

On February 3, 2012, petitioners filed their first motion to compel discovery seeking access to the Vaccine Safety Datalink (“VSD”) and requested that subpoenas be issued to ten different managed care organizations (“MCOs”).³ See Petitioners’ Motion to Compel dated Feb. 3, 2012, (“Motion to Compel”) (ECF No. 46). Both respondent and the MCOs filed briefs opposing petitioners’ motion for discovery. Respondent’s response highlighted the plethora of problems associated with the Motion to Compel, including that petitioners’ request was overbroad, burdensome, unreasonable, and unnecessary to prove their case. Respondent’s Response to Motion to Compel dated March 30, 2012, (ECF No. 58).

Petitioners’ Motion to Compel was denied in a lengthy and comprehensive order by then-Chief Special Master Patricia Campbell-Smith.⁴ See Order dated June 12, 2013, (ECF No. 78). The next day, the case was transferred to Special Master George Hastings, and petitioners filed a motion for reconsideration of the Chief Special Master’s order. Motion for Reconsideration dated July 12, 2013, (“Motion for Reconsideration”) (ECF No. 82). Petitioners’ Motion for Reconsideration was denied by Special Master Hastings, who agreed with Chief Special Master Campbell-Smith that petitioners’ discovery request was neither reasonable nor necessary. See Order dated October, 24, 2013, (ECF No. 93).

On October 1, 2015, petitioners renewed their motion to compel, again seeking access to the VSD and to issue subpoenas to the MCOs. Motion for Discovery dated October 1, 2015, (“Renewed Motion to Compel”) (ECF No. 164). For the reasons described below, the undersigned **DENIES** petitioners’ Renewed Motion to Compel. The undersigned agrees with the previous decisions of then-Chief Special Master Campbell-Smith and Special Master Hastings and incorporates their reasoning herein. This order will only address the new arguments raised by petitioners in the Renewed Motion to Compel.

II. Legal Standard

Pursuant to the Vaccine Rule 7(a), “[t]here is no discovery as a matter of right” in Program cases. The Vaccine Act further provides that “[t]here may be no discovery ... other than the discovery required by the special master.” 42 U.S.C. § 300aa-12(d)(ii)(B)(v). A special master:

- (i) may require such evidence as may be reasonable and necessary,
- (ii) may require the submission of such information as may be reasonable and necessary, [and]

³ As former Chief Special Master Campbell-Smith noted in her June 12, 2013 Order, “[b]ecause a portion of the VSD Project data is in the possession of the Centers for Disease Control and Prevention (“CDC”), and another portion is in the possession of the ten private MCOs, petitioners filed dual motions: one to compel discovery of CDC as a party and the other to issue subpoenas to the ten MCOs as multiple non-parties.” Order dated June 12, 2013, (ECF No. 78).

⁴ Judge Campbell-Smith was appointed Judge of the United States Court of Federal Claims on September 19, 2013. On October 21, 2013, President Obama designated her as Chief Judge.

- (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary.

§ 300aa-12(d)(3)(B).

III. Petitioners' New Arguments in Their Renewed Motion for Authority to Issue Subpoenas and to Compel Access to the Vaccine Safety Data Link

In the Renewed Motion to Compel, petitioners raise two new arguments. First, petitioners state that the criticism of respondent's expert, Dr. Fallin, of Dr. Deisher's research entitles petitioners access to the VSD. Renewed Motion to Compel at 2-5. Secondly, petitioners argue that the VSD constitutes the best evidence available to petitioners and thus due process protects petitioners' rights to access the information. *Id.* at 28. The undersigned discusses each of these arguments in turn.

a. Petitioners' argument that respondent's expert's criticism of Dr. Deisher's research does not entitle petitioners access to the VSD

The first basis for petitioners' Renewed Motion to Compel "is that respondent has taken a position through the opinion of her expert ... that petitioners' theory of causation fails not because of petitioners' expert's analysis but because the data on which she has relied is insufficient." Renewed Motion to Compel at 1-2 (referencing Resp's Ex. J, Dr. Fallin's expert report). Petitioners claim that respondent attacks Dr. Deisher's work as insufficient while denying her access to the data that allegedly could provide proof of petitioners' causation theory. *Id.* at 2. Petitioners further argue that respondent "attacks the validity of the only data available to petitioners. The best means of countering the respondent's argument is granting access to petitioners to data that is within respondent's control." *Id.* Petitioners' counsel quotes respondent's expert, Dr. Fallin, as claiming that the "only study that can be free of the potential for statistical fallacy is one keyed to individual medical records. The only such data set known to exist is the [VSD]." Pet'rs' Reply at 1. Petitioners also insist that their causation theories could be made "more reliable" if they had access to the VSD.

As then-Chief Special Master Campbell-Smith and Special Master Hastings have both previously explained, however, it is not appropriate for the court to grant petitioners' motion to access the VSD when there are established protocols for accessing this information.⁵ Indeed, the undersigned notes that experts and scientists may gain access to the VSD by following the protocols set up by the CDC to gain access to this data. To allow petitioners and their experts to gain access by court order circumvents established protocols, rules and regulations that apply to all interested parties and protects the data contained in the VSD.

