

Failure to Provide Informed Consent for Vaccination and/or Failure to Provide Proper Care for Vaccine Reactions: How to File a Complaint with the Medical Board

If you and your child (or children) were not given proper informed consent, or were treated unethically, improperly, or unprofessionally surrounding the issue of vaccination and vaccine reactions, you have the right to file a complaint with your state medical board*. Informed Consent in medicine is a basic human right for every person, and according to the American Medical Association, an ethical requirement for every physician.

*There are statutes of limitation for filing a complaint; this varies from state to state. In CA, complaints must be filed within 10 years after a child reaches adulthood, or around age 28. For adults, a complaint must be filed within about 6 years of when the negligence occurred.

There are two main areas of complaint:

1. Failure to provide proper informed consent with a thorough discussion of the risks and benefits *prior* to vaccination, which applies to most vaccinated people
 2. Failure to provide proper care *after* a patient suffers a moderate to severe vaccine reaction, which applies to some vaccinated people
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PART 1

FAILURE TO PROVIDE INFORMED CONSENT AND EXPLAIN THE RISK OF VACCINATION

- A. The United Nations Universal Declaration on Bioethics and Human Rights, adopted by 193 countries including the United States, states: “Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information” ([Article 6](#)). While it may not currently be a legal obligation in some states (like California), doctors are *ethically* required to discuss the risks and benefits of all medical treatments and procedures, including vaccination. **If your doctor failed to discuss the full risks of vaccination as directed by the vaccine Package Inserts (PIs) and explain the risks mandated by federal law prior to giving vaccines, then you did not receive Informed Consent.** All vaccine manufacturers provide Package Inserts (PIs) which detail ingredients, instructions, and warnings for the vaccine. Most PIs also contain explicit instructions for doctors in the Patient Counseling section. (*Note: language may vary; the following example is from the Daptacel brand of DTaP*):

Inform the parent or guardian of the following:

- *The potential benefits and risks of immunization with Daptacel*
- *The common adverse reactions that have occurred following administration of Daptacel or other vaccine containing similar components.*
- *Other adverse reactions can occur. Call healthcare provider with any adverse reactions of concern.*

Physicians are required by federal law (National Childhood Vaccine Injury Act of 1986) to give parents the CDC Vaccine Information Statements (VIS forms) prior to vaccination. These forms are usually given immediately before, or sometimes not until after, vaccination as a way of informing the patient. However, the CDC admits [here](#) that these forms are **not** providing Informed

Consent: "VISs are written to fulfill the information requirements of the National Childhood Vaccine Injury Act, not as informed consent forms." And if your doctor failed to give you adequate time to read the material, ask if you understood the material, or give you the opportunity to ask questions about the information, then you **were not properly informed**. VIS forms only provide limited information and do not include the more detailed warnings and risks from the manufacturers found in the Package Inserts. Many vaccine PI's provide the following instructions to doctors (*language varies*):

"Before administration of [particular vaccine], health care providers should inform the parent or guardian of the benefits and risks of the vaccine...The health care provider should inform the parent or guardian about the potential for adverse reactions that have been temporally associated with the vaccine and other vaccines containing similar components." (Patient Counseling Section of Act-HIB brand by Sanofi Pasteur, Pediarix brand of DTaP/Polio/HepB vaccine, Infanrix brand of DTaP vaccine by Glaxo Smith Kline, and Vaqta brand of Hepatitis A vaccine by Merck).

Temporally-associated adverse reactions are not included in the CDC VIS forms, and patients remain uninformed about these risks. The list for such reactions can be quite extensive and is specific to each vaccine.

Additionally, manufacturers of some vaccines advise doctors to **ask patients about adverse reactions to previous vaccines prior to giving these vaccines**:

The Varicella PI states in the Patient Counseling Section (page 12):

"Question the patient, parent, or guardian about reactions to previous vaccines."

The Recombivax HB brand of Hep B vaccine and Vaqta brand of Hep A vaccine state in the Patient Counseling Section:

"Question the vaccine recipient, parent or guardian about the occurrence of any symptoms and/or signs of adverse reaction after a previous dose of hepatitis B (or Hep A) vaccine."

If your doctor or an office staff member failed to ask about reactions to any prior vaccines before giving doses of Varicella vaccine, Hepatitis A vaccine, or Hepatitis B vaccine, then proper procedure and precautions as recommended by the vaccine manufacturer were not followed and your child was potentially put at risk.

