Burdick v Tonoga, Inc.
2019 NY Slip Op 35264(U)
November 15, 2019
Supreme Court, Rensselaer County
Docket Number: Index No. 253835
Judge: Patrick J. McGrath
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At an IAS Term of the Supreme Court of the State of New York, held in and for the County of Rensselaer, in the City of Troy, New York on the 9th day of August 2019

PRESENT: HON. PATRICK J. McGRATH
Justice of the Supreme Court

STATE OF NEW YORK
SUPREME COURT COUNTY OF RENSSELAER

JAY BURDICK, CONNIE PLOUFFE, EDWARD PLOUFFE, FRANK SEYMOUR, SUZANNE SEYMOUR, AND EMILY MARPE, as parent and natural guardian of E.B., an infant, and G.Y., and infant, JACQUELINE MONETTE, WILLIAM SHARPE, EDWARD PERROTTI-SOUSIS, MARK DENUE, and MEGAN DUNN, individually, and on behalf of all similarly situated,

Plaintiffs,

DECISION AND ORDER
Index No. 253835

- against -

TONOGA, INC. (d/b/a TACONIC),

Defendant.

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APPEARANCES: FARACI LANGE, LLP
WEITZ & LUXENBERG, PC
Co-Lead Class Counsel

GREENBERG TRAURIG, LLP
HOLLINGSWORTH, LLP
Attorneys for the Defendant

McGRATH, PATRICK J., J.S.C.

This case stems from the contamination of groundwater in the Town of Petersburgh, New York with perfluorooctanoic acid (hereinafter "PFOA"). In a decision and order dated July 3, 2018, this Court granted plaintiffs' motion to certify four (4) classes. Three of those classes allege harms related to property damage and nuisance stemming from contamination of class members' property and drinking water with PFOA. The fourth class seeks the establishment of a class-wide medical

monitoring program to provide medical surveillance to class members exposed to PFOA via the municipal water supply or contaminated wells within a seven mile radius of defendant's facility. Plaintiffs assert causes of action that sound in negligence and strict liability claims related to property, negligence and strict liability claims related to PFOA ingestion, private nuisance and trespass.

Defendant brings what it characterizes as a *Frye* motion to preclude the testimony of plaintiffs' medical monitoring experts. Plaintiffs challenge this characterization, arguing that the motion should not be considered under a *Frye* analysis and at most, constitutes subject matter for cross- examination or a *motion in limine.* Defendant has submitted a Reply.

The Frye Test

In determining the admissibility of expert testimony, New York follows the rule of Frye v United States, 293 F 1013 (1923), specifically, "that expert testimony based on scientific principles or procedures is admissible but only after a principle or procedure has `gained general acceptance' in its specified field." *See also* People v Wesley, 83 NY2d 417, 422 (1994); People v Wernick, 89 NY2d 111, 115 (1996). "'[G]eneral acceptance does not necessarily mean that a majority of the scientists involved subscribe to the conclusion. Rather it means that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in evaluating clinical data to reach their conclusions.'" Zito v Zabarsky, 28 AD3d at 44, *quoting* Beck v Warner-Lambert Co., 2002 NY Slip Op 40431[U], *6-7 (Sup. Ct., New York County, 2002). "The Frye 'general acceptance' test is intended to protect[] juries from being misled by expert opinions that may be couched in formidable scientific terminology but that are based on fanciful theories." Styles v General Motors Corp., 20 AD3d 338 (1st Dept. 2005) (Catterson, J., concur) [internal quotation marks omitted].

