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' REPLY MEMORANDUM IN SUPPORT OF MOTION TO CERTIFY CLASS

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I. INTRODUCTION

Plaintiffs' liability theory—that systemic storage failures rendered all Affected Medications adulterated and worthless—raises common questions, provable with common evidence, that far outweigh any individualized issues in prevalence and importance. Essentia does not dispute, or even engage with, Plaintiffs' actual theory of liability (the word "adulterated" does not appear once in its 40-page opposition). Instead, it constructs and attacks a strawman, arguing that Plaintiffs must prove that each individual dose experienced a temperature excursion that reduced its efficacy. Essentia's myriad arguments ignore the record, misstate the relevant standards under Rule 23, and/or raise issues that go to the merits or the appropriate allocation of damages after trial. Properly rooted in Plaintiffs' actual theory of liability, the record, and the law, this case satisfies all requirements of Rule 23 and is well-suited for class adjudication.

II. FURTHER BACKGROUND

A. Undisputed Facts and Conclusions.

While the "question at class certification is not whether the plaintiffs have already proven their claims," *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 619-20 (8th Cir. 2011), Essentia's Opposition is notable for what it *does not* dispute. Neither Essentia, nor its experts, take issue with the Plaintiffs' discussion of the federal and state regulatory framework that governs the storage and handling of pharmaceuticals. *See* Pl.'s Memo. ISO Class Cert. Mot. at 4-7 (Dkt. No. 341) (hereinafter "Mot."). Essentia does not dispute that federal law mandates that TTSPPs be stored under appropriate temperature conditions, in refrigerators suitable for that purpose by individuals with appropriate training and education, and monitored by functional and well-maintained temperature monitor systems. *See* 21 C.F.R. §§ 211.142(b), 211.25, 211.63; Ex. 2 at 14-16 (Boyson Rpt.) (discussing same) (Dkt. No. 341-1); Mot. at 5 (discussing same). Essentia does not dispute that federal law requires compliance with U.S. Pharmacopeia standards regarding

the storage of TTSPPs, which, among other things, mandate a strict temperature range of 2-8 C (or 36-46 F) for refrigerated TTSPPs. Ex. 2 at 7 (Boyson Rpt.); Mot. at 5-6. Essentia does not dispute that these requirements and obligations applied to itself and DCP in their storage of the Affected Medications at issue in this case. Mot. at 5-6 & n.7-8.[1] And Essentia does not dispute that failure to comply with these any of these requirements "shall render such drug to be adulterated." 21 C.F.R. § 210.1(b) ("failure to comply with any regulation set forth in this part" in the "holding of a drug shall render such drug to be adulterated"); 21 U.S.C. § 351(a)(2)(B)-(C) (defining drug adulterated if not stored "in conformity with current good manufacturing practice" or in conformity with "the official monographs of the United States Pharmacopoeia"); Mot. at 5-6. Essentia does not dispute that adulterated drugs may not be used and are legally worthless. 21 U.S.C. § 331; Mot. at 5; *see also* Mot. at 36-37 (collecting cases holding that adulterated medications are worthless). Essentia's entire Opposition fails to use the term "adulterated" a single time. *See generally* Defs.' Opp'n to Class Cert. Mot. at 3 (Dkt. No. 353) (hereinafter "Opp'n"). Nor does its expert Thomas Anchordoquy. *See* Defs.' Ex. 2 (Anchordoquy Rpt.). Its other expert, Eugenia Garibotti, uses the term only twice—quoting Plaintiffs both times—to explain that if Plaintiffs' theory is correct then large portions of her report "may no longer be relevant." Defs.' Ex. 3 ¶ 15, 56 n.82 (Garibotti Rpt.).

Nor does Essentia dispute that (1) DCP stored all TTSPPs at issue in this lawsuit or (2) that DCP's cold chain practices were grossly deficient under applicable federal and state regulations, industry standards and best practices, or Essentia's own policies. Mot. at 12-19; Ex. 2 at 18, 20-22 (Boyson Rpt.). Rather than dispute the facts, and citing the self-serving testimony of its own

[1] Similarly notable for its absence, Essentia takes no issue with Plaintiffs' recitation of the requirements of North Dakota and Minnesota law, well-established industry best practices, or even its own policies with respect to storage and handling of TTSPPs. Mot. at 6-9; Ex. 2 at 3-9 (Boyson Rpt.) (discussing cold chain regulatory standards and industry best practices).

employees, Essentia asserts that it "was not responsible for oversight or control of DCP" in carrying out its pharmaceutical storage obligations. Opp'n at 3. But in so doing, Essentia ignores the voluminous evidence demonstrating that it exerted legal, practical, and operational control over DCP's day-to-day operations and bore responsibility to ensure the proper storage of the Affected Medications.[2] These explicit and implicit concessions speak volumes.

Evidence belatedly produced *after* Plaintiffs filed their opening brief further demonstrates that Essentia had the ability to manage DCP's operation, knew of the DCP's inadequacies, and considered improving their temperature monitoring practices *but elected not to*. An email from a senior Essentia executive discusses the prospect of installing continuous temperature monitoring technology in DCP's fridges and notes that Essentia previously considered doing so but elected not to in part because "they don't have medical grade refrigerators in their pharmacies." Ex. 39, (EH059844-45 at 59844). Essentia eventually installed the temperature monitoring equipment in DCP's fridges and provided DCP staff with temperature monitoring training but not until late 2020—nearly a year after the temperature excursions at issue in this lawsuit were discovered. Ex.

