

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA**

JESSICA KRAFT, INDIVIDUALLY AND)
AS PARENT OF MINORS L.K., S.K., and)
O.K.; SHELLI SCHNEIDER,)
INDIVIDUALLY AND AS PARENT OF)
MINORS A.S. and W.S.; ANNE BAILEY,)
AS PARENT OF MINOR D.B.; AMY)
LAVELLE, AS PARENT OF MINORS)
Em.L. and El.L.; ELIZABETH BEATON,)
INDIVIDUALLY AND AS PARENT OF)
MINOR M.B.; AMANDA AND TYRELL)
FAUSKE, INDIVIDUALLY AND AS)
PARENTS OF MINORS C.R.F. and C.J.F.;)
JENNIFER REIN, INDIVIDUALLY; and)
JESSICA BERG, AS PARENT OF MINORS)
A.B. and S.B., individually and on behalf of)
all others similarly situated,)

Plaintiffs,)

v.)

ESSENTIA HEALTH, INNOVIS)
HEALTH, LLC d/b/a ESSENTIA)
HEALTH,)

Defendants.)

No. 3:20-CV-121

Hon. Peter D. Welte
Hon. Alice R. Senechal

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF
MOTION TO CERTIFY CLASS**

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I. INTRODUCTION

This case arises from a stunning and systemic failure by Defendants Essentia Health and Innovis Health, LLC (collectively, “Essentia” or “Defendants”) to safeguard thousands of vulnerable patients who entrusted them with their medical care. For over two and a half years, from at least January 2017 through February 2020, Essentia administered Time and Temperature Sensitive Pharmaceutical Products (“TTSPPs”)—including critical vaccines and chemotherapy drugs—that had been subjected to repeated temperature excursions, rendering them adulterated, invalid, ineffective, and worthless.

Essentia’s misconduct was not the result of an isolated incident or technical malfunction, but rather, a deliberate abdication of its fundamental responsibilities as a healthcare provider. Despite being subject to extensive federal and state regulations requiring proper pharmaceutical storage, despite having its own policies mandating appropriate temperature monitoring, and despite receiving explicit warnings from accrediting bodies about the need for oversight, Essentia chose to warehouse its pharmaceutical inventory through a wholly inadequate arrangement with its joint venture partner, Dakota Clinic Pharmacy (“DCP”).

The scope of Essentia’s failures is breathtaking. Essentia provided DCP with two antiquated, non-pharmaceutical grade refrigerators that regularly malfunctioned. It installed a temperature monitoring system in only one of two refrigerators, and it set that system’s alert parameters so wide—20 to 55 degrees Fahrenheit—that it would not trigger warnings even when pharmaceuticals, which required storage between 36 and 46 degrees, were freezing or overheating. Essentia provided no training to DCP personnel on pharmaceutical warehousing requirements, established no policies governing the storage operation, and conducted absolutely no oversight—not a single audit, inspection, or review—during a three-year period in which tens of thousands of patients were receiving compromised medications.

The consequences were predictable and severe. Temperature logs revealed that temperatures were rarely recorded, and of the few readings actually recorded, over 40 percent reflected temperature outside the required range, with documented excursions occurring in all but three months during the relevant period. When state health officials investigated, they invalidated thousands of vaccine doses as adulterated. Essentia itself ultimately acknowledged that at least 54,004 individuals had received potentially compromised medications, sending letters to each patient but refusing to provide refunds and offering no meaningful remedy for those whose medications could not be safely re-administered.

Plaintiffs Jessica Kraft, Shelli Schneider, Amy Lavelle, Elizabeth Beaton, Amanda and Tyrell Fauske, Jennifer Rein, and Jessica Berg, individually and on behalf of their minor children, bring this action on behalf of all similarly situated individuals who paid for and received adulterated TTSPPs at Essentia facilities. These patients and their families trusted Essentia to provide safe, effective medical care. Instead, they received worthless medications while paying full price, leaving them unprotected against serious diseases and, in some cases, requiring costly revaccination or additional treatment.

The proposed class easily satisfies all requirements for certification under Federal Rule of Civil Procedure 23. The class of over 54,000 individuals is readily ascertainable from Essentia's own records. Common questions of law and fact predominate, including whether the TTSPPs were adulterated due to temperature excursions, whether Essentia breached its warranties and violated consumer protection laws by administering worthless medications, and whether class members are entitled to full refunds. Damages can be calculated using objective criteria from Essentia's billing records. Most importantly, class treatment is plainly superior to individual litigation for claims averaging hundreds or low thousands of dollars that would otherwise go unredressed.

For the reasons set forth below, Plaintiffs respectfully request that this Court certify the proposed class, appoint Plaintiffs as class representatives, and appoint the undersigned counsel as class counsel.

II. FACTS

A. Pharmaceutical Cold Storage Is Critical to U.S. Healthcare, and It Is Subject to a Robust Regulatory Framework at Both the Federal and State Levels That Imposes Obligations on All Entities Participating in the Supply Chain

Millions of prescriptions for TTSPPs are given each year in the United States. According to the Centers for Disease Control (“CDC”), TTSPPs must be stored properly from the time they are manufactured through their administration to patients to ensure efficacy. Ex. 1, Vaccine Storage and Handling Toolkit, at NDDOH00000068.¹ The CDC defines a “temperature excursion” as “[a]ny temperature reading outside ranges recommended in the manufacturers’ package inserts.” *Id.* at NDDOH00000075, NDDOH00000097. Likewise, the World Health Organization has defined a “temperature excursion” as “[a]n excursion event in which a TTSPP is exposed to temperatures outside the range(s) prescribed for storage and/or transport.”²

Exposure to temperature excursions degrades pharmaceuticals, reducing their potency, which, in turn, leaves patients unprotected against the diseases or conditions their pharmaceuticals were intended to either prevent or treat. Ex. 2, Expert Report of Sandor Boyson (Sept. 19, 2025), at 3. The ramifications of receiving TTSPPs that were exposed to temperature excursions are significant. For instance, chemotherapy drugs like Doxorubicin have a maximum lifetime cumulative dose and cannot be safely administered multiple times, leaving few options for patients

¹All exhibits cited herein are attached to the Declaration of Michael von Klemperer in Support of Plaintiffs’ Motion for Class Certification.

² World Health Org., Annex 5 WHO Technical Rep. Series No. 957, WHO Good Distribution Practices for Pharmaceutical Products (2010), <https://perma.cc/3CCE-Q86P>.

whose cancer may have worsened over the time they believed they were receiving effective treatment.³ Further, vaccines degraded by temperature excursions may not cause the immune response required to develop immunity to serious, communicable diseases. Ex. 2, Boyson Rep., at 3, 21. Moreover, receiving repeat doses of certain vaccines can increase the risk of adverse reactions, so the CDC advises that “[i]t is better to not vaccinate than to administer a dose of a vaccine that has been mishandled.”⁴ Other vaccines, like the annually-updated flu vaccine, cannot be re-administered as the virus evolves each year.⁵ See Ex. 3, Email Regarding Flu Vaccine.

1. Federal and State Regulatory Framework

Refrigerated TTSPPs, as opposed to those that must be frozen or maintained at room temperature, must be continuously stored between 36–46° Fahrenheit, and any temperature reading outside of this range constitutes a temperature excursion.⁶ In the U.S., pharmaceutical cold storage is subject to overlapping layers of federal and state regulation, as well as industry best practices provided by leading governmental and professional bodies, together forming a robust framework to prevent temperature excursions. See Ex. 2, Boyson Rep., at 5-9.

Federal law imposes a series of requirements on the storage and handling of pharmaceuticals, primarily enforced by the Food & Drug Administration (“FDA”) under Title 21 of the U.S. Code and its related regulations. Those “engaged in the manufacturing, processing packing, or holding” of drugs must comply with the Current Good Manufacturing Practices

³ Chelsea Backler, *Oncology Drug Reference Sheet: Doxorubicin Hydrochloride*, Oncology Nursing Society (May 20, 2025), <https://perma.cc/8S56-Q5W9>.

⁴ Ctrs. for Disease Control, *Vaccine Storage and Handling Toolkit* (2024), <https://perma.cc/GV3W-9G3G>.

⁵ U.S. Food & Drug Admin., *It’s a Good Time to Get Your Flu Vaccine*, (Jan. 31, 2025), <https://tinyurl.com/2vtuvth8>.

⁶ See, e.g., U.S. Pharmacopeia, USP29-NF24 Vol. No. 30(6), *USP <1079> Good Storage and Distribution Practices for Drug Products*, <https://perma.cc/RZG2-ZG5N>; North Dakota Dep’t Health & Hum. Servs., *General Recommendations: Vaccine Transport Guidance*, <https://perma.cc/bty3-4y2r>.

“CGMPs”), which are codified in 21 C.F.R. §§ 210-11. The CGMPs require proper “storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected.” 21 C.F.R. § 211.142(b). Other obligations imposed include that each person responsible for holding a drug be provided sufficient training to perform their function; a system for monitoring environmental conditions be maintained; equipment used to hold drugs be appropriately designed for that intended purpose; temperature monitoring equipment be regularly inspected according to a written program and records of such inspections be maintained; and qualification procedures that demonstrate each refrigerator’s ability to remain within proper temperature ranges be established and conducted at regular intervals. *See, e.g.*, 21 C.F.R. §§ 211.42, 211.25, 211.63. Failing to satisfy CGMP requirements can render a drug adulterated. 21 U.S.C. § 351(a)(1); *see also* 21 C.F.R. § 210.1(a). Further, a drug may also be deemed adulterated if its storage does not meet the standards articulated by the U.S. Pharmacopeia (“USP”), which is addressed below. 21 U.S.C. § 351(b)(C). Adulterated drugs cannot be sold or distributed. 21 U.S.C. §§ 331(a)-(c).

