IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| CENTER CITY PERIODONTISTS, P.C., et al., *Plaintiffs*, | : | |
| | : | CIVIL ACTION |
| v. | : | NO. 10-774 |
| | : | |
| DENTSPLY INTERNATIONAL, INC., *Defendant*. | : | |

**Jones, II J.** **July 24, 2017**

**MEMORANDUM**

Plaintiffs bring this action, on behalf of a putative class of dentists and periodontists residing in Pennsylvania and New Jersey, for breach of express warranty claims arising from alleged deficiencies in the design and labeling of various models of the Cavitron ultrasonic scaler, a dental device used for a variety of procedures above and below the gum line. Amend. Compl. ¶¶ 9-10, ECF No. 36. Defendant Dentsply International, Inc., a Delaware corporation, manufactures and markets the Cavitron and sells the device through authorized distributors across the United States including Pennsylvania and New Jersey. *Id*. at ¶¶ 5-7.

The gravamen of Plaintiffs' claims is that the Cavitron is not, and never was, safe or suitable for its indicated uses because the internal walls of the device's waterlines naturally accumulate biofilm, exposing patients and dental staff to potentially hazardous bacteria levels in excess of safe water standards, even when operated and maintained in a manner consistent with the Directions for Use and related materials ("DFUs"). *Id*. at ¶¶ 28-35. According to Plaintiffs, that "inherent defect" constituted a breach of the Cavitron's express warranty against "defects in materials or workmanship" and, together with Dentsply's failure to disclose the defect, amounted

to a breach of an express warranty of safety and suitability contained in the DFUs. *Id* at ¶¶ 64-75.

Presently before this Court is Plaintiffs' motion for class certification and appointment of class counsel pursuant to Rule 23 of the Federal Rules of Civil Procedure (the "Class Motion"). ECF No. 54. Also pending before this Court are three motions to preclude expert testimony, filed in connection with the Class Motion, under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) (the "*Daubert* Motions"). ECF Nos. 104, 124, and 125. After careful consideration of the voluminous record and the parties' submissions, this Court decides the motions in Defendant's favor. Class certification is therefore denied.

## THE CLASS CERTIFICATION RECORD

Center City Periodontists, P.C., and Affiliated Periodontists of North Jersey, P.A., brought this action in February 2010, after their original action, commenced in December 2006, was dismissed for lack of subject matter jurisdiction. Mitchel Goldman, D.D.S., a Pennsylvania dentist, joined the instant suit as party plaintiff in August 2012.

Center City was established under the laws of Pennsylvania and is owned by the estate of the deceased Carole N. Hildebrand, D.D.S., a periodontist in Philadelphia County. Amend. Compl. ¶ 1. Affiliated Periodontists was established under the laws of New Jersey and is owned by Robert A. Jaffin, D.M.D., and Ashkay Kumar, D.M.D., periodontists in Bergen County, New Jersey. *Id*. at ¶ 2. Plaintiffs purchased Cavitrons for use in various non-surgical procedures, such as teeth cleaning and root debridement. *Id*. at ¶¶ 1-3.

One of the Cavitron's features is to deliver a high-pressure, pulsating water stream into a patient's mouth through a hand piece at the end of a flexible tube that is connected to the device's main body. *Id*. at ¶ 21. The water stream helps to keep the working area cool and free

of debris during procedures. Rowland Aff. ¶ 15, Pls.' Class Br., Ex. 1. Because water can be a vehicle for pathogenic microorganisms, various regulatory and professional guidelines instruct dental health care professionals ("DHCPs") to use water of a certain quality for non-surgical procedures like the ones performed with the Cavitron. *See id*. at ¶¶ 8-11.

In particular, the U.S. Centers for Disease Control and Prevention (CDC) publishes infection control guidelines and recommendations that DHCPs must follow to be licensed in Pennsylvania or New Jersey. *See* 49 Pa. Code § 33.211(a)(7); N.J. Admin. Code § 13:30-8.5(a)(2). In 1993, the CDC issued guidelines recommending that waterlines should be flushed with water at the beginning of each clinic day and after treating each patient. CDC, *Recommended Infection-Control Practices for Dentistry*, 42(RR-8) RECOMMS. & REP. 1, 7-8 (May 28, 1993), Class Opp'n Br., Ex. 18, ECF No. 60-8. It is undisputed that Dentsply incorporated these guidelines into "all of the Cavitron Directions for Use distributed throughout the relevant period." Class Opp'n Br. 15 n.19, ECF No. 61. By 2003, the CDC was advising DHCPs that the number of bacteria in water used for non-surgical dental procedures should be no greater than 500 colony forming units per milliliter (cfu/ml), the regulatory standard for potable water established by the U.S. Environmental Protection Agency. CDC, *Guidelines for Infection Control in Dental Health-Care Settings*, 52(RR-17) RECOMMS. & REP. 1, 29 (Dec. 19, 2003), Class Opp'n Br., Ex. 21, ECF No. 60-12. The CDC explained that water flushing was not enough to achieve this goal and recommended additional practices such as using adaptive devices or closed water systems combined with chemical flushing and other measures in consultation with manufacturers. *Id*.

Likewise, as early as 1996, the American Dental Association (ADA) started to advise members, including Plaintiffs, that biofilm formation in waterlines should be managed using a

combination of strategies such as chemical treatment and independent water reservoirs. *ADA Statement on Dental Unit Waterlines*, 127 J. AM. DENT. ASS'N __, 186 (Feb. 1996) ("*ADA Statement*"), Class Opp'n Br., Ex. 19-B, ECF No. 60-10. It noted, "Dental unit water systems currently designed for general dental practice are incapable of delivering water of an optimal microbiological quality." *Id*. at 185, Ex. 19-A, ECF No. 60-9. Like the CDC, the ADA advised dentists to monitor water quality in dental units and adhere strictly to maintenance protocols in consultation with manufacturers to reach water quality standards. *Id*. at 186, ECF No. 60-10.

The ADA also encouraged manufacturers "to develop accessory components that can be retrofitted to dental units currently in use, whatever sources (public or independent), to aid in achieving this goal." *Id*. at 185, ECF No. 60-9. Two years later, Dentsply introduced the Dual Select, an accessory that can be used to retrofit Cavitrons to deliver water from a closed water system. It also allows for chemical flushing of the device's waterlines. As of 1997, the Cavitron's DFUs identified the Dual Select as an available accessory. Ingram Decl. ¶¶ 27-28, Class Opp'n Br., Ex. 7, ECF No. 60-3. The ADA continued to update these recommendations about every three years and, by 2004, its advice had largely converged with the CDC's guidelines. Class Opp'n Br. 17-20; *see also* Ingram Decl. ¶ 29. According to Plaintiffs' infection control expert, it is reasonable to expect DHCPs to be familiar with the ADA's recommendations and, in the exercise of reasonable care, to incorporate them into their practices. Rowland 11/6/07 Dep. 237-242, Class Opp'n Br., Ex. 11, ECF No. 60-3.

In addition to these recommendations and guidelines, the Cavitron's DFUs provide installation, operation and maintenance instructions. The DFUs are a product of the regulatory regime that applies to Cavitrons under the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 360, *et seq*. *Id*. at 11-12. Under applicable regulations,

DFUs must include a description of the device's "indicated" uses, "contra-indications," "warnings" of any hazards or risks, and "precautions" as to any potential risks to the patient's health from receiving treatment with the device. *See* 21 C.F.R. § 801.109. The DFUs vary from model to model but, after 1997, the "indicated uses" for all Cavitrons included "[p]eriodontal debridement for all types of periodontal diseases" and "[e]ndodontic procedures." Pls.' Class Br. 14-15; *see, e.g.*, Directions for Use § 1, Pls.' Class Br., Ex. 18. And at least one version of the DFUs indicated that the device was an "open water system." *See, e.g.*, Directions for Use § 5.2, Pls.' Class Br., Ex. 21. The DFUs also directed users to flush the waterlines on a regular basis. *Id*. at § 9.1. It is undisputed that the DFUs lack any reference to biofilm or its pathogenic risks.

Since 1990, however, Cavitrons have also included an Infection Control Information card, which states:

> The objective of this information is to *supplement* published general guidelines for reducing cross contamination of infectious diseases when using a Dentsply® Cavitron® ultrasonic scaler during routine dental care. In the event any regulatory agency disagrees with this information, *the agency requirements take precedence*.