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[2] Undisputed evidence reflects that (a) all DCP personnel were directly employed by Essentia and bound to follow Essentia policies, (b) Essentia was responsible for the maintenance of the refrigerators in question and knew they did not consistently maintain temperature, (c) Essentia and Innovis executives' were deeply involved in DCP's management (including regarding appropriate temperature monitoring practices), and (d) an operating agreement that mandated Innovis presence on DCP's board and required Innovis approval for all DCP business decisions. Mot. at 10-13.

Other critical *undisputed facts* establishing Essentia's responsibility to ensure proper storage of the Affected Medications include: (a) Essentia retained title to the Affected Medications at all times from delivery by wholesaler McKesson to administration to the Class, (b) Essentia and DCP operated as a joint venture, (c) the Joint Commission recommended in 2016 that Essentia's in-house pharmacy—not DCP— perform its cold chain management and distribution, (d) DCP lacked any experience, qualifications, training, or policies to conduct cold chain management and distribution, and (e) despite these failures and over the Joint Commission's express recommendation, Essentia elected to utilize DCP for its cold chain management and distribution and then conducted zero oversight. Mot. at 11-12, 14-16; Ex. 2 at 16-18 (Boyson Rpt.).

40 (EH059850-52 at 51); Ex. 41 (EH059856-59 at 58); Ex. 42 (EH059866-69 at 66-67).[3] Another belatedly produced email further confirmed both that Essentia could inspect the DCP storage room at will and that Essentia owned the defective, non-pharmacy grade fridges DCP utilized to store the Affected Medications. Ex. 44 (EH059552-56) ("This was the third time I've been in that [DCP stock] room," and "the fridges they have are ours"); Mot. at 13, 15-16 (compiling other evidence).[4]

B. Essentia's Misleading Representations Concerning the Affected Medications.

As discussed below, differences among the Affected Medications are not legally significant under Plaintiffs' liability theory—Essentia does not dispute that every Affected Medication was adulterated and therefore legally worthless. But it is important to note that even Essentia's strawman itself is premised on misleading characterizations of the record. Both Essentia and its experts assert that the storage requirements for the Affected Medications varied widely, and that determining the impact of a temperature excursion would therefore require a "product-by-product analysis."[5] Essentia and its experts rely on Defendants' Exhibit 6 (EH031776), which Essentia describes as "a list of the potentially Affected Medications as well as the response from the manufacturers of a specific product." Defs.' Ex. 18 ¶ 4 (Kaufenberg Decl.).

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[3] When the Essentia-installed temperature monitoring system malfunctioned, Essentia's facilities team investigated the problem. Ex. 43 (EH059875).

[4] Essentia refers to the two refrigerators as "the DCP refrigerators." Opp'n at 3-4. But the evidence it cites in support of this proposition—testimony from Tony Kaufenberg and Laura Morris—does not state that DCP owned the refrigerators. Mr. Kaufenberg does not address the ownership at all, and Ms. Morris affirmatively testified that Essentia owned the fridges, was responsible for their maintenance, knew they were defective, and installed the defective temperature monitoring system. *See, e.g.*, Morris Tr. at 90:14-91:17, 92:20-93:6, 198:14-19 (Dkt. No. 297). Voluminous other evidence—including Essentia's own contemporaneous statements—is in accord. Mot. at 13.

[5] *See* Opp'n at 7, 20, 28-29, 38 (citing Defs.' Ex. 6 (EH031776) (Dkt. No. 353-5)); Defs.' Ex. 2 at 8-9 (Anchordoquy Rpt.) (citing Defs.' Ex. 6 (EH031776)); Ex 3 ¶ 39 (Garibotti Rpt.) (citing Anchordoquy Rpt. and Defs.' Ex. 6 (EH031776))).

But Essentia omits three critical pieces of information: (1) Defendants' Exhibit 6 contains both Affected Medications and *other* medications, (2) based on its investigation, including conversations with manufacturers, Essentia sorted these medications into "Throw" and "Keep" buckets based on the very "product-by-product analysis" Essentia contends is required, and (3) a more complete version of Exhibit 6 exists reflecting how it sorted medications into these buckets. Ex. 45 (EH055848). Based on its own investigation, Essentia classified every Affected Medication as one to "Throw." Von Klemperer Decl. ¶ 15. In other words, Essentia itself has already conducted the very product-by-product analysis it now contends is required and determined the Affected Medications were unsafe to use. Every medication specifically referenced in Essentia's brief or in its expert reports was either (a) not an Affected Medication and therefore completely irrelevant or (b) categorized as one to "Throw" based on Essentia's investigation. *See* **Appendix A**.

C. Key Discovery Remains Outstanding.

Almost all of the evidence summarized in Plaintiffs' Motion, at 21-22, or ordered produced by Judge Senechal on October 22 (Dkt. No. 345), remains outstanding. This includes a thousand documents withheld on dubious privilege claims under review by Special Master Klein and all responsive documents from the Essentia email accounts of Laura Morris and Robert Haskell.

III. ARGUMENT

A. The Named Plaintiffs Have Standing and the Affected Medications All Share Substantially Similar Characteristics Material To Plaintiffs' Theory.

