharmacy's general powers to regulate and discipline manufacturers. *See* Minn. Stat. § 151.06, subd. 1(a)(2), (7). Manufacturers must be licensed annually to sell their drugs or do business in Minnesota. Minn. Stat. §§ 151.06, .252; Minn. R. 6800.1400. To obtain or renew a license, manufacturers must agree to operate as prescribed by state law, including compliance with the Act. Minn. Stat. §§ 151.252, subd. 1(d), .74. And when a licensee flouts its license requirements or otherwise violates laws relating to drug manufacturers, including the Act, the Board may deny, revoke, or suspend a license to operate in Minnesota. *Id.* § 151.071, subds. 1(1), (3), (4), 2(1), (8), (9).

Complying with the Act is a licensing condition wholly consistent with *Valancourt*. 82 F.4th at 1232-33. In *Valancourt*, the court held that a taking occurred when a statute

required publishers of copyrighted materials to give the Library of Congress free copies, an act unrelated to securing a copyright. Because providing a copy was not a prerequisite for copyright protection, they received no benefit in exchange for the property. *Id.* at 1232. Unlike *Valancourt*, the benefits of a Minnesota manufacturer's license are not illusory. Complying with the Act is a condition of obtaining and maintaining a manufacturer license. Without a license, a manufacturer cannot legally sell insulin or other drugs in Minnesota. *Valancourt* supports Defendants, demonstrating that the licensing-benefit defense applies to alleged per se physical takings when a benefit is received.

Even if the Court ultimately disagrees, no case forecloses the defense and Defendants are at a minimum entitled to argue that the licensing-benefit defense applies here. *See, e.g.*, *Lunsford*, 570 F.2d at 229.

B. The Magistrate Erred in Striking Defendants' Nuisance Defense.

Striking Defendants' nuisance defense similarly disregarded *Cedar Point* and, if broadly applied, the magistrate's reasoning would curtail states' ability to abate nuisances. The magistrate erroneously presumed that whether the nuisance defense applies to per se physical takings is an open question. But *Cedar Point* made clear that no taking occurs when the government requires abatement of a nuisance, even if it would otherwise constitute a per se physical taking. 594 U.S. at 161. And the magistrate prematurely found that Defendants' had not yet proved the insulin manufacturers engaged in a nuisance. Defendants have not yet had discovery or the opportunity to make this showing. It is also incorrect because the manufacturer's actions constitute nuisances under Minnesota law.

First, the magistrate incorrectly stated that whether the nuisance defense applies to per se physical takings is an open question, citing *Placer Mining Co. v. United States*, 98 Fed. Cl. 681, 685-86 (2011). (*See* Doc. 133 at 15-16 & n.5). But *Placer* predated *Cedar Point*'s clarification that nuisance is a defense to per se physical takings claims. In rebutting the dissent's concerns that the majority opinion would broadly endanger state and federal regulations, the Court emphasized that "many government-authorized physical invasions will not amount to takings because they are consistent with longstanding background restrictions on property," including the government's right to abate nuisances. 594 U.S. 159-61. Therefore, while the scope of the nuisance defense may have been unsettled when *Placer* was decided, the Supreme Court has since closed the question.

In finding that Defendants failed to identify a nuisance, the magistrate incorrectly looked to the inherent qualities of the property rather than to the plaintiff's *use* of the property as a nuisance. (Doc. 133 at 17.) The nuisance defense to takings rests on the principle that the property owner has no interest in using property to effectuate a nuisance. *See Cedar Point*, 594 U.S. at 160 (recognizing no compensation is owed for requiring landowner to abate nuisance "because he never had a right to engage in the nuisance in the first place"). The *use* of property may create a nuisance; the property itself does not need to be inherently noxious or dangerous. *See Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1029-31 (1992). Here, Minnesota's long-standing laws prohibit using insulin to perpetuate a nuisance, and the government may take property to abate the nuisance.

