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

PAUL SVINDLAND, et al.	:	CIVIL ACTION
v.	:	
THE NEMOURS FOUNDATION, et al.	:	NO. 05-417

ROBERT DADDIO, et al.	:	CIVIL ACTION
v.	:	
THE A.I. DUPONT HOSPITAL FOR CHILDREN OF THE NEMOURS FOUNDATION, et al.	:	NO. 05-441

MEMORANDUM

McLaughlin, J. May 18, 2009

The plaintiffs in these medical malpractice cases are the parents of infants who died at some point after undergoing open-heart surgery at the A.I. duPont Hospital for Children ("the duPont Hospital"). The defendants that remain are the Nemours Foundation, which operated the Nemours Cardiac Center at the duPont Hospital, and William I. Norwood, M.D. ("Dr. Norwood"), who performed the surgeries.[1] The plaintiffs allege, among other things, that the technique used by Dr. Norwood to cool the children prior to their surgeries violated the standard of care and thus constitutes malpractice.

[1] Other defendants in these cases as originally filed include the duPont Hospital and other doctors and medical professionals.

This memorandum concerns three pretrial evidentiary motions filed by the parties. First, the defendants have moved, in the Svindland case, to preclude the plaintiffs from introducing evidence related to the morbidity and mortality rates of Dr. Norwood's patients, of other patients treated at the duPont Hospital, or of any other patients that are not Ian Svindland. Second, the defendants have moved for a protective order related to subpoenas that the plaintiffs directed to the Children's Hospital of Philadelphia ("CHOP") and Dr. James Goin, a statistician at CHOP, to obtain certain raw data underlying publications of studies done at CHOP (the "CHOP data"). Third, the plaintiffs have moved to compel CHOP and Dr. Goin to produce the CHOP data.[2] For the reasons herein stated, the defendants' motions are granted and the plaintiffs' motion is denied.

I. Background and Procedural Posture

Ian Svindland was born with a congenital heart defect known as a ventricular septal defect ("VSD"). A VSD is a hole in the wall separating the two pumping chambers of the heart. Dr. Norwood operated on Ian on June 25, 2003. After six hours of surgery, Ian's heart began to fail, and after eighteen hours, he

[2] The defendants' motion for a protective order was filed in both the Svindland and Daddio cases. The plaintiffs did not, however, dual-file their motion to compel. Nonetheless, the Court's decision and rationale for the CHOP data issue shall apply to both cases.

was placed on a heart-lung bypass machine for support. Ian's heart continued to fail, and eventually, other organs did as well. Ian died on July 14, 2003.

Michael Daddio was also born with congenital heart defects, including "hypoplastic left heart syndrome." On June 7, 2001, Dr. Norwood performed the first of three scheduled surgeries to correct Michael's heart defects. The second was performed on November 9, 2001. At some point after the second surgery, Michael developed persistent pleural effusions, which are liquid buildups surrounding the lungs. Michael died on July 23, 2003.

During the surgeries on both infants, Dr. Norwood utilized a technique known as "deep hypothermic circulatory arrest" ("DHCA"), in which the body is cooled to a certain temperature, blood is removed and stored, and the surgeon operates in a bloodless field on a heart that does not beat. Cooling serves the purpose of reducing the amount of oxygen required by the body's organs in the absence of blood flow.

These cases were initially assigned to the Honorable Berle M. Schiller of the Eastern District of Pennsylvania. Upon agreement of the parties, these two cases were consolidated with other cases filed against the defendants for the purposes of discovery. Pursuant to a stipulation filed by the parties, Judge Schiller would sit as the "discovery judge," and the parties

would agree which, if any, disputes would be heard before Judge Schiller as the discovery judge, and which would be heard by Judge Schiller as the trial judge for the Svindland and Daddio cases. See Svindland Docket No. 20; Daddio Docket No. 21.

The Svindland case proceeded to trial in May 2007. Prior to trial, the parties filed several evidentiary motions relating to the exclusion of certain data and expert testimony. The plaintiffs also sought to enforce subpoenas for the CHOP data. The Court precluded the plaintiffs from presenting evidence at trial related to the mortality of Dr. Norwood's patients or other patients of the duPont Hospital. It also quashed the subpoenas related to the CHOP data.