Largely relying on a single, unreported case from 2013, Essentia argues that Plaintiffs lack standing to represent a class that includes individuals who received Affected Medications other than the specific Affected Medications they personally received. Opp'n at 19-20. However, because the Affected Medications all share "substantially similar" characteristics material to Plaintiffs' claims, Plaintiffs may represent a class of anyone who received any of the medications.

First, there's no dispute that the Plaintiffs themselves have standing. *See* Order on Mot. to Dismiss at 6 (Dkt. No. 13). Yet Essentia relies on *Chin v. General Mills, Inc.*, a motion to dismiss decision where the plaintiffs *themselves* did not have standing. No. 12-2150, 2013 U.S. Dist. LEXIS 77345, at *7 (D. Minn. May 31, 2013). *Chin* did not address the separate question of the scope of a class a plaintiff with standing could represent. But many other courts have: in cases involving products, those products must simply be "substantially similar." *Seutter v. Mead Johnson Nutrition Co.*, 763 F. Supp. 3d 783, 792 (D. Minn. 2025) ("courts have found that plaintiffs in a consumer class action have standing to sue for injuries from products they did not buy so long as the products are 'substantially similar'") (citation omitted); *accord Barclay v. ICON Health & Fitness, Inc.*, No. 19-cv-2970, 2020 U.S. Dist. LEXIS 191215, at *19-20 (D. Minn. Oct. 15, 2020); *Moore v. Compass Grp. USA, Inc.*, Case No. 18-cv-01962, 2022 U.S. Dist. LEXIS 178773, at *14 (E.D. Mo. Sept. 30, 2022); *Boone v. Pepsico, Inc.*, 653 F. Supp. 3d 635, 644 (E.D. Mo. 2023).[6]

Substantial similarity is not analyzed in a vacuum. Rather, the subject products should be evaluated in the context of plaintiffs' specific claims about them, and not just a side-by-side comparison of their characteristics. For example, the court in *Barclay v. ICON Health & Fitness, Inc.* explained "[the 24 subject] treadmill models have different features[, but] only one feature—continuous horsepower—matters for purposes of Plaintiffs' claims" as to Defendants' misrepresentations about the models' continuous horsepower capabilities. 2020 U.S. Dist. LEXIS 191215, at **2, 4-5. "Any differences among treadmill models do not appear to be *material,* so

[6] Essentia's reliance on *Ferrari v. Best Buy Co.* is also misplaced. Opp'n at 19-20 (citing No. 14-2956, 2015 U.S. Dist. LEXIS 61988, at *19-21 (D. Minn. Mar. 18, 2015)). The *Ferrari* court was unaware of "any applicable case law from either the Eight Circuit or the District of Minnesota supporting" a substantially similar standard. 2015 U.S. Dist. LEXIS 61988, at *19-21. But courts in the Eighth Circuit have overwhelmingly accepted that standard since then.

they are not a basis to find that Plaintiffs lack Article III standing[.]" *Id.* at *20 (emphasis added); *see also Azimpour v. Select Comfort Corp.,* No. 15-4296, 2016 U.S. Dist. LEXIS 77126, at *5-6 (D. Minn. June 13, 2016).

Here, every Affected Medication shares the same critical characteristics: they are TTSPPs that must be stored within 36 to 46°F and subject to the same panoply of federal, state, and industry regulation and guidance that Essentia and DCP largely disregarded. They were all thereby rendered adulterated. *See, e.g.*, Section II(A), *supra.* The Plaintiffs themselves received a wide variety of these medications: including, e.g., vaccinations for various diseases; differing types of chemotherapy drugs; and other pharmaceuticals. *See* Mot. at 19-21. In short, the Affected Medications are "substantially similar" in the ways material to Plaintiffs' actual theory of liability, and Plaintiffs can represent a class that includes anyone who received any Affected Medication.

B. Not Only Is The Class Easily Ascertainable Using Objective Criteria, Essentia Has Already Identified The Class.

Defendants' own data identifies every class member. Membership is not only ascertainable—it has already been ascertained. *See* Mot. at 23. Incredibly, Essentia argues that membership cannot be determined because data does not exist reflecting whether a particular class member received a medication that was exposed to a temperature excursion or experienced a reduction in efficacy. Opp'n at 23. But that is not how Plaintiffs have defined the class. Plaintiffs used objective and easily determinable criteria: those who paid for or received the Affected Medications. Mot. at 24 (defining class). The use of objective criteria is all that is required. *Sandusky Wellness Ctr. LLC v. Medtox Sci., Inc.*, 821 F.3d 992, 996 (8th Cir. 2016); *McKeage v. TMBC, LLC*, 847 F.3d 992, 998 (8th Cir. 2017).

Essentia's reliance on *Sandusky Wellness Center, LLC v. ASD Specialty Healthcare, Inc.* is misplaced. 863 F.3d 460 (6th Cir. 2017). As Essentia acknowledges, in that case, the data necessary

to determine class membership was lost. *Id.* at 465. Here, the data exists, and based on the objectively defined class, membership is known.[7]

C. Plaintiffs Are Typical and Adequate Representatives For Patient Class Members.

Defendants posit that Plaintiffs' claims are not typical and they are not adequate class representatives because they stated in their depositions different reasons for receiving the Affected Medications, their desire to recover for non-economic injuries, and different reasons for pursuing this case. Opp'n at 24.[8] These purported differences have no bearing on their adequacy or the typicality of their claims, and certainly defeat neither adequacy nor typicality.