Class Opp'n Br. 26-27; *see also id*., Infection Control Information, Ex. 30, ECF No. 60-28 (emphasis added). The DFUs explicitly refer purchasers to this card, as well as applicable state laws and the CDC's and ADA's recommendations, for "maximal operator and patient safety." *See, e.g.*, Directions for Use § 4, Pls.' Class Br., Ex. 18. In 2001, Dentsply issued a Service Bulletin informing purchasers of the biofilm problem that can arise when failing to comply with the CDC's guidelines, and recommending the complete removal and replacement of biofilm-clogged waterlines. Pls.' Class Br. 23 n.26; *see also id*., Ex. 24. And, as of 2006, new DFUs started to advise purchasers against using the Cavitron in any procedure that required asepsis, i.e., the absence of pathogenic micro-organisms such as those found in biofilm. Pls.' Class Br.

15-16. The new DFUs also strongly *recommended*, but did not *require*, chemical flushing on a weekly basis. *Id.* at 16; *See* Directions for Use § 9.2, Pls.' Class Br., Ex. 21.

Because the DFUs did not require installation on a closed water system or chemical flushing, nor warned buyers of the biofilm problem, Plaintiffs purportedly believed that the Cavitron would always deliver potable water—consistent with safe water standards for its indicated uses—when installed on an open water source and flushed only with water in accordance with the DFUs. *See* Amend. Compl. ¶¶ 49, 55, 61; *see also* Pls.' Class Br. 14-17, ECF No. 54-1. Plaintiffs concede the Cavitron met those expectations at first. *See* Amend. Compl. ¶ 71. They also implicitly admit that the Cavitron can be used safely and effectively with "the purchase of expensive additional or substitute equipment or systems." *Id*. at ¶ 69. In fact, Plaintiffs used Cavitrons to treat patients without incident for years, even though they did not always connect them to a closed water system, attach a Dual Select or equivalent device, or flush the waterlines with a biocide on a regular basis. *See* Class Opp'n Br. 12-14. Over time, however, Plaintiffs discovered that, when left untreated, the Cavitron's waterlines naturally accumulated potentially hazardous levels of biofilm. *See* Amend. Comp. ¶¶ 49-50, 55-56, 61-62. They claim this "inherent defect" renders the Cavitron unsafe and unsuitable for its indicated uses; a material fact Dentsply supposedly omitted from the DFUs on purpose. *See id*. at ¶¶ 33, 41, 71-73, 89.

Plaintiffs initially raised three counts, or theories of liability, for Dentsply's allegedly wrongful conduct: (1) breach of express warranty, (2) negligent design, and (3) a violation of New Jersey's Consumer Fraud Act (NJCFA) specifically on behalf of class members residing in New Jersey. *Id*. at ¶¶ 64-91. This Court dismissed the NJCFA and negligent design claims, but denied summary judgment on breach of warranty; thus only the express warranty claims remain.

Plaintiffs now seek certification of the following class:

> All dentists, periodontists, dental and periodontal practices, and dental and periodontal schools and institutions (a) who are citizens of the State of New Jersey or the Commonwealth of Pennsylvania, respectively, (b) who purchased Cavitron ultrasonic scalers during the time period January 1, 1997 to the date of trial, and (c) who were using a public water source for their Cavitrons at the time of installation (the "Class").

Class Mot., ECF No. 54. Plaintiffs also request certification of two Subclasses: "Subclass 1: All members of the Class who are citizens of the State of New Jersey," and "Subclass 2: All members of the Class who are citizens of the Commonwealth of Pennsylvania." *Id*.

Plaintiffs submitted various expert reports and affidavits in support of the Class Motion, including the report of Timothy Ulatowski, a former administrator for the U.S. Food and Drug Administration (FDA) who opined on the regulatory regime applicable to the Cavitron, and the report of Steven Hazel, a public accountant who offered methods for calculating damages based on three distinct remedies. Dentsply submitted its own experts in opposition to certification, including Eric Gaier, Ph.D., an economist offered to rebut Hazel's opinions.

The Class Motion was fully briefed on December 6, 2013, and after a series of continuances requested by the parties, the certification hearings began on January 13, 2016. This Court adjourned the proceedings into the summer to allow counsel the opportunity to examine experts. In the interim, Dentsply moved to preclude Ulatowski's and Hazel's testimonies, and Plaintiffs moved to preclude Dr. Gaier's. The hearings concluded on August 9, 2016. This Court is now prepared to rule on the Class Motion and related *Daubert* Motions.

## DISCUSION

"To obtain class certification, plaintiffs must establish all four elements of Rule 23(a) along with one provision of Rule 23(b)." *Johnston v. HBO Film Mgmt. Inc.*, 265 F.3d 178, 183

(3d Cir. 2001). Rule 23(a) requires a numerous class, common questions, typical claims, and adequate representation. *Id*. Because Plaintiffs seek to proceed under Rule 23(b)(3), they must also show that common issues predominate over individual ones and that a class action is the superior vehicle for adjudicating the dispute. *Id*. at 184. The other "essential pre-requisite" under Rule 23(b)(3) is "ascertainability." *Byrd v. Aaron's Inc.*, 784 F.3d 154, 162 n.5 (3d Cir. 2015) (quoting *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 592-93 (3d Cir. 2012)).

The Third Circuit requires rigorous analysis and consideration of "all relevant evidence and arguments presented by the parties" to assure the requirements of Rule 23 are met. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 320 (3d Cir. 2008), *as amended* (Jan. 16, 2009). Rigorous analysis will frequently "entail some overlap with the merits of the plaintiff's underlying claim. That cannot be helped. '[T]he class determination generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff's cause of action.'" *Wal-mart Stores, Inc. v. Dukes*, 564 U.S. 338, 351 (2011) (quoting *General Tel. Co. of SW v. Falcon*, 457 U.S. 147, 160 (1982)) (alteration supplied).

With this in mind, this Court first resolves the *Daubert* Motions before proceeding to the Class Motion. *See In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187 (3d Cir. 2015) ("a district court must make a conclusive ruling on any challenge to [an] expert's qualifications or submissions before it may rule on a motion for class certification.") (citing *Messner v. Northshore Univ. HealthSystem*, 669 F.3d 802, 812 (7th Cir. 2012)).

## I. Defendant Prevails on the *Daubert* Motions

The *Daubert* analysis governing the admissibility of expert testimony emerges from Federal Rule of Evidence 702, which sets out three requirements commonly known as

"qualification, reliability and fit." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (quoting *Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003)).

Qualification demands that "the witness possess specialized expertise." *Id.* (quoting *Schneider*, 320 F.3d at 405). The Third Circuit has "interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training qualify an expert as such." *Id.* (internal quotation marks omitted).

For reliability, "the expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his or her belief." *Id.* (internal quotation marks omitted). "[T]he trial judge must determine whether the testimony has 'a reliable basis in the knowledge and experience of the relevant discipline.'" *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 294 (3d Cir. 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999)). The reliability prong "applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, [and] the link between the facts and the conclusion." *Id*. at 291 (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir.1999)) (alteration supplied).

Fit means that "the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Calhoun*, 350 F.3d at 321 (quoting *Schneider*, 320 F.3d at 405); *see also Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 790 (3d Cir. 2009) ("The expert's testimony must 'fit' under the facts of the case so that it will aid the [fact finder] in resolving a factual dispute.") (internal quotation marks omitted).

The proponent of the expert testimony has the burden of establishing its admissibility by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir.

1999) (citing *Daubert*, 509 U.S. at 592 n.10); *see also Mahmood v. Narciso*, 549 F. App'x 99, 102 (3d Cir. 2013).

**A. Ulatowski's Expert Opinion Is Inadmissible**

Plaintiffs have not demonstrated the admissibility of Ulatowski's expert testimony. Ulatowski is an "expert consultant on matters concerning medical device regulations, policies and procedures administered by the [FDA]." Ulatowski Report 4, Pls.' Class Br., Ex. 16. He also has experience in the field of infection control for medical devices, germicides, sterilizers and disinfectants. Pls.' Ulatowski Br. 6, ECF No. 111. His opinions focus almost exclusively on Dentsply's compliance (or non-compliance) with the FDA's labeling requirements and other regulations. *See* Ulatowski Report 37-52.