A *Frye* inquiry is directed at the basis for the expert's opinion and does not examine whether the expert's conclusion is sound. "*Frye* is not concerned with the reliability of a certain expert's conclusions, but instead with 'whether the experts' deductions are based on principles that are sufficiently established to have gained general acceptance as reliable.'" Nonnon v City of New York, 32 AD3d at 103, *quoting* Marsh v Smyth, 12 AD3d 307, 308 [2004]. Put another way, "[t]he court's job is not to decide who is right and who is wrong, but rather to decide whether or not there is sufficient scientific support for the expert's theory." Gallegos v Elite Model Mgmt. Corp., 195 Misc 2d 223, 225[2003]). "The appropriate question for the court at ... a [Frye] hearing is the somewhat limited question of whether the proffered expert opinion properly relates existing data, studies or literature to the plaintiff's situation, or whether, instead, it is 'connected to existing data only by the *ipse dixit* of the expert.'" Marsh v Smyth, 12 AD3d 307, 312 [1st Dept. 2004) (Saxe, J., concur.) *quoting* General Elec. Co. v Joiner, 522 US 136, 146 (1997).

Drs. Alan Ducatman, Donald Sloane Shepard and Donald R. Brandt

Dr. Donald Sloane Shepard performs subsidiary medical monitoring program-related

accounting and economic analysis.

Dr. Donald R. Brandt is the President of CTI Administrators, Inc., the company that plaintiffs have designated to administer the medical monitoring program and evaluate its cost.

Dr. Alan Ducataman provides the medical basis for the design and elements of the plaintiffs' proposed medical monitoring program. He is board certified in Internal Medicine and Occupational Medicine. He is Professor Emeritus at the West Virginia University, where he practiced medicine for 26 years. From 2012 to June 2018, he was a Professor of Public Health at West Virginia University School of Public Health and Professor of Medicine at West Virginia University School of Medicine. He was the Director of the Environmental Medical Service at Massachusetts Institute of Technology from 1986-1992. He has participated on and chaired an external scientific advisory committee to the Agency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NEHC) of the US Centers for Disease Control and Prevention (CDC). He has written extensively about the relationship of environmental chemicals to human disease, including, but not limited to PFAS such as PFOA. Dr. Ducataman advised the leaders of the C8 Health Project and has published approximately 30 peer-reviewed articles relating to PFAS, mostly based upon analysis of the C8 Health Project data and the nationally representative NHANES data. He has have created or participated directly in a number of medical monitoring projects in addition to the C8 Health Project mentioned above.

Dr. Ducataman states that the ATSDR is a lead agency in the CDC tasked with conducting health surveillance assessments to evaluate exposure to hazardous agents in the environment and identify trends in adverse health outcomes resulting from chemical exposures. The ATSDR provides criteria for considering the establishment of medical monitoring programs in its Final Criteria for Determining the Appropriateness of a Medical Monitoring Program under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), published in the Federal Register. He states that this methodology is generally accepted in the medical monitoring field for determining if medical monitoring is warranted in a particular community.

Dr. Ducataman has used the ATSDR's Federal Register routinely in the consideration/evaluation of requests for medical monitoring. The ATSDR states that "[m]edical monitoring should be directed toward a target community identified as being at significant increased risk for disease on the basis of its exposure. Significant increased risk will vary for particular sites depending upon such factors as the underlying risk of the selected outcome, the risk attributable to the exposure, and the presence of sensitive subpopulations." The ATSDR outcome criteria for considering medical monitoring states that 1) there should be documented human health research that demonstrates a scientific basis for a reasonable association between an exposure to a hazardous substance and a specific adverse health effect (such as an illness or change in a biological marker or effect); 2) the monitoring should be directed at detecting adverse health effects that are consistent with the existing body of knowledge and amenable to prevention or intervention measures and 3) the adverse health effects (disease process, illness, or biomarkers of effect) should be such that early detection and treatment or intervention interrupts the progress to symptomatic disease, improves the

quality of life of the individual, or is amenable to primary prevention."

Dr. Ducataman opines that the instant plaintiffs are at a significantly increased risk for diseases based on their exposure to PFOA from the Taconic facility. He notes theat peer-reviewed literature has established an association between PFOA exposure in the community and significantly increased risk of health effects as compared to the general population. He references the studies and opinions offered by Dr. Savitz, noting that the health concerns linked with PFOA exposure constitute serious health risks that are amenable to early detection and intervention. Dr. Ducataman recommends a program that is not duplicative of care that can be anticipated as already reliably provided to proposed program participants.

