

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

Pharmaceutical Research and)
Manufacturers of America)
)
Plaintiff)
)
v.)
)
Stuart Williams, et al.,)
)
Defendants.)

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

BRIEF OF T1INTERNATIONAL, MINNESOTA #INSULIN4ALL, NICOLE SMITH-HOLT, NATHAN LOEWY, CINDY BOYD, ABIGAIL HANSMEYER, MID-MINNESOTA LEGAL AID, AND THE NATIONAL HEALTH LAW PROGRAM AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS’ OPPOSITION TO PLAINTIFF’S MOTION FOR SUMMARY JUDGMENT

CORPORATE DISCLOSURE STATEMENT

Amici curiae T1International, Minnesota #insulin4all, Mid-Minnesota Legal Aid, and the National Health Law Program disclose that they have no parent corporation and issue no stock. Accordingly, no publicly held corporation owns ten percent or more of their stock.

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Statutes

2020 Minn. Laws ch. 73, § 4 2, 3

Other Authorities

Am. Diabetes Ass’n, *Standards of Medical Care in Diabetes—2020*, 43
 Diabetes Care (Supplement 1) S1 (2020) 4, 5, 6, 9

Am. Diabetes Ass’n & Vault Consulting, LLC, *Insulin Affordability Survey
 2018* (2018), [http://main.diabetes.org/dorg/PDFs/2018-insulin-affordability-
 survey.pdf](http://main.diabetes.org/dorg/PDFs/2018-insulin-affordability-survey.pdf) 9, 10, 11

Annual Update of the HHS Poverty Guidelines, 85 Fed. Reg. 3060
 (Jan. 17, 2020) 3

Julia Belluz, *Walmart’s \$25 insulin can’t fix the diabetes drug price crisis*,
 Vox (Apr. 11, 2019), [https://www.vox.com/science-and-
 health/2019/4/10/18302238/insulin-walmart-reilion](https://www.vox.com/science-and-health/2019/4/10/18302238/insulin-walmart-reilion) 10

Fuglesten Biniek & William Johnson, Health Care Cost Inst., *Spending on
 Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*
 (2019), [https://healthcostinstitute.org/diabetes-and-insulin/spending-on-individuals
 -with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices](https://healthcostinstitute.org/diabetes-and-insulin/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices) 8

Calculating Insulin Dose, Diabetes Educ. Online, Diabetes Teaching Ctr. at
 the Univ. of Cal., S.F., [https://dtc.ucsf.edu/types-of-diabetes/type1/treatment-of-
 type-1-diabetes/medications-and-therapies/type-1-insulin-therapy/calculating-
 insulin-dose/](https://dtc.ucsf.edu/types-of-diabetes/type1/treatment-of-type-1-diabetes/medications-and-therapies/type-1-insulin-therapy/calculating-insulin-dose/) (last visited Nov. 1, 2020) 5

William T. Cefalu, et al., *Am. Diabetes Ass’n, Insulin Access and Affordability
 Working Group: Conclusions and Recommendations*, 41 Diabetes Care 1299
 (2018), <https://care.diabetesjournals.org/content/diacare/41/6/1299.full.pdf>. 7

Ctrs. for Disease Control and Prevention, *National Diabetes
 Statistics Report, 2020* (2020), [https://www.cdc.gov/diabetes/pdfs/data/
 statistics/national-diabetes-statistics-report.pdf](https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf) 4, 12, 13

Continuous Glucose Monitoring, Nat’l Inst. of Diabetes and Digestive and
 Kidney Diseases (June 2017), [https://www.niddk.nih.gov/health-information/
 diabetes/overview/managing-diabetes/continuous-glucose-monitoring](https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring) 6

Nitesh K. Choudhry et al., *Drug Company-Sponsored Patient Assistance Programs: A Viable Safety Net*, 28 Health Aff. 827 (2009), <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.28.3.827> 11

Diagnosed Diabetes, Ctrs. for Disease Control and Prevention U.S. Diabetes Surveillance Sys., <https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html#> (last updated July 2020)..... 4

Diabetes Medication Use, Ctrs. for Disease Control and Prevention U.S. Diabetes Surveillance Sys., <https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html#> (last updated July 2020)..... 4

Austin Frerick, U.S. Dep’t. of the Treasury, Office of Tax Analysis, *The Cloak of Social Responsibility: Pharmaceutical Corporate Charity*, 153 Tax Notes 1151 (2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2874391. 12

Sherry Glied & Benjamin Zhu, The Commonwealth Fund, *Not So Sweet: Insulin Affordability over Time* (2020), https://www.commonwealthfund.org/sites/default/files/2020-09/Glied_not_so_sweet_insulin_affordability_ib.pdf. 7, 9

Markian Hawryluk, *Not Pandemic-Proof: Insulin Copay Caps Fall Short, Fueling Underground Exchanges*, Kaiser Health News (Oct. 5, 2020), <https://khn.org/news/not-pandemic-proof-insulin-copay-caps-fall-short-fueling-underground-exchanges/> 10

Darby Herkert et al., *Cost-Related Insulin Underuse Among Patients With Diabetes*, 179 JAMA Internal Med. 112 (2019)..... 9, 12

HHS, Notice of Benefit and Payment Parameters Rule for 2021, 85 Fed. Reg. 29229 (May 14, 2020) 11