Ulatowski's qualifications and the reliability of his testimony are not in doubt. He holds a bachelor's degree in microbiology and a master's degree in physiology with an emphasis on biomedical engineering. *Id*. at 4. To support his expert opinions, he draws upon "36 plus years of training, knowledge and utilization of the FDA medical device regulations, policies, review procedures and practices." *Id*. at 9. The totality of his "knowledge and experience" provides "a reliable basis," *ZF Meritor*, 696 F.3d at 294, for opining on the FDA's regulatory and administrative requirements involving medical devices and infection control practices.

The admissibility of Ulatowski's testimony hinges on whether his opinions "fit under the facts of this case." *Calhoun*, 350 F.3d at 321. For purposes of answering this question, the parties agree that the relevant factual inquiries are: (1) whether the Cavitron's DFUs contain an express warranty of safety and suitability, and (2) whether Dentsply breached that warranty. *Compare* Pls.' Ulatowski Br. 7 *with* Def.'s Ulatowski Br. 1, ECF No. 104-1.

Accepting these limitations, Ulatowski's testimony does not reach the relevant factual issues, nor can his expertise assist the trier of fact in any other way. After all, finding that the Cavitron includes a warranty of safety and suitability will depend on the language in the DFUs, not the text of the FDA's regulations. And establishing Dentsply's breach will depend on whether the Cavitron conformed to Dentsply's representations, not the FDA's regulatory requirements.[1] During the hearings, Ulatowski all but admitted his testimony was irrelevant to class certification or the merits of this case. He was unfamiliar with Rule 23's requirements. Class Cert. Hr'g Tr. 1/15/16 at 115:5-13. He agreed that the FDA does not deal with contractual or warranty issues for medical devices. *Id*. at 91:17-93:1-5. And he admitted he cannot opine on whether the DFUs create a warranty or whether prospective class members understood them as such. *Id*. 93:18-95:13. In a separate, but related case, he also conceded that he cannot opine as to whether or not dentists, "as a group," looked at the DFUs. Pls.' Ulatowski Br. at 8 n.8.

Plaintiffs' arguments to the contrary are not persuasive. To start, Plaintiffs do not cite any case in which a court admitted a regulatory expert's testimony in support of a breach of warranty or breach of contract claim, or any class certification case for that matter. Still, Plaintiffs argue that Ulatowski's testimony helps to show they can satisfy the commonality, typicality and predominance requirements under Rule 23, because those factors focus on "*defendant's* conduct, and Mr. Ulatowski's testimony will establish that Dentsply's representations . . . were both uniform throughout the class period and incorrect." Pls.' Ulatowski Br. 8 (emphasis in original).

But Ulatowski's expertise is not necessary for determining the DFUs' uniformity. The DFUs speak for themselves, and a layperson is able to evaluate their uniformity without expert

[1] Plaintiffs acknowledge as much when they assure this Court that that their breach of express warranty claim is not based on any purported violations of the FDA's regulations. Pls.' Ulatowski Br. 7.

assistance. Nor is Ulatowski able to opine on the correctness of the DFUs. Indeed, he does not know how Cavitron users interpreted the DFUs. Class Cert. Hr'g Tr. 1/15/16 at 95:7-23. He cannot comment on how the DFUs interact with infection control guidelines; he did not even know that DHCPs are required by law to comply with the CDC's recommendations. *Id*. at 126:15-25. And he is not qualified to offer clinical opinions as to the Cavitron's suitability for its intended uses when connected to an open water source. *Id*. at 101:3-10; *see also* Pls.' Ulatowski Br. 6-7. Ulatowski's testimony does not fit this breach of warranty case and is therefore inadmissible.

**B. Hazel's Expert Report Is Precluded**

Hazel's expert report is also precluded. Hazel is a certified public accountant and possesses other certifications and accreditations in fields such as financial forensics and business valuation. Hazel Report App. B, Pls.' Class Br., Ex. 40. He proposes procedures for calculating potential damages based on three remedies: reimbursement, retrofit, and replacement.[2] *Id*. at 3. He opines that each of these costs could be proven through a combination of invoices and self-reported eligibility "verification" forms. *Id*. at 3-6.

Dentsply does not attack Hazel's qualifications. Rather, it contends Hazel's opinions are unreliable and his "analysis does not fit this case." Def.'s Hazel Br. 1, 4-6, ECF No. 124-1. According to Defendant, Hazel incorrectly presumes that the Cavitron is "worthless" and therefore fails to consider, and could not account for, the device's value when used on an open system. *Id*. at 4-6. Also, "Hazel's class-wide damages do not fit Plaintiffs' theory of liability

[2] Hazel anticipates that some class members will be entitled to full reimbursement of the Cavitron's purchase price. Hazel Report 3. Other class members may be entitled to restitution for costs incurred from retrofitting eligible Cavitrons from an open onto a closed water source, including necessary auxiliary devices and chemical disinfectants. *Id*. 4-5. Lastly, Hazel identifies alternative scalers that "could" deliver potable water without biofilm formation, and posits that some class members would be entitled to recover the costs of replacing their Cavitrons for one of these other scalers. *Id*. at 5-6.

because they are not traceable to the alleged breach of express warranty," as required under *Comcast Corp. v. Behrend*, 133 S. Ct. 1426 (2013). *Id*. at 4, 6-7. Furthermore, Hazel's "opinions could not possibly prove damages here on a class-wide basis," because individualized trials would be required to determine class eligibility and "warranty damages." *Id*. at 1.

Dentsply's arguments are on point. When calculating damages for breach of warranty, both New Jersey and Pennsylvania credit "the value of the goods accepted," 13 Pa. Cons. Stat. § 2714 and N.J. Stats. Ann. § 12A:2-714, which includes any value obtained even with the alleged defect. *See, e.g.*, *Bouie v. Chrysler Corp.*, No. 95-cv-4146, 1996 WL 460768, at *2 (E.D. Pa. Aug. 14, 1996) ("the standard measure of damages is the difference between the good as warranted and the good in its defective condition," citing 13 Pa. Cons. Stat. § 2714(b))*; cf. Samuel-Bassett v. KIA Motors Am., Inc.*, 357 F.3d 392, 402 (3d Cir. 2004) (finding that the jurisdictional amount in a breach of warranty case could not be established solely from evidence of the purchase price because the record did not include any data to ascertain "the value of the automobile with and without the brake defect.").

Hazel's methodology fails to account for any revenue generated by class members from successfully using their allegedly non-conforming Cavitrons—value Hazel conceded should be discounted from any damages award. Hazel Hr'g Tr. 2/26/16 at 26:14-21. Hazel also indicated that he would have modified his methodology to account for any value gained had he known that Plaintiffs were using the device for its intended uses without incident. Hazel Hr'g Tr. 2/26/16 at 27:6-28:15. Failure to do so rendered his model unreliable and ill-fitting under the facts of this case. Because individualized inquiries will be necessary to identify any value obtained by each class member from using the Cavitron as accepted, Hazel's approach is also unhelpful for computing damages on a class-wide basis.

Another impediment to admitting Hazel's testimony is *Comcast*, which held that "a model purporting to serve as evidence of damages in this class action must measure only those damages attributable to that theory." *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 374 (3d Cir. 2015) (quoting *Comcast*, 133 S.Ct. at1433). As in *Comcast*, Plaintiffs originally brought this case under multiple theories of liability, including violations of New Jersey's consumer fraud laws in addition to breach of express warranties. Hence, Hazel submitted an "expert opinion on the range of damages that were sustained by Plaintiffs and the Class as a result of the breach of express warranties by Dentsply *and the conduct alleged under the New Jersey consumer fraud law*." Hazel Report 3 (emphasis added). Because this Court dismissed the consumer fraud claims, Hazel's undifferentiated methodology is now irrelevant for purposes of determining damages that are solely "the result of the wrong." *Comcast*, 133 S. Ct. at 1434.[3] As Hazel conceded, his model does not distinguish between damages attributable to the specific breach alleged in this case or "something else." Hazel Hr'g Tr. 2/26/16 at 58:14-59:4. Hazel's testimony is therefore precluded.