Additionally, 21 C.F.R. § 205.50, which applies to all “wholesale drug distributors and their officers, agents, and employees,” imposes further storage requirements.⁷ Section 205.50(c) provides that “all prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in . . . the United States Pharmacopeia.”

The USP is a scientific body that establishes pharmaceutical standards, publishes

⁷ Subsection (g) defines “wholesale distributors” to include “chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions” as defined in subsection (f). 21 C.F.R. § 205.3(g). Essentia and DCP’s activities fall well within the definition of “wholesale distribution” provided in subsection (f). *See* 21 C.F.R. §§ 205.3(f), (1)-(2), (4), (6), (10).

guidelines known as USP 1079, which contains a chapter known as Good Storage and Shipping Practices. Ex. 2, Boyson Rep., at 7. This chapter, which applies to all entities involved in the drug supply chain, requires that TTSPPs be stored within strict temperature ranges (e.g., 2–8°C for refrigerated products); personnel handling such drugs receive appropriate training on a continuing basis; and qualification procedures that demonstrate each refrigerator’s ability to remain within set temperature ranges be established and conducted at regular intervals.⁸ As discussed above, USP 1079 is incorporated into both 21 U.S.C. § 351 and 21 C.F.R. § 205.50.

On the state level, state departments of health and boards of pharmacy impose further cold storage and monitoring obligations and provide oversight. Ex. 2, Boyson Rep., at 8. The North Dakota Department of Health (“NDDoH”) requires twice daily recording of each refrigerator’s maximum and minimum temperatures. The NDDoH recommends that this monitoring be done using a certified, calibrated, and continuously recording digital data logger inside each fridge, and in the case of fridges that contain publicly-funded vaccines, it requires the use of such a logger. The NDDoH also requires that, upon the discovery of an out-of-range temperature, “actions must be taken and recorded,” including recording the temperature and the duration of the excursion and immediately isolating the affected product and labeling it “Do Not Use.”⁹ If a refrigerator is not maintaining temperatures, the NDDoH also requires transferring the products to other units and that staff “do[] not allow vaccines to remain in a unit while they are trying to fix it.”¹⁰ The NDDoH also ensures vaccine and community safety by invalidating in the state immunization database any

⁸ U.S. Pharmacopeia, USP29-NF24 Vol. No. 30(6), *USP <1079> Good Storage and Distribution Practices for Drug Products*, <https://perma.cc/RZG2-ZG5N>.

⁹ North Dakota Dep’t Health & Hum. Servs., *Vaccine Storage Troubleshooting Guide*, <https://perma.cc/ZRJ7-FEJY>.

¹⁰ *Id.*

vaccine doses that were administered after “being exposed to unknown or inappropriate temperatures,” often requiring patients to be revaccinated before they can continue attending public school.¹¹ The Minnesota Department of Health (“MNDoH”) imposes similar rules, including that all products be removed from fridges that are not maintaining temperatures, that pharmacy or lab grade refrigerators are used, and that temperature logs contain minimum and maximum daily temperatures, times, and initials of the responsible staff member.¹²

Moreover, the North Dakota Board of Pharmacy’s rules, codified in Title 61 of the North Dakota Administrative Code, require that all drugs “be stored in designated areas within hospital pharmac[ies] which are sufficient to ensure proper . . . temperature.”¹³ They impose several obligations on the director of pharmacy services for hospital pharmacies, including establishing written procedures for drug distribution and inspecting storage conditions at least once a month.¹⁴

2. Pharmaceutical Industry Guidance and Best Practices

At the federal level, the CDC is a major regulator of vaccine cold chains, providing the annual Vaccine Storage and Handling Toolkit as guidance to hospitals and clinics nationwide and hosting the Vaccine Adverse Event Reporting System (VAERS), through which healthcare facilities report excursions. *See* Ex. 2, Boyson Rep., at 5; Ex. 1, Vaccine Storage and Handling Toolkit, at NDDOH00000065. The NDDoH and MNDoH’s regulations largely reflect the CDC’s

¹¹ *See* North Dakota Dep’t of Health & Hum. Servs., *Vaccine Management Policy*, at 31-32, <https://perma.cc/3R5A-L5V4>; *see also* Ex. 4, Email explaining that free revaccination only provided for vaccines invalidated by NDDoH.

¹² *See generally* Minn. Dep’t of Health, *Vaccine Storage Guide*, <https://perma.cc/7XEN-8VC4>; Ex. 2, Boyson Rep., at 15-16.

¹³ N.D.A.C. 61-07-06. Article 61-07 governs hospital or medical center pharmacies, which are defined therein as “those portions of a hospital where drugs, medications, devices, and other materials... are manufactured, produced, sold, or distributed.” N.D.A.C. 61-07-01-01.

¹⁴ N.D.A.C. 61-07-01-13 (regarding inspection requirement); N.D.A.C. 61-07-01-07 (regarding general drug distribution).

recommendations, such as requiring each fridge to contain a temperature monitoring device. However, the Toolkit also outlines, and Essentia agrees with, the three main elements of effective pharmaceutical cold storage: a well-trained staff, reliable storage and temperature monitoring equipment, and accurate vaccine inventory management. *Id.*; Ex. 5, Vetter R. 30(b)(6) Tr. (May 23, 2025), at 94:13-16, 95:1-11. The Toolkit provides additional recommendations including, reviewing data from digital loggers on a weekly basis and repeating training on cold storage practices annually, upon the addition of new staff or new inventory, and upon the publication of new regulatory guidance. Ex. 1 at NDDOH00000065-69. The CDC, as well as the NDDoH, recommends “the use of pharmacy-grade, stand-alone refrigerator[s]... with built-in thermometers.”¹⁵

Further, in addition to the USP, many other non-governmental bodies issue guidance and provide industry best practices for pharmaceutical cold storage. The Joint Commission on Standards for U.S. Hospitals (the “Joint Commission”) is an independent, nonprofit organization that evaluates and accredits hospitals in the United States, and it maintains standards that accredited facilities must comply with, including that “medication storage practices and conditions are required to be in accordance with the original product manufacturer’s instructions.”¹⁶ Several other such non-governmental bodies provide cold storage guidance and inform healthcare industry standards for cold storage, including the American Society of Health-System Pharmacists, the International Society for Pharmaceutical Engineering, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use,

¹⁵ See, e.g., North Dakota Dep’t of Health & Hum. Servs., Refrigerator/Freezer Purchasing Guide, <https://tinyurl.com/ysj73nk3>.

¹⁶ Megan Cazares, *What is the Joint Commission and What Does it Mean to You?*, Univ. Tex. Medical Branch Health Sys. Newsletter (Mar. 29, 2024), <https://perma.cc/9Q27-G2DY>;

and healthcare logistics companies, such as the wholesaler McKesson. Ex. 2, Boyson Rep., at 8-9.

In addition to the layers of regulations, guidance documents, and industry standards, Essentia's own policies set forth temperature and storage obligations. According to Essentia's Temperature Monitoring for Refrigerators/Freezers policy, refrigerator temperatures must be maintained between 36 and 46 degrees Fahrenheit, individual temperature logs are required for each refrigerator/freezer, and "[s]taff logging temperature will document the current temperature, the Hi and Lo Readings, and initial log as complete." Ex. 6, Temperature Monitoring for Refrigerators, at EH002734. Further, if a unit contains any vaccines, Essentia's policy required twice daily recordings of the maximum and minimum temperature. *Id.* And if a unit contains any publicly-funded vaccines, monitoring is to be done with a digital data logger, and the information from the logger must be sent to the MNDoH and the NDDoH. *Id.* With regards to equipment, Essentia recommends "a medical grade" refrigerator and provided that only "Essentia approved thermometers and/or [state] department of health data loggers will be placed in all refrigerators or the factory installed thermometer . . . will be utilized." *Id.* In the event of an excursion, Essentia's excursion contingency plan requires steps like those required by the state health departments, including relocating the products to a different unit and recording the temperature of the involved refrigerator at the time of discovery. Essentia's policy requires that it educate staff on this plan. *Id.*

B. Essentia Controls Virtually All Aspects of Its Affiliate Dakota Clinic Pharmacy

Founded in 2003, Essentia is a network of hospitals, clinics, and other healthcare facilities throughout Minnesota, North Dakota, and Wisconsin.¹⁷ Dakota Clinic was founded in 1926.¹⁸

¹⁷ CBS Insights, About Essentia Health, <https://perma.cc/C87A-TEZ5>.

¹⁸ North Dakota State Univ. Libraries, Dakota Clinic & Dakota (Heartland Hospital), <https://perma.cc/ZBX7-BV7X>.

Since at least 1980, Dakota Clinic Pharmacy served as Dakota Clinic's in-house pharmacy, warehousing and distributing pharmaceutical products. Ex. 7, Haskell Tr. (Sept. 8, 2025), at 15:5-10. In 2000, Dakota Clinic formed Innovis Health.¹⁹ Essentia acquired Dakota Clinic and Innovis Health in or around January 2008.²⁰ The new entity was known as Innovis Health LLC d/b/a Essentia Health.²¹ Innovis Health LLC is Essentia's wholly-owned subsidiary. Ex. 8, Innovis Operating Agreement, at EH000006. Essentia employees commonly refer to Innovis Health LLC as "Essentia Health West." Ex. 9, Modich Tr. (Apr. 24, 2025), at 41:5-15.

