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United States Court of Federal Claims, Office of the 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.

July 3, 2002.

AUTISM MASTER FILE

GOLKIEWICZ, Chief J.

To be published

AUTISM GENERAL ORDER # 1

A. Background

*1 This Autism General Order # 1 is being issued by the Office of Special Masters (“OSM”), to address an unusual situation facing the National Vaccine Injury Compensation Program (“Program.”) [FN1](#) This situation arises out of concern in recent years that certain childhood vaccinations might be causing or contributing to an apparent increase in the diagnosis of a type of serious neurodevelopmental disorder known as “autism spectrum disorder,” or “autism” for short. [FN2](#) Specifically, it has been alleged that cases of autism, or neurodevelopmental disorders similar to autism, may be caused by Measles-Mumps-Rubella (“MMR”) vaccinations; by the “thimerosal” ingredient contained in certain Diphtheria-Tetanus-Pertussis (“DTP”), Diphtheria-Tetanus-acellar Pertussis (“DTaP”), Hepatitis B, and Hemophilus Influenza Type B (“HIB”) vaccinations; or by some combination of the two.

[FN1](#). The applicable statutory provisions defining the Program are found at [42 U.S.C. § 300aa-10 et seq. \(2000\)](#). Hereinafter, for ease of citation, all “ § ” references will be to 42 U.S.C. § 300aa (2000).

[FN2](#). An autism spectrum disorder is a brain disorder affecting a person's ability to communicate, form relationships, and/or respond appropriately to the environment. Such disorders sometimes result in death. The “spectrum” of such disorders includes relatively high-functioning persons with speech and language intact, as well as persons who are mentally retarded, mute, or with serious language delays. Symptoms may include, but are not limited to, avoidance of eye contact, seeming “deafness,” abrupt loss of language, unawareness of environment, physical abusiveness, inaccessibility, fixation, bizarre behavior, “flapping,” repetitive and/or obsessive behavior, insensitivity to pain, social withdrawal, and extreme sensitivity to sounds, textures, tastes, smells, and light. National Institute of Mental Health, Publication 97-4023.

To date, over 400 cases alleging a causal relationship between such vaccinations and autism disorders have been filed in this court; more than 300 of those cases have been filed in the past six months. Moreover, numerous civil lawsuits against vaccine manufacturers, alleging that the thimerosal ingredient caused autism, have been filed in courts around the country. One recent ruling in such a suit determined as a matter of law that such claims of vaccinees against vaccine manufacturers must be dismissed and brought to this court as Program claims. See [Owens v. American Home Products Corp., 2002 WL 992094 \(S.D.Tex. May 7, 2002\)](#).

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As a result of the influx of Program claims and the potential for many more such claims, the OSM has held a series of meetings with an informal advisory committee to address the task of dealing with these claims. This committee consisted of petitioners' counsel who represent many such current and potential Program claimants, along with legal and medical representatives of the Secretary of Health and Human Services. (*See Ex. C* for a list of the participants in that advisory committee.) The participating petitioners' counsel, who are in contact with many other petitioners' counsel, have estimated that due to the *Owens* decision, approximately 3,000 to 5,000 such Program petitions (or possibly even more) are likely to be filed with this court during the next several months.

Processing such a large number of cases will stretch thinly the resources of both the court and the bar. It is in the interests of all that the court aggressively, but fairly, manage this docket to ensure a timely presentation and resolution of the difficult medical and legal issues raised in these cases. This Autism General Order # 1 and the procedure detailed herein resulted from extensive discussions with the parties' representatives, and from the special masters' experience in handling other groups of cases presenting common issues. The court is confident that this procedure, coupled with the cooperative efforts and quality advocacy of counsel, will provide the necessary information for resolving these cases, within a reasonable time frame.

*2 During the advisory committee meetings, petitioners' representatives proposed a timetable for resolving the general causation issues involved in these cases which extended well over two years. In response, the OSM established one overriding principle governing all suggestions, proposals, and requests-the OSM's decision on the causation issues shall be rendered within two years after the filing of this General Order. The OSM's subsequently adopted procedure and schedule contained herein are designed to meet that two-year time frame.