Typicality is "easily met" where the claims are the same and "arise[] from the same event or course of conduct." *Alpern v. UtiliCorp United*, 84 F.3d 1525, 1540 (8th Cir. 1996). And "not every discrepancy among the interests of class members" defeats adequacy—"intra-class conflict must be so substantial as to overbalance the common interests of the class members as a whole." *Vogt v. State Farm Life Ins. Co.*, 963 F.3d 753, 767-68 (8th Cir. 2020). Any alleged conflict cannot be "speculative or hypothetical" or rest on "uncertain predictions." *Id.*

Here, the claims of the Plaintiffs and class are the same and arise from the same course of conduct. Rather than exhibit an intra-class conflict, the Plaintiffs exhibited remarkable selflessness—testifying, one after the other, how they filed this suit principally to help members

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[7] Moreover, as discussed further in Section E*, infra*, the very data necessary to make that types of determinations Essentia contends are required to determine class membership does not exist as a result of Essentia and DCP's grossly deficient temperature monitoring practices (e.g., failure to maintain twice daily logs). "It is settled that 'where a defendant's lack of records makes it more difficult to ascertain members of an otherwise objectively verifiable class, the individuals who make up that class should not bear the cost of the defendant's faulty record keeping.'" *Cline v. Sunoco, Inc. R&M*, No. 23-7090, 2025 U.S. App. LEXIS 29929, at *39-41 (10th Cir. Nov. 17, 2025) (quoting *Kelly v. RealPage Inc*., 47 F.4th 202, 223 (3d Cir. 2022)) (cleaned up).

[8] Essentia does not dispute the adequacy of class counsel. *See* Mot. at 27-28.

of the class. *E.g.,* Ex. 32 (Dkt. No. 343) J. Rein Dep. Tr. 77:3-19; Ex. 33 (Dkt. No. 343-001) E. Beaton Dep. Tr. 13:4-10, 17:23-18:4; Ex. 36 (Dkt. No. 343-003) A. Lavelle Dep. Tr. 11:25-12:14; Ex. 37 (Dkt. No. 343-004) S. Schneider Dep. Tr. 16:10-17:14. All were consistent in seeking relief for receiving the Affected Medications.[9] Essentia fails to explain how any of the examples it cherry-picks from various Plaintiffs' depositions defeats either typicality or adequacy. Tellingly, it does not even describe a purported intra-class conflict, let alone present a non-hypothetical conflict "so substantial as to overbalance the common interests of the class." *Vogt*, 963 F.3d at 767-68.

D. Plaintiffs Are Adequate Representatives for Health Plans.

Essentia contends that the Plaintiffs "lack standing" and are inadequate representatives for third-party payors, like health plans. Opp'n at 21-22, 24-25. Essentia is mistaken on both counts.[10]

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[9] Essentia falsely suggests that some Plaintiffs are seeking relief for emotional distress. But the Plaintiffs are not lawyers and were largely confused when Essentia asked them about technical legal concepts like "emotional distress" and "damages," and are relying on their attorneys to advance appropriate claims and forms of relief *E.g.*, Ex. 35 (Dkt. No. 333-37) J. Kraft Dep. Tr. 100:11-13; Ex. 34 (Dkt. No. 343-002) T. Fauske Dep. Tr. 75:1-25 ;Ex. 37 (Dkt. No. 343-004) S. Schneider Dep. Tr. 94:13-19, 95:1-10. While many discussed the emotional distress *they suffered* as a result of Essentia's actions in this case, they are not seeking *emotional distress damages*. To be adequate class representatives, a plaintiff is not required to have a detailed understanding of the facts or law, or the specific forms of relief available. *See In re GenesisIntermedia Sec. Litig.*, 232 F.R.D. 321, 330 (D. Minn. 2005).

Essentia also falsely states that none of the Plaintiffs based their decisions to receive an Affected Medication on "Essentia's representations or omissions." Opp'n at 24. But none were even asked about Essentia's omissions, and many testified they relied on the advice of Essentia's medical personnel. *E.g*., Ex. 34 (Dkt. No. 343-002) T. Fauske Dep. Tr. 15:15-16:1; Ex. 32 (Dkt. No. 343) J. Rein Dep. Tr. 75:23-76:7; Ex. 36 (Dkt. No. 343-003) A. Lavelle Dep. Tr. 12:9-14.

[10] This is an adequacy issue—Essentia's entire "standing" argument is a red herring. As noted above, there is no dispute that Plaintiffs have standing in this case. Likewise, third-party payors have standing because they would benefit from recovery for payments made for the adulterated Affected Medications. Essentia's suggestion that Plaintiffs must prove that *they were personally injured* as a result of payments made *by other class members* makes no sense and fundamentally misunderstands the concept of standing. *See* Opp'n at 21 (arguing that Plaintiffs were not "injured as a result of payments made by their health plans").