- B. If your child was given the MMR II vaccine, there are some additional consent steps required prior to administration. The MMR II vaccine PI has a separate Patient Information form that states:

"You should read it before you or your child receives the vaccine. If you have any questions about the vaccine after reading this leaflet, you should ask your health care provider. This is a summary only. It does not take the place of talking about MMR II with your doctor, nurse, or other health care provider."

The MMR II Patient Counseling form also lists some warnings about who should not get the MMR vaccine, including teens/adults who are pregnant or plan to get pregnant within the *next three months* (this live virus vaccine can cause birth defects). The doctor is also instructed to ask you about any of the following, as these can increase the risk of adverse reactions to the vaccine:

- *A history of seizures or a brain injury*
- *Active untreated tuberculosis*
- *An allergic reaction to any other vaccine*
- *A low platelet count*
- *Allergy to eggs (vaccination is still allowed, but a patient should be warned about the greater risk of an allergic reaction)*

Failure to allow you to read the MMR Patient Counseling form, ask questions, and discuss concerns with your doctor means that you did not receive Informed Consent.

C. There are three other unique circumstances that warrant extra informed consent. These specific risks are highlighted in the Warnings and Precautions section of these PIs:

- Those who are allergic to eggs: Not only is the MMR a risk, but the flu vaccine Package Insert clearly warns in the Patient Information Sheet that people who are allergic to eggs should not receive a flu vaccine (unless it is one of the new egg-free formulations).
- Infants born prematurely: all injected treatments, including vaccines, pose a higher risk of Apnea (stop-breathing spells) in infants who were born prematurely. Doctors are advised in most vaccine PIs to give careful consideration to a baby's medical status and risks versus benefits when vaccinating ex-premie babies.
- Infants with ongoing gastrointestinal disorders: the rotavirus vaccines (Rotarix and Rotateq) have specific warnings in the PIs against giving this oral vaccine to infants with active GI problems, including acute vomiting, acute or chronic diarrhea, failure to thrive, history of abdominal surgery, and any congenital abdominal defects.

PART 2

FAILURE TO PROVIDE PROPER CARE AFTER A VACCINE REACTION

- A. **Failure to evaluate your child in person after a significant reaction reported over the phone.** If you contacted your doctor's office over the phone regarding a moderate to severe vaccine reaction, and your doctor did not advise you to come into the office or go to an ER right away for an evaluation, then your doctor did not follow the warnings and instructions of the vaccine manufacturer. It is now more common for medical office staff to reassure parents over the phone that a vaccine reaction is "normal", "expected", and "not a cause for concern"; and they generally will not advise an in-person medical evaluation. This may be appropriate for mild reactions like fussiness, slight fever, and mild swelling and redness at the injection site. But all moderate to severe reactions, like hives, extreme lethargy or unresponsiveness, seizures, fever of 105 degrees, inconsolable crying lasting 3 or more hours or high pitched screaming (possible encephalitis), and sudden and extended changes in the child's behavior or personality warrant prompt in-person medical attention.
- B. **Failure to document adverse events following vaccination.** All adverse events that occur after vaccination are supposed to be documented in your child's medical record, regardless of whether or not your doctor or the medical staff personally believe the event was related to vaccination. The fact that your doctor does not agree that the reaction was related to vaccination does not release him or her from the responsibility to accurately document the adverse event in your child's medical record.

The American Medical Association's Principles of Medical Ethics (see link below) details a physician's ethical responsibility in two ways: First, to report adverse events in medical care, and second, that a physician *"need not be certain of, or does not need to even believe in a reasonable likelihood of, a causal relationship between a treatment and an adverse event"* in order to be ethically responsible to report that event. In fact, almost all vaccine Package Inserts advise physicians to *"instruct the patient, parent, or guardian to report any adverse reactions or any symptoms of concern to their healthcare professional."*

The polio vaccine PI (Sanofi Pasteur- IPOL brand) specifically says:

"Reporting by parents or guardians of all adverse events after vaccine administration should be encouraged. Adverse events following immunization with vaccine should be reported by healthcare providers to [VAERS]." Page 18, Reporting of Adverse Events

The HIB vaccine PI (Sanofi Pasteur- ActHIB brand) states:

"Vaccine recipients and guardians must report any adverse reactions upon administration of the vaccine to their healthcare provider..." Page 19

Unfortunately, many physicians do not document adverse reactions according to manufacturer and federal guidelines.