He opines that ATSDR's exposure criteria for considering Medical Monitoring have been met in this case. There is proven environmental exposure that meets a level reported in the peer-reviewed literature to result in some adverse health effect. Further, that ATSDR's outcome criteria for considering medical monitoring have been met as well, as the peer-reviewed medical literature demonstrates PFOA exposure is associated with excess risks of adverse health effects as compared to the background population. He states that the purpose of the program he proposed is to detect the diseases above as early as possible in order to minimize disease morbidity and mortality and improve health outcomes for class members. The program is designed to provide class members with targeted diagnostic monitoring - through annual survey questionnaires, meaningful clinical evaluation and testing, and education- that results in improved quality of life due to earlier detection and identification of the diseases for which class members are at a known higher risk due to their PFOA exposure.

Based on his clinical experience and significant experience in the evaluation and medical monitoring of humans exposed to PFOA, he has considered what clinical testing would best provide adequate medical monitoring and early disease detection for this exposed population, which is described in detail in his affidavit with respect to each health condition.

Defendant moves to preclude Dr. Ducataman's testimony in its entirety. Defendant relies on the affidavit of Stephen Washburn, principal of Ramboll Environ and a member of the Ramboll Group Executive Board. He has 30 years of experience in science and engineering, with emphasis on chemical fate and transport, exposure assessment and risk assessment. With respect to Dr. Ducataman, he states that the source of 1.86 ug/L as the 2013-2014 geometric mean "is not clear."

Defendant also relies on two affidavits provided by Jessica Herzstein, MD, MPH, a physician with more than 25 years of training and experience in the fields of environmental and occupational medicine. In 2012, she was appointed by the Secretary of HHS to the United States Preventive Services Task Force (USPSTF), an internationally recognized panel of experts in primary care and preventative medicine, which makes evidence based recommendations to guide the delivery of preventive services.

She argues that the epidemiologic studies of populations exposed to PFOA have not shown

that PFOA causes any specific disease. She compares mean exposures as measured by blood levels in other communities in which PFOA has been detected in the drinking water to that of the affected community here to support her opinion that the exposure here does not warrant monitoring. She states that Dr. Ducataman's proposed program will lead to unncessary tests, most of which will result in negative and false positive results. She argues that the testing he proposes is "highly unlikely" to discover the disease at the asymptomatic stage. Therefore , clinical outcome will not be improved as a result of screening. She also notes the harms of screening, which include "false alarms, indeterminate findings, worry for patients, and overdiagnosis and overtreatment." Additionally, that Dr. Ducataman's proposed program confuses diagnostic tests with screening tests. She reviews the six diseases and two biomarkers identified by Dr. Savitz and states her basis as to why medical monitoring of each would be ineffective and in some cases harmful. She notes that the proposed program includes a financial incentive to participate, which is "contrary to their best interest in that their judgment about what is acceptable risk versus benefit could be altered by a monetary reward for doing screening." She also states that the extent of administrative oversight of the proposed program is "vastly in excess of what is needed for a medical monitoring program in a population this size."

Dr. Ducataman responds that he now knows the geometric mean background level for 2015-2016 based on the US NHANES dataset is 1.56 μg/L. This data was published in January 2019 and reflects the geometric mean background level at the time the Petersburgh PFOA blood testing was conducted. Therefore, the threshold level for eligibility here (1.86 μg/L) is a conservative number.