Insulin, Medicines, & Other Diabetes Treatments, Nat’l Inst. of Diabetes and Digestive and Kidney Diseases (Dec. 2016), <https://www.niddk.nih.gov/health-information/diabetes/overview/insulin-medicines-treatments>. 5

IQVIA Inst. for Human Data and Science, *Diabetes Costs and Affordability in the United States* (2020), <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/diabetes-reports/diabetes-costs-and-affordability-in-the-us.pdf> 11

Ashish Jha et al., *Greater Adherence to Diabetes Drugs Is Linked to Less Hospital Use and Could Save Nearly \$5 Billion Annually*, 31 Health Aff. 1836 (2012).. 13

Kaiser Family Found., *2020 Employer Health Benefits Survey* (2020), <http://files.kff.org/attachment/Summary-of-Findings-Employer-Health-Benefits-2020.pdf> 11

Hyojung Kanga et al., *Cost-Related Medication Non-Adherence among U.S. Adults with Diabetes*, 143 *Diabetes Res. & Clinical Pract.* 24 (2018) 9

Jing Luo et al., *Strategies to Improve the Affordability of Insulin in the USA*, 5 *Lancet Diabetes & Endocrinology* 158 (2017), [https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(17\)30041-4/fulltext](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(17)30041-4/fulltext) 7

Managing Diabetes, Nat’l Inst. of Diabetes and Digestive and Kidney Diseases (Dec. 2016), <https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes#Blood%20Glucose>..... 6

M. Monami et al., *Long-acting Insulin Analogues vs. NPH Human Insulin in Type 1 Diabetes: A Meta-analysis*, 11 *Diabetes, Obesity & Metabolism* 372 (2009)..... 5

MPR News Staff, *Minnesota sees big jump in people without health insurance* (Feb. 20, 2018), <https://www.mprnews.org/story/2018/02/20/health-insurance-minn-big-jump-people-lacking-coverage> 9

Victoria Musey et al., *Diabetes in Urban African Americans: Cessation of Insulin Therapy is the Major Precipitating Cause of Diabetic Ketoacidosis*, 18 *Diabetes Care* 483 (1995). 13

Anne L. Peters et al., *Diabetes Technology – Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults; An Endocrine Society Clinical Practice Guideline*, 101 *J. Clinical Endocrinology & Metabolism* 3922 (2016), <https://academic.oup.com/jcem/article/101/11/3922/2764917>..... 5, 6

Preventing Diabetes Problems, Nat’l Inst. of Diabetes and Digestive and Kidney Diseases (Dec. 2016), <https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-problems/all-content> 13

Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95 *Mayo Clinic Proceedings* 22 (2020), <https://www.mayoclinicproceedings.org/action/showPdf?pii=S0025-6196%2819%2931008-0>..... 7, 8

T1International, *Costs and Rationing of Insulin and Diabetes Supplies, Findings from the 2018 T1International Patient Survey* (2018), https://www.t1international.com/media/assets/file/T1International_Report_-_Costs_and_Rationing_of_Insulin_Diabetes_Supplies_2.pdf 9, 12

Tiffany Stanley, *Life, Death and Insulin*, Wash. Post Magazine (Jan. 7, 2019), <https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/> 7

Type 2 Diabetes, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/diabetes/basics/type2.html> (May 30, 2019) 4

Types of Insulin, Diabetes Educ. Online, Diabetes Teaching Ctr. at the Univ. of Cal., S.F., <https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/medications-and-therapies/type-2-insulin-rx/types-of-insulin/> (last visited Oct. 29, 2020) 5

Univ. of Minn., *News Release, COVID-19 Impact: As many as 18.4 million Americans face disruptions and potential loss of health insurance coverage* (April 24, 2020), <https://twin-cities.umn.edu/news-events/covid-19-impact-many-184-million-americans-face-disruptions-and-potential-loss-health> 9

Dyanne P. Westerberg, *Diabetic Ketoacidosis: Evaluation and Treatment*, 87 *Am. Fam. Physician* 337 (2013), <https://www.aafp.org/afp/2013/0301/afp20130301p337.pdf> 12

What is Diabetes?, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/diabetes/basics/diabetes.html> (last updated June 11, 2020) 3, 4

Samantha Willner et al., *“Life or Death”: Experiences of Insulin Insecurity among Adults with Type 1 Diabetes in the United States*, *SSM - Population Health*, June 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7352063/pdf/main.pdf> 8, 10, 13

INTEREST OF AMICI

T1International is a nonprofit organization that envisions a world where everyone with type 1 diabetes has everything they need to survive and achieve their dreams. Led by people with and impacted by type 1 diabetes, T1International supports local communities by giving them the tools they need to stand up for their rights so that access to insulin and diabetes supplies becomes a reality for all.

Supported by T1International, Minnesota #insulin4all is a group of volunteer advocates raising awareness about the insulin price crisis and fighting for insulin pricing transparency and affordability in Minnesota.

The individual *amici* are Minnesota residents whose lives have been profoundly affected by the high price of insulin.¹ They include two mothers whose sons died because they could not afford the insulin they needed. They also include individuals who have struggled to afford insulin themselves. The individual *amici* are also advocates for people with diabetes and pushed for the introduction and passage of the Alec Smith Insulin Affordability Act.

