ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER, Various Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	AUTISM MASTER FILE Special Master Hastings

RESPONDENT'S RESPONSE TO PETITIONERS' FILING RE: SUBMISSION OF EXPERT REPORTS IN SUPPORT OF GENERAL CAUSATION[1]

In response to Petitioners' Filing Re: Submission of Expert Reports In Support of General Causation ("Pet. Filing"), respondent herein objects to the steering committee's proposal that their expert reports "not become due until mid-2006 at the earliest." Pet. Filing at 1. The special master must deny this request and set a schedule for the submission of expert reports that adheres as closely as possible to the Vaccine Act's statutory scheme mandating that the special master issue a decision "as expeditiously as practicable but not later than 240 days" from the date the petition was filed. 42 U.S.C. § 300aa-12(d)(3)(A).

[1] Petitioners' steering committee filed their pleading into the Autism Master File alone. Consistent with respondent's practice to date, respondent has also filed this document into the record of Taylor v. HHS, No. 02-699V.

Summary of Respondent's Argument

Petitioner's Steering Committee ("PSC") has requested an "ongoing extension of time in which to file expert reports in the Autism Omnibus Proceeding, at least until September 2006." Pet. Filing at 13. The crux of the steering committee's position is that the special master should not "let these legal proceedings get ahead of the science." Id. Arguably, by claiming that "a significant body of relevant, peer-reviewed, independent published science, unavailable today, will likely be available to petitioners, respondent, and the court within the next twelve months," petitioners' steering committee proffers what may seem at first blush to be an attractive case for delay. Id. In essence, however, petitioners' steering committee is requesting that the special master suspend proceedings for a time period well beyond the Act's 180-day limitation for suspension of proceedings, which would constitute an action expressly prohibited by the plain language of the Vaccine Act.

The special master must reject the steering committee's proposed schedule for the submission of expert reports and initiate a course for these cases that fits within the scope of the Vaccine Act's mandates, requiring that each individual case move forward in an efficient manner, as prescribed by Congress. To rule otherwise would be outside the scope of the special master's Vaccine Act authority, amounting to an action in

disregard of the Vaccine Act's overall statutory scheme, the imposed time limitations prescribed by the Act, and the specific role of the special master to issue decisions on individual Vaccine Act petitions "as expeditiously as practicable but not later than 240 days. . . after the date the petition was filed." 42 U.S.C. § 300aa-12(d)(3)(A)(ii).

Regardless of whether petitioners' steering committee considers the strict time frames of the Vaccine Act to be desirable limitations, the special master is statutorily obliged to conduct proceeding in accordance with these time requirements. There is no provision in the Vaccine Act that authorizes thousands of petitions to linger dormant in the Vaccine Injury Compensation Program while petitioners' steering committee develops their causation theory. To request as much from a Vaccine Act special master is to seek relief well beyond his limited authority.[2]

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[2] At the inception of the Vaccine Act, Congress's foremost intention was the efficient compensation of "recognized vaccine injuries," i.e., Table Injuries. H.R. Rep. No. 99-908, at 16 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6353. It was, most likely, within the Table Injury context that Congress established the time limitations for case completion. The Act, however, has always allowed for an off-Table theory of causation, and it has always required that supporting documentation of the off-Table theory be filed as part of the petition that initiates the proceedings. To the extent that the steering committee's request for such a lengthy suspension is grounded upon the notion that an off-Table petitioner should receive more time than a Table petitioner to develop his case while the matter is actually pending before the special master, there is nothing in the Act to support the distinction. Nor is it logical to assume Congress would want to favor petitioners whose injury is not a

The Vaccine Act was not designed for protracted litigation, nor was it intended to impose upon the special master the burden of ruling on general issues of vaccine causation in a class action setting. By continuing to proceed in this fashion, i.e., outside the factual context of an individual case and with disregard for the time restrictions of the Act, the steering committee and the office of special masters are twisting the legislation to function in a manner that is unauthorized and that cannot be accommodated within the Act's limitations. To remain within the authority of the Vaccine Act, therefore, the special master must order the future conduct of these cases to follow the Act's requirements, which do not allow for the requested 400-day suspension of proceedings.