**C. Dr. Gaier's Expert Testimony Is Admissible**

By contrast, Dr. Gaier's testimony satisfies the requirements under *Daubert*. Dentsply retained Dr. Gaier "to evaluate: (1) the ascertainability of the putative class, (2) the feasibility of a common class-wide damages methodology, and (3) the report and expert opinions of plaintiffs' damages expert Steven J. Hazel." Gaier Decl. ¶ 5, Class Opp'n Br., Ex. 55, ECF No. 60-31.

Dr. Gaier's qualifications and experience are more than sufficient to opine on methods for computing economic damages in a breach of warranty case involving medical devices. He holds a Ph.D. in economics from Duke University, and he "specialize[s] in performing economic

[3] Although *Comcast* turned on "the straightforward application of class-certification principles" under Rule 23, 133 S. Ct. at1433, the parties implicitly agree it applies under *Daubert*. Regardless, Hazel's methodology is unreliable and unhelpful under either a *Daubert* or Rule 23 analysis.

and statistical analyses of competition and pricing" for litigation and regulatory matters involving "health insurance, pharmaceutical pricing and reimbursement, medical devices, [and] surgical supplies." *Id*. at ¶ 4.

Dr. Gaier's opinions are reliable because they are supported by facts and do not venture into the realm of "subjective belief or unsupported speculation." *Calhoun*, 350 F.3d at 321. Specifically, his conclusions that an individualized inquiry is necessary to ascertain class membership and determine damages are based on his data analysis expertise, as well as his review of Plaintiffs' own experiences. Gaier Decl. ¶¶ 10-28. And his testimony fits this case precisely because it sheds light on the difficulties of ascertaining class membership in an objective manner and calculating damages on a class-wide basis pursuant to Rule 23(b)(3).

Plaintiffs do not offer any legitimate grounds for precluding Dr. Gaier's expert opinions. They do not challenge his qualifications other than to attack his supposed lack of "forensic expertise," Pls.' Gaier Br. 4, ECF No 125-1, which has no obvious bearing on his ability to opine on the feasibility of ascertaining class membership or class-wide damages. Plaintiffs' attempts to undermine his credibility and reliability fall short. Dr. Gaier's purported failure to review "the entire record" appears to be inconsequential; Plaintiffs did not identify a single document that would have led Dr. Gaier to a different conclusion had he reviewed it. *See id*. at 4-5.

Plaintiffs are also mistaken when stating that Dr. Gaier's "testimony does not fit any theory of liability under Pennsylvania or New Jersey law, or the facts of this case." *See id*. at 1. Even though Dr. Gaier did not cite the most relevant legal authorities, he based his damages formula on the applicable provisions of the Uniform Commercial Code (UCC), see Gaier Decl. ¶ 28, which New Jersey and Pennsylvania have adopted, see 13 Pa. Cons. Stat. § 2714 and N.J. Stats. Ann. § 12A:2-714. He also provides a fact-based explanation for why computing damages

in this case necessarily involves individualized inquiries based on Plaintiffs' own experiences and "each potential class member's particular configurations." *See* Gaier Decl. ¶¶ 23, 27. Dr. Gaier's testimony is admissible.

Having ruled on the *Daubert* Motions, this Court now addresses the Class Motion.

## II. Plaintiffs Have Not Met Their Burden for Class Certification

Class certification is not appropriate on the present record. Plaintiffs have not met their burden of proving, by a preponderance of the evidence, that each of the prerequisites under Rule 23(a) is satisfied or that the class fits within the desired categories of class actions set forth in Rule 23(b). *See In re Hydrogen Peroxide*, 552 F.3d at 320, n.14. "Failure to meet any of Rule 23(a) or 23(b)'s requirements precludes certification." *Danvers Motor Co., Inc. v. Ford Motor Co.*, 543 F.3d 141, 147 (3d Cir. 2008).

### A. Plaintiffs Do Not Meet All Four Requirements of Rule 23(a)

The analysis begins with the four requirements of Rule 23(a):

> (1) the class is so *numerous* that joinder of all members is impracticable; (2) there are questions of law or fact *common* to the class; (3) the claims or defenses of the representative parties are *typical* of the claims or defenses of the class; and (4) the representative parties will *fairly and adequately* protect the interests of the class.

Fed. R. Civ. P. 23(a) (emphasis added). Plaintiffs have demonstrated commonality, but failed to prove typicality, adequacy or numerosity.

#### 1. *Plaintiffs' claims satisfy commonality.*

Commonality is met so long as "the named plaintiffs share at least one question of fact or law with the grievances of the prospective class." *Reyes v. Netdeposit, LLC*, 802 F.3d 469, 486 (3d Cir. 2015) (quoting *Rodriguez v. Nat'l City Bank*, 726 F.3d 372, 382 (3d Cir. 2013)). "A court's focus must be 'on whether the defendant's conduct [is] common as to all of the class

members[.]'" *Id.* (quoting *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 298 (3d Cir.2011) (en banc)) (alterations supplied). The inquiry turns on "the capacity of a classwide proceeding to generate common *answers* apt to drive the resolution of the litigation." *Wal-Mart*, 564 U.S. at 350 (quoting Richard A. Nagareda, *Class Certification in the Age of Aggregate Proof*, 84 N.Y.U. L. REV. 97, 132 (2009)) (emphasis supplied). The bar for establishing commonality is "not high" and may be overcome even "when class members did not have identical claims[.]" *In re Cmty. Bank of N. Virginia Mortg. Lending Practices Litig.*, 795 F.3d 380, 397 (3d Cir. 2015).

According to Plaintiffs, commonality is met "because the breach of warranty claims all share as the common issue that Dentsply represented in the [DFUs] that the Cavitron was suitable for its indicated dental uses if purchasers followed Dentsply's installation and maintenance instructions." Pls.' Class Br. 38. Resolving this allegation, Plaintiffs argue, "will resolve an issue that is central to the validity of each one of the claims in one stroke." *Id.* (quoting *Wal-Mart*, 564 U.S. at 350). Besides needing to prove the uniformity of Dentsply's representations, Plaintiffs must also prove that Dentsply breached that warranty by designing a defective device and/or concealing the defect. Pl.'s Class Br. 39. This Court agrees that these questions "will result in common answers that apply across the board to all members of the Class." *Id.* That is enough for commonality.

2. *Plaintiffs do not satisfy typicality.*

Even when common issues exist, however, typicality is designed to "screen out class actions in which the legal or factual position of the representatives is markedly different from that of other members of the class[.]" *Marcus*, 687 F.3d at 598 (quoting 7A Charles Alan Wright, et al., *Federal Practice and Procedure* § 1764 (3d ed. 2005)). To determine whether a plaintiff's position is "markedly different," courts address "three distinct, though related,

concerns: (1) the claims of the class representative must be generally the same as those of the class in terms of both (a) the legal theory advanced and (b) the factual circumstances underlying that theory; (2) the class representative must not be subject to a defense that is both inapplicable to many members of the class and likely to become a major focus of the litigation; and (3) the interests and incentives of the representative must be sufficiently aligned with those of the class." *Id*. (quoting *In re Schering Plough Corp. ERISA Litig.*, 589 F.3d 585, 599 (3d Cir. 2009)).

Although the legal theory and factual basis for Plaintiffs' claims are the same for all class members (i.e., breach of express warranty based on Defendant's alleged representations and failure to deliver a conforming product), Dentsply raises several plaintiff-specific defenses that undermine typicality. For instance, Dr. Hildebrand (Center City's late owner) testified that she purchased her Cavitron at a steep discount from an *un*authorized Cavitron dealer. Class Opp'n Br. 83. That fact alone could defeat her claim since Dentsply will argue that any existing warranty covers only "products purchased from an authorized Dentsply Dealer." *Id*. Dr. Hildebrand also testified that she was aware of the biofilm problem, and even tried to close her open systems after reading the 2003 CDC guidelines, Hildebrand 9/17/07 Dep. at 65:9-69:10, Class Opp'n Br., Ex. 15, ECF No. 60-6, an admission that suggests she did not believe that following Dentsply's DFUs would be enough to comply with safe water standards. Likewise, Dr. Jaffin (Affiliated Periodontists' owner) and Dr. Goldman may have relied on their professional knowledge or business judgment, not Dentsply's DFUs, in deciding how to install and maintain their Cavitrons. *See* Jaffin Dep. 9/26/07 at 122:16-123:14, Class Opp'n Br., Ex. 13, ECF No. 60-4 (stating that cost and time may have factored into his decision to maintain his Cavitrons on an open water source); Goldman Dep. 9/19/07 at 163:1-164:3, Class Opp'n, Ex. 16,

ECF No. 60-7 (stating that he believed an open water system complied with safe water standards even after reading the 2003 CDC guidelines).