Mid-Minnesota Legal Aid (MMLA) has provided free legal services in civil matters to income-eligible Minnesotans in 20 counties across central Minnesota since 1913. MMLA's representation and advocacy focus on the legal problems of low-income families and individuals. MMLA is also designated by the Governor of Minnesota, pursuant to federal statutes, to serve as the Protection and Advocacy System for persons

¹ While some of the individual *amici* work for T1International and/or volunteer with Minnesota #insulin4 all, each individual joins the brief in their personal capacity.

with disabilities in Minnesota. MMLA performs this function through its Minnesota Disability Law Center (MDLC), a statewide project. MDLC provides individual advocacy to help persons with disabilities obtain appropriate and necessary health care, including medications and prescription drug coverage, and engages in systems and policy advocacy to develop, maintain, and improve the health care programs that help people with disabilities live healthy lives in their communities.

Founded in 1969, the National Health Law Program (NHeLP) is a public interest organization dedicated to improving access to quality health care, including prescription drugs, for low-income and underserved individuals. To achieve its mission, NHeLP advocates, educates, and litigates at the federal and state levels.

As such, each of the *amici* have a strong interest in the outcome of this case.²

SUMMARY OF ARGUMENT

In April 2020, the Minnesota legislature passed the Alec Smith Insulin Affordability Act. 2020 Minn. Laws ch. 73, § 4. Under the Act, Minnesota residents who have an urgent need for insulin can access a 30-day supply at the pharmacy for no more than \$35. *Id.* §4(2)-(3). And, residents who have an ongoing need for insulin and have household income below 400% of the federal poverty level (roughly \$51,000 for a household size of one) can continue to access insulin for no more than \$50 every three

² Counsel for *amici curiae* states that no counsel for a party authored this brief in whole or in part and no person, other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission.

months. *Id.* §4(4)-(6); Annual Update of the HHS Poverty Guidelines, 85 Fed. Reg. 3060 (Jan. 17, 2020).

This safety net is desperately needed. Individuals with type 1 diabetes, as well many individuals with type 2 diabetes, use insulin to control their blood glucose levels; these patients must administer insulin multiple times a day via injection or insulin pump. Without insulin, people with diabetes can quickly develop diabetic ketoacidosis, a potentially fatal medical condition. Over the long term, uncontrolled blood glucose levels can cause serious, irreversible health complications. Despite the fact that people with diabetes need insulin to survive, pharmaceutical manufacturers have increased the price of insulin exponentially over the past two decades, making it unaffordable for many people. Recent research demonstrates that roughly one-quarter of people with diabetes ration insulin due to cost. The individual *amici* represent those people. Their own stories and the stories of their family members reveal the incalculable human cost of the high price of insulin and the critical need for the programs created by the Act.

ARGUMENT

I. To Manage Their Condition, Individuals With Diabetes Need Insulin and Diabetes Medical Supplies

Diabetes is a serious condition that causes higher than normal blood glucose levels. *What is Diabetes?*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/diabetes/basics/diabetes.html> (last updated June 11, 2020). It occurs when the body cannot make or effectively use insulin, a hormone produced by the pancreas that allows the sugars from food to enter cells and be used for energy. *Id.* The

two most common forms of diabetes are type 1 and type 2. *See id.* In type 1 diabetes, the pancreas does not produce insulin. *Id.* In type 2 diabetes, while the pancreas does produce insulin, cells have become resistant to it, meaning they cannot properly absorb sugars.

Type 2 Diabetes, Ctrs. for Disease Control and Prevention,

<https://www.cdc.gov/diabetes/basics/type2.html> (last updated May 30, 2019).

Nationally, over 34 million people have some form of diabetes. Ctrs. for Disease Control and Prevention, *National Diabetes Statistics Report, 2020*, 2 (2020),

<https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

In Minnesota, 358,000 adults alone have been diagnosed with the condition. *Diagnosed Diabetes*, Ctrs. for Disease Control and Prevention U.S. Diabetes Surveillance Sys.,

<https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html#> (last updated July 2020). Notably,

diabetes disproportionately affects people of color. Ctrs. for Disease Control and Prevention, *National Diabetes Statistics Report, 2020*, *supra*, at 4 (finding rates of diagnosed diabetes highest among American Indians/Alaska Natives, Hispanics, and non-Hispanic Blacks).

All people with type 1 diabetes need injectable insulin to survive. Am. Diabetes Ass'n, *Standards of Medical Care in Diabetes—2020*, 43 *Diabetes Care* (Supplement 1) S1, S98 (2020). While there are various treatment options for type 2 diabetes, many people eventually require insulin therapy to lower their blood sugar. *Id.* at S105. In total, 8.2 million Americans rely on insulin. *Diabetes Medication Use*, Ctrs. for Disease Control and Prevention U.S. Diabetes Surveillance Sys.,

<https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html#> (last updated July 2020). The

amount of insulin a person requires varies based on a number of factors, including time of day, physical activity, and stress. *Calculating Insulin Dose*, Diabetes Educ. Online, Diabetes Teaching Ctr. at the Univ. of Cal., S.F., <https://dtc.ucsf.edu/types-of-diabetes/type1/treatment-of-type-1-diabetes/medications-and-therapies/type-1-insulin-therapy/calculating-insulin-dose/> (last visited Nov. 1, 2020).