B. Proposal of petitioners' representatives

Autism cases are not new to the court; a number have been pending for several years. However, in those pending cases, petitioners' counsel continue to request more time for the science to crystalize, to obtain experts, and in general to prepare their proof concerning the difficult medical and legal causation issues. Similarly, in the advisory committee discussions described above, petitioners' representatives have stated that they are not prepared to present their causation case at this time. Rather, petitioners request extensive discovery-documents, studies, and raw data from government agencies and possibly vaccine manufacturers-information relevant to the general causation issues, through this court's discovery process.

Accordingly, petitioners' representatives in the advisory committee meetings have proposed a general procedure by which the OSM could process the claims described above, both those already filed and those about to be filed. They propose that the OSM utilize a two-step procedure: first, conduct an inquiry into the *general causation issues* involved in these cases-*i.e.*, whether the vaccinations in question can cause autism and/or similar disorders, and if so in what circumstances; and then, second, apply the conclusions reached in that general inquiry to the individual cases. They propose that the OSM establish an "Autism Master File" with respect to the general causation issues, which would be open to inspection by any interested persons, and which would constitute an evidentiary record with respect to the general causation issues. They propose that a team of petitioners' lawyers be selected to represent the interests of all petitioners in these autism cases during the course of this general causation inquiry. They propose that the proceeding begin with a lengthy period of discovery concerning the general causation issues, followed by a designation of experts for each side, an evidentiary hearing, and a ruling on the general causation issues. Finally, the special master's determination on the general causation issues would be applied to the individual cases.

During the meetings of the informal advisory group, respondent's representatives did not oppose petitioners' general plan, as set forth above, that the OSM conduct a general inquiry into the causation question, then apply the conclusions reached in that inquiry to the individual cases.

C. Procedure adopted by the OSM

*3 After considering carefully the practical and thoughtful advice from petitioners' and respondent's representatives presented during the meetings of the advisory committee, the OSM responds to the challenge presented by this influx of cases with the following procedures.

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First, the OSM adopts the general approach to these cases suggested by the participants in the informal advisory committee. That is, the OSM will utilize a two-step procedure: First, the OSM will inquire into the *general causation issues* involved in these cases-*i.e.*, whether the vaccinations in question can cause autism and/or similar disorders, and if so in what circumstances; and then, second, the conclusions reached in that general inquiry will be applied to the individual cases. As proposed, the OSM will authorize a team of attorneys to represent the interests of all petitioners in these autism cases during the course of this general causation inquiry, which is officially entitled the "Omnibus Autism Proceeding." The inquiry will proceed as generally proposed by petitioners' attorneys-*i.e.*, a period for any court-approved discovery concerning the general causation issues, followed by a designation of experts for each side, an evidentiary hearing, and finally a special master's ruling on the general causation issues. Subsequently, the general causation conclusions will be applied to the individual cases.

The court will, as proposed, establish an "Autism Master File" with respect to the general causation issues involved in these cases. That file will be open to inspection by any interested persons, and will constitute an evidentiary record with respect to the general causation issues. All evidence relevant to the general causation issues, including transcripts of any evidentiary hearings, will be placed into that file. The first documents placed into that master file will be this Autism General Order # 1 and the attachments hereto.

In accordance with § 300aa-12(d)(1), the Chief Special Master hereby designates Special Master George Hastings to preside over the Omnibus Autism Proceeding, and to make any necessary rulings on the general causation issues.

Representing the interests of petitioners in the Omnibus Autism Proceeding will be a Petitioners' Steering Committee. This committee will be comprised of counsel who are representing Program petitioners in autism cases. Currently, the vast majority of pending Program autism cases have been filed by a small number of law firms. The OSM invited attorneys from those firms to participate in the informal advisory committee described above. Those counsel have organized the initial Petitioners' Steering Committee, whose members are set forth at Ex. D to this Order. Other counsel who are interested in serving on the Steering Committee may contact the members of that committee to express their interest. The OSM believes that membership on the Steering Committee should be determined by petitioners' counsel, interacting among themselves. The Committee shall keep the presiding special master apprised, however, of changes in its membership. The Committee shall designate two attorneys as "lead counsel," authorized to sign and file documents on behalf of the Committee into the Autism Master File, and to represent the Committee at status conferences. In the unlikely event that disputes arise as to the Committee membership, the presiding special master shall be informed immediately and will resolve any issues.

