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April 8, 2025

Honorable David S. Doty
Senior U.S. District Judge, District of Minnesota
United States District Court
12W U.S. Court House
300 South Fourth Street
Minneapolis, MN 55415

Re: *Pharmaceutical Research and Manufacturers of America v. Chakolis et al.*,
No. 20-CV-1497-DSD-DTS

Dear Judge Doty:

Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) writes in response to Defendants' April 4, 2025 letter advising the Court of a settlement between Minnesota and PhRMA's member Novo Nordisk Inc. under which Novo Nordisk "must make its insulin products available for \$35 per month or less to cash-paying customers, as defined therein, and continue offering free insulin to certain Minnesota residents, among other terms." ECF No. 164 at 1. Defendants argue that entry of this settlement supports their argument that PhRMA lacks standing because Minnesota residents will obtain insulin products under the settlement—not under the challenged law. That is incorrect. As shown in PhRMA's opposition to Defendants' motion to dismiss, PhRMA's members have in the past—and will continue to—suffer the injury of being forced to give away their insulin products under the challenged law. *See* ECF No. 159 at 16–18.

PhRMA's argument finds further confirmation in the Minnesota Board of Pharmacy's most recent report to the Minnesota Legislature on the law's Insulin Safety Net Program. *See* Ex. 1. That report, dated February 26, 2025, confirms that each PhRMA member discussed in the Amended Complaint gave away insulin under the challenged law in 2024. *See id.* at 4, 5. That is true even though two of those members entered into settlements with Minnesota akin to Novo Nordisk's settlement in 2024. *See* ECF No. 155 at 16.

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Respectfully submitted,

/s/ Benjamin M. Mundel

Benjamin M. Mundel
Partner

Attachment

cc: All counsel of record (via e-filing)

EXHIBIT 1



MINNESOTA BOARD OF PHARMACY

Report to the Legislature on the Minnesota Insulin Safety Net Program. (In compliance with Minnesota Statutes Section 151.74, Subd. 13)

Data Year ending 2024

Aaron Patterson PharmD

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February 26, 2025

COST OF REPORT

Minnesota Statutes §3.197 states that a “report to the legislature must contain, at the beginning of the report, the cost of preparing the report, including any costs incurred by another agency or another level of government”. The estimated cost of preparing this report was \$1,200.00. That is the approximate value, in terms of salary and benefits, of the time that Board staff spent communicating with manufacturers, administering any exemptions, and preparing the report.

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Introduction

The Board of Pharmacy (Board) is submitting this report to the Legislature in compliance with Minn. Stats. §151.74, subdivision 13, which states:

Subd. 13. **Reports.** (a) By February 15 of each year, beginning February 15, 2021, each manufacturer shall report to the Board of Pharmacy the following:

1. (1) the number of Minnesota residents who accessed and received insulin on an urgent-need basis under this section in the preceding calendar year;
2. (2) the number of Minnesota residents participating in the manufacturer's patient assistance program in the preceding calendar year, including the number of Minnesota residents who the manufacturer determined were ineligible for their patient assistance program; and
3. the value of the insulin provided by the manufacturer under clauses (1) and (2).

For purposes of this paragraph, "value" means the wholesale acquisition cost (WAC) of the insulin provided.

(b) By March 15 of each year, beginning March 15, 2021, the Board of Pharmacy shall submit the information reported in paragraph (a) to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance. The board shall also include in the report any administrative penalties assessed under subdivision 10, including the name of the manufacturer and amount of the penalty assessed.

Reporting By Manufacturers

Changes in the Minnesota insulin manufacturers market included that "Mylan Specialty LP, a Viatris Company" transitioned all insulin products to Biocon between 2023 and 2024. Additionally, Baxter Healthcare company and MannKind were identified for single product offerings within the Minnesota marketplace. Other manufacturers participating in the Minnesota insulin market or Insulin Safety Net Program include Eli Lilly and Company, Sanofi, and Novo Nordisk. The total number of Minnesota insulin manufacturers increased to six.

Three companies including Baxter, Biocon, and MannKind sought exemption waivers from the Insulin Safety Net program as specified in Minn. Stats. §151.74, subdivision 1 (c) which states:

(c) Any manufacturer with an annual gross revenue of \$2,000,000 or less from insulin sales in Minnesota is exempt from this section. To request a waiver under this paragraph, the manufacturer must submit a request to the Board of Pharmacy that includes documentation indicating that the manufacturer is eligible for an exemption.

All manufacturers submitted the required data and/or exemptions for calendar year 2024. The data and other information reported are provided below. The data submitted indicate that collectively the reporting manufacturers provided insulin under the Minnesota Insulin Safety Net Program to as many as **217 residents**. Since some residents may have received insulin under both the Urgent and Continuing Needs Programs, fewer total residents may have benefited. For comparison, the 2024 figure is down from the 2023 total of 269 residents.

The total value of the insulin received by residents was **\$82,174**. (Based on the wholesale acquisition cost of the insulin – not the cost that the residents would have paid if they had purchased the insulin on their own).

All dollar amounts provided were rounded to the nearest whole dollar for this report.

