

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

Pharmaceutical Research and  
Manufacturers of America,

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

Plaintiff,

**DEFENDANTS' ANSWER  
TO PLAINTIFF'S  
COMPLAINT**

v.

Stuart Williams, et al.,

Defendants.

Defendants James Bialke, Ronda Chakolis, Barbara Droher Kline, Michael Haag, Ben Maisenbach, Kendra Metz, Amy Paradis, Rabih Nahas, and John Zwier, in their official capacities as members of the Minnesota Board of Pharmacy, and for their answer to Plaintiff Pharmaceutical Research and Manufacturers of America's (PhRMA) complaint, state as follows:<sup>1</sup>

Except as expressly admitted, qualified, denied, or otherwise answered, Defendants deny every allegation in the complaint.

1. As to paragraph 1, admit that the Minnesota Legislature enacted the Alec Smith Insulin Affordability Act ("Act") but state that it is no longer "newly" enacted as it

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<sup>1</sup> The Court previously denied as futile PhRMA's motion to supplement the complaint. (Mar. 15, 2021 Order 13-14, ECF No. 81.) On remand, PhRMA confirmed to the defendants that it intended to proceed on the original complaint rather than amend or supplement it. While that complaint named board members of MNsure, the Court previously dismissed them based on the parties' stipulation. (Sept. 17, 2020 Order, ECF No. 22.) Under Fed. R. Civ. P. 25(d), current Board of Pharmacy members Ronda Chakolis, Barbara Droher Kline, Michael Haag, Ben Maisenbach, and John Zwier should be substituted in their official capacities for former board members Andrew Behm, Stacey Jassey, Mary Phipps, Samantha Schirmer, and Stuart Williams.

was enacted in 2020; admit that the Act addresses a public concern; and deny that the Act is unconstitutional.

2. As to paragraph 2, admit that the public concerns stated in the first sentence exist, but deny to the extent that the paragraph implies that insurers are the sole or primary source of the insulin-affordability crisis. As to the second sentence, state that it is too vague for the board members to properly respond to and deny to the extent that it implies that Minnesota has taken unlawful steps to address the insulin-affordability crisis. As to the third sentence, deny.

3. As to paragraph 3, deny.

4. As to paragraph 4, lack sufficient information to admit or deny the beliefs of PhRMA or its members; deny that the Act is confiscatory; admit that three of PhRMA's members collectively manufacture most of the insulin sold in the United States; admit that, to the defendants' knowledge, some insulin manufacturers have affordability programs but lack sufficient information to admit or deny the scope of those programs or the degree of resources that manufacturers invest in them; and deny that individuals living with diabetes have not been forced to ration or forgo life-saving insulin because they cannot afford it.

5. As to paragraph 5, for the first sentence the defendants lack sufficient information to admit or deny the extent of any voluntary efforts by the insulin manufacturers; state that any efforts were insufficient to prevent or significantly abate the insulin-affordability crisis; and otherwise deny the allegations. As to the second sentence, deny and state that the Act provides for increasing civil penalties for non-exempt insulin manufacturers that fail to comply with the Act. As to the third and fourth sentences, admit

that the Act itself contains no specific provision to compensate insulin manufacturers; deny that the Act creates an unlawful compulsory appropriation of manufacturers' property; admit that insulin disbursed under the Act is for public use; and lack sufficient information to admit or deny that they incur substantial costs to comply with the Act.

6. As to paragraph 6, for the first sentence, deny that the Act applies to all insulin manufacturers, admit that the existence and scope of insurance coverage may affect Minnesotans' out-of-pocket costs for insulin, and deny to the extent that the paragraph implies that manufacturers have no control over insulin prices. As to the second sentence, admit that the Act allows pharmacies to charge a co-payment for dispensing insulin under the Act and deny the remaining allegations.

7. As to paragraph 7, state that this paragraph asserts only hypothetical facts and legal conclusions, which the defendants deny. Further, the defendants state that the insulin-affordability crisis maintained and permitted by an oligopoly of insulin manufacturers is unique and incomparable to other manufacturers and products. The defendants further state that the manufacturers agreed to the Act in exchange for the benefit of a Minnesota drug-manufacturer license.

8. As to paragraph 8, deny the first sentence; lack sufficient information to admit or deny the second sentence; for the third sentence, admit that the insulin-affordability crisis is a matter of public concern and deny the remaining allegations; for the fourth sentence admit that *Armstrong* is properly quoted and deny to the extent it implies the Act violates the Takings Clause.

9. As to paragraph 9, deny.

10. As to paragraph 10, based on information and belief, admit that PhRMA is a non-profit corporation that represents pharmaceutical companies and lack sufficient information to admit or deny the remaining allegations.