Essentia speculates that differences between Plaintiffs and health plans "could create intraclass conflict." Opp'n at 25. But as with their arguments above, Essentia offers nothing but hypothetical concerns—they offer no evidence of an actual, substantial conflict. *See Vogt,* 963 F.3d at 767-68. Because none exists. Indeed, in analogous cases, courts regularly find that consumers and third-party payors share "an 'alignment of incentives' because they both seek to prove that defendants' illegal conduct caused them to sustain injuries in the form of overpaying" for a defective or worthless product or pharmaceutical. *In re EpiPen Mktg., Sales Pracs. & Antitrust Litig.*, No. MDL No: 2785, 2020 U.S. Dist. LEXIS 40789, at *79-82 (D. Kan. Feb. 27, 2020) (collecting cases and rejecting adequacy argument challenging consumer's ability to represent third-party payors); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2017 U.S. Dist. LEXIS 170676, at *46-49 (D. Mass. Oct.16, 2017) (rejecting "argument that "third-party insurers and consumers are two fundamentally different groups" and finding that "hypothetical conflicts, particularly regarding damages allocation, are insufficient to defeat a showing of adequacy"). "If a conflict actually emerges," the court can address it "when damages are allocated." *In re EpiPen Mktg.,* 2020 U.S. Dist. LEXIS 40789, at *82; *In re Solodyn*, 2017 U.S. Dist. LEXIS 170676, at *49.

Here, as in these analogous cases, Plaintiffs and health plans paid, in part, for worthless adulterated medications and their interests are wholly aligned: proving Plaintiffs' claims and recovering for charges associated with these worthless medications. To the extent there is any hypothetical conflict between them, that is a question of damage allocation, not adequacy. And Essentia has "no interest in the method of distributing the aggregate damages award among the class members." *In re Urethane Antitrust Litig*., 768 F.3d 1245, 1269 (10th Cir. 2014).

Essentia also asserts that the two groups are subject to "unique defenses." Opp'n at 24-25.

But Essentia's premise—that Plaintiffs seek "the costs associated with revaccination," is simply wrong. Plaintiffs seek to recover the costs associated with the original administration of the Affected Medications. Essentia also asserts that "[h]ealth plans have various [reimbursement] agreements with Essentia." Opp'n at 25. But again, Essentia offers no evidence or bothers to explain how these purported "agreements" create a fundamental conflict that defeats adequacy.

E. Essentia's Predominance Arguments Miss The Mark By Focusing On Theories Plaintiffs Do Not Advance.

Predominance turns on whether a *plaintiff's theory of liability* "is suitable for class certification." *Custom Hair Designs by Sandy v. Cent. Payment Co.*, 984 F.3d 595, 601 (8th Cir. 2020) (internal citation omitted). The court "does not need to conclude whether the theory of liability is viable" or will win on the merits *Id.* Rather, the court should "den[y] certification only if the theory of liability is a highly individualized question," i.e., one that requires "evidence that varies from member to member." *Id.* Predominance requires only one "central issue . . . common to the class," and certification is appropriate "even though other important matters will have to be tried separately such as damages or some affirmative defenses peculiar to some individual class members." *Id.* (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016)).[11]

In Essentia's telling, "Plaintiffs' liability theory boils down to the following: because the class members received a notice that the medication or vaccination they received *may* have been impacted by a temperature excursion, *all* of the medications that were stored in the DCP refrigerators between 2017 and 2020 were worthless." Opp'n at 27. According to Essentia, to prove this theory, Plaintiffs must present evidence that each individual dose of the Affected Medications

[11] *See also In re Zurn Pex Plumbing*, 644 F.3d at 619 (question is not whether plaintiffs have "proven their claims," but "whether questions of law or fact capable of resolution through common evidence predominate over individual questions.").

was subject to a temperature excursion and became less efficacious. *Id.* at 27-29.

But that is not Plaintiffs' theory of liability. At its core, Plaintiffs' theory of liability is that Essentia and its joint venture DCP's storage and monitoring practices were so fundamentally deficient that every medication warehoused by DCP was legally adulterated and therefore worthless. These deficiencies—which should be considered in the aggregate and not in isolation—include but are not limited to (a) failure to maintain temperature monitoring policies, (b) failure to provide temperature monitoring training to individuals responsible for temperature monitoring, (c) failure to utilize and properly calibrate temperature monitoring hardware, (d) failure to utilize pharmaceutical grade refrigerators and, instead, utilize refrigerators that were knowingly defective and frequently experienced temperature excursions, (e) failure to conduct inspections and audits of refrigerators and temperature monitoring practices and equipment, (f) failure to maintain twice-daily temperature logs, (g) for the limited logging that was done, temperature logs that reflect regular temperature excursions below permissible minimum temperatures over a three year period, (h) failure to take, document, and/or report corrective actions for these known frequent temperature excursions, and (i) intentional disregard of required temperature ranges for TTSPPs (36-46° F) because they were "comfortable" with the fridges being at 32 or 31°F. These deficiencies violate even the most basic requirements of federal and state law, U.S. Pharmacopeia guidance, industry standards and best practices, and even Essentia's own internal policies. Mot. at 4-18; Ex. 2 at 18-22 (Boyson Rpt). Dr. Boyson opined that the degree of failure "was of a scale I have never previously seen." Ex. 2 at 21 (Boyson Rpt).