Dakota Clinic Pharmacy has always been and remains deeply embedded in Essentia and Innovis' operations.²² Discovery has revealed that Innovis continues to exert operational and practical control over DCP's day-to-day operations. Innovis is guaranteed membership on DCP's board, and because any board action requires super-majority approval, any decision of the board requires Innovis approval. *See* Dkt. 297, Morris Tr., at 129:25-131:1, 133:17-134:5; Dkt. 296-3, DCP Operating Agreement. Essentia, as part owner of DCP, receives regular disbursements. Dkt. 300, Loy Tr., at 117:25-118:11. While Essentia has attempted throughout this litigation to frame Innovis' involvement in DCP's management as minor and passive, contemporaneous documents, including the minutes from DCP's board meetings, paint a very different picture. Innovis

¹⁹ Duluth News Tribune, More About Dakota Clinic and Innovis (Nov. 27, 2007), <https://perma.cc/7XT4-D7DM>.

²⁰ Pioneer Press, Fargo's Dakota Clinic/Innovis to Merge with Minnesota's Essentia (Nov. 27, 2007), <https://perma.cc/8v8n-qfvl>.

²¹ *Id.*

²² In approximately 2007 or 2008, Innovis sold 51 percent of Dakota Clinic Pharmacy to several individual pharmacists solely to comply with a change in a North Dakota law, which required pharmacies to be majority pharmacist-owned. Ex. 7, Haskell Tr., at 106:5-10; Dkt. 297, Morris Tr., at 138:21-140:6; Dkt. 296-3, DCP Operating Agreement, at § 10.4 ("absent such laws, Innovis would own and operate all such pharmacies"). Innovis also retains the right to re-purchase the 51 percent share at any time if the North Dakota law changes. *See* Ex. 9, Modich Tr., at 62:9-14; Dkt. 296-3, DCP Operating Agreement, at § 10.4.

executives attend every board meeting, are regularly in touch outside of board meetings, and are closely involved in DCP's business decisions. *E.g.*, Ex. 7, Haskell Tr., at 42:19-44:21, 46:9-20, 49:8-51:15, 52:22-53:1, 53:13-18, 54:2-22, 58:9-19. Innovis executives even proposed improvements to DCP's temperature monitoring practices, but only after discovery of the temperature excursions at issue in this suit. *Id.* at 49:8-51:15, 52:22-53:1, 53:13-18. Consistent with the foregoing structure, Essentia and Innovis classify DCP as a "joint venture."²³ Ex. 10, Corporate Org. Chart; ECF 300-1 (Hurley Tr.), at 176:23-25; *see also* Dkt. 291-8, Pharmacies List.

Dakota Clinic Pharmacy has two locations—both on Essentia property, leased to DCP by Innovis, and registered with the North Dakota Board of Pharmacy. *See* Dkt. 297, Morris Tr., at 216:21-217:21, 221:7-17. All DCP personnel, including the pharmacist-owners, are directly employed by Innovis, and Innovis executives control the terms of their employment, including, for instance, their salaries and benefits. *See, e.g.*, Ex. 7, Haskell Tr., at 46:9-20; Dkt. 291-9, Morris Personnel File, at EH048494-516, EH048540-56; Ex. 11, DCP Annual Bd. Mtg., at DCP 000178; Dkt. 284-11, Shared Servs. Agreement, at EH000125 ("Innovis shall employ and furnish to DCP all pharmacists, technicians, and clerical staff needed to operate DCP's Pharmacy."). DCP personnel must sign several Essentia employee forms agreeing that they will comply with various Essentia policies, including, among others, the Essentia Code of Conduct. *See, e.g.*, Dkt. 291-9, Morris Personnel File, at EH04511-18. DCP personnel are also issued Essentia ID badges and Essentia email accounts, and they are even given performance reviews by Innovis executives. *See, e.g.*, Dkt. 297, Morris Tr., at 171:9-22; Dkt. 291-9, Morris Personnel File at EH048540-41.

²³ Consistent with this understanding, both DCP and Innovis contribute time, money, and skill to the undertaking, exert a proprietary interest and right of control over the undertaking, and share in its profits and losses. *See Sandvick v. LaCrosse*, 2008 ND 77, ¶ 11, 747 N.W.2d 519, 522 (2008) (listing elements of joint venture).

C. The Temperature Excursions at Issue

DCP has been warehousing and distributing TTSPPs since at least 1980, first for Dakota Clinic, then for Innovis and Essentia. Ex. 7, Haskell Tr., at 15:5-10. In 2016, the Joint Commission audited Essentia's practices and recommended that Essentia take over this process from DCP "to gain quality controls" and "to streamline formulary, inventory, and medication best practices within Essentia Health Clinic and managed by Essentia Health Pharmacy." Ex. 13, Essentia Memo Regarding Construction of Distribution; Ex. 14, Witten Tr. (June 5, 2025), at 102:11-104:20; Dkt. 300-1, Hurley Tr., at 133:24-134:9.

Essentia ignored the Joint Commission's recommendations and, in 2017, formalized DCP's TTSPP warehousing role by entering into a Shared Services Agreement. It did so without any consideration of whether DCP was qualified to perform these storage activities. *See* Dkt. 284-11, Shared Servs. Agreement; Ex. 7, Haskell Tr., at 15:16-17:15; Ex. 14, Witten Tr., at 46:19-48:18.

Under the Shared Services Agreement, DCP would continue warehousing Essentia's pharmaceutical inventory and distributing it to Essentia's facilities across North Dakota and Minnesota. *See* Ex. 7, Haskell Tr., at 15:5-17:15. Meanwhile, Innovis would "employ and furnish to DCP all pharmacists, technicians, and clerical staff," as well as provide administrative, accounting, and additional human resource services to DCP. Dkt. 284-11, Shared Servs. Agreement, at EH000125. But the Agreement did not define how DCP was to perform these services, set any performance metrics, or provide any formal monitoring schedules that could have been used to evaluate DCP performance. *See id.*; Ex. 2, Boyson Rep., at 13, 20.

Under this arrangement, DCP personnel used Essentia's payment information and Essentia's account with drug wholesaler, McKesson, to place orders for pharmaceutical products from McKesson. Dkt. 297, Morris Tr., at 167:4-168:16. DCP would accept delivery of the products from the wholesaler on Essentia's behalf, thereby transferring title from the wholesaler to Essentia.

See, e.g., id. at 224:2-225:8; Ex. 2, Boyson Rep., at 16-17; Dkt. 291-14, Email Between Morris and MNDoH Official; Ex. 15, Mar. 27, 2025 Ltr. from Essentia. Essentia provided DCP with two old refrigerators that DCP would use to warehouse the stock. *See, e.g.,* Ex. 16, Text message between Haskell and Morris; Ex. 7, Haskell Tr., at 18:16-19, 61:19-25; Dkt. 297, Morris Tr., at 90:25-92:5, 92:20-93:6; Ex. 17, Essentia Investigation Meeting Minutes, at EH049463 (discussing transfer of “EH owned products and refrigerators” after discovering excursions). Essentia installed a temperature monitoring system in only one of the two refrigerators. Ex. 17, at EH049463. Despite a mandatory temperature range of 36-46 degrees for refrigerated TTSPPs, Essentia set the system to send an alert only if the fridge went below 20 degrees or above 55 degrees—a fact that shocked DCP personnel when they learned it. Ex. 16, Text message between Haskell and Morris; Dkt. 297, Morris Tr., at 78:15-81:3, 94:9-95:4; 104:19-107:1; 109:12-21; Ex. 7, Haskell Tr., at 69:6-16, 97:9-15; Ex. 17, at EH049462. Essentia’s own documentation reflects that this monitoring system was “antiquated.” Ex. 17, at EH049463. Essentia’s Rule 30(b)(6) witness agreed. Dkt. 297-3, Kaufenberg Tr., at 47:15-48:3. There was no monitoring system at all in the second fridge.

Essentia was responsible for the maintenance of the fridges, and it arranged for maintenance to be performed on the fridges because they regularly ran outside of the required temperature range. Dkt. 297, Morris Tr., at 91:14-94:1; Ex. 18, 2019 Dakota Refrig. Work Order; Ex. 19, 2015 Dakota Refrig. Work Order. Contrary to recommendations from regulators and Essentia’s own policies, the refrigerators were not pharmaceutical grade. Dkt. 300, Loy Tr., at 100:2-101:21; Dkt. 297, Morris Tr., at 244:7-14. DCP personnel requested that Essentia replace or upgrade the fridges on multiple occasions, but Essentia did not do so. Dkt. 297, Morris Tr., at 91:14-94:1. In fact, Morris blames the excursion at issue on Essentia’s failure to adequately maintain or replace the fridges in question. *Id.* at 63:16-66:9, 91:14-92:6, 196:16-197:16.

Despite lacking any monitor in one of the fridges and having the only monitor set to 20 and 56 degrees in the other fridge, DCP believed it was not necessary to conduct daily monitoring of fridge temperatures. *Id.* at 45:2-46:25 (stating “we didn’t need to”). DCP maintained a single temperature log from December 2016 through February 2020 for both fridges as a “backup” to the monitoring system given the unreliability of Essentia’s refrigerators. *Id.* at 49:12-50:1; Ex. 20, Temperature Logs. DCP’s pharmacist owners did not even know how infrequently the logs were being maintained. *See, e.g.*, Ex. 17, Essentia Investigation Meeting Minutes. Given the complete lack of any standards or expectations, DCP pharmacists and staff received no training, certification, or education on wholesale distribution and cold storage practices. Ex. 7, Haskell Tr., at 16:6-17:10; Dkt. 297, Morris Tr., at 247:8-19. While DCP had a temperature monitoring policy governing its retail operations, it had no such policy for its warehousing operation. *Id.* at 34:15-35:21; Ex. 21, DCP Manual; Ex. 7, Haskell Tr., at 16:22-17:1. DCP’s owners did not know if Essentia policies applied to its inventory, and they were even confused about which pharmacist was in charge of the wholesale operation, with both owners Laura Morris and Rob Haskell identifying the other as being in charge and disclaiming any personal involvement. Dkt. 297, Morris Tr., at 55:24-56:9; Ex. 7, Haskell Tr., at 20:12-21:5, 31:22-32:1, 62:1-10, 64:22-25, 65:19-66:10, 69:17-20, 73:11-19, 76:16-77:5. Haskell indicated a clerk was responsible for the wholesale temperature monitoring, but both he and Morris disclaimed any responsibility for overseeing her. Dkt. 297, Morris Tr., at 44:4-23; Ex. 7, Haskell Tr., at 71:21-72:3.