There are a number of different insulin products, which vary in properties including how fast they take effect and how long they last. *Types of Insulin*, Diabetes Educ. Online, Diabetes Teaching Ctr. at the Univ. of Cal., S.F., <https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/medications-and-therapies/type-2-insulin-rx/types-of-insulin/> (last visited Oct. 29, 2020). Insulin products contain traditional “human” insulin, newer “analog” insulin, or a combination of the two. *Id.* Human insulin products are less expensive than analog insulin products. Am. Diabetes Ass’n, *Standards, supra*, at S106-07. However, among people with type 1 diabetes, the use of analog insulin is associated with fewer episodes of dangerously low blood glucose levels. *See, e.g.*, M. Monami et al., *Long-acting Insulin Analogues vs. NPH Human Insulin in Type 1 Diabetes: A Meta-analysis*, 11 *Diabetes, Obesity & Metabolism* 372, 377 (2009). Insulin can be injected using a syringe or a “pen” injector device. *Insulin, Medicines, & Other Diabetes Treatments*, Nat’l Inst. of Diabetes & Digestive & Kidney Diseases (Dec. 2016), <https://www.niddk.nih.gov/health-information/diabetes/overview/insulin-medicines-treatments>. To improve management of blood glucose levels, many people with diabetes, particularly those with type 1, use a pump that delivers insulin continuously. *See id.*; Anne L. Peters et al., *Diabetes Technology – Continuous*

Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults; An Endocrine Society Clinical Practice Guideline, 101 J. Clinical Endocrinology & Metabolism 3922 (2016), <https://academic.oup.com/jcem/article/101/11/3922/2764917>.

People with diabetes generally use a home blood glucose meter and disposable testing strips to check their blood glucose levels and determine how much insulin they need. *Managing Diabetes*, Nat'l Inst. of Diabetes and Digestive and Kidney Diseases (Dec. 2016), <https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes#Blood%20Glucose>. Typically, people with type 1 diabetes need to test their blood glucose levels using a home meter six to ten times every day. Am. Diabetes Ass'n, *Standards, supra*, at S78. Some people with diabetes also use a continuous glucose monitor (CGM), which measures blood glucose level throughout the day and can sound an alarm when it is dangerously low. *Continuous Glucose Monitoring*, Nat'l Inst. of Diabetes and Digestive and Kidney Diseases (June 2017), <https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring>. CGMs have been shown to improve blood glucose management for people with diabetes. *See* Anne L. Peters et al., *supra*, at 3929-30.

II. The Price of Insulin Has Risen Dramatically, Forcing Many Individuals With Diabetes to Ration Insulin

Recognizing that access to insulin is a life-or-death issue for people with diabetes, the original discoverers of insulin assigned the patent rights to the University of Toronto for \$1, so that it would be made as widely available as possible, without any cost-related

barriers. See Jing Luo et al., *Strategies to Improve the Affordability of Insulin in the USA*, 5 *Lancet Diabetes & Endocrinology* 158 (2017),

[https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(17\)30041-4/fulltext](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(17)30041-4/fulltext).

However, their goodwill is not shared by the current manufacturers of insulin, who have increased the price of insulin and related products exponentially in the past several decades. See William T. Cefalu, et al., *Am. Diabetes Ass'n, Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 41 *Diabetes Care* 1299 (2018), <https://care.diabetesjournals.org/content/diacare/41/6/1299.full.pdf>. The high price of insulin has led to significant affordability and access challenges for people with diabetes, putting their health and lives at risk. *Id.*

A. In Recent Years, the Price of Insulin in the U.S. Has Risen Dramatically

Just three pharmaceutical manufacturers – Eli Lilly, Novo Nordisk, and Sanofi – control the U.S. insulin market. *Id.* at 1300. Although the exact reasons remain unclear, the manufacturers have increased the price of insulin dramatically in recent years. *Id.* at 1299-1300.

For example, between 2003 and 2016, the list price for a vial of NovoLog (a popular analog insulin) increased by 310%. Sherry Glied & Benjamin Zhu, The Commonwealth Fund, *Not So Sweet: Insulin Affordability over Time* 3 (2020), https://www.commonwealthfund.org/sites/default/files/2020-09/Glied_not_so_sweet_insulin_affordability_ib.pdf. Similarly, the price for one vial of Humalog (another analog insulin) increased by more than 1000% (from \$21 to \$332 per vial) between 1999 and 2019. S. Vincent Rajkumar, *The High Cost of Insulin in the*

United States: An Urgent Call to Action, 95 Mayo Clinic Proceedings 22, 22 (2020),

[https://www.mayoclinicproceedings.org/action/showPdf?pii=S0025-](https://www.mayoclinicproceedings.org/action/showPdf?pii=S0025-6196%2819%2931008-0)

[6196%2819%2931008-0](https://www.mayoclinicproceedings.org/action/showPdf?pii=S0025-6196%2819%2931008-0). The insulin Lantus was \$35 a vial when it was introduced in

2001; by 2019 it cost \$270. Tiffany Stanley, *Life, Death and Insulin*, Wash. Post

Magazine (Jan. 7, 2019),

[https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-](https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/)

[lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-](https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/)

[tragic/](https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/). Due to these price increases, the most widely used analog insulin products cost

ten times more in the U.S. than in any other developed country. Rajkumar, *supra*, at 22.