*4 Similarly, respondent shall designate two "lead counsel" for respondent in the Omnibus Autism Proceeding, who will be authorized to file documents on behalf of respondent into the Autism Master File, and to represent respondent at status conferences.

When either "party" to the Omnibus Autism Proceeding-*i.e.*, the Petitioners' Steering Committee or respondent-files documents into the Autism Master File, if the document is less than 20 pages, the party shall file an original and two copies. For documents of 20 or more pages, an original and one copy will suffice. By rule, the Clerk of the Court will file the original in the Autism Master File and send the copy or copies to the presiding special master. Unless requested, separate mailings to the presiding special master are unnecessary. The Steering Committee will serve a copy of each filed document on each of the two designated lead counsel for respondent. The respondent will serve a copy of each filed document on each member of the Steering Committee.

Attached to this General Order as Exhibit A is the "Master Autism Petition for Vaccine Compensation" ("Master Petition"). This document was drafted and presented to the OSM by the Petitioners' Steering Committee. It sets forth the general allegation that a vaccinee's autistic disorder or similar disorder was caused by one or more of the MMR and thimerosal-containing vaccinations. It provides that any Program petitioner filing a "Short-Form Autism Petition for Vaccine Compensation," in a form similar to that set forth as Exhibit B to this General Order, represents that such petitioner's claim meets the criteria set forth in the Master Petition. As will be detailed below, by filing such a short-form petition, a petitioner will elect into the Omnibus Autism Proceeding, and simultaneously opt to stay case-specific proceedings on his own petition until the conclusion of the Omnibus Autism Proceeding.

D. *The Autism Master Schedule*

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To meet the court's self-imposed two-year timetable for decision, the Omnibus Autism Proceeding will be conducted according to an Autism Master Schedule, appended to this General Order as Exhibit E. This schedule has been determined through cooperative discussions at the advisory committee meetings. Petitioners' representatives proposed the first draft of the schedule. They proposed a schedule covering two years, from issuance of an initial General Order (*i.e.*, this Order) until the date of an evidentiary hearing on the general causation issues, with an additional unspecified period of time obviously needed for the presiding special master to analyze the evidence introduced at the hearing and produce a written opinion. In that proposed schedule, essentially 470 of the 730 days in the two-year period were devoted to the discovery process. The first proposal extended beyond two years and thus was rejected by the OSM. After discussion, petitioners submitted a revised schedule which shortened the discovery period to 410 days, moved the hearing date up, and built in sufficient time to decide the causation issues within the two-year period. This second proposal is adopted, with slight modifications and three observations.

***5** First, and foremost, the OSM expects that the parties will act promptly and vigorously to *adhere* to this schedule, if not move more quickly. Because the interests of thousands of petitioners are affected, the presiding special master will be disinclined to allow the Omnibus Autism Proceeding to slip behind schedule. In fact, the OSM and the presiding special master will strictly manage these proceedings in an effort to resolve the causation issues in less than the allotted two-year time period.