Despite taking place on Essentia property, using Essentia-owned equipment and inventory, and being done by Essentia-employed personnel, Essentia has disclaimed that its policies governed DCP’s warehousing operations, while also having no knowledge of whether DCP even had temperature monitoring policies of its own. Dkt. 300, Loy Tr., at 101:6-21. Likewise, Essentia did

not know if, per its own temperature monitoring policies, DCP used the N.D. Department of Health data loggers or if DCP used Essentia-approved thermometers for the Fridges. *Id.* at 102:12-22. Countless documents and multiple deponents confirmed that the Fridges were not medical grade as recommended by numerous regulators and manufacturers. *See e.g., id.* at 39:12-40:3.

As a result of these failures, the temperature logs DCP maintained for the two fridges were extremely deficient. As an initial matter, during the 38-month period of December 2016 to February 2020, absolutely no logs exist for 11 months. Ex. 20, Refrigeration Logs. For the remaining 27 months, each log contains, on average, only 10.3 recorded readings per month. *See id.*; Ex. 2, Boyson Rep., at 21-22. This represents only 17.1 percent of the 60 average monthly readings required by both federal and state provisions. Ex. 2, Boyson Rep., at 21-22. Of those readings that were actually recorded, over 40 percent were outside of the temperature range required by federal and state law, as well as manufacturers. Ex. 2, Boyson Rep. at 10, 21, 27. In fact, upon reviewing the 27 months' worth of logs, former Essentia executive, Diane Witten, identified *only three months without a documented temperature excursion*. Ex. 14, Witten Tr., at 42:18-25. Yet, when presented with the logs, DCP's pharmacist-owner, Robert Haskell, expressed no concern. Ex. 7, Haskell Tr., at 72:21-73:2. Despite required temperature ranges of between 36 and 46 degrees, he believed it was fine for refrigerator TTSPPs to be stored at temperatures of 32 or even 31 degrees. *Id.* at 73:23-74:7. He was confident that a later visual inspection of the medications would confirm that they were unaffected. *Id.* at 72:21-73:5. Federal guidelines say otherwise. Ex. 1, Vaccine Storage and Handling Toolkit, at NDDOH00000071; Ex. 5, Vetter Tr., at 95:12-96:19.

During this time—from 2017 through February 2020—DCP warehoused over 100 types of TTSPPs, totaling thousands of doses. Still, Essentia exercised absolutely no oversight over DCP's

operations throughout this time; there was not one single audit, inspection, or event attempt to review DCP's operations, policies, or logs. Ex. 14, Witten Tr., at 134:11-19; Dkt. 297-3, Kaufenberg Tr., at 69:15-18, 70:14-71:11; Ex. 7, Haskell Tr., at 17:17-18:3, 104:13-18; Dkt. 297, Morris Tr., at 166:15-167:3. As Loy testified, nothing stood in the way of Essentia personnel reviewing the temperature logs or inspecting the Fridges at any point, and "nobody from Essentia ever laid eyes on the temperature logs before Loy did in February 2020 upon learning of the Excursions." Dkt. 300, Loy Tr., at 105:8-106:9 (confirming that she was immediately given access to the logs when she asked and the logs were all readily available in one location).

In late 2019, Essentia finally elected to follow the Joint Commission's recommendation and take over the warehousing function from DCP. In making that transition, Essentia cited the need to "ensure oversight of the medication safety and security processes and ensure that we are complying with the JC regulations." Ex. 22, Email regarding DCP Services and Transition; Ex. 14, Witten Tr., at 94:9-95:3; Ex. 12, Email Regarding Direct Org. Reporting, at EH046351 (acknowledging that Essentia has "no oversight," no "accountability," and no "metrics to measure [DCP's] performance").

As part of that transition, Essentia moved its two fridges to a space in the hospital basement and immediately recognized that they were defective and the temperature monitoring system it had installed and setup was completely inadequate. Ex. 23, Text Messages between Maari Loy and Laura Morris ("You won't believe this. The fridges went out of range and are too cold all Of A sudden Ugh. They're at like 31 and 28." (sic)). Upon investigating, Essentia confirmed that one fridge used the "antiquated" Electro-watchman monitoring system, which was "set to 20 and 54 degrees range," that there was no monitoring system at all in the other fridge, and that there was "only one log for both refrigerators," that "includes documentation of freezing temperatures

multiple times.” Ex. 17, Essentia Investigation Meeting Minutes. Essentia determined that at least 54,004 individuals received TTSPPs that had been stored in the defective, poorly monitored fridges. Recognizing that the TTSPPs had been adulterated, Essentia quarantined all remaining stock that had been stored in those fridges—worth at least \$400,000—and they remain sitting in an Essentia basement to this day. *Id.* at EH049462; Dkt. 297-3, Kaufenberg Tr., at 145:22-147:14.

Essentia notified each of these individuals by letter on or about April 6, 2020, stating that they received one or more medications that may have been subject to a temperature excursion. *See* Ex. 24, Deiss (Apr. 24, 2025) Tr., at 28:2-29:22; Ex. 25, Essentia Ltr. to Parents. Essentia never determined that any of these TTSPPs were *not* subject to a temperature excursion and never sent any corrective notice to any patients. Ex. 24, Deiss Tr., at 29:9-30:6.

State health officials reached the same conclusion, invalidating thousands of vaccine doses because the excursions rendered them adulterated. *See, e.g.*, Ex. 26, Email Regarding Titers Following Nonviable Vaccines. Essentia offered nothing to those who received vaccines that are updated annually (e.g., the flu vaccine) or those whose vaccines were not invalidated by the NDDoH. *See, e.g.*, Ex. 4; Ex. 3. Similarly, Essentia offered nothing to those who received Affected Medications that cannot be safely re-administered, such as chemotherapy drugs. For those who received invalidated vaccines that do not need annual updating, Essentia offered free revaccination at Essentia facilities rather than offering refunds. *See, e.g.*, Ex. 4. Those who received a handful of certain other Affected Medications, such as the rabies vaccine or penicillin for the treatment of syphilis, may have been provided, on an individual basis, a single booster at no cost or blood testing to determine their concentration of the relevant antibodies. *See, e.g.*, Ex. 27; Ex. 28.

A review of the relevant regulations, industry standards, best practices, and Essentia’s own policies confirms that the Affected Medications were adulterated. Federal law imposes several

requirements concerning fridge and temperature monitoring equipment, including that inspections be done at regular intervals, inspection and maintenance records be maintained, and qualification criteria for fridges be written and maintained. Ex. 2, Boyson Rep., at 14-15. State law also requires inspections of storage conditions. *Id.* at 15-16. Essentia complied with none of these laws. The fridges were nearly 30-year old non-pharmaceutical grade units with a known history of performance issues; no maintenance or inspections of the fridges or the Electro Watchman system were performed at prescribed regular intervals; and neither equipment qualification procedures nor equipment maintenance and inspection records exist. *See id.* at 18-20. Federal law also requires that personnel tasked with storing TTSPPs be given training on cold storage practices and that such training be regularly repeated. *Id.* at 15. No such training was provided. *Id.* at 18-20. State law imposes additional requirements, such as written storage procedures, moving products when a fridge is awaiting maintenance, and twice daily temperature recordings. *Id.* at 15-16. Essentia and its joint venture DCP ignored these requirements too. An average of only 10 temperature readings were taken each month; there were no written storage procedures applicable to these fridges; and there is no indication that the Affected Medications were ever removed from the fridges despite frequent out-of-range temperatures and the repeated need for fridge repairs. *Id.* at 18.

Put plainly, Essentia and its joint venture DCP's storage practices do not comport with nearly any of the applicable state and federal laws, nor established industry best practices or even baseline guidance. Their failings resulted in years of persistent excursions. In sum, Essentia and DCP's shocking abdication rendered the Affected Medications adulterated. Dr. Boyson, a supply chain expert and research professor at the University of Maryland who frequently provides advice on supply chain risks to major institutions, agrees. Dr. Boyson opines that Essentia's failure to perform due diligence in contractor and equipment selection, provide policies or training for cold

storage, exercise oversight of DCP, or maintain adequate storage and monitoring equipment in good repair, “caused thousands of medication doses to be compromised, leading to serious consequences on a significant patient population that entrusted Essentia with their healthcare.” *Id.* at 22.

D. Experiences of the Named Plaintiffs

Plaintiffs are individuals, many of whom are minors, who entrusted Essentia with their medical care. Jessica Kraft and her children, L.K., S.K., and O.K. all received Affected Medications. Jessica Kraft received the Hep. A vaccine in February 2018 and two influenza vaccines in October 2018 and December 2019, all of which occurred at Essentia facilities in North Dakota. Ex. 38, Def.’s Resp. to Requests for Admission Nos. 43, 49. Also at Essentia facilities in North Dakota, S.K. and O.K. each received a flu vaccine in October 2018, and L.K. received each of the following four vaccines once between November 2017 and October 2018: DTAP, Hep. A, HiB, and influenza. *Id.* at 52, 56, 59, 63, 66. Jessica Kraft received letters from Essentia on or around April 2020, advising her that one or more vaccinations administered to her and her minor children may have been affected by the temperature excursions. She also received a communication, indicating that L.K.’s vaccines were among the medications affected by the excursion.