A recent study by the Health Care Cost Institute examined how these price hikes affected

a type 1 diabetes patient who uses the most common insulin products and found that,

between 2012 and 2016 alone, their annual insulin spending nearly doubled. Jean

Fuglesten Biniek & William Johnson, Health Care Cost Inst., *Spending on Individuals*

with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices 9 (2019),

[https://healthcostinstitute.org/diabetes-and-insulin/spending-on-individuals-with-type-1-](https://healthcostinstitute.org/diabetes-and-insulin/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices)

[diabetes-and-the-role-of-rapidly-increasing-insulin-prices.](https://healthcostinstitute.org/diabetes-and-insulin/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices)

B. Due to the High Price of Insulin, Many People With Diabetes Ration Insulin and Supplies

Given the high price of insulin, many people with diabetes, including those with health insurance, simply cannot afford the insulin they need. They are forced to use various strategies to get by, including rationing. Samantha Willner et al., “*Life or Death*”: *Experiences of Insulin Insecurity among Adults with Type 1 Diabetes in the*

United States, SSM - Population Health, June 2020, at 4-6,

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7352063/pdf/main.pdf>. Multiple studies have found that roughly a quarter of people with diabetes in the U.S. ration insulin. *See, e.g.,* Darby Herkert et al., *Cost-Related Insulin Underuse Among Patients With Diabetes*, 179 *JAMA Internal Med.* 112, 113 (2019); T1International, *Costs and Rationing of Insulin and Diabetes Supplies, Findings from the 2018 T1International Patient Survey* 6 (2018), https://www.t1international.com/media/assets/file/T1International_Report_-_Costs_and_Rationing_of_Insulin_Diabetes_Supplies_2.pdf; Am. Diabetes Ass'n & Vault Consulting, LLC, *Insulin Affordability Survey 2018* 8, 16 (2018), <http://main.diabetes.org/dorg/PDFs/2018-insulin-affordability-survey.pdf>. The burden of rationing does not fall evenly across the population. For example, Black people are more likely to have to ration their diabetes medications than White people. Hyojung Kanga et al., *Cost-Related Medication Non-Adherence among U.S. Adults with Diabetes*, 143 *Diabetes Res. & Clinical Pract.* 24, 29 (2018).

It is also common for people with diabetes to ration diabetes supplies. For example, one survey found that nearly 40% of people with type 1 diabetes ration blood glucose testing strips. *See* T1International, *supra*, at 7.

Instead of or in addition to rationing insulin, many people who cannot afford analog insulin, particularly those without health insurance, turn to use older, less effective human insulin.³ *See* Sherry Glied & Benjamin Zhu, *supra*, at 4; Am. Diabetes Ass'n,

³ The number of Minnesota residents without health insurance has increased over the past several years. MPR News Staff, *Minnesota sees big jump in people without health*

Standards, supra, at S99; Julia Belluz, *Walmart's \$25 insulin can't fix the diabetes drug price crisis*, Vox (Apr. 11, 2019), <https://www.vox.com/science-and-health/2019/4/10/18302238/insulin-walmart-reilion>. Individuals also sometimes turn to the underground market, obtaining insulin through informal networks of patients who have extra vials and are willing to share or trade. Willner et al., *supra*, at 5-6; Markian Hawryluk, *Not Pandemic-Proof: Insulin Copay Caps Fall Short, Fueling Underground Exchanges*, Kaiser Health News (Oct. 5, 2020), <https://khn.org/news/not-pandemic-proof-insulin-copay-caps-fall-short-fueling-underground-exchanges/>. Some people with diabetes also attempt to reduce their need for insulin by limiting their food intake or exercising excessively – strategies that carry significant health risks. Willner, et al., *supra*, at 5.

Even using these strategies, people with diabetes often have to forgo other basic life necessities to pay for their insulin. In a recent survey of people with diabetes and their caregivers, 36% of respondents reported choosing between insulin and other health-related purchases (*e.g.* other medications). Am. Diabetes Ass'n & Vault Consulting, LLC, *supra*, at 8. Many people also reported choosing between insulin and transportation (32%), utilities (30%), and housing (27%). *Id.* at 18-20.

insurance (Feb. 20, 2018), <https://www.mprnews.org/story/2018/02/20/health-insurance-minn-big-jump-people-lacking-coverage>. Because of job losses due to the COVID-19 pandemic, uninsured rates are likely increasing. See Univ. of Minn., *News Release, COVID-19 Impact: As many as 18.4 million Americans face disruptions and potential loss of health insurance coverage* (April 24, 2020), <https://twin-cities.umn.edu/news-events/covid-19-impact-many-184-million-americans-face-disruptions-and-potential-loss-health>.

Notably, while the Plaintiff touts insulin manufacturers' existing coupons and patient assistance programs (PAPs), *see* Compl. ¶¶ 56-63, these programs have not prevented widespread insulin rationing. Only 17% of people with diabetes who have trouble affording insulin report using coupons. Am. Diabetes Ass'n & Vault, LLC, *supra*, at 16. And, even when people manage to use coupons, their annual insulin expenses remain high. IQVIA Inst. for Human Data and Science, *Diabetes Costs and Affordability in the United States* 6 (2020), <https://www.iqvia.com/insights/the-iqvia-institute/reports/diabetes-costs-and-affordability-in-the-united-states>.