DISCUSSION

The Vaccine Act creates a unique program of efficient adjudication and no-fault compensation for vaccine injury claims. Its scheme is plain and its directives to petitioners and to the special masters are clear. 42 U.S.C. § 300aa-11(b) and (c); 42 U.S.C. § 300aa-12(d). Persons seeking compensation for vaccine injuries must file a petition that includes particular medical records, together with affidavits and other supporting

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"recognized" vaccine injury, i.e., a Table Injury, but rather an *alleged* vaccine injury, i.e., an off-Table injury. In this regard the Vaccine Act's language cannot be stretched by the special master to accommodate the steering committee. In light of the Vaccine Act's plain language, the steering committee's only relief is legislative.

documentation demonstrating vaccine causation. 42 U.S.C. § 300aa-11(c). Thereafter, the special master is statutorily obliged to issue a decision on the petition, including findings of fact and conclusions of law "not later than 240 days" after the date the petition was filed, exclusive of suspension time. 42 U.S.C. § 300aa-12(d)(3)(A). The authorized suspension time is expressly limited to an automatic "30 days on the motion of either party" with an additional "aggregate period not to exceed 150 days" if upon either party's motion, the special master determines that "the suspension is reasonable and necessary." 42 U.S.C. § 300aa-12(d)(3)(C).

Despite the clarity of the Act's directives, and over respondent's objections, from the outset of the Autism Omnibus Proceeding petitioners' steering committee has been excused from the documentary filing obligations of Section 11, and the presiding special master has been excused from the time restrictions of Section 12. Autism General Order #1, 2002 WL 31696785 (July 3, 2002). Respondent has respectfully set forth a number of objections in the Stewart case pertaining to these issues, which pleadings have been entered into the Autism Master File by Order of the Special Master dated October 20, 2003. See www.uscfc.uscourts.gov/OSM/AutismDocket.

In these filings and others, respondent outlined numerous objections including concerns that Autism General Order #1, by authorizing Short Form Petitions and setting a protracted

schedule for proceedings, guaranteed that no statutory time goal could be realized in any of these cases.[3] Respondent's consistent position has been that many of the initiatives outlined Autism General Order #1 are beyond the limited authority granted the special masters by the Act. In addition to the numerous issues raised by the Short Form Petitions and the initial scheduling order, of significant concern to date has also been the instigation of a "lengthy discovery period of a type clearly never envisioned by Congress." 2002 WL 31696785, at *2 (July 3, 2002).

This "lengthy discovery period" is now very near completion. See Autism Update (Fed. Cl. Spec. Mstr. June 27, 2005) (http://www.uscfc.uscourts.gov/OSM/OSMAutism.htm). Notwithstanding respondent's formerly noted objections to the nature, the scope, and the length of discovery as it was

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[3] In Stewart v. HHS, No. 02-819V, respondent asserted his position that when a petition is filed in the absence of the documentation required by 42 U.S.C. § 300aa-11(c), the special master is without the ability to consider fully the merits of the petition, and therefore, Congress did not intend for the submission of an incomplete petition to start the running of the 240-day limitations period for the resolution of cases. See Respondent's Motion for Appropriate Relief filed Jan. 30, 2003. In denying respondent's motion, the special master rejected this statutory interpretation, ruling that the 240-day period begins on the date that a Short Form Petition is filed. Stewart v. HHS, 2003 WL 22300298 (Fed. Cl. Spec. Mstr. Sept. 3, 2003). Having made this determination, the special master must now adhere to this decision and the clear implications that flow from it. That is, according to the Stewart decision, the "clock" for the resolution of cases has started running on Short Form Petitions. As such, the special master's statutory charge is to conduct proceedings so that each of these cases is resolved in 240 days.

conducted in these proceedings, with the discovery period's termination, the cases are ripe to resume scheduling consistent with the Vaccine Act's mandate for speedy resolution of petitions. See Respondent's Response to Petitioners' Motion to Compel filed May 14, 2004. Adopting the instant proposal of the steering committee would fail to accomplish this charge. The proposal requests that the due date for petitioners' expert reports be extended for over a year. This extension alone - not even accounting for the three years that passed since the issuance of Autism General Order #1 - is at least 160 days beyond the time period which the Act allows for the conduct of an entire case. To adopt a scheduling proposal that is so contrary to the strictures of the Act itself would be an unlawful extension of the special master's Vaccine Act authority.