Plaintiff Amy Lavelle and her minor children, Em.L. and El.L. are residents of Minnesota and received flu vaccines at an Essentia facility in Minnesota on or about February 7, 2018. Ex. 36, Lavelle Tr., at 8:5-7, 30:25-31:4.

Plaintiff Elizabeth Beaton and her minor child, M.B., are residents of North Dakota. Between approximately December 2018 and January 2019, Beaton received at least 13 doses of various chemotherapy medications at Essentia facilities in North Dakota to treat her cancer. M.B. also received a meningococcal vaccine at an Essentia facility in North Dakota in September 2019.

In March 2020, Beaton received a telephone call from an individual who indicated they were a consultant hired by Essentia, and they informed her that at least some of her chemotherapy treatments were subject to the excursions. Additionally, Beaton received a letter in March 2020 from Essentia advising that the vaccination may have been affected by the excursions. Ex. 33, Beaton Tr., at 27:22-28:25, 43:12-15, 49:13-15.

Amanda and Tyrell Fauske, and their minor children, C.R.F. and C.J.F., are all residents of North Dakota. Amanda Fauske received three vaccines at an Essentia facility in North Dakota between October and December 2018. C.R.F. and C.J.F. received eight and nine vaccinations at Essentia facilities in North Dakota, respectively, between August 2017 and April 2020. The Fauskes received a message from Essentia in April 2020, notifying them that the vaccines they received may have been affected by excursions. Ex. 34, T. Fauske Tr., at 19:21.

Jennifer Rein is a resident of Minnesota, and she received two vaccinations at an Essentia facility in North Dakota in November 2017. Ex. 38, Def.'s Resp. to Requests for Admission Nos. 35, 36, 40. Rein received a communication from Essentia in April 2020, advising her that the vaccines she received may have been affected by the excursions. Ex. 32, Rein Tr., at 67:21-68:4.

Jessica Berg and her minor children, A.B. and S.B., are residents of North Dakota. A.B. received 15 vaccines at Essentia facilities in North Dakota between January 2018 and March 2019. Berg also received four vaccines at Essentia facilities between October 2017 and January 2018. Berg received an electronic communication from Essentia in January 2021, informing her that nine of the vaccinations given to A.B. were rendered "invalid" by the excursions and recommending revaccinations. S.B. also received a flu shot at an Essentia facility in North Dakota in October 2020. The notice also stated that A.B. and S.B. received multiple flu vaccinations that may have been affected by the excursions. Berg also received communications from the North

Dakota Department of Health, informing her that A.B. and S.B. will not be permitted to enroll in public school if she does not revaccinate them.

Plaintiff Shelli Schneider and her minor children, A.S. and W.S., are residents of North Dakota. In April 2020, Schneider received an electronic communication from an Essentia nurse, advising her that W.S. received eight vaccinations that were affected by the excursions. She also received a letter informing her that A.S. received vaccinations that were affected by the excursions. W.S. and A.S. both received all of these vaccines at Essentia facilities in North Dakota. Ex. 37, Schneider Tr., at 82:16-83:12.

E. Procedural Posture and the State of Discovery

This case was filed on July 10, 2020. Dkt. 1, Compl. Plaintiffs bring five claims against Essentia and Innovis: breach of express and implied warranties (Counts I-II), violation of Minnesota and North Dakota consumer protection and deceptive practices law (Count III), unjust enrichment (Count IV), and negligence (Count V). Dkt. 119, 2d. Am. Compl.

Essentia has gone to great lengths to delay and obstruct the fact-finding process. By way of example only, nearly every key document Essentia has produced in this case was previously withheld on baseless privilege grounds.²⁴ Obtaining these documents has been an ordeal. Plaintiffs had to file dozens of briefs; the Court, Judge Senechal, and the Special Master had to issue no less than eight decisions; and Essentia even attempted a frivolous interlocutory appeal and petition for a writ of mandamus from the Eighth Circuit, both of which were unsuccessful. As Judge Senechal noted during a recent conference, this case is one of the oldest cases on the Court's docket.

As of the filing of this motion, the following discovery disputes remains outstanding.

²⁴ A review of the exhibits submitted with this motion demonstrate that nearly all contain an "EHPRIV" bates stamp—an indication that Essentia had previously withheld the document.

Essentia has refused to designate witness under Rule 30(b)(6) to address eight highly relevant topics, including topics on (a) Essentia’s temperature monitoring policies, practices, and systems; (b) other temperature excursions and Essentia’s remedial measures; and (c) Essentia’s representations to class members about the safety and efficacy of the Affected Medications. Essentia has refused to produce documents from the Essentia-issued email accounts of DCP pharmacist owners Laura Morris and Robert Haskell. Essentia has failed to conduct a reasonable search in response to nine RFPs seeking documents related to Essentia’s marketing and representations to the class; instead permitting its employees to self-collect with little to no oversight. Essentia has refused to produce class member medical records. A motion to compel on these issues remains pending. *See* Dkt. 296, Pls.’ Mot. to Compel.; Dkt. 310, Pls.’ Supp. Br.

Essentia also continues to withhold nearly 1,000 responsive documents on highly dubious privilege claims. The Special Master is currently conducting an *in camera* review. *See* Ex. 29, Pls.’ Aug. 11, 2025 Ltr. to SM Klein. Finally, to date, Essentia has refused to search the files of numerous Essentia executives that served on DCP’s Board of Governors for documents related to that role. A discovery conference to address Essentia’s intransigence is scheduled for October 7. Dkt. 327, Notice.²⁵

III. LEGAL STANDARD

This Court has “‘broad discretion’ to determine whether certification is appropriate.” *Stuart v. State Farm Fire & Cas. Co.*, 910 F.3d 371, 375 (8th Cir. 2018) (citation omitted). The party moving for certification must demonstrate “that the proposed class satisfies Rule 23(a)’s threshold

²⁵ In light of Essentia’s failure to produce effectively any evidence relevant to Plaintiffs’ Express Warranty Claim (Count I), Plaintiffs move to certify only Counts II-V. Plaintiffs reserve the right to move for certification of their Express Warranty claim and/or otherwise supplement the record once Essentia completes production of the relevant evidence.

requirements of numerosity, commonality, typicality, and adequacy, and that the class fits within one of the three subsections of Rule 23(b).” *Id.* at 374 (internal quotation marks and citation omitted). To certify a class under Rule 23(b)(3), “questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” Fed. R. Civ. P. 23(b)(3).

“Rule 23 grants courts no license to engage in free-ranging merits inquiries at the certification stage.” *Amgen, Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 466 (2013). “Merits questions may be considered to the extent—but only to the extent—that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied.” *Id.*; *accord Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 178 (1974) (“In determining the propriety of a class action, the question is not whether the plaintiff or plaintiffs have stated a cause of action or will prevail on the merits, but rather whether the requirements of Rule 23 are met.”).

IV. ARGUMENT

Plaintiffs’ motion proceeds in three parts. First, Plaintiffs demonstrate that the proposed class is readily ascertainable from Essentia’s own records, as Essentia has already identified and contacted all 54,004+ affected individuals. Second, Plaintiffs establish that all Rule 23(a)(1), (3), and (4) requirements are satisfied: the class is sufficiently numerous, the named plaintiffs’ claims are typical of the class, and both the class representatives and the undersigned counsel will adequately represent the class’s interests. Third, Plaintiffs show that certification under Rule 23(a)(2) and (b)(3) is appropriate because common questions of law and fact predominate over individual questions and class treatment is superior to alternative methods of adjudication. The predominance analysis focuses on the core liability questions that apply uniformly to all class members—including whether the TTSPPs were improperly stored and adulterated, whether

Essentia breached its obligations and violated consumer protection laws in administering adulterated TTSPPs to the class, and whether Plaintiffs have proposed a method of measuring damages on a classwide basis—all of which can be resolved through common proof. Plaintiffs also present a straightforward damages model that calculates full refunds using Essentia’s billing data. Finally, superiority is easily met given the modest individual claim amounts that would be uneconomical to pursue separately, the absence of any reasonable alternative procedure, and the efficiency gains from consolidated adjudication of Essentia’s uniform course of conduct affecting tens of thousands of patients.

A. The Proposed Class is Ascertainable

In addition to Rule 23’s explicit requirements, courts recognize that the class itself “must be adequately defined and clearly ascertainable.” *Sandusky Wellness Ctr., LLC v. Medtox Sci., Inc.*, 821 F.3d 992, 996 (8th Cir. 2016) (quoting *Ihrke v. N. States Power Co.*, 459 F.2d 566, 573 n.3 (8th Cir. 1972)). There is no “heightened test for ascertainability.” *Id.* at 995-96 (rejecting Third Circuit’s “heightened test”). Rather, a class defined with “objective criteria” is sufficient. *Id.* at 997-98; *see also In re Pork Antitrust Litig.*, 665 F. Supp. 3d 967, 1011 (D. Minn. 2023) (noting that “ascertainability is not an explicit requirement under Rule 23,” but “even if it was,” plaintiffs “have in fact established that class membership is capable of being ascertained via objective criteria—which is all that is required at the class certification stage”).

The proposed Class is defined as:

All persons and health plans that paid, in whole or in part, for Affected Medications that were administered at Essentia Health or by Innovis Health, and all persons who were administered the Affected Medications at Essentia Health or by Innovis Health.

Or, in the alternative, the proposed Subclasses²⁶ are:

- (i) All persons and health plans that paid, in whole or in part, for Affected Medications that were administered at Essentia Health or by Innovis Health in North Dakota, and all persons who were administered the Affected Medications at Essentia Health or by Innovis Health in North Dakota.
- (ii) All persons and health plans that paid, in whole or in part, for Affected Medications that were administered at Essentia Health or by Innovis Health in Minnesota, and all persons who were administered the Affected Medications at Essentia Health or by Innovis Health in Minnesota.