As for PAPs, the application processes are often complex and difficult to navigate, and researchers found little transparency from manufacturers on how many patients they actually serve. *See* Niteesh K. Choudhry et al., *Drug Company-Sponsored Patient Assistance Programs: A Viable Safety Net*, 28 Health Aff. 827, 831-832 (2009), <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.28.3.827>. Furthermore, while the eligibility criteria vary, individuals who have insurance often do not qualify for PAPs, even if they have high out-of-pocket costs.⁴ A report by a U.S. Department of the Treasury official found that coupons and PAPs actually help maintain high list prices and

⁴ While the Affordable Care Act (ACA) caps out-of-pocket expenses for plans sold through the marketplace and other individual and small group plans, annual out-of-pocket expenses can still be substantial – up to \$8150 (for self-only coverage) and \$16,300 (for other than self-only coverage) in 2020. *See* HHS, Notice of Benefit and Payment Parameters Rule for 2021, 85 Fed. Reg. 29229 (May 14, 2020). *See also* Kaiser Family Found., *2020 Employer Health Benefits Survey* Figure E (2020), <http://files.kff.org/attachment/Summary-of-Findings-Employer-Health-Benefits-2020.pdf> (finding that the percentage of workers with an annual deductible of more than \$2000 has more than doubled over the past decade).

provide pharmaceutical manufacturers significant tax breaks. *See* Austin Frerick, U.S. Dep't. of the Treasury, Office of Tax Analysis, *The Cloak of Social Responsibility: Pharmaceutical Corporate Charity*, 153 Tax Notes 1151, 1161 (2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2874391.

C. Insulin Rationing Can Lead to Serious, Life-threatening Health Complications

The health effects of rationing and/or using cheaper, less medically appropriate treatments can be severe, long-term, and irreversible. Even brief interruptions in insulin access can have far reaching health complications for people with diabetes. Individuals who ration insulin are more likely to have elevated blood glucose levels, which can lead to serious short- and long-term health complications and death. Herkert et al., *supra*, at 113 (finding that patients who reported rationing due to cost were more than three times more likely to have poor blood glucose management); *see also* T1International, *supra*, at 2.

In the short term, lack of insulin can cause an acute and life-threatening condition called diabetic ketoacidosis (DKA). *See* Dyanne P. Westerberg, *Diabetic Ketoacidosis: Evaluation and Treatment*, 87 Am. Fam. Physician 337 (2013), <https://www.aafp.org/afp/2013/0301/afp20130301p337.pdf>. In DKA, the blood glucose level becomes high and the blood becomes acidic, which can rapidly lead to coma and death. *See id.* at 337-338. In 2016, 188,000 Americans were hospitalized with DKA. Ctrs. for Disease Control and Prevention, *National Diabetes Statistics Report, 2020*, *supra*, at 12. One study found that insulin rationing was the primary cause of hospital admissions

for DKA. See Victoria Musey et al., *Diabetes in Urban African Americans: Cessation of Insulin Therapy is the Major Precipitating Cause of Diabetic Ketoacidosis*, 18 *Diabetes Care* 483, 485-486 (1995).

Over the long term, high blood glucose levels leads to a number of complications, including heart disease, stroke, kidney disease, blindness, dental problems, peripheral neuropathy (damage to nerves, most often in the limbs), and autonomic neuropathy (damage to the nerves that control involuntary bodily functions). See *Preventing Diabetes Problems*, Nat'l Inst. of Diabetes and Digestive and Kidney Diseases (Dec. 2016), <https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-problems/all-content>. These complications can result in the need for foot and leg amputation. *Id.* And, they are extremely prevalent – over one-third of adults with diabetes have chronic kidney disease, and 12% have vision disability. Ctrs. for Disease Control and Prevention, *Nat'l Diabetes Statistics Report, 2020*, *supra*, at 12. Diabetes is the seventh leading cause of death in the United States.⁵ *Id.* Given their life-or-death need for insulin, many people with diabetes report feelings of desperation and significant psychological distress over insulin access, which in turn affects their blood glucose levels. Willner et al., *supra*, at 3, 4.

⁵ In addition to the immeasurable human costs, insulin rationing also adds costs to the U.S. health care system by increasing preventable complications. For example, one model found that all people with diabetes adhering to their diabetes medications would save \$8.3 billion in direct medical costs per year by averting one million emergency department visits and 618,000 hospitalizations. See Ashish Jha et al., *Greater Adherence to Diabetes Drugs Is Linked to Less Hospital Use and Could Save Nearly \$5 Billion Annually*, 31 *Health Aff.* 1836, 1842 (2012).

III. The Experiences of the Individual *Amici* and Their Loved Ones Illustrate the Need for the Act

The statistics and studies discussed above reflect the painful experiences of real people, including the individual *amici*. They share their own stories and the stories of their family members with the Court to demonstrate what is at stake in this case – the financial stability, health, and lives of people across the State.

Alec Smith

Alec Smith was diagnosed with type 1 diabetes when he was 23 years old. At the time, his mother, *amicus* Nicole Smith-Holt, had health insurance through her employer, and Alec was covered as a dependent. With that insurance, Alec spent roughly \$200 to \$300 dollars out of pocket every month for insulin and supplies.