11. As to paragraphs 11 and 12, lack sufficient information to admit or deny.

12. As to paragraph 13, for the first sentence, admit that PhRMA purports to bring this lawsuit on behalf of itself and its members, but deny that it has standing or associational standing. As to the second and third sentences, deny that the Act directly affects PhRMA or its core goals and deny that the Act is unconstitutional and unlawfully harms its members. As to the fourth sentence, admit that PhRMA's three members manufacture most of the insulin sold in the United States and were subject to the Act, and lack sufficient information to admit or deny the remaining allegations.

13. As to paragraph 14, deny.

14. As to paragraph 15, admit that the defendants are members of the Board of Pharmacy, named only in their official capacities; state that members of the Board of MNsure are no longer defendants to this action; state that the Board of Pharmacy is charged with enforcing the Act, not its individual members; deny that the Board of MNsure, or its members, are charged with enforcing the Act.

15. As to paragraphs 16-19, deny the individuals named are currently members of the Board of Pharmacy.

16. As to paragraphs 20-22, admit.

17. As to paragraphs 23, deny that the individual named is currently a member of the Board of Pharmacy.

18. As to paragraph 24, admit.

19. As to paragraphs 25-26, deny.

20. As to paragraphs 27-29, admit that they hold the alleged positions but deny that they remain defendants to this case.

21. As to paragraph 30, deny.

22. As to paragraphs 31-32, admit that they hold the alleged position but deny that they remain defendants to this case.

23. As to paragraph 33-34, deny.

24. As to paragraph 35, admit that venue lies in this district but deny that the Act will be enforced by each defendant in this district as only the Board of Pharmacy as a whole, not the individual members, has enforcement authority, and state that the Board of Pharmacy has not yet taken an enforcement action under the Act since it became effective.

25. As to paragraphs 36-42, state that: the most recent data from the Centers for Disease Control and the Minnesota Department of Health reflect that approximately 37.3 million Americans, including approximately 390,000 Minnesotans (as of 2020), have diabetes; the CDC also recognizes gestational diabetes as a type of diabetes in addition to type 1 and type 2 diabetes; and, upon information and belief, that the companies named in paragraph 42 have additional insulin products not listed. Defendants lack sufficient information to admit or deny the specific statistics cited regarding expected lifespans and the extent of PhRMA's members' investments in developing insulin products, but generally admit that, before the discovery of insulin, those with diabetes generally did not

live long after diagnosis and that the early forms of injectable insulin extended life expectancies. Defendants admit the remaining allegations.

26. As to paragraph 43, admit that Lilly, Novo Nordisk, and Sanofi have worked to improve insulin products and diabetes-management options and lack sufficient information to admit or deny the second sentence and the specific statistics alleged.

27. As to paragraph 44, lack sufficient information to admit or deny allegations related to PhRMA's members current research efforts and product development, but admit generally that manufacturers have released insulin products.

28. As to paragraph 45-46, lack sufficient information to admit or deny how manufacturers use sales revenue or the length or costs of their research and development process and admit that PhRMA has made the stated assertions in the publication it cites, but lack sufficient information to admit or deny the accuracy of the claims.

29. As to paragraph 47, state that the language of the United States Code speaks for itself, admit manufacturers sell some products to wholesalers, and lack sufficient information to admit or deny the remaining allegations.

30. As to paragraph 48, deny as to the uninsured and individuals on high-deductible insurance plans.

31. As to paragraphs 49-51, deny to the extent that PhRMA implies that insulin manufacturers do not establish the cost of insulin and that the wholesale acquisition costs they set have no role in the prices that people with insurance pay; state that not all insulin users have insurance coverage; assert that, based on information and belief, the wholesale acquisition cost for insulin reflects neither the actual cost to manufacture insulin nor the

cost necessary for manufacturers to still recognize a profit, and that the insulin prices set by manufacturers operate as a benchmark that health plans, pharmacy benefit managers, wholesalers, and pharmacies will use to set the prices they charge; state that the paragraph is vague as it refers to general processes for unspecified medications, and otherwise admit.

32. As to paragraph 52, lack sufficient information to admit or deny the first and second sentences. As to the third sentence, admit that Minnesota enacted Minn. Stat. § 62Q.48, and that it applies to health plans issued or renewed on or after January 1, 2020; state the statute speaks for itself; and lack sufficient information to admit or deny the specific problems the legislators were seeking to address in enacting the law. As to the last sentence, deny and state that the insulin manufacturers agreed to the Act in exchange for the valuable benefit of a Minnesota drug-manufacturer license.

33. As to paragraph 53, as to the first sentence, admit that federal and state laws and regulations may affect drug costs for Medicaid beneficiaries but deny to the extent that it implies that the cost established by the manufacturer does not affect insulin prices. As to the second sentence, state that the cited statute speaks for itself.

