

From: [Reiss, Dorit R.](#)
To: [Paul Offit](#); [Stanley Plotkin](#)
Subject: Fw: Op-ed on vaccines
Date: Tuesday, May 29, 2018 2:46:02 PM
Attachments: [Reiss.053018.docx](#)

- A. Are the edits okay?
- B. Do you have pictures you can send - either to Ben directly, or to me and I will forward?
- C. I think my signature covers all of us, but will let you know if that's not the case.

best,
Dorit.

Dorit Rubinstein Reiss
Professor of Law
UC Hastings College of the Law
415-5654844
reissd@uchastings.edu

From: Ben Armistead <Ben_Armistead@dailyjournal.com>
Sent: Tuesday, May 29, 2018 9:17 PM
To: Reiss, Dorit R.
Subject: RE: Op-ed on vaccines

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Also, our freelance agreement is [here](#).

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From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]
Sent: Tuesday, May 29, 2018 11:59 AM
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Dear Ben,
Please see attached my piece. As you will see, it's a multi-author piece. Please tell me if it fits the Daily Journal, or if it would fit after specific changes.

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To: Reiss, Dorit R.
Subject: RE: Op-ed on vaccines

That'd be great.

From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]
Sent: Tuesday, May 29, 2018 10:03 AM
To: Ben Armistead <Ben_Armistead@dailyjournal.com>
Subject: Re: Op-ed on vaccines

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From: Ben Armistead <Ben_Armistead@dailyjournal.com>
Sent: Tuesday, May 29, 2018 4:03 PM
To: Reiss, Dorit R.
Subject: RE: Op-ed on vaccines

Hi Dorit –

Sure, that'd be great! When do you think you can have it by?

Best,
Ben

From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]
Sent: Monday, May 28, 2018 9:48 PM
To: Ben Armistead <Ben_Armistead@dailyjournal.com>
Subject: Op-ed on vaccines

Dear Ben,
I wonder if you would be interested in an op-ed describing a problem that came up in family law cases where one parent wants to vaccinate and another does not, and a new resource prepared to respond to that?

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By Dorit Reiss, Stanley A. Plotkin and Paul A. Offit

Legal Resource

In 2016, an unvaccinated California ~~nine~~9-year-old contracted tetanus. Luckily, the girl did not die, but she spent several weeks in a hospital, conscious but paralyzed and suffering repeated spasms. She faced a long and hard recovery period after returning home. The child's mother is anti-vaccine. The child's father, who remarried after the parents divorced, wanted her vaccinated. The father, however, did not go to court until after the child was hospitalized. In other cases where parents disagree on vaccines, they typically they often go to court before a vaccine-preventable disease happened. And courts, following the voluminous science that shows that ~~vaccinating is much safer than not vaccinating~~vaccinating is much safer than not vaccinating and hence in the best interest of the child, usually, ~~though not always~~though not always, side with the parents seeking to vaccinate.

In a few recent divorce cases anti-vaccine activists have mobilized to support the parent opposed to vaccination. Lawyers well versed in anti-vaccine claims have challenged expert witnesses, occasionally using claims based on dubious articles in predatory journals, or incorrect representation of valid articles. Even pediatricians or scientists well versed in vaccine science may not always anticipate anti-vaccine claims, or be prepared to answer them. And they are unlikely to be familiar with articles that are not part of the accepted body of literature because they are of such low quality, and/or are published in journals without serious quality control or peer review, that experts have either not seen them or seen them and dismissed them. In an equivalent situation, a scientist who writes about climate change but is not also a science communicator might not be immediately prepared to rebut arguments of climate change deniers. Knowing the science, without having heard claims from the fringes of the discipline, may not be sufficient to enable an expert to have such answers ready in real time during deposition or trial.

Lawyers in such cases, too, have no reason to be familiar with the arguments opponent may raise, and may have difficulty knowing enough about anti-vaccine claims to warn experts, especially since such cases are uncommon.

Attorneys representing parents who seek to vaccinate their children, and expert witnesses for those parents should be well-versed in anti-vaccination claims in order to counter them effectively. As a resource to help experts prepare for such situations, the Vaccine Education Center at The Children's Hospital of Philadelphia has prepared a library of the most recent and strongest references on the issues that are commonly raised by anti-vaccination lawyers, to provide an aid and refresher to experts facing these claims. We hope that this library will be helpful in preparing to meet anti-vaccine arguments -as well as protect children and the public from the risks of preventable diseases.

The ~~CHOP~~ legal library may be entered ~~through the web address:~~via vaccine.chop.edu/safety-references.

Authors:

Dorit Reiss, ~~LLB, PhD,~~ is a pProfessor of ~~l~~Law, University of California at UC Hastings College of the Law.