The magistrate's incorrect legal standard is highlighted by the discussion of *Fleet Farm*. There, the State properly stated a nuisance claim by alleging that the company sold

firearms to straw purchasers. The magistrate distinguished *Fleet Farm*, stating that "guns, unlike insulin—are themselves dangerous." (Doc. 133 at 19). This statement reflects an incorrect focus on the property rather than its use, and inaccurate factual assumptions about insulin. Insulin is a highly regulated prescription drug precisely because it can be lethal if taken incorrectly. But, regardless, guns versus insulin is not a meaningful distinction because the *Fleet Farm* nuisance was not the guns themselves but the act of selling guns to straw purchasers endangering the community's safety and health. *Minn. v. Fleet Farm LLC*, 2023 WL 4203088 at *1 (D. Minn. June 27, 2023) Here, one part of the nuisance is the unlawful act of monopolistic drug pricing endangering the safety and health of the community by causing death, hospitalization, and other injuries from insulin rationing. Moreover, the magistrate's attempt to distinguish of *Fleet Farm* by stating it is not a takings case ignores that it is a *nuisance* case and that it recognizes that selling lawful products can be a nuisance under state law. *See id.* at *12.

Further, the magistrate picked a single citation in Defendants' nuisance briefing to suggest that they rely on only non-binding precedent. (Doc. 133 at 19-20.) Defendants cited Minnesota laws prohibiting nuisances that predate the existence of insulin. *See, e.g.*, Minn. Stat. §§ 325D.52 (monopoly), 609.74 (public nuisance); Doc. 129 at 7-8; *see also State v. Duluth Bd. of Trade*, 121 N.W. 395, 398-99, 404 (Minn. 1909) (discussing history of Minnesota's monopoly laws); Minn. Stat. ch. 99, § 319 (1888) (nuisance).

The core question is whether the manufacturers' conduct meets Minnesota's definitions of nuisance. Minnesota has long defined "nuisance" as an act or omission that "unreasonably annoys, injures or endangers the safety, health, morals, comfort, or repose

of any considerable number of members of the public." Minn. Stat. § 609.74; Minn. Stat. ch. 99, § 319 (1888). Minnesota nuisance law is broad and fact dependent, without fixed rules. *See, e.g., Meagher v. Kessler*, 179 N.W. 732, 734 (Minn. 1920) (holding a funeral home a nuisance). Violating a law enacted for the protection of the public, like Minnesota's monopoly statute, has been held a public nuisance. *See State ex rel. Goff v. O'Neil*, 286 N.W. 316, 319 (Minn. 1939) (holding violating usury laws public nuisance). And, despite the magistrate's contention, a nuisance may exist regardless of whether there is a prior case precisely on point. *See State v. Juul Labs, Inc.*, No. 27-cv-19-19888, 2023 WL 2586110, at *13 (Minn. Dist. Ct. Mar. 14, 2023) (finding marketing strategy may constitute public nuisance despite no precedent).

Minnesota's nuisance law encompasses the circumstances that the Act attempts to remedy. The Act addressed the increasing unaffordability of insulin, due in part to the manufacturers' insulin pricing, which led to death and other injuries to Minnesotans forced to ration their insulin. (Docs. 16 at 1-8; 66 at 3-4.) The manufacturers' conduct endangered the health and safety of a considerable number of persons, rendering them insecure in life—meeting the definition of nuisance under Minnesota law.

Last, the magistrate's determination that Defendants cannot assert a nuisance defense because other available remedies exist contorts the underpinnings of the nuisance defense to takings. (Doc. 133 at 20-21.) Defendants are not voluntarily in this lawsuit. That the State pursued other claims against the manufacturers before the legislature enacted the Act is not a basis for barring state defendants from defending themselves in litigation that the manufacturers later initiated. The State's lawsuit did not give the manufacturers new

property rights and it is not the role of the Court to second-guess the State's litigation strategy.

As previously addressed, a plaintiff cannot claim a taking for property being used to perpetuate a nuisance because the plaintiff "never had a right to engage in the nuisance in the first place." *Cedar Point*, 594 U.S. at 160. The government's ability to take separate legal action against the manufacturers did not confer property rights where none exist. States are not limited to abating nuisances in any specific way and may exercise their judgment under the circumstances. *See Hadacheck v. Sebastian*, 239 U.S. 394, 413-14 (1915) (holding city validly exercised authority even if other actions "would have been better or less harsh.").