Example: an infant has an encephalitis-type reaction (inconsolable crying lasting 3 or more hours), and the parents report this reaction to the doctor, either by phone call, during an immediate return visit, or a subsequent check-up. The doctor, however, only documents "parents report that the baby was fussy after the last vaccines." In fact, encephalitis is listed as one of many potentially-severe reactions which are mandated by federal law to be reported to the government. (See VAERS reporting below).

A doctor's failure to document a vaccine reaction puts the child in danger of suffering a repeated or more severe reaction later under another doctor's care. Parents may not be informed enough to know that a reaction is moderate or severe, so it is the doctor's responsibility to make sure reactions are properly documented to facilitate accurate communication with future health care providers.

- C. **Failure to conduct and/or document a detailed neurologic exam after an adverse event.** Infants who suffer a neurological reaction, such as extreme lethargy, inconsolable crying for 3 or more hours (encephalitis), seizure, sudden loss of developmental skills, extreme personality changes, or any other reaction involving the nervous system should undergo a complete neurological exam by a physician to document their current neurological status and to check for neurological injury. Such symptoms should always be considered a potentially-serious medical problem because infection, trauma, brain tumor, stroke, medication overdose, accidental poisoning, and vaccination can all be potential causes of neurological injury. It is the duty of every physician to thoroughly evaluate such complaints regardless of the initially-suspected cause. Failure to take such symptoms seriously, perform an exam, or failure to document the findings of an exam, constitutes negligence on the part of the physician.
- D. **Failure to advise you to report the reaction to VAERS.** Vaccine manufacturer PI's recommend that physicians advise their patients to report adverse events following vaccination to www.vaers.hhs.gov. Doctors are also **mandated by law** to report certain severe adverse events. The VAERS reporting form states:

"Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization." (Page 1, in fine print)

These include anaphylaxis, brachial neuritis (dysfunction of the nerves in the arm), encephalopathy (brain injury), encephalitis (the most common of these mandatory reportable events after a Pertussis-containing vaccine or an MMR vaccine), chronic arthritis, thrombocytopenia purpura (bleeding complications), paralytic polio, or any events categorized as a contraindication listed in the manufacture's package insert. See below for a complete list of mandatory reportable events.

- E. Failure to inform you about the risk of repeated or worsened adverse reactions following a moderate to severe reaction.** In the Warnings and Precautions section of every Package Insert, vaccine manufacturers advise physicians to carefully consider the benefits and risks before administering a repeated vaccine after certain moderate to severe reactions have occurred. These reactions are different for each vaccine. For example, for the DTaP vaccine reactions include fever greater than or equal to 105 degrees F, collapse or shock-like state within 48 hours of a dose, persistent inconsolable crying lasting more than or equal to 3 hours within 48 hours of a dose, seizures with or without fever within 3 days, and history of Guillain-Barre syndrome (temporary muscle weakness/partial paralysis) within 6 weeks of a vaccine.

EXAMINING YOUR CHILD'S MEDICAL RECORDS

1. You have a legal right to view your minor child's medical records. Examine your child's medical records to determine what your doctor wrote in the chart about providing informed consent for vaccinations. See if your doctor documented that the CDC VIS forms were provided to you (usually in the check-up section or the section where all vaccines are recorded together). Also note whether or not your signature or initials are present next to such documentation. If there is no documentation that VIS forms were provided, and you have no recollection of being given these forms, then you should inform the medical board of these facts. It is common practice for electronic medical records to automatically include a statement saying that VIS forms were provided to the patient. If you are certain that this was not the case, then you should inform the medical board.
2. Read through the visits that involved a vaccine reaction. If you called the office about a reaction, confirm that this was documented accurately. If the doctor saw your child in person for the reaction, confirm that what the doctor wrote down matches your child's reaction and see if the doctor documented a neurological exam. If you reported the reaction to your doctor at the next check-up, confirm that what the doctor or nurse wrote down matches the information that you gave them. If the reaction was moderate or severe, did the doctor warn you about the risks of repeating that vaccine again during the next checkup? Then compare this written information to what you remember about your visits and your child's reaction. Report any discrepancies or missing information in your board complaint.
3. Find what brands of vaccines were given to your child so you can investigate the proper Package Inserts and attach them to your complaint. The medical record is required to either list the brand name of the vaccine or the manufacturer. If only the manufacturer is listed, you will still be able to find the right PI by looking on the [FDA website](#) and finding the one that matches the manufacturer listed in your medical records. If you aren't sure, you can contact your doctor's office and ask what brands of each vaccine they use. You may also see lot numbers of the vaccines given to your

child, and an online search of that vaccine and lot number should tell you what brand and manufacturer it is.