As much to the point, moreover, the substance of this proposal amounts to nothing other than a motion to suspend proceedings for at least 400 days. Again, not even accounting for the three years that passed since the issuance of Autism General Order #1, such a suspension exceeds the statutorily prescribed limit for a suspension of proceedings by over 200 days. The Act's prohibition of such a lengthy extension is plain:

> In conducting a proceeding on a petition a special master shall suspend the proceedings **one time for 30 days** on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master

> determines the suspension is reasonable and necessary, **for an aggregate period not to exceed 150 days.**

42 U.S.C. § 300aa-12(d)(3)(C)(emphasis added).

It would be disingenuous to consider this request anything other than a suspension of proceedings. Petitioners' steering committee is seeking in plain terms a stay in their obligation to present their case because they deem it prudent for the special master to consider evidence that does not yet exist, i.e., ongoing autism research. Congress, under the terms of the Vaccine Act as quoted above, put strict time limitations on the amount of time a special master may provide Vaccine Act litigants. Indeed, the provision is quite detailed in its directives, requiring that the special master grant a 30-day suspension on the motion of either party without regard to cause. When either party seeks suspension beyond the 30-day period, Congress authorized the special master to consider further suspension up to a limit of 150 additional days. When this amount of suspension time is at issue, moreover, Congress required a showing of good cause for the stay, i.e., that the suspension is "reasonable and necessary." Beyond these measured amounts of time, however, Congress stripped the special master of the authority to suspend proceedings, directing that the aggregate period of suspension, even with good cause, is "not to exceed 150 days."

Whatever the motivation behind Congress's directive in this

regard, and indeed, whether Congress even contemplated the situation at present are of no matter to the special master's consideration of the issue because the statutory limitation is clear. That is, even assuming that the "state of the science" on the broad issue of vaccines and autism will develop as outlined in petitioners' filing, Congress denied the special master the authority to delay the proceedings to accommodate such scientific development. In doing so, Congress itself effectively determined where the balance falls between swift moving cases and the risk that Vaccine Act legal proceedings might "get ahead of the science." Congress struck that balance at an aggregate period of 180 days and no more.[4] Accordingly, the special master is without Vaccine Act authority even to consider a suspension for

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[4] The 180-day time limitation for suspensions of proceedings is a guidepost that the special master simply cannot ignore, for without adhering to this express direction, it would be difficult to conceive of any justifiable stopping point in the foreseeable future. Currently, petitioners' steering committee suggests that the state of the science may be at a sufficient point to warrant consideration of the pending claims in about September 2006. However, the steering committee themselves reference studies that are not even scheduled to be completed until after September 2006. Furthermore, the ongoing research, as well as recently completed research could certainly lead to other research deemed to be as important and as relevant as those described here -- even assuming that the estimated time for completion of the studies remains accurate and their own completion does not extend beyond September 2006. Indeed, if the arguments raised by petitioners' steering committee with respect to the state of the science are deemed to be good cause for suspension, the requests for continued suspension from either side could be indefinite. The Act includes a 180-day limitation for a suspension of proceedings precisely to prohibit such an outcome.

the amount of time requested, and petitioner's proposal must be rejected.[5]

To date, motivating the special master's accommodation for delay has been deference to the steering committee's litigation strategies. See, e.g., In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2004 WL 1660351, at *17 (Fed. Cl. Spec. Mstr. July 16, 2004)(Ruling Concerning Motion For Discovery From Merck Re MMR Vaccine). Reasoning that the Act's fast-paced scheme is to benefit petitioners, the special master has thus far

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[5] The Vaccine Act itself does not reveal the extent to which Congress contemplated a scientific backdrop such as petitioners' steering committee describes in their filing. Nevertheless, the Act implicitly recognizes that the merits of a petitioner's case may change with developing science, yet Congress still did not allow for an extended stay of proceedings due to the state of scientific research. Rather, to accommodate this situation, under 42 U.S.C. § 300aa-16, notwithstanding whether an individual unsuccessfully sought Vaccine Act relief before, a petition may be filed:

> If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining such compensation.

42 U.S.C. § 300aa-16(b).

Accordingly, Congress determined that if scientific research were to demonstrate that a current non-Table Injury, such as autism, were caused by covered vaccines, and if the condition were added to the Vaccine Injury Table, Congress gave unsuccessful petitioners another opportunity to seek relief under the statute. Congress did not, however, accommodate this situation by allowing claims to remain pending until the research is completed.

deemed it appropriate to allow a slower pace at the steering committee's request. In these circumstances, however, applying this motivation would misconstrue the role of the special master and attribute to him authority not granted by the limited jurisdiction he is given through the Act.[6]