Alec and Nicole knew that when Alec turned 26, he would no longer qualify as her dependent and would lose his insurance. They spent the months leading up to his 26th birthday looking for an alternative source of coverage, but could not find an affordable option. Alec was living alone in Minneapolis, Minnesota and making roughly \$40,000 a year as a restaurant manager. His employer did not provide an employee health plan. He was not eligible for Medical Assistance or MinnesotaCare because his income was too high. Plans available through the State's health insurance marketplace had a \$450 monthly premium and a \$7600 annual deductible. Alec decided to forgo coverage and pay out of pocket for his insulin and supplies, which he estimated would cost roughly \$1000 per month.

Alec celebrated his 26th birthday on May 20, 2017, and he became uninsured on June 1, 2017. He applied for every PAP offered by the insulin manufacturers, but was told that he was not eligible because his income was too high. On June 22nd, Alec went to the pharmacy to pick up his insulin and supplies. The price of his insulin had risen again, making the total cost more than he expected – \$1300, which was more than half of his monthly paycheck. He did not have \$1300 in his bank account, so he left the pharmacy without any insulin. Alec did not tell his mother or his girlfriend that he could not afford his prescription. It appears that instead, he rationed the insulin he had left, hoping to make it last the eight days until June 30th, his next payday.

On June 27, 2017, just three days before payday, Alec died alone in his bedroom of diabetic ketoacidosis. The medical examiner explained to Nicole that Alec had no insulin left in his apartment. And, it looked like he had tampered with his insulin pens in an effort to extract every last drop of insulin from them.

Since Alec's death, Nicole has dedicated her life to making sure people with diabetes have access to affordable insulin, so that no other family has to go through what her family did.

The Loewy Family

Amicus Nathan Loewy is 32 years old and lives with his wife and three children (ages 10, 7, and 2) in Winthrop, Minnesota. Nathan has been living with type 1 diabetes for more than thirty years. His wife, Sheri, was diagnosed with type 2 diabetes in 2004. Their oldest child, Jett, was diagnosed with type 1 diabetes in 2017.

Sheri is a registered nurse. Nathan used to work as a retail store manager. When Sheri started her current job in late 2018, Nathan decided to stop working outside of the home so that he could care for their children. Sheri makes roughly \$75,000 per year, and the entire family is enrolled in the health insurance plan offered by her employer. The plan provides comprehensive benefits (including no deductible for diabetes care), enabling the family to afford the insulin and supplies they need.

To manage his diabetes, Nathan uses four vials of Novolog per month. Jett uses three vials of Humalog per month. Nathan and Jett each use an insulin pump, a continuous glucose monitor, and a small number of blood glucose testing strips (four to eight strips each per week). While Sheri does not need insulin, she does take Trulicity, an injectable medication that helps her body use insulin more effectively.

With their current insurance, they pay a total of roughly \$135 out of pocket every month for insulin, supplies, and Trulicity. In addition, when Nathan or Jett has to replace his insulin pump (roughly once every four years), they pay another \$700 out of pocket for the pump. Without any insurance, their insulin, supplies, and medication would be completely unaffordable. Nathan estimates that at retail price, they would pay \$4600 per month, with insulin alone accounting for more than \$2500 of that total. And, that figure does not include the \$8000-\$10,000 they would have to pay to replace an insulin pump.

Given the magnitude of these expenses, Nathan and Sheri worry constantly that Sheri could lose her job or that her employer could change their health insurance. Because there is no guarantee that they will keep their current coverage, they scrimp and save wherever they can. Nathan and Sheri also worry what the future holds for Jett. How

will he possibly be able to afford insulin when he is a young adult? Will he be forced to ration his insulin, putting his life at risk?

That worry stems in part from their own experiences. They know what it is like not to be able to afford insulin. When Nathan was in his teens and 20s, he often had to choose between getting his insulin or keeping himself housed and fed. Faced with those choices, he rationed his insulin. He also used various strategies, such as not eating enough, to reduce the amount of insulin that he needed. This put his health at risk and likely contributed to his neuropathy.

And, after Jett was diagnosed in February 2017, Nathan and Sheri struggled to pay for insulin and supplies. At the time, the family was enrolled in an employee health plan with a \$7500 annual deductible. Before meeting the deductible, they paid roughly \$2400 out of pocket every month for insulin and supplies. Even after meeting the deductible, Nathan and Sheri still had to pay roughly \$1600 out of pocket per month for insulin and supplies. Nathan tried to enroll himself and Jett in the manufacturers' PAPs. He spent hours and hours filling out detailed applications and following up with phone calls. Ultimately, his applications were denied because the family made too much money to qualify, even though at the time, the family's income was roughly \$40,000.

When the family's deductible reset in January 2018, the cost of their insulin and supplies ballooned to \$4000 per month. Nathan and Sheri maxed out two credit cards so that Nathan and Jett could get their insulin and supplies. They have yet to pay off one of those cards.

While the high price of insulin has had serious health and financial consequences for Nathan and Sheri, the Act, which Nathan lobbied to help pass, has eased some of their worry. They take comfort in knowing that as long as Jett is in Minnesota, he will be able to access the insulin he needs. Nathan continues to fight to preserve that protection and to extend it to others outside of Minnesota.