Both the Class and the Subclasses are objectively defined and readily identifiable sets of individuals. Indeed, Essentia has already identified them, first by sending them notice of the temperature excursions at issue in April 2020, and then again during discovery in this case. *See, e.g.*, Dkt. 103, Answer ¶ 5. Essentia has already produced billing data for the Class. *See, e.g.*, Ex. 30, Expert Report of Wes Pennington (Sept. 19, 2025) § II. Ascertainability is therefore satisfied.

B. The Proposed Class Satisfies Rule 23(a)

1. Numerosity

In general, courts have found that a class of over forty is sufficiently large to make joinder impracticable and satisfy the numerosity requirement. William B. Rubenstein, *NEWBERG ON CLASS ACTIONS* § 3:12 (5th ed. 2017 update); *Lockwood Motors, Inc. v. Gen. Motors Corp.*, 162 F.R.D. 569, 574 (D. Minn. 1995); *see also Postawko v. Mo. Dep't of Corr.*, 910 F.3d 1030, 1037 (8th Cir. 2018) (class size of 2,000 satisfied numerosity). Here, the class consists of at least 54,004 individuals, far exceeding this threshold. Ex. 31, Essentia Resp. to Interrog. 5 (Mar. 11, 2021).

2. Commonality

²⁶ It is well recognized that the Court has broad discretion to define and amend the class definition, including creating subclasses, through entry of final judgment. *See Portz v. St. Cloud State Univ.*, 297 F. Supp. 3d 929, 942 (D. Minn. 2018); *In re Select Comfort Corp. Sec. Litig.*, 202 F.R.D. 598, 606 (D. Minn. 2001); *In re VMS Secs. Litig.*, 136 F.R.D. 466, 476 (N.D. Ill. 1991).

Because “[c]ommonality is subsumed within the predominance requirement,” *Cody v. City of St. Louis*, 103 F.4th 523, 530 (8th Cir. 2024), Plaintiffs address both commonality and predominance together below.

3. Typicality

“Typicality ‘is fairly easily met so long as other class members have claims similar to the named plaintiff.’” *Postawko*, 910 F.3d at 1039 (quoting *DeBoer v. Mellon Mortg. Co.*, 64 F.3d 1171, 1174 (8th Cir. 1995)). “Factual variations in the individual claims will not normally preclude class certification if the claim arises from the same event or course of conduct as the class claims, and gives rise to the same legal or remedial theory.” *Id.* (quoting *Alpern v. UtiliCorp United, Inc.*, 84 F.3d 1525, 1540 (8th Cir. 1996)).

Typicality is easily met here. Plaintiffs and the Class were all harmed by the same conduct and all have the same claims. Essentia and its joint venture DCP failed adequately to store TTSPPs and then administered them to Plaintiffs and the Class at their North Dakota and Minnesota clinics over at least a 27-month period. Plaintiffs and the Class all suffered the same harm: paying for worthless medications. Finally, Plaintiffs and the Class all seek the same relief: full refunds for worthless medications and associated charges.

4. Adequacy

“Adequacy of representation extends to both the named plaintiff and class counsel.” *Advance Tr. & Life Escrow Servs. v. N. Am. Co. for Life & Health Ins.*, 592 F. Supp. 3d 790, 805 (S.D. Iowa 2022). For the named plaintiffs, courts look to: (1) whether the representatives have common interests with class members; and (2) whether the representatives will vigorously prosecute the interests of the class. *Rattray v. Woodbury Cnty.*, 614 F.3d 831, 835 (8th Cir. 2010). The “common interests” factor of adequacy asks whether the interests of the named plaintiffs conflict with the interests of putative class members. *Sabata v. Neb. Dep’t of Corr. Servs.*, 337

F.R.D. 215, 269 (D. Neb. 2020). Courts have found a conflict, for instance, where named plaintiffs were seeking forms of relief different from that available to class members. *See, e.g., Foster v. St. Jude Med., Inc.*, 229 F.R.D. 599, 604 (D. Minn. 2005). As to vigorous prosecution, “class representatives in complex cases are not required to have the detailed level of firsthand knowledge of facts or law that defendants seek to impose,” but they must make some showing of their commitment to and knowledge of the litigation. *In re Genesis Intermedia, Inc. Secs. Litig.*, 232 F.R.D. 321, 330-31 (D. Minn. 2005).

Here, Plaintiffs’ interests are identical to those of the class. Plaintiffs assert the same claims as class members and seek the same relief. *See* Ex. 30, Pennington Rep. at App’x. II, Schs. I and V. Plaintiffs have also testified that their primary motivation in pursuing this matter is to advance the interests of the class, even over their own interests. *See, e.g.,* Ex. 32, Rein Tr., at 19:11-20, 77:3-8; Ex. 33, Beaton Tr., at 12:1-12:9, 13:7-10, 17:23-18:4; Ex. 34, T. Fauske Tr., 11, 2021 at 11:5-11, 11:25-12:7; Ex. 35, Kraft Tr., at 11:7-13; Ex. 36, Lavelle Tr., at 12:1-2, 12:9-14, 12:24-13:4, 15:20-16:1, 47:11-20; Ex. 37, Schneider Tr., at 11:7-20, 16:10-14, 16:25-17:14, 21:22-22:2, 22:14-16, 23:3-6.

Each Plaintiff has vigorously prosecuted this case and will continue to do so. These efforts include answering burdensome interrogatories, producing voluminous documentation, and preparing and sitting for invasive depositions. *See* M. von Klemperer Decl. ¶ 3. They have stayed in contact with counsel and up-to-date on the progress of the case despite the years-long delays that Essentia’s discovery conduct has caused. Indeed, the time and energy each has devoted to this case is remarkable given the modest individual recovery each can expect to receive. *Id.*

Further, in certifying a class, a court must also appoint class counsel that will “fairly and adequately represent the interests of the class.” Fed. R. Civ. P. 23(c)(1)(B), (g)(1)(B), and (4). The

court must consider counsel's work to date on the case, counsel's experience in handling class actions and other complex litigation, counsel's knowledge of the applicable law, and the resources counsel will commit to representing the class. Fed. R. Civ. P. 23(g)(1)(A)(i)-(iv).

Undersigned counsel have extensive experience in prosecuting complex litigation, including class actions and consumer protection cases. Fegan Decl. ¶¶ 3-13; Goplerud Decl. They have committed substantial time and resources vigorously litigating this case on behalf of the class over the past five years, and will continue to do so. Adequacy is satisfied.

C. The Proposed Class Satisfies Rule 23(b)(3)

1. Commonality and Predominance

To satisfy the commonality inquiry, “plaintiffs must show their claims involve a common question or contention of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.” *Postawko*, 910 F.3d at 1038 (cleaned up). The “predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation.” *Stuart*, 910 F.3d at 374-75 (quoting *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623 (1997)). “Certification is appropriate if ‘the common, aggregation-enabling, issues in the case are more prevalent or important than the non-common, aggregation-defeating, individual issues.’” *Id.* at 375 (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1045 (2016)); *accord Meek v. Kan. City Life Ins. Co.*, 126 F.4th 577, 583 (8th Cir. 2025). Both commonality and predominance are satisfied by showing a “common injury capable of classwide resolution” with “generalized classwide proof.” *Meek*, 126 F.4th at 583 (cleaned up). Similarly, even if individual damages vary, “what matter[s]” is that the plaintiff “provide[s] a way of measuring them ‘on a classwide basis.’” *Id.* at 584 (quoting *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013)); William Rubenstein, *NEWBERG ON CLASS ACTIONS* § 12:4 (5th ed. 2013) (a “common method that can be

used to measure and quantify the damages of each class member” is sufficient). And “[a] class may be certified based on common issues ‘even though other important matters will have to be tried separately, such as damages or some affirmative defenses peculiar to some individual class members.’” *Stuart*, 910 F.3d at 375 (quoting 7AA Wright, Miller & Kane, FED. PRAC. & P. § 1778, at 123-24 (3d ed. 2005)); *Tyson Foods*, 136 S. Ct. at 1045.

a. Common Issues Predominate as to the Implied Warranty Claims

“Considering whether ‘questions of law or fact common to class members predominate’ begins, of course, with the elements of the underlying cause[s] of action.” *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 809 (2011). Both North Dakota and Minnesota have adopted the UCC and provide for an implied warranty that goods sold by a merchant of such good be merchantable, i.e., “fit for the ordinary purposes for which such goods are used.” N.D.C.C. § 41-02-31(2)(c) (2025); Minn. Stat. Ann. § 336.2-314(2)(c) (2025). The elements of an implied warranty claim are identical in both states: “the existence of a warranty, a breach of warranty, and that the breach of warranty proximately caused the damages alleged.” *Eggl v. Letvin Equip. Co.*, 2001 ND 144, ¶ 8, 632 N.W.2d 435, 438 (2001); *Schweich v. Ziegler, Inc.*, 463 N.W.2d 722, 730 (Minn. 1990).