Indeed, none of the Plaintiffs read, or recall reading, all the relevant provisions of their Cavitrons' DFUs, yet they were all at least generally aware of the biofilm problem and the various strategies for dealing with it based on their review of industry guidelines. *See* Class Opp'n Br. 43-38, 44-46, 49-50 (citing each plaintiff's deposition testimony). Because awareness of a seller's affirmations is a basic element of a breach of warranty claim in New Jersey and Pennsylvania, Plaintiffs who were not aware of the DFUs' relevant content cannot be typical representatives of a class that was allegedly misled and damaged by Defendant's representations in those same DFUs. *See Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 171 F.3d 818, 825 (3d Cir. 1999) ("a promise is presumed to be a 'part of the basis of the bargain' under New Jersey law 'once the buyer has become aware of the affirmation of fact or promise'") (quoting *Cipollone v. Liggett Grp., Inc.*, 893 F.2d 541, 568 (3rd Cir.1990), *overruled on other grounds*, 505 U.S. 504 (1992)); *Green v. Saturn Corp.*, No. 685, 2001 WL 1807390, at *6 (Pa. Com. Pl. Oct. 24, 2001) ("the disparate and distinct ways and times that the Class members became aware of the [alleged] representation, if they did at all, complicates the Court's ability to determine whether this representation became" a class-wide warranty).

Even assuming Plaintiffs lacked any knowledge about biofilm and relied solely on Dentsply's DFUs (a factual finding that would be at odds with their legal obligation to comply with the CDC's recommendations), Plaintiffs' claims would still be markedly different from those of class members like "schools and institutions" who were certainly familiar with the biofilm problem and selected their equipment and infection control practices accordingly. *See* Class Opp'n Br 24-25 (listing academic articles, starting in 1994, on biofilm in dental units).

These plaintiff-specific defenses, among other factors discussed below, make Plaintiffs' positions different enough from those of the broader class so as to make it more likely that they will "devote time and effort to the defenses at the expense of issues that are common and controlling for the class." *Beck v. Maximus, Inc.*, 457 F.3d 291, 297 (3d Cir. 2006).

Plaintiffs' claims are thus not sufficiently typical.

*3. Plaintiffs do not satisfy adequacy.*

In addition to defeating typicality, those same defenses weigh against Plaintiffs' ability to be adequate class representatives because plaintiff-specific defenses produce diverging "interests and incentives" between Plaintiffs and the Class. *See In re Cmty. Bank of N. Virginia*, 795 F.3d at 393 ("the linchpin of the adequacy requirement is the alignment of interests and incentives between the representative plaintiffs and the rest of the class") (quoting *Dewey v. Volkswagen Aktiengesellschaft*, 681 F.3d 170, 183 (3d Cir. 2012)); *see also Beck*, 457 F.3d at 301 ("A proposed class representative is *neither typical nor adequate* if the representative is subject to a unique defense that is likely to become a major focus of the litigation.") (emphasis added)); *J.H. Cohn & Co. v. Am. Appraisal Assocs.*, 628 F.2d 994, 999 (7th Cir. 1980) ("the presence of even an arguable defense peculiar to the named plaintiff or a small subset of the plaintiff class may destroy the required typicality of the class *as well as bring into question the adequacy* of the named plaintiff's representation.") (emphasis added).

Another plaintiff-specific defense implicates the applicable statutes of limitations, an issue that plagues two of the named Plaintiffs and militates against both typicality and adequacy. *In re Cmty. Bank of N. Virginia*, 622 F.3d 275, 294 (3d Cir. 2010) (noting that timeliness of claims touch on typicality and adequacy, but analyzing the issue under adequacy). Since breach of warranty claims must be brought within four years of purchase, 13 Pa. Cons. Stat. § 2725(a),

(b) and N.J. Stats. Ann. § 12A:2-725(1), (2), any claims based on purchases pre-dating December 2006 (the date the original action was commenced) would be time-barred. *See Floyd v. Brown & Williamson Tobacco Corp.*, 159 F. Supp. 2d 823, 831 (E.D. Pa. 2001) (the statute of limitations starts "to run on the date of sale of the product."). Center City acquired two Cavitrons in February 2002 and Affiliated Periodontists purchased two in December 2001. Any claims based on those purchases would therefore be untimely.

Plaintiffs argue that their untimely claims are saved by equitable tolling provisions "allowing plaintiffs to bring claims for products purchased more than four years before, where the defect was fraudulently concealed by the manufacturer and/or not discovered by the purchaser until a later time or the warranty is unconscionable." Pls.' Supp. Br. 1, ECF No. 102. This argument only highlights the complications that ensue from having plaintiffs with *un*timely claims representing a class with timely claims. *See In re Cmty. Bank of N. Virginia*, 622 F.3d at 303 (noting that plaintiffs' reliance on equitable tolling to save their claims was a "substantial hurdle" that class members with timely claims did not need to overcome). Timely claims are more valuable than untimely claims, because they require less effort to prosecute. *Id*. at 304 (citing *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 857 (1999)). Having class representatives with untimely claims creates an "intra-class conflict" because plaintiffs may be incentivized to spend resources to save their less valuable claims without any obvious benefit to class members with more valuable, timely claims. *Id*. at 303 (citing *McAnaney v. Astoria Fin. Corp.*, No. 04-cv-1101, 2007 WL 2702348, at *12 (E.D.N.Y. Sept. 12, 2007), *on reconsideration in part*, No. 04-cv-1101, 2008 WL 222524 (E.D.N.Y. Jan. 25, 2008) (finding that named plaintiffs with untimely claims did not "possess the same interest" as class members with timely claims and were

therefore "inadequate representatives of the instant class")). Thus, Center City's and Affiliated Periodontists' potentially untimely claims further separate their interests from those of the Class.

In addition to aligning "interests and incentives," adequacy also concerns "the experience and performance of class counsel." *Dewey*, 681 F.3d at 181 (citing *In re Cmty. Bank of N. Virginia*, 418 F.3d 277, 303 (3d Cir. 2005)). "When a close personal relationship exists between the named representative and class counsel, 'courts fear the danger of champerty,'" especially in cases like this one where "attorneys' fees will greatly exceed the class representative's recovery." *Martz v. PNC Bank, N.A.*, 2007 WL 2343800, at *5 (W.D. Pa. Aug. 15, 2007) (denying class certification) (quoting *London v. Wal-Mart Stores, Inc.*, 340 F.3d 1246, 1254 (11th Cir.2003)); *see also Mowry v. JP Morgan Chase Bank, N.A.*, 2007 WL 1772142, at *4 (N.D. Ill. June 19, 2007) ("[g]iven that the potential recovery for Plaintiffs is minimal compared to the potentially high amount of attorneys' fees . . . [Plaintiffs] may be more concerned with helping to maximize the monetary return of his friend, [class counsel], than to zealously advocate on behalf of the class' interests.").

*Mowry* is particularly instructive. There, the plaintiff had been a personal friend of class counsel for six years, and testified, "I'm here to help [the firm]." 2007 WL 1772142, at *4 (alteration supplied). Even though the friendship between the plaintiff and class counsel did not rise to the level of a "familial relationship," the court found them to be sufficiently close to raise "serious concerns as to [the plaintiff's] adequacy to represent the instant class." *Id.*

These alarms sound even louder in the present case where Dr. Jaffin and one of plaintiffs' counsels of record, Dr. Edwin Zinman, have been friends for twenty-five years—far longer than the six years in *Mowry*—and "they still regularly keep in touch despite living on opposite coasts." Class Opp'n Br. 86 (citing Jaffin Dep. 9/26/07 at 30, Corrected Ex. 13, ECF No. 61-1).