Jesimya Scherer-Radcliff

Jesimya (Jesy) was diagnosed with type 1 diabetes when he was 10 years old. At age 21, Jesy was living in a house with two roommates in Minneapolis, Minnesota. He was working full time at a restaurant, earning roughly \$13 per hour. He also had a part-time job at a movie theater, where he made about \$11 per hour. His mother, *amicus* Cindy Boyd, had health insurance through her employer, and Jesy was covered as a dependent.

Despite working and having health insurance, Jesy struggled to afford his insulin and supplies. In April 2019, Jesy did not have enough money to pick up his insulin prescription. He decided to ration the remainder of his insulin until his next payday. Jesy became so ill that he was forced to call Cindy and ask her to purchase a vial of insulin for him from the pharmacy. Even with insurance, that single vial cost \$55 or \$65 out of pocket. When Cindy got to his house to drop off the insulin, Jesy was weak, short of breath, and confused. She rushed him to the emergency room, and Jesy spent two nights in the hospital with diabetic ketoacidosis. The hospital did not give him any insulin to take home. And, instead of billing his insurance directly, the hospital sent Jesy a bill for \$14,000.

The following month, Jesy talked about needing to make more money. His dad suggested that he become an electrician. Jesy completed an application for an apprenticeship, but never had the chance to submit it. On June 27, 2019, Jesy called in sick to work. The next day, he died in his home of diabetic ketoacidosis. Detectives told Cindy that they did not find any insulin in his house – only an empty vial.

Cindy has become a vocal advocate for insulin affordability, fighting to help others avoid unnecessary complications or hospitalizations and to prevent additional deaths from insulin rationing.

Abigail Hansmeyer

Amicus Abigail Hansmeyer is 30 years old and lives with her husband and two daughters (ages 9 and 8) in New Brighton, Minnesota. Abigail has been living with type 1 diabetes since she was 6 years old.

For much of her adult life, Abigail has been unable to afford the insulin and supplies she needs. When she turned 18, she aged off of her parents' health insurance and became uninsured. She started working as a nursing assistant and made \$12 to \$13 dollars per hour. But without any insurance, her insulin cost about \$200 per vial, for a total of more than \$1000 every month. Abigail was too proud to tell her parents that she was unable to pay for insulin. Even if she had told them, her parents did not have the financial resources to help. So, she was forced to ration her insulin. Abigail was hospitalized with diabetic ketoacidosis six times in 18 months.

After her oldest daughter, Bianca, was born in 2010, Abigail could no longer work outside the home. She was a single mother, and Bianca was born with complex medical

conditions that require around-the-clock monitoring and care. She felt that she had no choice but to ignore her diabetes. She was often able to get only one of the five vials of insulin she needed every month.

Abigail has had health insurance periodically. Most recently, she was enrolled in Medical Assistance, but she lost that coverage in August 2019 due to an increase in family income. Her husband, Ryan, is a small business owner, and his income fluctuates. He expects to make approximately \$30,000 in 2020.

Since losing coverage through Medical Assistance, Abigail has been uninsured. She stopped using an insulin pump and a continuous glucose monitor because of the expense. Even without the devices, her supplies and gabapentin (which she takes for a chronic pain condition) cost about \$260 per month. At retail price, the insulin she needs – three vials of Novolog and two vials of Tresiba – is roughly \$1400 every month. About six months ago, she received a coupon from an insulin manufacturer after submitting an application. However, when she brought it to the pharmacy, she was told she was not eligible to use the coupon. While she has applied for other patient assistance programs in the past, she has never had an application approved.

Unable to pay \$1660 every month, Abigail has again been forced to ration her insulin. After many years of rationing, Abigail has developed significant, permanent health complications. She has peripheral neuropathy, gastroparesis (a condition caused by autonomic neuropathy in which the stomach does not empty properly), kidney disease, and dental problems. Between managing her diabetes and seeking treatment for these

additional medical complications, Abigail has incurred tens of thousands of dollars in medical debt.

Finally, about a month ago, when she was running low on insulin, Abigail applied for the emergency safety-net program created by the Act, which she fought to help pass. She was approved and given a 30-day supply of insulin for \$35. Using the program – and knowing that the continuous use safety-net program is available – has given Abigail an enormous sense of relief. She no longer has to worry that she will not be able to get the insulin she needs or that she will end up in the hospital due to rationing. And, she no longer has to worry that her family will have to forgo other basic needs due to the high price of insulin. Given her experience with insulin insecurity, Abigail shares information and resources with other people with diabetes and works to ensure affordable access to insulin.

CONCLUSION

Amici curiae respectfully request that this Court deny Plaintiff's motion for summary judgement and grant Defendants' motion to dismiss.

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Respectfully submitted,

Catherine McKee (*pro hac vice pending*)
Wayne Turner (*pro hac vice pending*)
National Health Law Program
1512 E. Franklin St., Suite 110
Chapel Hill, NC 27514
(919) 968-6308
mckee@healthlaw.org
turner@healthlaw.org

/s/ Barnett Rosenfield
Barnett Rosenfield (Reg. No. 212854)
Mid-Minnesota Legal Aid
111 N. 5th St., Suite 100
Minneapolis, MN 55403
(612) 746-3758
brosenfield@mylegalaid.org

Counsel for Amici Curiae