Second, the OSM recognizes that two years is a relatively long time to ask petitioners to wait for a ruling on the general causation issues. Congress clearly envisioned rulings on Program petitions rendered in a much shorter time frame. However, the short decision-making time periods provided in the Program statute were obviously based upon the assumption that most Program claims would present far different issues than those presented in these autism cases. The assumption clearly was that in most Program cases the question for the special master would simply be whether petitioner's case fit within one of the "Table Injury" categories set forth at § 300aa-14(a). It was also assumed that even in those relatively few cases where no Table Injury was alleged and a petitioner attempted to prove that the vaccine "actually caused" an injury, the petitioner would file *along with his petition* all of his proof concerning the causation issue, including a report from an expert supporting the claim. In contrast, in these autism claims petitioners have requested a period of 500 days from now-almost a year-and-one-half-before filing expert reports explaining and supporting their theory of causation. These reports will follow a lengthy discovery period of a type clearly never envisioned by Congress. However, it is clear to the OSM that the reality of the difficult medical issues involved and the stringent legal standards applied to causation cases justifies petitioners' request for a reasonable discovery opportunity and the extended time for filing expert reports. Unfortunately, resolution of the general causation inquiry must await longer than Congress envisioned and the OSM would ideally wish; but it is clear to all involved that without the requested extended time frames, petitioners would be unable to prosecute their claims. In this instance, quick justice would mean no justice.

Third, the above pages have referenced the "general causation issues." The OSM recognizes that the Omnibus Autism Proceeding is in its earliest phase. While petitioners' representatives have mentioned multiple potential theories of causation, until discovery is completed and expert reports are filed it will not be known whether one or more causation theories are at issue. As noted above, there have been suggestions that autistic disorders can be caused by (1) MMR vaccinations; (2) the thimerosal component of the DTP, DTaP, Hepatitis B, and HIB vaccinations; and/or (3) a combination of (1) and (2). Accordingly, the presiding special master, working with the parties' representatives, will decide at a later date the most efficient procedure for resolving the causation issues, depending upon the development of the causation theories put forth by Petitioners' Steering Committee.

E. Opting into, or out of, the Omnibus Autism Proceeding

***6** All persons with pending petitions or potential Program claims involving an autistic or autistic-like disorder should assess their own cases in light of the Omnibus Autism Proceeding. Many petitioners with pending claims have already requested and have been granted stays in their own cases until the conclusion of the Omnibus Proceeding. [FN3](#) The presiding special master will conduct no case-specific proceedings in those "stayed" cases until the conclusion of the Omnibus Proceeding, unless otherwise requested by a party. The OSM will keep all petitioners or their counsel updated as to the progress of the Omnibus Proceeding. After the Omnibus Proceeding is concluded by the special master's ruling concerning the general causation issues, the individual cases will then be addressed. If the ruling on the general causation issues appears favorable to

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an individual petitioner's case, the petitioner will be ordered to demonstrate that his or her case qualifies for compensation under the general ruling, and proceed to a damages determination. If the general ruling, on the other hand, appears unfavorable to an individual petitioner's case, then the petitioner will be given the opportunity to introduce additional supportive case-specific evidence, including expert reports, or to dismiss the case for want of proof. The court will determine how to process individual cases, following the resolution of the general causation issues, only after ample time and opportunity is granted to each petitioner to review the evidence from the Omnibus Proceeding, to consult with counsel and medical experts, and then to make a reasoned choice.

[FN3](#). Such cases will be officially transferred from the docket of the originally-assigned special master to the docket of Special Master Hastings, the special master presiding over the Omnibus Autism Proceeding.

Any petitioner with a *pending* autism-related claim, who has not yet requested to have proceedings in his own case stayed for the duration of the Omnibus Autism Proceeding, may do so simply by filing a Notice to Stay Proceedings, similar to that contained at Ex. F to this General Order. Once that is done, no case-specific proceedings will be held in that case until further notice, and that case will be treated as described in the previous paragraph.

Persons who have autism-related claims for which they have *not yet filed* Program petitions, and who wish to have their cases stayed during the Omnibus Autism Proceeding, may file their petitions by filing a "Short-Form Autism Petition for Vaccine Compensation" in a form similar to the one set forth as Ex. B to this General Order. [FN4](#) No medical records need be filed with such a short-form petition, though each petitioner or his counsel is encouraged to assemble, organize, and keep all relevant medical records so that they will be available for filing if, and when, the petitioner is directed to do so by the special master. Once such a short-form petition is filed, no case-specific proceedings will be held in the case during the course of the Omnibus Autism Proceeding, and the case will be treated as described above.