Collectively and individually, these deficiencies rendered the Affected Medications adulterated and legally worthless: conclusions that Essentia does not even address, let alone dispute. *See* Mot. at 36-37 (compiling undisputed authority that adulterated medications are

worthless); Section II(A), *supra* (discussing undisputed facts). These deficiencies, and the core question of whether the medications were adulterated, can be proven with common evidence—principally testimony and documentation from Essentia and DCP personnel and Plaintiffs' expert(s). *See Custom Hair Designs*, 984 F.3d at 601; *In re Zurn Pex Plumbing*, 644 F.3d at 619. And these questions are far more important, and therefore predominate, over any individual issues.

Essentia's entire predominance argument is premised on a strawman—a theory Plaintiffs do not advance. *See Burnett v. Nat'l Ass'n of Realtors,* No. 19-cv-00332, 2022 U.S. Dist. LEXIS 73682, at *43-44 (W.D. Mo. Apr. 22, 2022) (rejecting argument that "misstates Plaintiffs' theory of the case").[12] Essentia's misguided effort is unsurprising given that the very data needed to demonstrate that individual doses were subject to a temperature excursion that impacted their efficacy does not exist and/or was withheld in discovery. For instance, in violation of both federal and state law, the temperature logs were so deficiently maintained that there is simply no temperature data on most days and some months are entirely missing. Ex. 2 at 20-21 (Boyson Rpt). Essentia and DCP failed to maintain (or improperly withheld) invoice data or other records reflecting when medications arrived, were distributed to clinics, and were administered to patients. And Essentia refused to produce class member medical records, which may have reflected the impact of the temperature excursions on individual class members. *See* Pl.'s Supp. Disc. Br. at 13-14 (Dkt. No. 310). It is well settled that "gaps in the records kept and produced by a defendant cannot be used to hinder class certification." *Cline*, 2025 U.S. App. LEXIS 29929, at *39-41 (citing

[12] In addition to challenging a theory Plaintiffs do not advance, Essentia's arguments also ignore or flatly mischaracterize key facts, including that state health departments invalidated every dose of affected vaccines and that Essentia itself had determined that all remaining Affected Medications should be thrown out. *See* Mot. at 17; Section II(B), *supra.* Essentia also references medications like the MMR vaccine that are *not Affected Medications* to misleadingly highlight the purported differences in storage requirements. *See* Section II(B), *supra*; App'x A.

Kelly, 47 F.4th at 223). As one appellate court explained:

> It is often the case that class action litigation grows out of systemic failures of administration, policy application, or records management that result in small monetary losses to large numbers of people. To allow that same systemic failure to defeat class certification would undermine the very purpose of class action remedies.

Young v. Nationwide Mut. Ins. Co., 693 F.3d 532, 539-40 (6th Cir. 2012).

***Implied Warranty Claim*:** Relying on their mischaracterization of Plaintiffs' theory of liability, Essentia argues that Plaintiffs' implied warranty claims fail because they cannot demonstrate that each medication was subject to temperature excursion or that they contracted the disease the product was designed to prevent. Opp'n at 30. But the Eighth Circuit has affirmed certification of an implied warranty claim involving a "universal inherent defect," noting that a plaintiff need not suffer physical injury "for a defect to be manifest." *In re Zurn Pex Plumbing*, 644 F.3d at 617. Under Plaintiffs' actual theory, every Affected Medication was adulterated and therefore legally not suitable for its ordinary purpose. Indeed, administering adulterated medications is a crime. 21 U.S.C § 333(a). This was a universal defect in every Affected Medication, manifest upon administration to each class member. The existence of this "universal defect raises a critical question common to all members of the classes certified by the district court" that may be proven with "common evidence." *In re Zurn Plex Plumbing,* 644 F.3d at 619 & n.7.

Consumer Protection Claims: Essentia argues that Plaintiffs' consumer protection claims are ill-suited for class treatment because they raise issues of individual reliance on Essentia's misrepresentations. Opp'n at 31. But showing reliance is not required. *See, e.g.*, *Curtis v. Altria Grp., Inc.*, 792 N.W.2d 836, 858 (Minn. Ct. App. 2010). And Essentia ignores that both the North Dakota and Minnesota consumer protection statutes prohibit deceptive conduct through *omission* as well as *unconscionable* conduct—neither requires affirmative misrepresentations to consumers. N.D.C.C. § 51-15-02; Minn. Stat. Ann. § 325F.69; *Graphic Commc'ns Local 1B Health & Welfare*

Fund "A" v. CVS Caremark Corp., 850 N.W.2d 682, 695 (Minn. 2014).[13] Essentia's conduct was unconscionable because it was responsible for ensuring that the Affected Medications were stored properly, it knew or should have known that they were not stored properly, and it elected to administer those medications nevertheless without informing patients or its own frontline staff. *See* Section II(A), *supra* (summarizing voluminous, largely undisputed evidence of Essentia and DCP's failings and Essentia's knowledge, responsibilities, and abdications regarding the same).[14]

Plaintiffs' claims aren't based on misrepresentations by Essentia's frontline staff: the doctors and nurses administering the medications—*the frontline staff did not know*. Essentia's Rule 30(b)(6) witness on medication administration practices confirmed that the personnel interfacing directly with patients and administering medications generally have no way to know that medications had been improperly stored by the pharmacy, distributor, and other entities upstream in the distribution chain. Ex. 46, Horning Rule 30(b)(6) Tr. 53:21-54:19. Rather, the nurse injecting a medication into a patient's arm places her faith that those entities had complied with their legal, professional, and ethical duties. *Id.* Essentia's Rule 30(b)(6) witness on vaccination administration confirmed that had she known *any single one of the legion of problems with DCP's storage of the Affected Medications*, she would not have been comfortable administering those medications to patients. Ex. 47, Nefzger Rule 30(b)(6) Tr. 72:22-79:7, 79:20-81:13.