Dr. Jaffin has even "treated members of Dr. Zinman's family." *Id*. As in *Mowry*, Dr. Jaffin also testified that, when Dr. Zinman approached him about this lawsuit, Dr. Jaffin assured him, "If there's anything I can do to help you . . . let me know." Jaffin Dep. 9/26/07 at 31:12-15. Plaintiffs ignore these concerns.

For all these reasons, Plaintiffs are not adequate class representatives.

4. *Plaintiffs have not proven numerosity.*

The final requirement under Rule 23(a) is numerosity. Plaintiffs estimate that there are more than 1,000 putative class members in each state based on "common sense assumptions." Pl.'s Class Br. at 36-37 (quoting *Alberton v. Commonwealth Land Title Ins. Co.*, 247 F.R.D. 469, 476 (E.D. Pa. 2008)). Dentsply does not contest Plaintiffs' numbers, but the court must make a factual finding nonetheless. *See Marcus*, 687 F.3d at 596.

In *Marcus*, the Third Circuit found the district court had abused its discretion when it "assumed," "speculated," or deferred to "common sense" with respect to how many class members existed. *Id*. at 595-97. A plaintiff must produce evidence, direct or circumstantial, "specific to the products, problems, parties, and geographic areas actually covered by the proposed class definitions to allow a court to make a factual finding." *Id.* at 596.

Although the Class may seem numerous at first glance, the record does not support it. As in *Marcus*, Plaintiffs have not supplied sufficient evidence here to allow this Court to find that the Class and Subclasses satisfy numerosity. Plaintiffs have adequate estimates for the number of dentists practicing in New Jersey and Pennsylvania, but merely speculate as to how many of them actually purchased Cavitrons during the class period based on Dentsply's "company-wide" rather than "state-specific" market share. *See id*. (holding that "nationwide" evidence "is not necessarily sufficient to establish numerosity" for state-specific classes).

The estimated class size becomes even more speculative when trying to deduce how many of the dentists who purchased Cavitrons in each state also connected their devices to an open water source. For that calculation, Plaintiffs rely on a 2008 survey estimating that approximately thirty-eight percent of dentists *nationwide* used public water in their practices without even acknowledging that this study looked only at *surgical* rather than *non-surgical* procedures, as would be relevant in this case. *See* Pls.' Class Br. 37 (citing Jennifer Cleveland, et al., *Advanced Infection Control in Dental Care Settings*, 143(10) *J. American Dental Ass'n* 1127 (October 2012)). None of the evidence supplied by Plaintiffs suffices to ascertain, or even infer, the number of dentists who unwittingly used Cavitrons with public water for non-surgical procedures in Pennsylvania or New Jersey. Plaintiffs have not met their burden on numerosity.

In sum, Plaintiffs failed to meet three of four requirements under Rule 23(a).

**B. The Class Does Not Fit within the Contours of Rule 23(b)(3)**

Even though failure to satisfy all of Rule 23(a)'s criteria precludes class certification, the court must nonetheless address the conditions of Rule 23(b)(3), which requires a finding that "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) (emphasis added). To be certifiable under Rule 23(b)(3), the proposed class must also be objectively and easily "ascertainable." *Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d 349, 354 (3d Cir. 2013) (citing *Marcus*, 687 F.3d at 592-93). The court "must examine each element of a legal claim 'through the prism' of Rule 23(b)(3)." *Marcus*, 687 F.3d at 600 (quoting *In re DVI, Inc. Sec. Litig.*, 639 F.3d 623, 630 (3d Cir. 2011)).

*1. <u>Common questions do not predominate over individual ones.</u>*

The predominance analysis "begins, of course, with the elements of the underlying cause of action." *Neale*, 794 F.3d at 370 (quoting *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 809 (2011)); *see also In re Modafinil Antitrust Litig.*, 837 F.3d 238, 260 (3d Cir. 2016) (stating that predominance "is especially dependent upon the merits of a plaintiff's claim") (internal quotation marks omitted).

Plaintiffs must "demonstrate that the element of the [legal claim] is capable of proof at trial through evidence that is common to the class rather than individual to its members." *Marcus*, 687 F.3d at 600 (quoting *Hydrogen Peroxide*, 552 F.3d at 311) (alteration supplied); *see also In re Modafinil*, 837 F.3d at 260 ("the nature of the evidence that will suffice to resolve a question determines whether the question is common or individual") (internal quotation marks omitted). Thus, an "individual question is one where 'members of a proposed class will need to present evidence that varies from member to member,' while a common question is one where 'the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof.'" *In re Class 8 Transmission Indirect Purchaser Antitrust Litig.*, No. 15-3791, 2017 WL 532296, at *2 (3d Cir. Feb. 9, 2017) (citing *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1045 (2016) (quoting 2 W. Rubenstein, Newberg on Class Actions § 4:50, pp. 169-197 (5th ed. 2012)) (alteration supplied). If more elements, or the more important elements, require individual rather than common proof, then class certification is unsuitable. *Tyson*, 136 S. Ct. at 1045.

To prevail on their legal claims, Plaintiffs must first prove the existence of an express warranty in Pennsylvania and New Jersey, both of which have adopted the UCC. *See* 13 Pa. Cons. Stat. § 2313; N.J. Stats. Ann. § 12A:2-313. The focus of this inquiry usually turns on whether the relevant affirmations or descriptions became "part of the basis of the bargain." *See*

*Liberty*, 171 F.3d at 825 (quoting UCC § 2-313(1)(a)). "[T]he focus is not on any particular language at a particular point in time but whether the seller's actions or language when viewed in light of his relationship with the buyer were fairly regarded as part of the contract to purchase the good." *Id*.; *see also* UCC § 2-313, cmt. 7.

Although New Jersey and Pennsylvania differ slightly on how express warranties arise, both states require awareness of extrinsic representations to activate the presumption that they became a part of the sales contract. *See Liberty*, 171 F.3d at 825 (noting that "a promise is presumed to be a 'part of the basis of the bargain' under New Jersey law once the buyer has become aware of the affirmation of fact or promise," and remanding for trial as to the existence of an express warranty in post-sale, extended service plans) (internal quotation marks omitted); *Green*, 2001 WL 1807390, at *6 (denying class certification for express warranty breach involving pre and post-sales representations in a product's handbook, and stating that Pennsylvania requires that "the buyer at least be aware of the seller's representation prior to the transaction's consummation").

Both states also require reliance on the affirmations to perfect an express warranty, even though New Jersey only requires proof of reliance upon a showing by the defendant that the plaintiff did not believe the representations were true. *See Liberty*, 171 F.3d at 825 n.7 ("If the defendant has proven non-belief, the plaintiff may still recover economic damages if he can prove reliance despite non-belief" under New Jersey law) (citing *Cipollone*, 893 F.2d at 568 n.31); *Mazur v. Milo's Kitchen, LLC*, No. 12-cv-1011, 2013 U.S. Dist. LEXIS 89126, at *14 (W.D. Pa. May 24, 2013) ("in order to succeed [in a class action for breach of express warranty based on representations on the product's packaging and website], the plaintiff must allege the statements made by the seller" *and* "reliance on those statements by the plaintiff").

The parties agree that the Cavitron includes an express warranty against "defects arising from faulty materials or workmanship" (although they disagree on the applicability and breach of that warranty). The most vigorous disagreement persists, however, on the existence of an express warranty of safety and suitability. Plaintiffs have not offered any suggestions for how individual awareness of those representations, as well as a shared understanding of their meaning, can be established using common evidence—a critical flaw that undercuts class certification. *See Green*, 2001 WL 1807390, at *6 ("the disparate and distinct ways and times that the Class members became aware of the [alleged] representation, if they did at all, complicates the Court's ability to determine whether this representation became a 'basis of the bargain' for the Class as a whole."). And, because information about biofilm was circulating widely, and DHCPs have an independent obligation to comply with infection control guidelines, individual inquiries will be necessary to determine whether each class member relied solely on the DFUs, or something else, when deciding how to install and operate their Cavitrons in compliance with safe water standards.