Requiring petitioners to adhere to the Act's time limitations is entirely consistent with a limited waiver of sovereign immunity. See, generally, Brice v. HHS, 240 F.3d 1467 (Fed. Cir. 2001)(holding that the statutory period for bringing claim was not subject to equitable tolling, as limitations period was part of detailed statutory scheme that included other strict deadlines). Indeed, it is well settled that a Vaccine Act petitioner must meet the strict time requirements for filing a petition even if relaxing the deadline would arguably enure to a

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[6] The unfortunate fact, as noted by the special master, that "over the history of the Vaccine Act, many cases have taken longer to arrive at a final decision than the ideal 240-day period" is not a valid reason for granting the unlawful stay requested here. In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2004 WL 1660351, at *17 (Fed. Cl. Spec. Mstr. July 16, 2004)(Ruling Concerning Motion For Discovery From Merck Re MMR Vaccine). To be sure, circumstances in particular cases have made adherence to the strict time limitations difficult. Nevertheless, the special master cannot schedule these future proceedings in complete disregard of the time limitations, altogether ignoring his statutory obligation to facilitate the speedy resolution of these cases, in reliance on the fact that in other cases the charge for efficiency has not been met. Furthermore, the derogation of these statutory mandates is of particular concern in the Autism Omnibus Proceedings because any effort to meet the Acts time limits was abandoned from the outset by Autism General Order #1.

particular petitioner's benefit. 42 U.S.C. § 300aa-16; Brice, 240 F.3d at 1373 (rejecting the argument that the Vaccine Act's "benevolent framework" justifies equitable tolling). It is similarly well settled that a Vaccine Act petitioner must meet the time requirements for seeking review of a special master's decision, even when the consequences of these limitations disfavor petitioners. 42 U.S.C. § 300aa-12(e)(1); see Widdoss v. HHS, 989 F.2d 1170 (Fed. Cir. 1993)(affirming Court of Federal Claims dismissal of appeal because petitioner moved for review one day late).

Furthermore, it cannot be argued that the Act's limitations on suspending proceedings, in that it references either party, was crafted to enure entirely to petitioners' benefit. It simply does not make special accommodation for the particular desires of petitioners in this regard, nor does it encourage considerations of what amounts to petitioners' "litigation strategy."

Clearly, in 42 U.S.C. § 300aa-12(d)(3)(C), Congress did not give leeway for petitioners to request a lengthier extension, although it could have. This structure is in keeping with the intent of the Act to serve as a forum for efficient, speedy case resolutions. It is also in keeping with the specific time limitations imposed on the special master for the processing of the cases. Congress simply did not allow for the special master to disregard the time deadlines at the request of one party. In any event, notwithstanding the consistency of the Act's scheme,

the special master here need not even consider Congressional intent with the directive so plain and the prohibition on the requested extension so clear.[7]

CONCLUSION

The instant effort of petitioners' steering committee is an attempt to twist the Vaccine Injury Compensation Program to function in a manner that they may deem more suitable for their particular litigation needs but for which it was clearly never designed. The scheme of the Act is deliberate and its time constraints are clear. The special masters have been tasked with conducting proceedings that adhere to these time restrictions and resolving cases brought into the Program quickly. While it may be the case that individuals, including petitioners' steering committee, believe the Vaccine Act in its present form does not serve their particular interests well, the fact remains that all involved must adhere to its limits and work within its scheme.

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[7] In addition to arguing for a suspension of proceedings on the grounds of developing science, petitioner's steering committee also suggests that certain cases on appeal to the Federal Circuit warrant a stay. As argued throughout, to the extent the special master considers pending appeals to constitute good cause, he may only stay the proceedings pursuant to 42 U.S.C. § 300aa-12(d)(3)(C) for a total of 180 days. In any event, however, the appealed issues should not be deemed good cause to suspend the proceedings at this point in these proceedings. The medical experts need not be mindful of a legal causation standard when determining whether a particular vaccine caused a particular condition in a specific case to a reasonable degree of medical probability. That is to say, there is no valid reason that a medical expert's opinion on causation should be affected by a legal ruling.

Petitioners, respondent, and the special master have no choice but to follow the Act as written. For this reason, petitioners' steering committee must be ordered to file promptly an expert report and should be required to file the report in a particular case that would enable the special master to issue a causation decision in a specific factual context, which is the manner in which the Act was designed to function.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this 12th day of July, 2005, a copy of **RESPONDENT'S RESPONSE TO PETITIONERS' FILING RE: SUBMISSION OF EXPERT REPORTS IN SUPPORT OF GENERAL CAUSATION** was served, by prepaid overnight delivery, upon:

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