34. As to paragraph 54, deny the first and second sentences to the extent that they imply that the prices uninsured individuals pay for insulin are not tied to the manufacturers' wholesale acquisition costs. As to the third sentence, admit that, based on information and belief, some insulin manufacturers have insulin-affordability programs but lack sufficient information to admit or deny the scope or effectiveness of these programs.

35. As to paragraph 55, lack sufficient information to admit or deny but state that the insulin manufacturers control the wholesale acquisition costs, discounts, rebates, and net price.

36. As to paragraphs 56-63, based on information and belief, admit that the identified manufacturers have different insulin-assistance programs, but lack sufficient information to admit or deny allegations relating to the scope, details, or impact of those programs, or the manufacturer's motives related to those programs. The defendants state that, on information and belief, the programs' application processes are often complex and difficult to navigate, that the programs may not provide immediate access to insulin, and that insulin manufacturers have denied the applications of Minnesotans, including Alec Smith's applications before he died of diabetic ketoacidosis. The defendants further state that the manufacturers can change or eliminate their programs at any time and, upon information and belief, have changed some of their programs since commencing this action. Defendants further state that the Inflation Reduction Act now caps out-of-pocket costs to \$35 a month for each insulin product covered under a Medicare Part D plan with similar limits for insulin supplied under Part B.

37. As to paragraph 64, admit the first and third sentence. As to the second sentence, deny that the Act applies to all insulin manufacturers and insulin products and that the Act's urgent-need program requires manufacturers to provide insulin; and state that the Act speaks for itself.

38. As to paragraphs 65-71, deny that the Act applies to all insulin manufacturers and insulin products and state that the Act speaks for itself.



39. As to paragraphs 72-74, deny that the Act applies to all insulin manufacturers and insulin products, deny that the Act's urgent-need program requires manufacturers to provide a "30-day supply of free insulin" or "free insulin," *see* Minn. Stat. § 151.74, subd. 3(d); and state that the Act speaks for itself.

40. As to paragraph 75, deny that manufacturers are being "forced to give away their insulin for free"; state that manufacturers agreed to the Act in exchange for the benefit of a Minnesota drug-manufacturer license; and lack sufficient information to admit or deny whether the non-exempt manufacturers will incur significant expenses in developing or administering the programs under the Act.

41. As to paragraph 76, deny that the Board of MNsure has authority to impose the alleged penalties and state that the Act speaks for itself.

42. As to paragraph 77, deny that the Act applies to all insulin manufacturers or insulin products and that the Act's exceptions are "limited," and state that the Act speaks for itself.

43. As to paragraph 78, lack sufficient information to admit or deny given the manufacturer's recently announced price reductions and state that, upon information and belief, the manufacturers have insulin products that are exempt under the Act.

44. As to paragraph 79, admit that the alleged numbers were assumptions stated in a fiscal note in 2020, but state that the fiscal note was for an earlier and different version of the Act, and deny that the assumptions were accurate.

45. As to paragraph 80, the defendants incorporate their prior answers to the paragraphs incorporated by reference.

46. As to paragraph 81, the allegations contain only legal conclusions to which no response is required, but otherwise admit.

47. As to paragraphs 82-85, deny.

48. As to paragraph 86, the defendants incorporate their prior answers to the paragraphs incorporated by reference.

49. As to paragraph 87, admit the first sentence and state the act speaks for itself; lack sufficient information to admit or deny what PhRMA is aware of and state that, upon information and belief, there are insulin manufacturers that sell insulin products for \$8 per milliliter or less in the U.S.; and deny the remaining allegations.

50. As to paragraph 88, state that this paragraph asserts only legal conclusions and deny to the extent a response is required.

51. As to paragraph 89, state that this paragraph asserts only legal conclusions and deny to the extent a response is required.

52. As to PhRMA's request for relief, admit that it is seeking the stated relief but deny that it is entitled to any relief.

## **DEFENSES**

1. The complaint fails, in whole or in part, to state a claim against the defendants upon which relief can be granted.

2. PhRMA lacks standing and associational standing to bring this action on behalf of its members.

3. Defendants are immune from this lawsuit.

4. The Act does not violate the Takings or Dormant Commerce Clauses.

5. PhRMA's members maintained and permitted a public nuisance that the Act seeks to abate.

6. PhRMA's members agreed to the Act in exchange for the benefit of a Minnesota drug-manufacturer license.

7. To the extent any harm is alleged, PhRMA's members failed to mitigate it.

8. Defendants reserve the right to supplement or amend their affirmative and other defenses as the action progresses.

WHEREFORE, the defendants ask this Court to dismiss the complaint and the causes of action therein, enter judgment in the defendants' favor with respect to PhRMA's complaint, and award the defendants their costs and disbursements incurred in connection with PhRMA's complaint, including reasonable attorney's fees.

Dated: August 17, 2023

Respectfully submitted,

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