He states that Dr. Herzstein's opinion regarding whether PFOA exposure causes disease in humans is not generally accepted in the scientific community and is contradicted by a significant body of epidemiological literature. Moreover, causation is not required under the generally accepted ATSDR criteria. He states that Dr. Herzstein ignores that fact that approximately 508 of 1,500 or so residents (33%) were tested, and the NYSDOH did not have geographically-targeted screening criteria, but generously tested those who wanted to be tested. He states that it is not scientifically sound that Dr. Herzstein then uses this "all comers" number to determine the mean serum in a specific contaminated community because it does not represent the population that would be eligible for screening here. He acknowledges Dr. Herzstein's concerns regarding overtesting as a valid consideration for the general population, but argues that the target population here has PFOA in their blood and is already aware it is at increased risk of disease as a result. He states that the context within which the screening occurs must be taken into account, and Dr. Herzstein fails to do so. He notes that improved clinical outcomes is not the only goal of ATSDR, which states "the adverse health effects (disease process, illness, or biomarkers of effect) should be such that early detection and treatment or intervention interrupts the process to symptomatic disease, improves the quality of life of the individual, or is amendable to primary prevention." He states that early detection of these diseases, which leads to intervention and/or treatment, including lifestyle interventions that beneficially avoid treatment, is reasonably likely to improve the quality of life of a participant. He states that the issue of screening versus diagnostic monitoring is "simply semantics and is irrelevant." The program is clearly stated to have both intake and follow-up characteristics. He

addresses and contests Dr. Herzstein's opinions as to each health conditions, and how early detection and treatment have the potential to improve a the participants' quality of life. Both Dr. Shepard and Dr. Ducataman support a financial incentive to participate.

Dr. Ducataman notes that Dr. Herzstein does not cite any authority to support her proposition concerning the financial incentive or explain how an incentive payment would affect a person's judgment about risk versus benefit. He notes that Dr. Herzstein does not cite mainstream literature which acknowledges the possibility of undue influence in enrollment in the context of research, yet emphasizes the cost of participation to participants and the desirability of payments. In this case, the purpose is not research, the costs of exposure to participants have already been substantial, and participation is the most empowering means to address and reduce the health aspects of the costs and harms *post hoc.* He states that incentives are a reasonable and small way to account for effort and time from participants, among so many accounted and unaccounted costs of exposure. He notes that monetary incentives were used in the C8 Health Project, and it is probable that compensation along with public concern contributed to participation. Finally, he states that incentive payments are as or more appropriate here, in a biomonitoring program without research intent, and there is no evidence that they would affect participant's ability to analyze risks and benefits.

Defense counsel argues that even if the plaintiffs experts are permitted to testify about their MMP, they still should not be permitted to include certain costs and elements that are not generally accepted components of such monitoring, such as costs to facilitate/conduct research and the designation of a retained testifying expert as the beneficiary of a 30 year stream of work that could cost in excess of $36 million dollars. Counsel argues that plaintiffs have designated their retained expert, Dr. Brandt, and his company to play a principal role "in return for substantial compensation in violation of fundamental principles that are generally accepted in the community of persons who regularly engage in decisions as to whether and how to medically monitor an exposed population." Defendant does not present any expert testimony as to the specific fundamental principles referenced herein, or how they have been violated.

Dr. Ducataman responds that a Third Party Administrator (TPA) would be beneficial for implementation and administration of the medical monitoring program because it ensures payment of costs that are incurred on behalf of an exposure population. The TPA can also provide quality assurance and also review program fidelity in key areas. Services provided by a TPA may include ensuring the following:

a. That program participants are truly qualified to participate, and that the program has collected and secured the eligibility documents in a responsive and consistent manner;
b. That payments to consultants are consistent with expectations;
c. That clinical testing and associated costs are consistent with expectations; and
d. That quality assurance data (e.g., the technique used by the selected laboratory to measure PFOA) are archived and accessible to program personnel, and that technological changes, which are inevitable over time, are recorded

Further, Dr. Ducataman states that the expert panel, consisting of an Epidemiologist and a Clinician, who represents local community interests is consistent with Phase II of the ATSDR guidance concerning medical monitoring concerning community feedback concerning efficacy and benefit of the program.