At trial, the Svindlands concentrated on two issues. They claimed that Dr. Norwood only cooled Ian for six minutes, which was not long enough to protect Ian's organs, and ultimately caused his death. They also claimed that the information given to them in order to constitute informed consent did not acquaint them with the mortality risks for Ian's operation.

The jury ruled for the defendants. It found that Dr. Norwood was negligent. However, the jury also found that the Svindlands' proof was not adequate to establish that Dr. Norwood's cooling technique proximately caused Ian's death. The jury also found no lack of informed consent.

The plaintiffs appealed the jury verdict to the United States Court of Appeals for the Third Circuit, challenging several of the Court's rulings, including orders quashing the subpoenas for the CHOP data and precluding the plaintiffs from introducing mortality evidence. The Court of Appeals vacated the jury verdict, in part, because it could not determine on the record before it the rationale for some of the Court's evidentiary rulings. See Svindland v. The Nemours Foundation, 287 F. App'x 193, 195 (3d Cir. 2008). The Court of Appeals did not reach the merits of the legal issues that were presented on appeal, and instead remanded the case for decision on these evidentiary issues and for a new trial.[3]

The Daddio case has not yet proceeded to trial. Although the case was set to be tried in July 2007, it did not proceed as scheduled. After the Court of Appeals vacated the jury verdict in Svindland, both cases were reassigned to the undersigned judge.

The Court held an on-the-record status conference with the parties on September 16, 2008, to isolate the issues for

[3] The legal issues on appeal included "the admissibility of mortality data introduced by one of [the Svindlands'] experts, the enforceability of a subpoena issued to two non-parties, the admissibility of testimony from one of the Svindlands' prior physicians, and the legality of one of the jury instructions." Svindland, 287 F. App'x at 195 n.1. The Court of Appeals did not decide these issues because it found that they would be better addressed by the district court in a new trial. Id.

decision in light of the Svindland appeal and to discuss schedules for the retrial of the Svindland case and for the trial of the Daddio case. See Svindland Docket No. 145; Daddio Docket No. 127. After that conference, the Court issued scheduling orders setting trial dates in both cases, as well as schedules for the filing of pretrial motions. See Svindland Docket No. 149; Daddio Docket No. 131.

Shortly after the conference, the parties filed various evidentiary motions. These include: (1) the defendants' motion to preclude the plaintiffs from introducing comparative morbidity or mortality data at trial ("Defs.' Mot. to Preclude," Svindland Docket No. 148); (2) the defendants' motion for a protective order relating to the subpoenas of the CHOP data ("Defs.' Mot. for P.O.," Svindland Docket No. 147; Daddio Docket No. 130); and (3) the plaintiffs' motion to compel the production of the CHOP data (Svindland Docket No. 150).

II. Discussion

The parties' motions concern two sets of data. The first set of data includes evidence of morbidity and mortality rates for the patients of Dr. Norwood, the surgeon in this case, and for other patients at the duPont hospital and at other hospitals who have undergone the types of cardiac surgery at issue. The second set of data consists of raw data that served

as the basis for two publications of studies done at CHOP. As the Court understands it, the plaintiffs seek this latter evidence so that their expert can independently analyze the data and further evaluate whether the cooling technique used by Dr. Norwood created a heightened risk of adverse outcomes. The Court will address each set of data in turn.

A. Morbidity and Mortality Data

The defendants' motion to preclude mortality data pertains to two forms of evidence. First, the defendants argue that the testimony of the plaintiffs' expert, Dr. Robert L. Hannan, is inadmissible under Daubert because it is based on scientifically unreliable data and methods. Second, the defendants seek to preclude the defendants from introducing any evidence of morbidity or mortality rates more generally. Such evidence, they argue, is irrelevant, unreliable, prejudicial, and based on hearsay. The Court agrees with the defendants, and will grant the defendants' motion to preclude the plaintiffs from introducing either form of evidence at trial.

1. The Admissibility of Dr. Hannan's Testimony

The defendants expect that the plaintiffs will try to introduce expert testimony to prove that Dr. Norwood's mortality rate was "too high" and that it was caused by his cooling

technique. This testimony will come from the plaintiffs' expert witness, Dr. Robert L. Hannan. As the Court understands it, Dr. Hannan will compare data from the Delaware Health Statistics Center (the "DHSC data") to data from Children's Hospital Boston (the "Boston data"). The Court finds that Dr. Hannan's testimony and report comparing these data are inadmissible under Daubert.