Courts readily find implied warranty claims appropriate for class certification. *See, e.g., Glazer v. Whirlpool Corp.*, 722 F.3d 838, 854 (6th Cir. 2013) (affirming certification of implied warranty claim because whether product was in fact defective “is a common issue for all members of the certified class”); *Wolin v. Jaguar Land Rover N. Am., LLC*, 617 F.3d 1168, 1173 (9th Cir. 2010) (“[Plaintiff] alleges breach of implied warranty because the vehicles were defective and not of merchantable quality at the time they left [defendant’s] possession. Common issues predominate such as whether [defendant] was aware of the existence of the alleged defect, [and] whether [defendant] had a duty to disclose its knowledge”); *Flynn v. FCA US, LLC*, 327 F.R.D. 206, 226

(S.D. Ill. 2018) (“For Plaintiffs’ implied warranty claims, there appears to be no difference among class members with respect to proving merchantability and the defectiveness of the class vehicles”); *cf. City of Farmington Hills Emps. Ret. Sys. v. Wells Fargo Bank, N.A.*, 281 F.R.D. 347, 355 (D. Minn. 2012) (certifying breach of contract class because whether defendant breached uniform contract provision will be subject to common proof); *Perez-Benites v. Candy Brand, LLC*, 267 F.R.D. 242, 249 (W.D. Ark. 2010) (certifying breach of contract class given that claims of all class members relate to defendants’ alleged breach of uniform contract).

Here, there are numerous common questions including, (1) in administering TTSPPs, Essentia created an implied warranty that the TTSPPs had been properly stored, had not been adulterated, and were fit for their ordinary purpose; (2) whether the TTSPPs were adulterated; (3) whether Essentia breached that warranty by failing to ensure that the TTSPPs were properly stored and not adulterated; and (4) whether the class or subclasses were damaged as a result of receiving improperly stored and adulterated TTSPPs. These questions will be answered with class-wide proof, including: (1) testimony of an expert on Essentia’s obligations under applicable law, regulations, and industry standards (and its failure to comply with them); (2) contracts, internal documents, and testimony from senior Essentia and DCP personnel regarding Essentia’s relationship with its joint venture DCP; (3) temperature logs, internal documents, and testimony from senior Essentia and DCP personnel and/or an expert that the TTSPPs here were adulterated and thus not fit for their ordinary purpose; and (4) and testimony of the named plaintiffs, class members, and senior Essentia personnel, and internal Essentia documents, reflecting the impact of Essentia’s breach on the class including, e.g., invalidated vaccines. These questions predominate—they are both more prevalent and more important than any individualized issues. *See Stuart*, 910 F.3d at 374-75.

b. Common Issues Predominate as to the Consumer Protection Claims

The requirements of the North Dakota Consumer Protection Law and the Minnesota Consumer Fraud Act are largely identical: Plaintiffs must show deceptive, fraudulent, or unconscionable acts or omissions in connection with the sale of goods or services.²⁷ Both statutes focus on the defendant’s conduct: the standard is objective and does not require a showing of actual deception. N.D.C.C. § 51-15-02 (defining deceptive conduct as unlawful “whether or not any person has in fact been misled, deceived, or damaged thereby”); Minn. Stat. Ann. § 325F.69, subd. 1 (same). Treble damages are available under North Dakota law where “the defendant knowingly committed the conduct.” N.D.C.C. § 51-15-09.

Courts regularly certify classes asserting consumer protection claims that involve objective inquiries like those required under North Dakota and Minnesota law. *See, e.g., City of Farmington Hills*, 281 F.R.D. at 356 (certifying Minnesota consumer protection claim because defendant made same misrepresentation to all class members and liability can be proven on classwide basis with direct or circumstantial evidence); *Khoday v. Symantec Corp.*, No. 11-180, 2014 U.S. Dist. LEXIS 43315, at *89, *100 (D. Minn. Mar. 31, 2014) (certifying California and Minnesota consumer protection claims “because the class was exposed to uniform misrepresentations and omissions” and claims can be proven “on a class-wide basis”); *Curtis v. Altria Grp., Inc.*, 792 N.W.2d 836, 858 (Minn. Ct. App. 2010) (affirming certification of Minnesota consumer protection claims

²⁷ N.D. Cent. Code § 51-15-02 (2025) (defining unlawful practices under Act); N.D. Cent. Code § 51-15-01(3) (2025) (defining “merchandise” to include both goods and services); N.D. Cent. Code § 51-15-09 (2025) (providing private cause of action); *accord Jorgenson v. Agway, Inc.*, 2001 ND 104, ¶ 8, 627 N.W.2d 391, 394 (2001); Minn. Stat. Ann. § 325F.69, subd. 1, 8 (2025) (defining unlawful practices under Act); Minn. Stat. Ann. § 325F.68, subd. 2 (2025) (defining “merchandise” to include both goods and services); Minn. Stat. Ann. § 8.31, subd. 3a (2025) (providing for private cause of action); *accord Engstrom v. Whitebirch, Inc.*, 931 N.W.2d 786, 790 (Minn. 2019); *see also State v. Minn. Sch. of Bus., Inc.*, 935 N.W.2d 124, 133 (Minn. 2019).

because claim “does not require proof of individual reliance”), *rev’d on other grounds*, 813 N.W.2d 891 (Minn. 2012).

Here, common questions about whether Essentia’s act and omissions were deceptive, fraudulent, or unconscionable include: (1) whether Essentia bore responsibility for joint venture DCP’s warehousing practices; (2) what Essentia knew or should have known about the inadequacy of joint venture DCP’s practices; (3) whether Essentia knew or should have known that the TTSPPs it administered to the Class were adulterated; and (4) whether Essentia’s administration to the Class and receipt of payment for adulterated TTSPPs was deceptive, fraudulent, or unconscionable. These common questions will be answered with classwide proof, including testimony from senior Essentia and DCP personnel and/or an expert and Essentia and DCP documents reflecting DCP’s wholly deficient cold chain practices, Essentia’s responsibility for ensuring that the Affected Medications were properly stored, Essentia’s total abdication of that responsibility, and the resulting administration of adulterated TTSPPs to tens of thousands of unwitting patients. Answering these questions will be central to the consumer protection claims and predominate over any individualized issues.

c. Common Issues Predominate as to the Unjust Enrichment Claims

While phrased slightly different, the elements of unjust enrichment are effectively identical under North Dakota and Minnesota law. The claims require a showing that the plaintiff conferred a benefit on the defendant and that would be inequitable for the defendant to retain, and the lack of an adequate remedy at law. *See Wades Welding, LLC v. Tioga Props., LLC*, 2021 ND 214, ¶ 28, 966 N.W.2d 912, 919 (2021); *Acton Constr. Co. v. State*, 383 N.W.2d 416, 417 (Minn. Ct. App.

1986).²⁸

Courts have found unjust enrichment claims premised on a defendant's common course of conduct appropriate for class certification. *See, e.g., Walker v. Cedar Fair, L.P.*, 750 F. Supp. 3d 812, 823 (N.D. Ohio 2024) (finding commonality and predominance satisfied and certifying unjust enrichment class because the "ultimate question for all Plaintiffs is the same: whether Defendants' decision not to refund [for disputed season passes] violates the law"); *Khoday*, 2014 U.S. Dist. LEXIS 43315, at *100-02 (certifying unjust enrichment claim and noting that consumer protection claims and unjust enrichment claims are often considered together for class certification purposes); *In re Global Tel*Link Corp.*, No. 5:14-cv-5275, 2017 U.S. Dist. LEXIS 15093, at *27 (W.D. Ark. Feb. 3, 2017) (certifying unjust enrichment class and state-specific subclasses challenging defendant's common course of unfair conduct).

The common questions here largely overlap with those relevant to Plaintiffs' other causes of action. These include, for instance, whether the TTSPPs were adulterated and whether it would be inequitable for Essentia to retain the money it received in return for administering the adulterated TTSPPs in light of its legal and professional obligations to ensure that its TTSPPs are stored appropriately. This question will be answered with the same common evidence already discussed, e.g., testimony from senior Essentia and DCP personnel and/or an experts regarding DCP's wholly deficient storage practices, Essentia's knowledge of the same, Essentia's legal and professional obligations, and Essentia's failings to live up to those obligations. The other common question—whether Plaintiffs conferred a benefit on Essentia—is easily satisfied with classwide

²⁸ While unjust enrichment requires the lack of an adequate remedy at law, the claim is brought in the alternative, "and a legal claim which has yet to fail or succeed does not preclude a plaintiff from also asserting an unjust enrichment claim." *McDougall v. AgCountry Farm Credit Servs.*, 2021 ND 98, 960 N.W.2d 792, 800; *see also* Fed. R. Civ. P. 8(d)(3) (permitting pleading in the alternative).

evidence: Essentia's billing records.

d. Common Issues Predominate as to the Negligence Claims

The elements of negligence are identical under both North Dakota and Minnesota law: duty, breach, injury, and proximate cause. *Nelson v. Gillette*, 1997 ND 205, ¶ 40, 571 N.W.2d 332, 340 (1997); *Engler v. Ill. Farmers Ins. Co.*, 706 N.W.2d 764, 767 (Minn. 2005). It is well “recognized that hospitals owe a duty of care directly to patients to protect them from harm by third persons.” *Larson v. Wasemiller*, 738 N.W.2d 300, 305 (Minn. 2007). This includes, for instance, the obligation to provide adequate, trained staff, and to exercise due care in hiring individuals or contractors that will be providing patient care. *See id.* at 305-06.

Courts have certified cases sounding in negligence where the defendant's common course of conduct raised common questions for all members of the class. *See, e.g., Glazer*, 722 F.3d at 853, 854-55 (finding that, given defendant's common conduct toward class, existence of duty, breach, and proximate cause are “central questions are common to the entire liability class” that can be answered with “[c]ommon proof . . . in one stroke for all members of the class”) (citation omitted); *Bruzek v. Husky Oil Ops. Ltd.*, 520 F. Supp. 3d 1079, 1098 (W.D. Wis. 2021) (certifying negligence class action involving mass tort because common questions predominated, including whether defendant breached its duty to class); *Widdis v. Marathon Petrol. Co.*, No. 13-cv-12925, 2014 U.S. Dist. LEXIS 196445, at *22 (E.D. Mich. Nov. 17, 2014) (certifying mass negligence claim given numerous common legal and factual questions including questions about the cause of the incident, its foreseeability, precautions defendant could have taken to prevent it and legal causation). These courts have found that the class mechanism is the “best suited vehicle” to resolve a defendant's liability involving “a single course of conduct which is identical for each of the plaintiffs.” *Id.* at *20 (quoting *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1197 (6th Cir. 1988)).