The Court does not find that defendant has made a motion requiring a *Frye* analysis with respect to Drs. Ducataman, Sloane Shepard or Brandt. Defendant appears to argue that they may have a conflict of interest based on potential financial gain, but nothing in the defendant's motion asserts that either expert has rendered an opinion based on principles that are not sufficiently established to have gained general acceptance in their respective fields. Nor is there even a foundational question here. The true issue here is the parameters of the medical monitoring program, which have been developed and proposed by Dr. Ducataman, and its administration.

The Court finds that *Frye* issues are not directly implicated in the instant motion, as defined by the parties' arguments, because Dr. Ducataman is not utilizing novel methodology or principle here. To the contrary, defendant's experts acknowledge that the methodology adopted by ATSDR is generally accepted in the field for determining if medical monitoring is warranted in a particular community. Rather, the inquiry here is foundational and the central issue is whether a legally sufficient foundation exists for admissibility of Dr. Ducataman's testimony. This in turn, depends upon whether the procedures Dr. Ducataman employed were appropriately applied to generate his opinions and conclusions.

The foundation for Dr. Ducataman proposed medical monitoring program relies heavily on the research and conclusions of the C8 study as well as his own research, which demonstrate a "more probable than not" casual relationship between PFOA exposure at or near background and six health conditions and two elevated biomarkers. He proposes a medical monitoring program founded on the well established dictates of ATSDR. The Court has reviewed both sets of affidavits here in detail to highlight the numerous factual disagreements between the parties' experts regarding the specific parameters of the proposed program. However, Dr. Ducataman's opinions are foundationally sound because, as noted above, his conclusions are grounded in evidence. Factual disagreements go to the weight to be accorded to the testimony, not admissibility. As previously noted, the court should not render an assessment as to the ultimate merit of the opinion testimony of the plaintiffs' experts. *See* People v Wesley, *supra* at 425. The weight of this evidence can be debated by the parties' experts at trial, but the court will not exclude the proposed testimony under *Frye* or based on a lack of foundation.

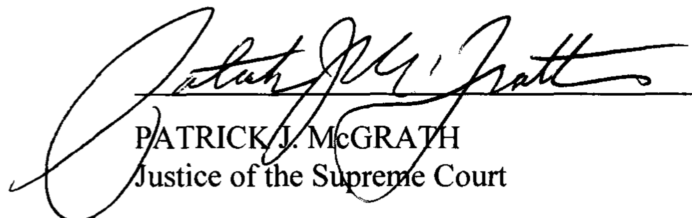
In accordance with the foregoing, it is hereby

ORDERED that the defendant's motion to preclude the testimony of Drs. Alan Ducatman, Donald Sloane Shepard and Donald R. Brandt is **DENIED**.

This shall constitute the Decision and Order of the Court. This original Decision and Order is returned to Weitz & Luxenberg, PC, co-lead class counsel. All other supporting papers are being

delivered by the Court to the Rensselaer County Clerk for filing. The signing and delivery of this Decision and Order does not constitute entry or filing under CPLR 2220. Plaintiffs are not relieved from the applicable provisions of that rule respecting filing, entry and notice of entry.

Dated: November 15, 2019
Troy, New York



PATRICK J. McGRATH
Justice of the Supreme Court

Papers Considered:

1. Notice of Motion; Affidavit of Thomas R. Smith, with Exhibits attached; Affidavit, Jessica Herzstein, MD, dated March 28, 2018; Affidavit, Jessica Herzstein, MD, dated February 28, 2019; Affidavit, Stephen Washburn; Taconic's Memorandum of Law in Support of Motion to Exclude Expert Testimony of Drs. Alan Ducatman, Donald Sloane Shepard and Donald R. Brandt.

2. Affidavit, Alan Ducatman, MD; Plaintiffs' Omnibus Memorandum of Law in Opposition to Defendant's Motion to Exclude Plaintiffs' Experts.

3. Taconic's Omnibus Reply in Support of Its Motions to Exclude Testimony of Plaintiffs' Experts; Affidavit, Jessica Kaplan, Esq., in Support of Taconic's Reply in Support of Its Motions to Exclude Testimony of Plaintiffs' Experts.

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