Defendant's nuisance defense is supported by state law, Supreme Court precedent, and the minimal factual record. The Court should correct the magistrate judge's "extreme measure" of sua sponte striking Defendants' defenses.

II. THE MAGISTRATE ERRED IN HOLDING THE INJUNCTIVE RELIEF FACTORS ARE IRRELEVANT IF THERE IS A TAKING.

The magistrate incorrectly held that, when a per se physical taking is alleged, "the injunctive factors analysis collapses into (or is coterminous with) the question whether a taking has occurred." (Doc. 133 at 26.) Neither PhRMA nor the magistrate cited any takings cases to support this determination. Their First Amendment and preemption cases are inapposite to takings law, where compensation is the prescribed remedy and injunctions are generally unavailable. *See* U.S. Const. amend. V; *Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2176, 2179 (2019) (holding equitable relief generally unavailable for

takings claims); *Watkins v. Lawrence Cnty., Ark.*, No. 17-cv-272, 2023 WL 2760001, at *2, 4-6 (E.D. Ark. Mar. 31, 2023) (evaluating factual evidence and denying injunction after jury found taking).

And contrary to the magistrate's determination, even outside the takings context, a district court maintains discretion to deny an injunction even when a constitutional violation is found. *See Calzone v. Summers*, 942 F.3d 415, 419-20, 426 (8th Cir. 2019) (en banc). For example, in *Calzone*, the court held that granting a permanent injunction lied within the district court's discretion, even though the law's application would violate the First Amendment. *Id*. Although *Calzone* was decided after the cases cited by the magistrate, and cited by Defendants, neither PhRMA nor the magistrate addressed it.

Courts must balance the harms when considering whether to enjoin a taking and act with caution when large public interests are concerned. *Hurley v. Kincaid*, 285 U.S. 95, 104 n.3 (1932). Unlike other constitutional rights, the Takings Clause does not bar the government's interference with a right; it "presupposes that the government has acted in pursuit of a valid public purpose" and requires compensation for the interference. *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005). The magistrate's determination that those injunctive factors fall from consideration when a taking is established is contrary to takings law, which the magistrate failed to address. Further, the Eighth Circuit's determination that PhRMA may *seek* equitable relief, does not relieve PhRMA from *proving* it is entitled to equitable relief. (*See* Doc. 133 at 26.)

This Court should reject the magistrate's determination that the injunctive relief factors fall from consideration if an uncompensated taking occurred and should allow discovery on the injunctive factors.

III. THE COURT SHOULD EXPAND THE SCOPE AND LENGTH OF DISCOVERY IN THE ORDERS.

Defendants recognize that magistrate judges generally have broad discretion in issuing scheduling orders and establishing discovery deadlines. In this case, however, the magistrate expressly relied on his improper resolution of the legal claims to limit discovery. He recognized that if available, Defendants' defenses would require more significant discovery and a longer time. (Doc. 133 at 1.) If the Court sustains Defendants' objections on the legal issues, the Court should further direct the magistrate to issue a new scheduling order.

Alternatively, if this Court adopts the magistrates legal determinations, it should modify the orders to allow some discovery on Defendants' topics 10, 12, 17-21, 25, 29, 32 as these topics relate to standing and PhRMA's affirmative allegations, not the struck defenses. (*See* Doc. 133-1.) For example, topic 10 includes the manufacturers' annual gross revenue, which is necessary to determine whether they are subject to the Act and topic 12 requests information on insulin provided under the continuing-need program of the Act. *See* Minn. Stat. § 151.74 subd. 1(c)(exempting manufacturers with an annual gross revenue of $2,000,000 or less from insulin sales). Further, the schedule should be extended. The magistrate limited discovery to three months, a length of time generally reserved for

expedited trials. Because the discovery permitted is still significant and is predominately in the possession of third parties, at least six months is necessary to conduct fact discovery.

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Respectfully submitted,

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