Eli Lilly

	2024
Urgent Need Recipients	45
Value of Insulin Provided to Urgent Need Recipients	\$15,700
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Continuing Need Applicants	
Total number of participants	4
Total number of ineligible applicants	1
Value of Insulin Provided to Continuing Need Recipients	\$3,364
Total Value of Insulin Provided	\$19,064

The report reflects participation in Lilly's Minnesota patient assistance programs only. Lilly offers a number of other insulin affordability solutions for patients. Minnesota residents may have accessed Lilly insulin through Lilly's other assistance programs, and these patients (and the value of the associated insulin) are not included in this report. Note a patient may have applied to the Continuing Needs Program to receive more than one product or used the Urgent Needs Program for more than one product. In those cases, the patient is counted only one time in the respective program.

The "Total number of participants" in the Lilly MN Continuing Needs Program reflects the number of unique patients who received product in 2024. This includes individuals who may have enrolled in 2023, but who continued to receive product in 2024 (when their enrollment expired), as well as new patients who enrolled in the program and received product in 2024.

Value of Insulin Provided is the WAC price of the product on the date filled by the patient.

Novo Nordisk (Novo Nordisk Inc.)*

	2024
Urgent Need Recipients	19
Value of Insulin Provided to Urgent Need Recipients	\$4,355
Continuing Need Applicants	
Total number of participants	9
Total number of ineligible applicants	9
Value of Insulin Provided to Continuing Need Recipients	\$35,601
Total Value of Insulin Provided	\$39,956

*Nordisk reported two separate reports, one for each virtual manufacturer business unit registered with the board.

Novo Nordisk Pharma Inc (MN 461644)

Novo Nordisk, Inc (MN 460293)

Novo also maintains another manufacturer registered with the board as a contract manufacturer.

Novo Nordisk Pharmaceutical Industries, LP (MN 461798)

The method of reporting this information varies from previous reports provided. It is represented as separate reporting manufacturers.

Novo Nordisk also provided an additional letter describing the company's own Patient Assistance Program offerings. A copy of the letter directly follows this report. See *Appendix A*.

Novo Nordisk (Novo Nordisk Pharma, Inc.)*

	2024
Urgent Need Recipients	20
Value of Insulin Provided to Urgent Need Recipients	\$4,077
Continuing Need Applicants	
Total number of participants	0
Total number of ineligible applicants	0
Value of Insulin Provided to Continuing Need Recipients	0
Total Value of Insulin Provided	\$4,077

*Nordisk reported two separate reports, one for each virtual manufacturer business unit registered with the board.

Novo Nordisk Pharma Inc (MN 461644)

Novo Nordisk, Inc (MN 460293)

Novo also maintains another manufacturer registered with the board as a contract manufacturer.

Novo Nordisk Pharmaceutical Industries, LP (MN 461798)

The method of reporting this information varies from previous reports provided. It is represented as separate reporting manufacturers.

Sanofi

	2024
Urgent Need Recipients	105
Value of Insulin Provided to Urgent Need Recipients	\$14,217
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Continuing Need Applicants	
Total number of participants	6
Total number of ineligible applicants	7
Value of Insulin Provided to Continuing Need Recipients	\$1,224
Total Value of Insulin Provided	\$15,441

The figures above are reflective of the Minnesota mandated programs that Sanofi offers only, and do not include data for any other Sanofi run programs.

With regard to the "number of Minnesota residents participating in the manufacturer's patient assistance program in the preceding calendar year including the number of Minnesota residents who the manufacturer determined were ineligible for their patient assistance program, the "manufacturer's patient assistance program" is only referring to the Minnesota mandated program that Sanofi offers.

**The "Total number of participants" for continuing need applicants means the total number of Minnesota residents that received at least 1 shipment of product in calendar year 2024

Biocon Biologics

As of September 1, 2023, Biocon Biologics Inc. assumed the marketing of insulin products in Minnesota from “Mylan Specialty L.P., a Viatris company”.

	2024
Urgent Need Recipients	9
Value of Insulin Provided to Urgent Need Recipients	\$3,636
Continuing Need Applicants	
Total number of participants	0
Total number of ineligible applicants	0
Value of Insulin Provided to Continuing Need Recipients	0
Total Value of Insulin Provided	\$3,636

Note: All Minnesota patients are reviewed under Biocon Biologics’ current free drug PAP (Patient Assistance Program) eligibility criteria; however, if a patient from Minnesota does not qualify for free drug under our PAP, then that patient would be immediately reevaluated under our Minnesota Insulin Continuing Need (Safety Net) Program eligibility criteria.

Baxter Healthcare

Baxter provided information which indicated it is exempt from the Insulin Safety Net Program. Baxter’s single product offering is not a consumer insulin product and is only used intravenously via administration by licensed healthcare personnel in inpatient or urgent/emergent healthcare settings.

MannKind

MannKind provided information which indicated it is exempt from the Insulin Safety Net Program.

Assessment of Civil Penalties

All insulin manufacturers complied with the provisions of Minn. Stats. §151.74. The Board did not assess any civil penalties under subdivision 10.