Here, common questions include (1) whether Essentia owed its patients a duty to ensure that the TTSPPs it administered were properly stored and not adulterated, and (2) whether Essentia breached that duty by, for instance, (a) administering adulterated TTSPPs to the class; (b) providing DCP with defective refrigerators to warehouse the TTSPPs; (c) relying on DCP to warehouse the TTSPPs despite its lack of adequate policies, training, or equipment; or (d) conducting no oversight of DCP's activities despite a legal and professional obligation to do so and well-documented notice that DCP was not capable of adequately warehousing TTSPPs. Further common questions include whether members of the class were injured when Essentia required them to pay for and then administered adulterated TTSPPs. Plaintiffs will answer these common questions with the same types of common evidence they will present to prove their other claims: testimony and documents reflecting Essentia's (and its joint venture DCP's) common course of conduct and its classwide failure to ensure the safety of its patients.

e. Plaintiffs' Damages Model Satisfies the *Comcast* Standard

Damages need not be identical; to certify a class under Rule 23(b)(3), a plaintiff need only provide a common method of calculating damages on a classwide basis. *Comcast*, 569 U.S. at 34; *Meek*, 126 F.4th at 584; William Rubenstein, *NEWBERG ON CLASS ACTIONS* § 12:4 (5th ed. 2013). A plaintiff's model must measure damages attributable to her liability theory. *Comcast*, 569 U.S. at 35. But questions about plaintiffs' actual damages, or the value of a defendant's goods or services provided, go "to the proof of the merits of plaintiffs' claims,' not their amenability to certification." *Rodriguez v. It's Just Lunch Int'l*, No. 07-cv-9227, 2018 U.S. Dist. LEXIS 131870, at *13 (S.D.N.Y. Aug. 6, 2018) (quoting *In re Scotts EZ Seed Litig.*, 304 F.R.D. 397, 408 (S.D.N.Y. 2015); accord *In re Dollar Gen. Corp.*, No. 16-02709, 2019 U.S. Dist. LEXIS 58082, at *80-81 (W.D. Mo. Mar. 21, 2019).

Plaintiffs' implied warranty claims, under both North Dakota and Minnesota law, permit

recovery of the difference in the value between the goods as warranted and their actual value. N.D.C.C. § 41-02-93; Minn. Stat. § 336.2-714. Plaintiffs' consumer protection claims, under both North Dakota and Minnesota law, permit "recovery of 'any moneys' paid out due to an unlawful practice defined under" the Acts. *Woodmont Co. v. Lasalle Shopping Ctr., LLC*, No. 1:17-cv-00073, 2021 U.S. Dist. LEXIS 262511, at *11 (D.N.D. Apr. 12, 2021) (quoting N.D.C.C. § 51-15-09); see *Workers' Comp. Reinsurance Ass'n v. Wells Fargo Bank, N.A.*, No. A11-1260, 2012 Minn. App. Unpub. LEXIS 299, at *26 (Apr. 16, 2012) (discussing relief available under Consumer Fraud Act, including damages) (quoting Minn. Stat. Ann. § 8.31, subd. 3a (2025)). Under their unjust enrichment claims, Plaintiffs "may obtain a judgment for money in the amount of the defendant's unjust enrichment." RESTATEMENTS OF THE LAW 3D, RESTITUTION AND UNJUST ENRICHMENT, § 49; *Herlache v. Rucks*, 990 N.W.2d 443, 451 (Minn. 2023) (relief for unjust enrichment includes "what the person allegedly enriched has received") (citation omitted); *Enerplus Res. (USA) Corp. v. Wilkinson*, No. 1:16-cv-103, 2017 U.S. Dist. LEXIS 204020, at *17, *18 (D.N.D. Dec. 12, 2017) (remedy for unjust enrichment is "to return money" that "should be restored to its rightful owner") (citing *Gust v. Wilson*, 60 N.W.2d 202, 207 (1953)). Finally, Plaintiffs may recover for the monetary losses suffered as a result of Essentia's negligence. N.D.C.C. § 32-03.2-04(1) (2025); *Noske v. Friedberg*, 713 N.W.2d 866, 876 (Minn. Ct. App. 2006) (explaining that damages for negligence are compensatory and include out-of-pocket losses).

Voluminous authority supports proposition that adulterated pharmaceuticals have no residual value and entitle a plaintiff to a full refund. See, e.g., 21 U.S.C. § 331(a)-(c) (providing that adulterated medicines cannot be sold or received); *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019) (citing 21 U.S.C. § 331(a) and "conclud[ing] that the purchaser of [an adulterated] supplement received a defective product that had no value"); *United States v.*

Milstein, 401 F.3d 53, 74 (2d Cir. 2005) (affirming district court’s finding that adulterated medication “is worthless to the consumer”); *United States v. Gonzalez-Alvarez*, 277 F.3d 73, 78 (1st Cir. 2002) (citing 21 U.S.C. § 331(a) to find that adulterated milk “has a value of zero”); *United States v. Bhutani*, 266 F.3d 661, 670 (7th Cir. 2001) (“The medical effectiveness of the drug or its dangerousness after adulteration ought not be the core of the inquiry,” rather, “consumers bargained for FDA-approved drugs that were in compliance with the law” and “[t]his they did not get”); *United States v. Segredo*, No. 07-20766, 2010 U.S. Dist. LEXIS 152730, at *10, *11 (S.D. Fla. Feb. 19, 2010) (holding that “where [an FDA-regulated] product has a value of zero, as a matter of law [because it is adulterated], but consumers pay for the product as if it had value, the buyers have been robbed of the benefit of their bargain,” and the “loss” is “the full amount paid for the product”); *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 2875, 2021 U.S. Dist. LEXIS 5908, at *41-43 (D.N.J. Jan. 12, 2021) (accepting damages theory that adulterated drugs were worthless).

Plaintiffs’ theory is that the Affected Medications were adulterated and worthless. While Plaintiffs need not prove the merits of their case at class certification, ample evidence demonstrates that the Medications were adulterated and worthless. *See* Section II(C), *supra*. Indeed, Essentia’s own conduct upon discovering just how deficiently the Affected Medications had been stored confirms as much—Essentia immediately quarantined the remaining stock in a basement (where it remains to this day) and wrote off a \$400,000 loss. Dkt. 297-3, Kaufenberg Tr., at 145:22-147:14; Ex. 17, at EH049462. Consistent with this theory, Plaintiffs seek full refunds for the medications themselves and all associated expenses. Using Essentia’s billing data, Plaintiffs’ forensic accountant, Wes Pennington, conducted straightforward analyses and presents a common method of calculating class damages. Ex. 30, Pennington Rep. at § III & Appx. II at Sch. 1 and Sch. 5.

These damages include charges for the Affected Medications along with the associated office visits and administration charges. *Id.*

2. Superiority

“The superiority requirement involves showing ‘that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.’” *Custom Hair Designs by Sandy v. Cent. Payment Co.*, 984 F.3d 595, 605 (8th Cir. 2020) (quoting Fed. R. Civ. P. 23(b)(3)). Class actions are superior when “the class members’ claims are generally small and unlikely to be pursued individually.” *Id.* (quoting *Stuart*, 910 F.3d at 377) (affirming a finding of superiority where individual claims “are for tens or hundreds of dollars” therefore unlikely to be pursued individually); *In re Pork*, 665 F. Supp. 3d at 1009 (class adjudication is “superior if the alleged damages are small, and absent a class action most plaintiffs would not realistically have a day in court”). The inquiry is comparative, asking courts to weigh the relative benefits of proceeding with and without a class. *See, e.g., Levya v. Medline Indus., Inc.*, 716 F.3d 510, 515 (9th Cir. 2013) (reversing where the “district court concluded that class certification is not the superior method of adjudication but did not suggest any other means for putative class members to adjudicate their claims”); *Williams v. Mohawk Indus.*, 568 F.3d 1350, 1358 (11th Cir. 2009) (“[W]e are not assessing whether this class action will create significant management problems, but instead determining whether it will create relatively more management problems than any of the alternatives.”) (citation omitted).

Here, the class members’ damages are largely in the hundreds or low thousands. *See Ex. 30, Pennington Rep.*, at App’x. II, Sch. 1.1. There is effectively zero prospect that class members will pursue individual claims and none—beyond the Plaintiffs—have come forward to do so in the five years since this lawsuit was initiated. Accordingly, the choice for class members is not between proceeding as a class or individually: it is between proceeding as a class or not at all. *See Phillips*

Petrol. Co. v. Shutts, 472 U.S. 797, 809 (1985) (class actions permit plaintiffs to “pool claims which would be uneconomical to litigate individually” to redress wrongs that otherwise will “have no realistic day in court”).

Nor is there any reason to believe that managing this case as a class will be more complex or challenging than managing tens of thousands of individual suits by class members. Indeed, given that the entire class has already been identified, and Essentia maintains detailed records on each member, including their medical history, billing records, and personal contact information, managing a certified class here should be far more efficient than in many other certified cases. *Cf. In re Pork*, 665 F. Supp. 3d at 1009, 1011 (finding class mechanism superior despite class of millions who largely lacked any “records of what pork products they purchased,” let alone records showing that their “purchased pork was processed by a Defendant”).

V. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court certify this case as a class action, define the class as set forth above, appoint them class representatives, appoint undersigned counsel as class counsel, and grant such other relief as it deems appropriate.

Dated: Oct. 21, 2025

Respectfully submitted,

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