Instead of offering class-wide proof of awareness or reliance, Plaintiffs argue incorrectly that neither of these elements is necessary. The most specious case, under Pennsylvania law, that Plaintiffs cite in support of that proposition is *Samuel-Bassett v. Kia Motors America, Inc.*, 34 A.3d 1 (Pa. 2011). Unlike the instant case, *Samuel-Bassett* involved warranties that were based on "terms in each class member's sales contract," not extrinsic pre or post-sale affirmations. *Id.* at 24-25. That holding is consistent with basic contract law; parties are bound to the written terms of their agreement "without regard to whether the terms thereof were read and fully understood." *Simeone v. Simeone*, 581 A.2d 162, 165 (1990). Plaintiffs also misread the Honorable William F. Smith's majority opinion in *Pritchard v. Liggett & Myers Tobacco Co.*,

350 F.2d 479 (3d Cir. 1965) (applying Pennsylvania law). The "majority view on the question of reliance is discussed in the opinion of [the Honorable Abraham L.] Freedman," joined as to that part by the Honorable James C. Ganey. *Id*. at 487. Contrary to Judge Smith's minority view, which would eliminate reliance altogether, Judge Freedman's concurrence states: "the element of reliance on the part of the buyer will be absorbed in the determination of the basis of the bargain, but it will remain a question of fact to be determined by the jury where the seller seeks to show that his affirmation was not a part of the basis of the bargain." *Id*. at 492 (footnote omitted).

Similarly, in *Gladden v. Cadillac Motor Car Div.*, the case Plaintiffs consider to be "controlling" under New Jersey law, the state's highest court noted that reliance "need not be shown" for express warranties based on "dickered" aspects of the individual bargain. 416 A.2d 394, 402 (N.J. 1980). Even though that case involved representations in a handbook, the defendant did not raise non-belief and thus the court presumed reliance consistent with New Jersey law. *See id*. at 402. Lastly, the related case *Weinstat v. Dentsply Int'l, Inc.*, 103 Cal. Rptr. 3d 614 (Cal. Ct. App. 2010), is unpersuasive. There, a California court of appeals found that the Cavitron's DFUs became part of the basis of the bargain without reliance, even though the DFUs were not part of the "dickered" terms. *Wienstat*, at 627-33. But that case was decided under California law, not Pennsylvania or New Jersey law; both of which require awareness and reliance to perfect an express warranty rooted in representations made outside the four corners of the sales contract. In effect, the alleged warranty of safety and suitability cannot be proven using common evidence.[4]

[4] Besides being improvable with common evidence, the alleged warranty of safety and suitability may also be legally untenable. In the course of this litigation, the Third Circuit ruled that general statements about a medical product being "'safe and effective' for its intended use—contained on a label disclosing contraindications, risk factors, and potential side effects" pursuant to FDA regulations—are insufficient to create an express warranty in New Jersey as a matter of law. *In re Avandia Mktg. Sales Practices & Products Liab. Litig.*, 588 F. App'x 171, 176 (3d Cir. 2014) (dismissing class action for failure to state a claim). Other federal courts have similarly construed their respective states' laws. *See, e.g., House v. Bristol-Myers Squibb Co.*, No. 15-cv-00894, 2017 WL 55876, at *6

Even if the warranty could be proven in one swift swoop, Plaintiffs would still need to show that Dentsply breached any of the applicable warranties. *See In re Avandia Mktg. Sales Practices & Products Liab. Litig.*, 588 F. App'x 171, 175 (3d Cir. 2014) (applying New Jersey law); *Samuel-Bassett*, 34 A.3d at 35 (applying Pennsylvania law). They would also need to prove that they suffered damages and that the breach was the proximate cause of those damages. *Marcus*, 687 F.3d at 600 n.8 (citing *Collins v. Uniroyal, Inc.*, 315 A.2d 16, 20 n.4 (N.J. 1974)); *Samuel-Bassett*, 34 A.3d at 35.

Proving causation, like reliance, is not possible on a class-wide basis. Individualized inquiries will be necessary to determine what each class member knew about biofilm, when they knew it, where they found the information, and on what basis they decided to operate their Cavitrons on an open water source without respect for the CDC's recommendations. *See Demmick v. Cellco P'ship*, No. 06-cv-2163, 2010 WL 3636216, at *17 (D.N.J. Sept. 8, 2010) (concluding that common issues did not predominate, even though the wireless service plans "were sufficiently uniform," because not all plaintiffs "were faced with the same information when making their decisions" and thus it was "hard to imagine that any causal connection for this claim could be established absent resort to individualized evidence").

Nor are damages provable with common evidence. As explained earlier, when calculating damages for breach of warranty, both New Jersey and Pennsylvania credit "the value of the goods accepted," 13 Pa. Cons. Stat. § 2714 and N.J. Stats. Ann. § 12A:2-714, which includes any value derived from their use. Contrary to Plaintiffs' assertion, it is not true that Cavitrons had "zero value" at the time of sale. *See* Pls.' Br. 9, ECF No. 127-1. An informed and

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(W.D. Ky. Jan. 4, 2017) ("a determination that a drug is safe and effective—a determination which is made by the FDA as part of its new drug approval process—is not, on its own, sufficient to create an express warranty."); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 818 (N.D. Ohio 2004) (finding that assurances that a prescription drug was "safe and effective" were not sufficiently clear to create an express warranty), *aff'd sub nom. Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006).

diligent class member could have known, and perhaps should have known, that the device could be used safely in accordance with the CDC's guidelines. Many class members may have actually used it that way, just as Dr. Hildebrand believed she did. As Dr. Gaier explained, any damages award that does not account for revenue gained from successfully using the Cavitron as accepted would amount to a "windfall." *See* Gaier Hr'g Tr. 2/26/16 at 163:25-166:11, Def.'s Hazel Br., Ex. 2, ECF No. 124-3. Determining damages will therefore require individualized inquiries based on "each potential class member's particular configurations." *See* Gaier Decl. ¶¶ 23, 27. All these individual issues—awareness, reliance, causation, and damages—predominate over the only element that could be proven with common evidence: the alleged breach.

Plaintiffs are correct that Defendant's conduct is the focus of the breach. In New Jersey, like in Pennsylvania, a breach occurs where "the product ultimately did not conform to the affirmation of fact, promise, or description." *In re Avandia*, 588 F. App'x at 175. In essence, Plaintiffs aver that Dentsply delivered a non-conforming product because the Cavitron's waterlines naturally accumulate biofilm when operated and maintained on an open water source in accordance with their understanding of the DFUs. Since biofilm theoretically increases the odds of infection during non-surgical procedures, and Dentsply allegedly knew of this risk and intentionally concealed the problem, Plaintiffs assert Dentsply breached both an express warranty of safety and suitability and the express warranty against defects. *See* Amend. Compl. ¶¶ 64-70.

Notwithstanding Plaintiff's allegations, common evidence does not support a finding that a breach actually occurred. The Cavitron is capable of delivering potable water on its own when connected to an open or closed water source *so long as* DHCPs follow the CDC's recommendations as directed by the Cavitron's Infection Control Information card. In fact,

Plaintiffs testified that they used their Cavitrons without incident since the date of purchase, employing a variety of configurations. *See* Class Opp'n Br. 12-14. Under the warranties as alleged, Dentsply apparently delivered a conforming device. According to Plaintiffs, however, it does not matter whether class members could, or in fact did, use the Cavitron safely. *See*, *e.g.*, Pls.' Hazel Br. 2. They claim Dentsply nevertheless acted wrongfully by failing to warn purchasers of the biofilm problem. *See, e.g.*, Pls.' Clas Br. 5, 12, 16, 21, 22 nn.22, 24; Class Reply 37, 42. In other words, Plaintiffs argue that class members would not, or perhaps should not, have used Cavitrons at all had Dentsply disclosed the biofilm problem in the DFUs.