The defendants argue that Dr. Hannan's testimony is inadmissible under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), for three reasons: (1) the DHSC data are unreliable; (2) the Boston data are unreliable; and (3) the method employed by Dr. Hannan to compare these two sets of data is unreliable.

The Court held a hearing on the parties' evidentiary motions on March 11, 2009. At the hearing, the defendants presented the testimony of two live witnesses, Dr. Jeffrey P. Jacobs[4] and Dr. Jane Newburger.[5] The defendants also submitted

[4] Dr. Jacobs is a cardiovascular and thoracic surgeon, the surgical director of heart transplantation at the Congenital Heart Institute of Florida, and a clinical associate professor at the University of South Florida. Dr. Jacobs is also a member of the Society of Thoracic Surgeons ("STS"), the largest professional organization of cardiac and thoracic surgeons in the country. The STS has developed a database of patient outcomes, which is the largest such database in North America. Dr. Jacobs has chaired the STS congenital heart surgery database committee since 2006.

[5] Dr. Newburger is in the Department of Cardiology at Children's Hospital Boston, and is the Department's Associate Chief for Academic Affairs. She is also the Commonwealth Professor of Pediatrics at Harvard Medical School.

to the Court the videotaped deposition of Dr. Murray M. Pollack.[6] These witnesses presented testimony relating to the reliability of the data and method used by Dr. Hannan. The plaintiffs did not present any witnesses.

For the reasons argued by the defendants, and based on the testimony they presented at the hearing, the Court agrees that the DHSC and Boston data are unreliable, and that the method used by Dr. Hannan to compare the two is also unreliable. Dr. Hannan's testimony and report, insofar as they pertain to the mortality issue, are inadmissible under Daubert.

a. The DHSC Data

The defendants argue that the DHSC data are not scientifically reliable for several reasons. First, the data are not risk-adjusted - i.e., they do not reflect for other factors that might increase or decrease the likelihood of death for particular patients. Second, the data - which are primarily in the form of administrative billing codes - do not differentiate between surgeons, do not identify patient co-morbidities - i.e., whether the patient may have also had other, unrelated diseases - and do not reveal the complexities of the underlying heart defects.

[6] Dr. Pollack is currently the chief medical officer and chief academic officer of the Phoenix Children's Hospital.

At the March 11 hearing, the defendants' witnesses corroborated these arguments. Dr. Jacobs testified that the DHSC data relied upon by Dr. Hannan are gleaned from Delaware State Health Department medical records, and utilize International Classification of Disease Codes, Version 9 ("ICD-9 codes"). The primary function of ICD-9 codes, according to Dr. Jacobs, is not to facilitate the prediction of outcomes in particular cases, but rather, to facilitate billing.

Dr. Jacobs stated that several publications have studied the reliability of ICD-9 codes as a source of mortality rates, and that these codes should not be used to predict outcomes. He also stated that any use of these codes for outcomes analysis is subject to major errors and misinterpretation. Dr. Jacobs further testified that ICD-9 codes are not assigned by heart surgeons, but rather, by billing clerks who have never seen the patients. This arrangement creates the potential for misclassification of operations and procedures.

According to the defense witnesses, the issue of nomenclature is of significance to outcomes analysis. Dr. Jacobs stated that the first step to being able to compare outcomes between two centers or databases is that each must use the same terminology. If the data are being used to analyze patient outcomes in particular, that nomenclature should be clinical nomenclature - as opposed to billing nomenclature. In other

words, the name assigned to a procedure by a billing clerk, who may not understand the differences between particular procedures, is not as reliable from an outcomes standpoint as the name assigned to a procedure by a performing surgeon.[7]

Dr. Pollack further explained that the use of ICD-9 codes in the context of VSDs can be misleading. He stated that although a "VSD" can be an isolated defect, it can be a "small isolated defect," or a "large isolated defect." Thus, the coding of a defect as a "VSD" in an ICD-9 code "does not tell the whole story." See Pollack Dep. Tr. 13-14, 3/6/2009.