Further, Dr. Fallin's criticism of Dr. Deisher's study does not entitle petitioners to access the VSD data. Dr. Fallin states, "[t]here are several major weaknesses of [Dr. Deisher's] study,

⁵ See U.S. National Center for Health Statistics, Centers for Disease Control, Procedures & Costs for Use of the Research Data Center, App. IV Vaccine Safety Datalink (VSD) Data Sharing Program (2005); see also Order dated June 12, 2013, (ECF No. 78) at 8-9.

including its ecological study design, its reliance on inappropriate assumptions, and its grossly over-stated conclusions in light of the evidence presented.” Resp’s Ex. J at 2. It is common, if not routine, for an expert to criticize the opposing expert in litigation, as well as any studies or research authored by the expert. In every hearing over which the undersigned has presided, experts have criticized the opposing experts and have testified about the inadequacy of studies presented in medical journal articles, or research performed by the opposing expert, similar to what Dr. Fallin has done here.

Moreover, there are many studies and investigations related to the question of whether injuries and illnesses are vaccine-related that do not rely on data from the VSD. Here, the petitioners are not limited to the VSD. In fact, petitioners concede that the VSD is not the only evidence available. See Renewed Motion to Compel at 2, footnote 2. Cases in the Program routinely proceed to resolution without VSD information or evidence. The undersigned is not aware of any case in the Program where an expert has been given access to the VSD through a court order for the purpose of performing research to establish evidence in support of a medical theory.

b. There is No Violation of Due Process

Secondly, petitioners argue that the VSD is the “best available source of information” and “the best evidence available” to allow petitioners to prove their medical theory of causation. Renewed Motion to Compel at 2. Petitioners insist that a denial of their motion would result in a violation of their due process rights, stating that “[d]iscovery [in the Vaccine Program] may be discretionary with the Special Master, but in this extreme case it is mandated by the overriding requirement that no matter the details, even Congress may not deny a litigant, within the borders of this nation, due process of law.” Renewed Motion to Compel at 5. Petitioners cite only one case, Greater Baltimore Center for Pregnancy Concerns, Inc. v. Mayor and City Council of Baltimore, 721 F.3d 264 (4th Cir. 2013), in support of their argument that due process protects their right to the discovery they seek.

In Greater Baltimore, the Fourth Circuit determined that the trial court had not given the City of Baltimore sufficient time to conduct discovery, and thus, there was a violation of due process. 721 F.3d at 280. The Court did not, however, mandate specific discovery such as that sought here, only the opportunity to conduct discovery. The holding related to discovery in Greater Baltimore does not apply here, where petitioners have been given ample time to conduct discovery, and where in fact, petitioners have conducted extensive discovery⁶, filing more than five expert reports, numerous medical records, and over 355 medical articles.

To repeat, there is no right to discovery in the Vaccine Program. See Vaccine Rule 7(a). Special masters are not governed by the Federal Rules of Civil Procedure, which were at issue in Greater Baltimore. Instead, discovery in the Vaccine Program is permitted to the extent that the evidence at issue is deemed to be reasonable and necessary. 42 U.S.C. § 300aa-12(d)(3)(B)(i). Here, there has been no showing by the petitioners that the information that petitioners seek in order to evaluate their claims for compensation under the Vaccine Act is necessary for the undersigned to consider. Further, petitioners’ argument that a denial of their motion constitutes a

⁶ To date, 629 exhibits have been filed.

violation of their due process rights fails because there exists a “procedure” to request the discovery they seek, and that procedure has been followed. The fact that the specific discovery request was denied is not itself a due process violation.

The undersigned’s task in presiding over this Omnibus proceeding is to adjudicate these cases in accordance with the statutory scheme set forth in the Vaccine Act, codified at 42 U.S.C. § 300aa et seq., to determine whether petitioners are entitled to compensation for a vaccine-related injury. The statute provides that the undersigned should base her decision on pre- and post-injury medical records, vaccination records, provider notes, test results, and expert medical opinions. 42 U.S.C. § 300aa-13(b). The statute does not give the special master authority to grant the parties discovery for the purpose of conducting vaccine research. See Werderitsh v. Sec’y of Health & Human Servs., No. 99-310V, 2005 WL 3320041 (Fed. Cl. Nov. 10, 2005). Legislative history “suggests[] that the special master’s investigative power is limited to ‘factual elements’ of a petitioner’s claim.” H.R. Rep. No. 99-908, pt. 1, at 17 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 63447.

Thus, in the special master’s view, the Program is not the appropriate forum for – and a special master should not preside over wide-ranging discovery, or should not devise unique procedures, aimed at – developing original scientific or medical theses. Indeed, scientific or medical ‘research’ conceived and conducted in the context of litigation poses an inherent danger: scientific or medical ‘research’ conceived and conducted in the context of litigation is not subjected usually to the time-honored practices in the scientific and medical communities of peer-review and of publication – two of several, significant touchstones of evidentiary reliability (citations omitted).

Schneider v. Sec’y of Health & Human Servs., No. 99-160V, 2005 WL 318697, at *5 (Fed. Cl. Spec. Mstr. Feb. 1, 2005), *aff’d* by 64 Fed. Cl. 742 (2005).

IV. Conclusion

For all of the foregoing reasons, petitioners’ Renewed Motion to Compel discovery is **DENIED.**

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master