Indeed, Essentia's conduct was particularly unconscionable because it failed to provide its

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[13] Essentia acknowledges in a footnote that Plaintiffs may rely on omissions, but notes that there must be a "special circumstance" triggering a duty to disclose. Opp'n at 32 n.14. But as Essentia's own example illustrates (a party with special knowledge unavailable to the other party), the existence of a special circumstance here raises a common question—not an individualized one.

[14] Essentia claims, without citing evidence, that it "did not have knowledge." Opp'n at 32 n.14. But what Essentia knew (or should have known) is a common question that will be answered with common evidence. The answer itself is a merits issue for summary judgment or trial.

own medical personnel with the information they needed to ensure they were administering only unadulterated medications to their patients. And unsurprisingly, Essentia cites no evidence that any patient would have agreed to receive an Affected Medication had they known about Essentia and DCP's failings. The existence of legitimate individualized defenses that will purportedly predominate over common issues "must be subjected to the same rigorous inquiry as plaintiffs' claims." *In re Zurn Pex Plumbing*, 644 F.3d at 619. The evidence from Essentia's own Rule 30(b)(6) witness *testifying on behalf of Essentia* that she would not have administered the medications had she known of the deficiencies, and the lack of any evidence that any patient would have accepted the medications had he known of the deficiencies, distinguishes this case from *St. Jude* and *Johannessohn*, where the defendants presented *actual individualized evidence* undermining elements of the plaintiffs' claims. *Compare In re St. Jude Med., Inc*., 522 F.3d 836, 838-40 (8th Cir. 2008) (discussing affirmative evidentiary showing); *Johannessohn v. Polaris Indus.*, 450 F. Supp. 3d 931, 985 (D. Minn. 2020) (same), *with City of Farmington Hills Emps. Ret. Sys. v. Wells Fargo Bank, N.A.*, 281 F.R.D. 347, 356 (D. Minn. 2012) (certifying Minnesota Consumer Fraud Act class where defendant failed to present rebuttal evidence).

***Unjust Enrichment Claim*:** Essentia's unjust enrichment arguments again mischaracterize Plaintiffs' theory, asserting that Plaintiffs' must demonstrate that every individual dose experienced a temperature excursion or individuals contracted diseases the vaccines were designed to prevent. Opp'n at 33. But "the class members' theory of unjustness depends on shared rather than individualized circumstances"—payment for uniformly adulterated medications—so "the unjustness question is common to the class and does not defeat predominance." *Menocal v. GEO Grp., Inc.*, 882 F.3d 905, 925 (10th Cir. 2018) (affirming certification of unjust enrichment claim); *Payne v. Tri-State Careflight*, 332 F.R.D. 611, 696 (D.N.M. 2019) (certifying unjust enrichment

claim premised on theory that defendant's conduct was not "legally" permissible, because answer "applies uniformly to the proposed class"); *see also* Mot. at 33 (collecting cases).

Essentia notes that some class members were revaccinated. Opp'n at 33. Revaccination is a form of mitigation—a defense that Essentia bears the burden to prove. *Sayre v. Musicland Grp., Inc.,* 850 F.2d 350, 354 (8th Cir. 1988). And courts have consistently held that mitigation, like other individualized damages issues, does not preclude class certification. *Herman v. Seaworld Parks & Ent., Inc*., 320 F.R.D. 271, 298-99 (M.D. Fla. 2017) (collecting cases and listing management tools courts possess to address damages issues). While Plaintiffs dispute that revaccination is a valid form of mitigation for a host of reasons, that itself is a common question and determining which class members were revaccinated is a straightforward process that will not overwhelm common questions. *See* Ex. 48 at 7, Pennington Supp. Rpt.

***Negligence Claim*:** As to Plaintiffs' negligence claim, Essentia asserts that causation will raise individual questions, but does not explain how or why such questions would predominate over common ones. Opp'n at 34. Essentia merely cites to an earlier section of its brief that mischaracterizes Plaintiffs' theory of liability. Courts frequently certify negligence claims that turn, as this case does, on a defendant's common course of conduct that harmed members of the class the same way. *See* Mot. at 34 (collecting cases); *see also In re Zurn Pex Plumbing*, 644 F.3d at 618-19 (affirming certification of negligence claim premised on "a universal defect," because plaintiffs may rely on common evidence to establish prima facie case); *Cromeans v. Morgan Keegan & Co.*, 303 F.R.D. 543, 558 (W.D. Mo. 2014) (certifying negligence claim turning on defendant's common course of conduct that damaged class in the same way).

Damages: The parties agree that at the class certification stage, a plaintiff must merely present a method for calculating damages that aligns with its liability theory. *In re Pork Antitrust*

Litig., 665 F. Supp. 3d 967, 1007 (D. Minn. 2023) (citing *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013)). "The fact that the damages calculation may involve individualized analysis is not by itself sufficient to preclude certification when liability can be determined on a class-wide basis." *Id.* (cleaned up). Essentia's criticisms of Mr. Pennington's damages model lack merit.