In contrast to ICD-9 codes, Dr. Jacobs stated that there is another set of codes called the International Pediatric and Congenital Cardiac Code ("IPCCC"). The IPCCC is a clinical-based nomenclature that was created by a multi-institutional, multi-national group of cardiologists and cardiac surgeons. The coding for the IPCCC is done by healthcare professionals that actually take care of the patients. These codes, which are entered into the STS database, are monitored by "database police" who ensure that the database is complete and accurate. On the

[7] This conclusion is supported by medical literature submitted by the defendants. One article in particular, entitled "The Importance of Nomenclature for Congenital Cardiac Disease: Implications for Research and Evaluation," specifically concludes that analyses based on the use of ICD-9 codes may have "substantial misclassification of congenital heart disease. Isolating the major defect is difficult, and certain codes do not differentiate between variants that are clinically and developmentally different." See Jacobs Ex. 3.

other hand, the ICD-9 codes contained in the DHSC data have no such verification mechanism in place.

Based on this evidence, which the plaintiffs have not contradicted, the Court agrees that the DHSC data are not scientifically reliable.

b. The Boston Data

The defendants argue that the data from Children's Hospital Boston are also unreliable. These data, taken from the hospital's website, also do not identify the operating surgeon or any patient co-morbidities. The website does not state how it defines terms such as "survival" or "VSD," and what cooling techniques were used in any of the cases reported.

At the March 11 hearing, the defendants presented evidence to show that the data gleaned from the Children's Hospital Boston website are scientifically unreliable. As stated by Dr. Jacobs, one problem with the Boston website is that it only reported thirty-day mortality. That is, if a baby died on the thirty-first day following a procedure, that baby is still counted as a survivor. The website was not created for institutional comparison of outcomes, but rather, to share information with the people reading the website. The website itself states: "Because hospitals present data differently and because of the uniqueness of each child's situation, it is

important that statistics and outcomes are fully explained. We are happy to speak with parents regarding Children's Hospital Boston's outcomes anytime." See Defs.' Mot. to Preclude Ex. F.

For the reasons advanced by the defendants and their witnesses, the Court finds that the Boston data are not scientifically reliable.

c. The Reliability of Dr. Hannan's Method

Finally, the defendants argue that even if the DHSC and Boston data were risk-adjusted and reliable, there is no scientific basis to conclude that a lower mortality rate at one hospital is evidence of negligence or causation. In other words, the method used by Dr. Hannan to compare the DHSC and the Boston data is unreliable.

To compare the data, Dr. Hannan utilized a method known as the Risk-Adjustment in Congenital Heart Surgery ("RACHS-1") method. RACHS-1 is a system of complexity stratification of children's heart surgeries. This method classifies a procedure into one of six categories, based upon the relative level of riskiness of the procedure, as agreed upon by a panel of experts.[8]

[8] As Dr. Jacobs explained, the STS has developed another method of risk-stratification for congenital cardiac surgeries. As explained by Dr. Jacobs and Dr. Pollack, this method, known as "Aristotle," requires examination of "very detailed" diagnostic - as opposed to administrative - information. Dr. Jacobs further

Dr. Newburger is one of the eleven members of a panel who developed the RACHS-1 method. Both she and Dr. Jacobs stated that Dr. Hannan's use of RACHS-1 was improper. They both testified that RACHS-1 was created to help medical institutions benchmark their performance from a mortality standpoint among institutions nationwide. In other words, RACHS-1 was designed to compare the whole body of work of a given program to a national standard for each classification group. It was not meant to compare one surgery to another surgery, or to look at the performance of an individual surgeon for a given operation.[9] RACHS-1 also cannot be utilized to draw a conclusion about Dr. Norwood's performance by simply comparing DHSC billing codes with the data on the Boston website.

Dr. Hannan's testimony is inadmissible under Daubert. Under Daubert and Federal Rule 702, an expert's testimony must be based on sufficient facts or data and must be the product of

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explained that there is a group of investigators that is in the process of discussing the potential of merging the RACHS-1 method and the Aristotle method into a "RACHS-2" method. Dr. Jacobs is a member of that group.

[9] The defense witnesses each stated that even within the category of "VSDs," not every VSD is the same, and that just because an infant has a VSD, that does not mean that the same treatment should be applied to each. Dr. Pollack explained at his deposition that the VSD patients examined by Dr. Hannan were "not a group of simple VSD patients." In particular, at least 92 of the 101 patients had at least one secondary diagnosis, 76 with at least two secondary diagnoses, 64 with at least three, 48 with at least four, and 38 with at least five. See Pollack Dep. Tr. 13-14, 3/6/2009.

reliable principles and methods. An expert's opinion must also be based on a reliable application of the principles and methods to the facts of the case.