[FN4](#). The OSM acknowledges that respondent opposes the use of a short-form petition. The court's reasoning on this topic will be set forth in a separate document.

One important caveat, however, is drawn to the attention of all petitioners and their counsel! There may be cases involving autistic-like disorders which manifested following an injury defined in the Vaccine Injury Table. That is, a vaccinee may have suffered an episode involving a severe acute encephalopathy within 72 hours after a pertussis vaccination (DTP or DTaP), or 5 to 15 days after an MMR vaccination. If so, such an acute encephalopathy and any residual effects thereof would be *presumed* to be vaccine-caused pursuant to the Vaccine Injury Table. See [42 C.F.R. § 100.3\(a\)](#) (10-1-97 version of CFR). [FN5](#) However, this would apply only to cases falling within the current Vaccine Injury Table's definition of "acute encephalopathy," in which the vaccinee suffered a sudden, dramatic, and severe change in level of consciousness lasting at least 24 hours. [42 C.F.R. § 100.3\(b\)\(2\)\(i\)\(A\) and \(D\)](#). The incident must have been "sufficiently severe so as to require hospitalization," though actual hospitalization at the time need not have occurred. [42 C.F.R. § 100.3\(b\)\(2\)\(i\)](#). Autism cases involving Table Injuries have been compensated under the Program. If in a particular case there exist medical records demonstrating that such a qualifying "acute encephalopathy" occurred within the appropriate time frame, petitioner or counsel should bring that to the assigned special master's attention so that, if appropriate, the case can be processed without delay as a Table Injury.

[FN5](#). Note that the Vaccine Injury Table contained in the statute at § 300aa-14(a) is *not* applicable to Program petitions filed since March 10, 1995. For any petition filed on or after March 24, 1997, the applicable Vaccine Injury Table is found at [42 C.F.R. § 100.3 \(1997\)](#).

*7 Finally, petitioners should note that even after electing to have their case stayed pending the conclusion of the Omnibus Autism Proceeding, such election is not irrevocable. That is, if at a future time a petitioner determines that his own case should be separated from the Omnibus Autism Proceeding and processed separately, with the petitioner introducing case-specific proof of causation, such petitioner may request that a special master analyze his case. A special master will be assigned and the case will be processed as expeditiously as possible.

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F. *Obtaining Information About the Progress of the Omnibus Autism Proceeding*

As noted above, during the course of the Omnibus Autism Proceeding, the individual autism cases will be stayed, with no case-specific proceedings conducted. During that time, however, the OSM will keep the petitioners in such cases well informed as to the progress of the Omnibus Autism Proceeding, by two devices.

First, the OSM from time-to-time will issue additional Autism General Orders detailing the progress of the Omnibus Autism Proceeding. Such general orders will be sent to all counsel, or petitioners appearing *pro se*, in autism cases.

Secondly, a specific page on this court's internet website will be devoted to the Omnibus Autism Proceeding. Relevant filed documents and periodic updates regarding the proceedings will be posted on that site. This page may be accessed by logging onto this court's website at www.uscfc.uscourts.gov, then clicking on the "Special Masters" icon.

G. *Conclusion*

The Office of Special Masters is determined to process these autism petitions as swiftly and efficiently as possible, while giving all interested parties a fair opportunity to present their claims and evidence. We appreciate the assistance of all petitioners, petitioners' counsel, and respondent's representatives in this challenging endeavor.

MASTER AUTISM PETITION FOR VACCINE COMPENSATION

Pursuant to the Autism General Order # 1 issued by the Office of Special Masters of this Court on July 3, 2002, this Master Autism Petition for Vaccine Compensation is hereby placed into the Omnibus Autism Master File created in the Office of the Clerk of this Court. As detailed in that Autism General Order # 1, any petitioner desiring that his or her Vaccine Act claim be processed along with the other "Omnibus Autism" cases may file a "Short-Form Autism Petition for Vaccine Compensation" similar to that contained at Ex. B to the Autism General Order # 1. Any petitioner who files such a short-form petition will be deemed to be representing that such petitioner's own particular claim meets the following criteria:

1. The petitioner alleges a vaccine-related injury and/or death, and requests compensation under the National Vaccine Injury Compensation Program, codified at [42 U.S.C. § 300aa-10 et seq. \(Supp.1996\)](#).
2. No civil action against a vaccine manufacturer or administrator for the vaccine-related injury or death alleged by the petitioner is pending. No person has previously collected an award or settlement of a civil action for damages for the vaccine-related injury or death being claimed.
- *8 3. As a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the vaccinee in question has developed a neurodevelopmental disorder, consisting of an Autism Spectrum Disorder [FN*](#) or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the "thimerosal" ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza Type B(HIB) vaccinations; or by some combination of the two.

[FN*](#) An autism spectrum disorder is a brain disorder affecting the petitioner's ability to communicate, form relationships, and/or respond appropriately to the environment. Such disorders sometimes result in death. The "spectrum" of such disorders includes relatively high-functioning persons with speech and language intact, as well as persons who are mentally retarded, mute, or with serious language delays. Symptoms may include, but are not limited to, avoidance of eye contact, seeming "deafness," abrupt loss of language, unawareness of environment, physical abusiveness, inaccessibility, fixation, bizarre behavior, "flapping," repetitive and/or obsessive behavior, insensitivity to pain, social withdrawal, and extreme sensitivity to sounds, textures, tastes, smells, and light. National Institute of Mental Health, Publication 97-4023.

4. The vaccinee received the vaccination or vaccinations in question in the United States, or otherwise in compliance with [42 U.S.C. § 300aa-11\(c\)\(1\)\(B\)](#).
5. The petition is being filed within three years after the first symptom of the disorder, or within three years after the first symptom of a vaccine-caused significant aggravation of the disorder. (If the vaccine-related death is alleged, the petition is

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being filed within two years after the date of death and no later than 48 months after onset of the injury from which death resulted.)

6. The vaccine-related injury either has persisted for more than six months or resulted in death.

Therefore, by filing a "Short-Form Autism Petition for Vaccine Compensation," a petitioner will be deemed to be seeking an award under the National Vaccine Injury Compensation Program. Such a petitioner will be deemed to have deferred specific compensation demands, pursuant to [42 U.S.C. § 300aa-11\(e\)](#), until the issue of entitlement to compensation is determined.

EXHIBIT B

Special Master [_____]

SHORT-FORM AUTISM PETITION FOR VACCINE COMPENSATION

The petitioners, on behalf of their minor child, hereby petition for compensation under the National Vaccine Injury Compensation Program, and adopt the MASTER AUTISM PETITION FOR VACCINE COMPENSATION.

Sign:

Date

Print Name:

Address:

City, State, Zip:

Phone Number:

Fax Number:

Check One:

Attorney

Pro Se

CERTIFICATE OF SERVICE

I hereby certify that a copy of the attached Autism Petition for Vaccine Compensation was sent by First Class or Certified Mail on _____, to:

Secretary of Health and Human Services
c/o Director, Bureau of Health Professions
5600 Fishers Lane, Suite 8-05
Rockville, MD 20857

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Signature of person mailing Petition

EXHIBIT C

AUTISM ADVISORY COMMITTEE PARTICIPANTS

Participants from the Office of Special Masters

Chief Special Master Gary Golkiewicz

Special Master George Hastings

Special Master John Edwards

Petitioners' Counsel Participants

Clifford Shoemaker

Ghada A. Anis

SHOEMAKER & ASSOCIATES

Vienna, VA

Jeff Thompson

WILLIAMS BAILEY, L.L.P.

Houston, TX

John Kim

GALLAGHER, LEWIS, DOWNEY & KIM

*9 Houston, TX

Ben C. Martin

LAW OFFICES OF BEN C. MARTIN

Dallas, TX

Ronald Homer

Kevin Conway

CONWAY, HOMER & CHIN-CAPLAN, P.C.

Boston, MA

Participants Representing Respondent

Mark Raby

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Vince Matanoski

U.S. Department of Justice

Fed.Cl.,2002.

In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder

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