First, Essentia contends that Mr. Pennington inappropriately included charges and unrelated services in his calculations. Opp'n at 35. This criticism goes to the merits of Plaintiffs' damages model, not whether that model aligns with Plaintiffs' theory of liability. Such criticisms are appropriate for resolution "at summary judgment or trial," and "do not prevent class certification." *In re CenturyLink Sales Pracs. & Sec. Litig*., 337 F.R.D. 193, 213 (D. Minn. 2020).

Recovery for office visits and other charges associated with the administration of the Affected Medications is, and always has been, consistent with Plaintiffs' damages theory. *See, e.g.*, Ex. 49, Pls.' Supp. Initial Discls. at 13. Where a class member received both an Affected Medication and other, unrelated services or medications during a single visit, Mr. Pennington excluded the unrelated charges from the damages calculation to the extent possible given the limits of Essentia's billing data. Ex. 48 at 6. This was possible in "the vast majority of cases." *Id.* But in some instances, Essentia bundled multiple medications together as a single charge in its billing data, such as for an Affected Medication *and saline.* Both Mr. Pennington and Essentia's own expert acknowledge there was no way to isolate the cost of the Affected Medication because *Essentia elected not to do so in its own billing data*. *Id.* As discussed above, Plaintiffs should not be penalized for Essentia's failures. In those limited instances where charges were bundled, Mr. Pennington, relying on the best available evidence, and utilizing accepted forensic accounting practices, included the full charge. *Id.* This approach is consistent with Plaintiffs' theory—it is just as unlawful to administer a cocktail of drugs that includes an adulterated medication as it is to

administer an adulterated medication by itself. To the extent Essentia disagrees, that dispute goes to the merits.

Second, Essentia argues that a large portion of the class was uninjured and/or lacks standing. Opp'n at 36-37 & n.15. But again, "the contention that some class members were uninjured misstates Plaintiffs' theory of this case." *Burnett*, 2022 U.S. Dist. LEXIS 73682, at *43-44 (where plaintiff's theory is that value of disputed charge was "zero," every class member was injured because they all "paid more than that amount"). Under Plaintiffs' actual theory, the class received and paid for a worthless product. Arguments that a particular class member was uninjured because the particular dose of a vaccine she received was not subject to a temperature excursion, or that she received a free revaccination, "go to the merits of plaintiffs' claims," not standing, and do not preclude class certification. *Stuart v. State Farm Fire & Cas. Co*., 910 F.3d 371, 377-78 (8th Cir. 2018) (rejecting challenge to certification premised on receipt of discounted or free repairs, given plaintiffs' liability theory, and noting that "[w]hether some plaintiffs are unable to prove damages because they eventually recouped the withheld depreciation . . . is a merits question").

Third and relatedly, Essentia argues that Plaintiffs' damages conclusions are "fundamentally flawed" because they do not identify which specific doses experienced a temperature excursion, whether each dose experienced a reduction in efficacy, or whether each class member received partial immunity. Opp'n at 39. But Mr. Pennington's model must be (and is) tied to Plaintiffs' actual theory—not Essentia's theory. And he appropriately assumes Plaintiffs will establish liability and restricts his analysis to calculating damages. *See Glasscock v. Sig Sauer, Inc*., No. 6:22-cv-03095, 2025 U.S. Dist. LEXIS 144818, at *42 (W.D. Mo. July 28, 2025) (noting that expert assumed the plaintiffs' "legal and factual allegations" were true and proposed a sufficient "damage framework" for the class certification "stage of the litigation"). Finally, it is

worth reiterating that Essentia ignores that the very data necessary to conduct the types of analyses it argues are essential does not exist (or was withheld from discovery) as a result of Essentia and DCP's woefully deficient temperature monitoring practices and litigation decisions.

F. Plaintiffs Easily Satisfy the Superiority Requirement.

As to superiority, Essentia does not dispute that it would be economically infeasible for individual class members to litigate their two, three, or four figure individual claims. *See, e.g.*, Ex. 48, Pennington Supp. Rep. at Sch. 1.3. Nor does Essentia dispute that it would be unmanageable for this Court to adjudicate over 54,000 individual claims. The choice is not between class or individual adjudication—it's between a class action or nothing at all. *See Custom Hair*, 984 F.3d 605 (superiority satisfied where class claims were for "tens or hundreds of dollars," so "[a]bsent a class action, no plaintiff is likely to pursue their claim individually"); *Douglas Phillip Brust, D.C. v. Opensided MRI of St. Louis LLC*, 343 F.R.D. 581, 594 (E.D. Mo. 2023).

Rather, Essentia repeats its predominance argument—namely that each class member's claims will need to be "individually analyzed." Opp'n at 39. But for the reasons already stated, Essentia's argument is premised on a fundamental mischaracterization of Plaintiffs' theory of liability. Essentia also argues, without citing any legal basis, that most of the class's damages "belong to health plans." Opp'n at 40. But as discussed above, third-party payers are in the class, and allocation is best addressed after damages are awarded. Further, Essentia's contention that health plans may seek to litigate separately is belied by the actual record—no such litigation has been filed—and ignores that any class member so interested will be free to opt-out.

IV. CONCLUSION

Plaintiffs respectfully request that the Court grant the Motion.

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Respectfully submitted,

/s/Michael von Klemperer

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