Dr. Hannan's testimony does not meet the Daubert standard. The expert testimony presented by the defendants at the March 11 hearing clearly establishes that use of the data by Dr. Hannan is not based on scientifically reliable evidence or on a reliable application of the methods used to the facts of the case. This testimony is therefore inadmissible under Daubert.

2. Evidence of Mortality Generally

The defendants expect the plaintiffs will also try to introduce evidence of morbidity and mortality by introducing isolated pages of medical records of other patients who had poor outcomes or who died following pediatric open-heart surgery. In addition, at the first trial of this case, counsel for the plaintiff attempted to question Dr. Norwood about the outcomes of prior surgeries, and Dr. Hannan referred to his and to Dr. Norwood's mortality rates.[10] The defendants have moved to preclude the plaintiffs from introducing any such evidence or

[10] For example, Dr. Hannan testified that "we never had a baby . . . that died" and that "we haven't had [a baby with VSD] die." See Trial Tr. 20, 22, Defs.' Mot. to Preclude Ex. B. He also stated that the technique used by Dr. Norwood "resulted in a ten times higher incidence of seizures post-operatively than other potential techniques" and "that the incidence of death would be increased." Id. at 52.

testimony, or from engaging in lines of questioning that would lead to the production of such testimony. In other words, they wish to exclude all evidence referring to the morbidity and mortality rates of Dr. Norwood's other patients, of other patients at the duPont hospital, or of patients of other doctors at other hospitals.

The defendants have four main arguments as to why the Court should preclude this evidence. Their first argument is that such evidence is not relevant to show whether Dr. Norwood was negligent in this case, as it will not establish causation or a standard of care. They state that what the correct standard of care is will not be made more or less likely by mere comparison of mortality rates without consideration of other factors. As for causation, they argue that the course of Ian's treatment was the same regardless of whether Dr. Norwood or other surgeons performed operations on other patients who died, and that a comparison of mortality rates at other institutions - especially where these rates are not properly risk-adjusted - will also not provide evidence about the causes of the underlying deaths.

The defendants' next argument for preclusion is that any probative value of this evidence is outweighed by the danger of unfair prejudice. The evidence, they contend, will be taken out of context by the jurors, who may believe that the deaths of

Dr. Norwood's other patients were due to negligence, and thus decide the case on an improper basis.

Third, the defendants argue that mortality evidence - i.e., evidence of deaths in prior surgeries - is analogous to prior bad act evidence that is inadmissible under Rule 404(b). They further argue that, in most jurisdictions, evidence of a physician's prior surgical or malpractice history cannot be used to prove that the surgical team acted in accordance with these prior acts. See Defs.' Mot. to Preclude 15 (citing, e.g., Weil v. Seltzer, 873 F.2d 1453 (D.C. Cir. 1989)).

The defendants' final argument is that this evidence will confuse the jury and waste judicial resources. The introduction of such evidence, they contend, will lead to collateral mini-trials regarding the medical histories and other circumstances in prior cases and prior outcomes.

Although the Court cannot say at this stage that mortality evidence will never be appropriate in particular lines of examination at trial, the Court agrees with the defendants that such evidence is generally not relevant to the elements of the plaintiffs' malpractice claim. See supra note 4. In particular, the evidence will not tend to establish causation or the standard of care. Even if mortality rates might seem relevant to the plaintiffs' informed consent claims, the plaintiffs have not persuaded the Court that the mortality data

that they would seek to introduce have taken into account co-morbidities or have otherwise been risk-adjusted so as to be relevant to the surgeries at issue. The Court also believes that such evidence may confuse or otherwise be taken out of context by the jurors, thus creating the risk of unfair prejudice to the defendants. The introduction of this evidence might lead to a confusing and lengthy trial.

The Court will grant the defendants' motion to preclude this evidence. The plaintiffs may not introduce evidence or testimony pertaining to the morbidity or mortality rates of Dr. Norwood's patients or of other doctors' patients. They shall also refrain from engaging in lines of questioning that will lead to the production of such testimony.