4. Send any pertinent pages from the medical record, with references to these pages in your complaint, to the medical board. You may write notes or highlight any part of the medical record to draw attention to these facts; the board will also obtain their own unmarked copy of the records directly from your doctor.

NOTE: You may submit a complaint without reviewing your medical records if your recollection of events is clear enough

SUBMIT YOUR COMPLAINT, WITH ALL SUPPORTING DOCUMENTS, TO YOUR STATE MEDICAL BOARD (hard copy preferred)

Find your specific medical board online and carefully read all instructions as you submit your complaint. Include copies of the pertinent pages of your child's medical record and any supporting documents listed below, such as the Vaccine PI Patient Counseling instructions and other sections, CDC VIS forms that you refer to in your complaint, VAERS information, the AMA statements on medical ethics and the statement of physician's duty from the National Childhood Vaccine Injury Act. Keep a photocopy of your entire file.

Note: while you can submit a medical board claim online, it may be more effective to send your claim as a hard copy.

The Medical Board of California website: <http://www.mbc.ca.gov>

Medical Board of California
Central Complaint Unit
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

For all other State Medical Boards: here is a link to the Federation of State Medical Boards directory of State Medical and Osteopathic Boards: <https://www.fsmb.org/policy/contacts>

SUPPORTING DOCUMENTS FOR YOUR COMPLAINT

Vaccine Package Inserts (PIs)

The FDA website lists the package insert for every vaccine licensed in the United States here: [FDA Listing of Package Inserts](#). Find the name brand of each vaccine your child was given on the right hand side of this list, click on the particular vaccine, and you will find a link to the PI. The following sections contain specific details on risks that should have been disclosed to you as part of your Informed Consent regarding vaccine reactions:

Patient Counseling Information, Adverse Reactions, Warnings and Precautions, Contraindications

National Childhood Vaccine Injury Act of 1986

This federal law mandates that patients be given VIS forms prior to vaccination, and the standard of care for informed consent is to allow patients time to understand and ask questions about these forms and about vaccines. The specific wording of this section of the law can be found here: [National Childhood Vaccine Injury Act](#), under section D, Health Care Provider Duties:

"Each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a) of this section, supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine."

For more information on the National Childhood Vaccine Injury Act, click [here](#).

VAERS (Vaccine Adverse Events Reporting System) Table of Reportable Events Following Vaccination

Visit the [VAERS website](#) for more information on reporting vaccine reactions. Make sure to report your child's vaccine reaction even if your doctor has not or will not. [This link](#) contains the list of the most severe vaccine reactions which a doctor is mandated by federal law to report, *and*, if such a reaction occurs, to make sure your child is not given that vaccine again.

American Medical Association Code of Medical Ethics

This code states the following about Informed Consent:

"The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice...The physician's obligation is to present the medical facts accurately to the patient...The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice...Informed Consent is a basic policy in both ethics and law that physicians must honor...Physicians should sensitively and respectfully disclose all relevant medical information to patients."

Here you can view and print the [AMA policy](#). This second AMA document details a physician's responsibility to report adverse events even if he or she doesn't believe the treatment (vaccine) caused the reaction: Chapter 8.8 - [Required Reporting of Adverse Events](#)

United Nations Universal Declaration on Bioethics and Human Rights: Article 6

"Any preventive, diagnostic, and therapeutic medical intervention is only to be carried out with the prior, free, and informed consent of the person concerned, based on adequate information. The consent...may be withdrawn...without disadvantage or prejudice." Read the U.N. policy, unanimously adopted by 193 countries in 2005 [here](#).

Centers for Disease Control Vaccine Information Statements

These [VIS forms](#) provide the bare minimum level of "informed consent" that your doctor is obligated to make sure you receive before giving your child vaccinations. It highlights only some of the most important moderate and severe reactions to watch out for.

The CDC states on their [website](#) that the VIS forms contain only what is legally required by the 1986 Vaccine Act and are **not** actual Informed Consent forms. This adds to the concern that many children are receiving these comprehensive and invasive medical treatments without their parents giving the proper level of consent that is ethically (and in some states, legally) mandated by our modern standards of medical care.