There is a fundamental disconnect between this failure to warn theory and Plaintiff's express warranty claim. Under this theory, the focal question becomes: did the DFUs contain "accurate and adequate instructions"? *See* Class Reply Br. 39, ECF No. 67. But that inquiry is a red herring unless Dentsply *expressly* warranted that the DFUs alone contain all the necessary instructions to prevent biofilm; an allegation that is absent from Plaintiffs' pleadings perhaps because they also assert that the duty to ensure appropriate labeling and maintenance instructions arises under the FDA's regulations, not the DFUs. *See* Pls. Br. 11-14, 18-25. To be sure, this is why Plaintiffs sought to introduce the opinions of an FDA expert, Ulatowski, to show that Dentsply had a legal obligation to deliver complete and accurate DFUs, but failed to do so, under the applicable regulations. Here is where the incongruity crystallizes: If Dentsply's obligation to warn or adequately label arises from the applicable regulations, then Dentsply's alleged omissions establish a regulatory violation or, at best, a common law tort, but not a breach of an express warranty.[5]

[5] Without any express representations concerning biofilm in the DFUs, Plaintiffs are left to argue that Dentsply's "silence" gives rise to the express warranty. *See*, *e.g.*, Pls.' Class Br. 12 (averring that the DFUs "are the primary vehicle for both *omissions* from and representations Dentsply made to the Plaintiffs and class members about the installation, use and maintenance of the Cavitron.") (emphasis added). But an express warranty cannot arise from

Consider instead the inverse question: should DHCPs be expected to supplement the DFUs with their professional judgment and their legal duty to comply with the CDC's recommendations? In this Courts' opinion, the better answer is yes. The DFUs must operate in tandem with each class member's professional and legal obligations, especially since the Infection Control Information card states that published guidelines and "agency requirements take precedence." ECF No. 60-28. From that perspective, the DFUs were more than adequate; they were explicitly clear. More importantly, even if a breach did occur, that question does not predominate over individual issues such as awareness, reliance, causation, and damages.

Therefore, Plaintiffs do not meet the predominance requirement.

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something that is left unsaid; that is the textbook definition of an *implied* warranty. *See* Warranty, Black's Law Dictionary (10th ed. 2014) (defining an "implied warranty" as an "obligation imposed by the law when there has been no representation or promise"). Plaintiffs recognize as much when they argue that a "necessary *implication*" of the DFUs' absolute silence "on the likelihood of the Cavitrons developing biofilm in their internal water lines" is "that the Cavitrons remain safe and suitable for all 'Indicated Uses' if connected to a potable public water source and flushed periodically with tap water." Pls.' Class Br. 16 (emphasis added). If that's the case, then Plaintiffs' claims, premised on an *express* warranty of safety and suitability, would dissipate.

*2. A class action is not a superior vehicle for Plaintiffs' claims.*

Turning to the superiority requirement, the court must "balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication." *In re Processed Egg Prods. Antitrust Litig.*, 284 F.R.D. 278, 293-94 (E.D. Pa. 2012) (quoting *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 316 (3d Cir. 1998)). For this analysis, courts use the factors listed in Rule 23(b)(3): "(A) the class members' interests in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already begun by or against class members; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (D) the likely difficulties in managing a class action." *In re Processed Egg Prod.*, 284 F.R.D. at 293 (quoting Fed. R. Civ. P. 23(b)(3)).

Defendant focuses on the unmanageability of the proposed class action. Because of the various individualized issues—awareness, reliance, causation, and timeliness, among others—Dentsply correctly points out that a "flurry" of mini-trials would be needed to fairly adjudicate each class member's claim, vitiating any potential efficiencies from using the class action mechanism. *See* Class Opp'n Br. 89-90. Plaintiffs' own Trial Plan acknowledges Dentsply's right to challenge the merits of each class member's claim and the computation of their individual damages. *See* Revised Trial Plan § IV(C)(1), Pls.' Class Br., Ex. 57. Their avowal that "the Class and Subclasses present no management difficulties" is surely an understatement. *See* Pls.' Class Br. 58.

The individual issues also raise the prospect that class members might wish to exercise more control over the prosecution of their own claims. As noted, class members with timely claims, for example, have nothing to gain from investing resources to prove equitable tolling.

And, although class members have not brought any other cases that could interfere with this one, Plaintiffs have not identified any reasons for concentrating these state claims in federal court.

Plaintiffs' main argument focuses on the prohibitive costs of pursuing these claims on an individual basis. According to Plaintiffs, Cavitrons are worth somewhere between $1,500 and $3,500 each, plus installation and maintenance costs. *Id*. Plaintiffs maintain that the costs of bringing individual actions would exceed the potential recovery, but offer no calculations or data to substantiate that assertion. Litigation is expensive, but without even a semblance of a cost-benefit analysis, this Court will not presume that litigating a class action will be more efficient than pursuing individual claims in state court. Plus, fairness to defendants, not just plaintiffs, is "an explicit criterion for a superiority determination." *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 761-762 (3d Cir. 1974). Because the merits of Plaintiffs' claims are in serious doubt, it would be unfair to put Defendant in a position to settle a non-meritorious action for fear of reputational harm. *Id*. (certification creates "additional settlement leverage which results from the disruption or injury which may occur to a defendant's business relationships regardless of the merits of the claim by the mere sending of the [class certification] notice.").

Plaintiffs failed to prove superiority.

*3. <u>The proposed Class and Subclasses are not objectively ascertainable.</u>*

Lastly, to be certifiable under Rule 23, a class must be "currently and readily ascertainable based on objective criteria," not "by potential class members' say so." *Marcus*, 687 F.3d at 593, 594. "Ascertainability provides due process by requiring that a defendant be able to test the reliability of the evidence submitted to prove class membership." *Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013). When nothing in company databases shows whether individuals should be included in the class, the court must consider "whether there is a

reliable, administratively feasible alternative." *Marcus*, 687 F.3d at 594. "Accordingly, a trial court should ensure that class members can be identified without extensive and individualized fact-finding or mini-trials." *Carrera*, 727 F.3d at 307 (internal quotation marks and citations omitted). The Third Circuit has also emphasized that a party cannot "merely propose a method of ascertaining a class without any evidentiary support that the method will be successful." *Byrd*, 784 F.3d at 164 (quoting *Carrera* 727 F.3d at 306, 307, 311).

The critical characteristic of the Class and Subclasses is water source, yet Plaintiffs have provided no objective, class-wide method for ensuring that only dentists who unwittingly connected their Cavitron to an open water source can recover on any potential judgment. Dr. Gaier's expert opinion on this point is helpful. He explains that, even if Plaintiffs could produce a reliable list of purchasers in New Jersey and Pennsylvania for the class period, there is no objective method to ascertain which purchasers operated their Cavitrons on an open water source "given the variety of configurations in which a Cavitron device can be installed," as exemplified by Plaintiffs' own experiences. Gaier Decl. ¶¶ 22-24. Neither Dentsply's records nor any other business records will show water source on a class-wide basis. Plaintiffs suggest asking each class member to submit affidavits "attesting that his, her or its Cavitron(s) was (were) connected to a public water supply." Class Reply Br. 23. But that would be the same as accepting the class members' "say so," which is not enough. *Marcus*, 687 F.3d at 594.

Furthermore, even if class members could provide invoices showing that they installed their Cavitrons on an open water source or retrofitted them to a closed water source, due process concerns arise because the Class definition is over-inclusive. As Plaintiffs have pointed out, many DHCPs use public water to supply their dental equipment including their Cavitrons. Because many of those same DHCPs may also use biocides and adaptive devices, consistent with

their professional training and industry guidelines, they would have no basis to complain about the Cavitron's water quality or bring a claim under Plaintiffs' express warranty theory. Yet, if Plaintiffs were to prevail, those same DHCPs will be able to file claims merely because they were "using a public water source" for their Cavitrons, despite having no basis for seeking recovery.[6] *See* Class Opp'n Br. 58.

The composition of the Class is not objectively or reliably ascertainable.

## CONCLUSION

Plaintiffs have not persuaded this Court as to the *Daubert* Motions. Nor have they satisfied the requirements of Rules 23(a) and 23(b)(3). Class certification is therefore denied.

BY THE COURT:

*/s/ C. Darnell Jones, II*
C. Darnell Jones, II J.

[6] Plaintiffs argue that an "overly-broad" class is not a bar to certification, citing *In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 722 F.3d 838 (6th Cir. 2013). That case is distinguishable on its facts. Unlike Cavitrons, whose waterlines can be treated by DHCPs to prevent biofilm formation, the washers in *Whirlpool* developed biofilm "in places inside the machines that consumers cannot clean themselves." 722 F.3d at 846. Because the machine's defect was inherent to the design, and unrelated to each purchaser's maintenance practices, it makes sense that the class definition would encompass purchasers who were satisfied with their washers or whose washers had not yet accumulated biofilm.