B. CHOP Data

On September 3, 2008, the plaintiffs served subpoenas to obtain the raw data underlying publications of studies done at CHOP, in order to allow their expert to independently evaluate the data and offer an opinion on whether the cooling technique at issue increased the risk of adverse surgical outcomes. These subpoenas were served on CHOP and on Dr. James Goin, a CHOP statistician. The defendants have moved for a protective order

over this data, and the plaintiffs have moved for an order compelling the production of the data.[11]

The CHOP data are raw data that served as the basis for two articles, "Allopurinol Neurocardiac Protection Trial in Infants Undergoing Heart Surgery Using Deep Hypothermic Circulatory Arrest" ("Allopurinol") and "Risk of Seizures in Survivors of Newborn Heart Surgery Using Deep Hypothermic Circulatory Arrest" ("Risk of Seizures"). The "Allopurinol" article is a pharmacologic study of the efficacy of the drug, Allopurinol, in preventing adverse neurological outcomes in infants who underwent DHCA. This article did not describe any relationship between cooling durations and outcomes.

The "Risk of Seizures" article is a study of the variables associated with postoperative neurological events in survivors of congenital heart surgery. One of the variables examined was DHCA time. The study found that DHCA time "was not significantly associated with" the occurrence of acute neurological events. See Defs.' Mot. for P.O. Ex. F at 595.

According to CHOP, which filed a third-party opposition to the plaintiff's motion to compel, the data for these studies was collected in accordance with an NIH contract that authorized

[11] The Court previously denied the plaintiffs' motion to enforce the subpoenas in the Daddio case and their motion for reconsideration of that decision. See Daddio Docket No. 98. By order dated March 23, 2007, those decisions were incorporated into the Svindland case. See Svindland Docket No. 98.

CHOP to study the efficacy of Allopurinol. The patients analyzed were treated by four different surgeons at CHOP, including Dr. Norwood, from 1992-1997. According to the defendants and CHOP, Dr. Norwood did not have access to this data after he left CHOP in 1994. Although he was listed as an author of these studies, the defendants and CHOP claim that this is merely because some of his patients were used as test cases.[12] The plaintiffs have not disputed this point.

The defendants present five main arguments for the protection of this data. First, they argue that the proposed reexamination of this data by the plaintiffs' experts will not show what Dr. Norwood knew when he operated on Ian Svindland. Other than the fact that Dr. Norwood is identified as a contributor to the two articles, there is no other connection between Dr. Norwood and the data to suggest that he knew or should have known that his cooling technique was beneath the standard of care when he performed the surgeries at issue.

Second, the defendants argue that a present-day evaluation of the CHOP data will not demonstrate what the applicable standard of care was in 2001 or in 2003. This standard, they contend, can be established by expert testimony,

[12] CHOP notes that authorship in biomedical journals is often conferred merely for use of a doctor's patients in a research study. CHOP Opp. to Pls.' Mot. to Compel 9 n.3 (discussing the concept of "gift authorship").

by reference to published guidelines, and through cross-examination at trial. The articles for which the data were gathered did not conclude that surgeons should cool for a particular length of time, and even if the data could be assessed now to establish that conclusion, Dr. Norwood cannot be held liable for failing to follow such a standard when he operated.

Third, the defendants argue that the data will not establish either proximate or but-for causation. The "Allopurinol" article did not discuss any relationship between cooling duration and outcomes, and the data set involved in the "Risk of Seizures" article had a mean cooling time of 11.5 minutes. Thus, the plaintiffs cannot establish that 15 minutes of cooling were required using this data.[13] Moreover, the "Risk of Seizures" article itself concluded that there was no significant association between cooling time and adverse outcomes. As for but-for causation, the defendants argue that even the plaintiffs' experts previously give conflicting opinions concerning the cause of Ian's death or Michael's death. For these reasons, the CHOP data would not shed further light on the outcome in this case.

[13] Throughout the course of the proceedings before this Court, the plaintiffs have referred to both fifteen- and twenty-minute cooling times as the standard of care. Most recently, the plaintiffs stated that they intend to show that fifteen minutes of cooling are necessary.

Fourth, the defendants argue that any probative value that this evidence might have would be outweighed by its prejudicial impact. The jury, they contend, will confuse the new findings of the plaintiffs' expert with the relevant standards from 2001 or 2003, and may, as a result, improperly decide the case using those findings.

Fifth, the defendants argue that the plaintiffs, as biased litigants, should not have access to confidential non-party data, especially where they have not made a showing of substantial need. The plaintiffs should not be permitted to reexamine confidential data that was objectively assessed by non-biased researchers so that they could prove the theory that they have already decided to pursue at trial.[14]

CHOP has also presented several additional arguments against the production of this data. First, it argues that peer review is the correct process for testing scientific ideas, and

[14] The defendants also argue that because the Daddio case never actually proceeded to trial before Judge Schiller, the evidentiary rulings in Daddio still stand as the law of the case. These rulings include an order denying the plaintiffs access to the CHOP data. See Daddio Docket No. 98. The defendants argue that these rulings should not be overturned because there is no new evidence or new law that would affect the issues resolved by that ruling, and because the ruling is not clearly erroneous. See Defs.' Mot. for P.O. 7-8. In light of the Court of Appeals's rationale for vacating the jury verdict in Svindland, the Court will take no position on this issue at this juncture, and instead will here decide the CHOP data issue on the merits.

not litigants and their biased experts reanalyzing raw research data without any peer review.

Second, CHOP argues that even if the data were produced, the plaintiffs could not perform a statistically valid analysis because the data are skewed, given that too few patients had cooling times of fifteen minutes or more. In the "Risk of Seizures" article, for example, the majority of patients had cooling times under thirteen minutes. CHOP also argues that the plaintiffs have not identified an individual qualified to analyze such complex data. It has also stated that an order requiring CHOP to produce the data would be unduly burdensome, as it no longer has the relevant case report forms, which were used to collect patient information. It states that these forms would be needed to validate the data.

Third, CHOP argues that the plaintiffs have not demonstrated substantial need for the data, as is required to compel production from third parties under Rule 45. Although the plaintiffs argue that no privilege applies to medical research, CHOP argues that the clear terms of Rule 45 apply to the data here because they are "other confidential research information" and also "an unretained expert's . . . information that does not describe specific occurrences in dispute." CHOP Opp. to Pls.' Mot. to Compel 16.

Fourth, CHOP argues that federal and state privacy protections weigh heavily against disclosure. As a preliminary matter, the data is owned by NIH, and under the terms of the NIH contract, the consent of both NIH and each patient in the study would be needed. CHOP also argues that the information is protected under the Privacy Act, and that medical privacy is a fundamental right under the Pennsylvania Constitution. Even if the Court were to order CHOP to produce a redacted version of the data, CHOP also contends that production of the data would be unduly burdensome because the effort required to redact and to interpret the data would be vastly disproportionate to any relevance to this action.

Finally, CHOP argues that the production of research data should be prohibited on public policy grounds - namely, that scientists should be able to conduct research without fear that raw data will be subject to subpoena and biased reinterpretation in unrelated lawsuits. A contrary holding, CHOP claims, would have a profound chilling effect on medical research.

The Court agrees with the defendants and with CHOP that the plaintiffs have not stated a reason to compel the production of the CHOP data. The data are not relevant to show what Dr. Norwood knew when he operated on Ian Svindland or Michael Daddio. Nor will they prove the applicable standard of care in 2001 or 2003. They also will not shed further light on the issues of

proximate and but-for causation. The plaintiffs essentially seek to have their expert duplicate the efforts of the CHOP researchers who performed the studies and wrote the publications at issue. However, in neither study did the researchers find a correlation between cooling time and adverse outcomes.

Even leaving aside policy considerations, the Court will not allow the plaintiffs to redo the CHOP studies. The Court finds that the benefit of doing so is outweighed by the prejudice and burden that doing so would create for the defendants and for CHOP. First, to the extent that the plaintiffs' expert reaches a conclusion using the CHOP data, the jury may confuse the new findings of the plaintiffs' expert with the standards from 2001 or 2003. Second, even if the plaintiffs are willing to pay for the time and effort required to gather, redact, produce, and interpret the data, the probative value of this data is disproportionately small in comparison with the burden that would be placed upon CHOP and Dr. Goin, who are not parties to this litigation.

For these reasons, the Court will deny the plaintiffs' motion to compel and will grant the defendants' motion for a protective order.

III. Conclusion

For the foregoing reasons, the defendants' motion in limine and motion for a protective order will be granted, and the plaintiffs' motion to compel will be denied. The plaintiffs may not introduce evidence relating to mortality or morbidity at trial, as explained herein. In addition, the plaintiffs may not enforce the subpoenas directed to CHOP or Dr. Goin or obtain the raw data related to the CHOP studies.

An appropriate Order shall issue separately.