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Stanley A. Plotkin ~~MD, is e~~Emeritus ~~p~~Professor of ~~p~~Pediatrics, ~~at the~~ University of Pennsylvania.

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Paul A. Offit ~~MD, is d~~Director ~~of the~~ Vaccine Education Center at the Children's Hospital of Philadelphia.

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From: [Reiss, Dorit R.](#)
To: [Paul Offit](#); [Stanley Plotkin](#)
Subject: Fw: Potential Submission to the Family Advocate
Date: Friday, June 01, 2018 6:38:40 AM

So, the Family Advocate is the more fitting outlet, I think - we do not have a full law review article planned - but it's a long process. My inclination is to start it anyway, because this is a population we want to reach (family lawyers), while working to get the word out in other ways. But if a year ahead seems too long to you, I won't bother.

Thoughts?

Dorit

From: lisa_comforty@comforty.com <lisa_comforty@comforty.com>
Sent: Friday, June 1, 2018 11:54 AM
To: Reiss, Dorit R.
Subject: RE: Potential Submission to the Family Advocate

Hello, Dorit:

Thank you very much for your inquiry. As you may know, *Family Advocate* is the Section's magazine—articles are short (2,500 words), not footnoted, conversational in tone, and oriented towards the practitioner. The legal analysis is still, of course, required to be rigorous and accurate. *Family Law Quarterly*, on the other hand, is our law journal, with the typical footnoted and more academically oriented (though still practical) format. Articles are often 10,000 words or so. It would seem that you could write for either, of course.

That said, *Family Advocate* is planned very far in advance and in accordance with specific themes--authors have to wait a year or two sometimes just to be assigned a place in an issue. *FLQ* slots are a bit more flexible. I could put you in touch with either of the editors in chief. Do you have a preference?

Lisa

Lisa V. Comforty
Lisa Comforty Consulting, LLC

Managing Editor
Family Advocate/Family Law Quarterly
ABA Section of Family Law

Email: lisa_comforty@comforty.com

Telephone: 224-425-6833

From: Reiss, Dorit R. <reissd@uchastings.edu>

Sent: Thursday, May 31, 2018 10:10 PM

To: lisa_comforty@comforty.com

Subject: Potential Submission to the Family Advocate

Dear Ms. Comforty,

I am a professor of law in UC Hastings College of the Law. Over the past five years my focus has been on law and policy related to vaccines. In that role I have been watching and communicating with family lawyers in cases in which the parents debate whether to vaccinate or not.

I would like to write an article about the legal situation in such cases and the potential pitfalls, with some advice. Does that sound like something that might be of interest? I am not a lawyer. But I have received multiple queries over the years from family law lawyers wanting to discuss it.

best,
Dorit.

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From: [Reiss, Dorit R.](#)
To: ["Stanley Plotkin, MD"](#)
Cc: [Karen Ernst](#)
Subject: Manual vaccines and the law
Date: Sunday, August 31, 2014 3:20:30 PM
Attachments: [Vaccines and the Law Manual Edits.pptx](#)

Dear Dr. Plotkin,

Following your advice - and thank you, it's a great idea - I added slides about the diseases we vaccinate and their risks - in very short format - to the manual about Vaccines and the Law. I hoped you'd be willing to glance at them to see if they are accurate. I'm reattaching the manual, and the slides are slide 5-9. Any advice is welcome. I am counting on Karen and team to make everything more visually appealing, since I'm not that good on that side.

best,
Dorit.

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Vaccines and the Law: An Introduction

Voices for Vaccines

Prepared by Dorit R. Reiss and Amanda Z. Naprawa

Goals:

- This Document Will:
 - Explain basic facts about the law as it relates to vaccines.
 - Highlight how the law can improve immunization rates.
 - Raise some policy options to consider.
 - Provide answers to some inaccurate claims you may hear about the law and vaccines.

Introduction: Vaccines' Benefits and Risks

Vaccines: The Benefits

- Has one of the “Top 10” public health achievements of the 20th Century.
- Impressive gains continue in the 21st Century as well.
- It has been estimated that immunizing the 2009 birth cohort led to:
 - Prevention of 42,000 early deaths.
 - Prevention of 20 million cases of disease.
 - Saving \$13.5 billion in direct costs.
 - Saving \$68.8 billion in costs to society.
- Zhou et. Al, Economic Evaluation of the Routine Childhood Immunization Program in the United States, 2009 (2014)

Disease we vaccinate against	Risks include
Chicken Pox (Varicella)	Death (70 in 10,000) Bacterial infection of lesions Pneumonia
Diphtheria	Death (1 in 10) Heart disease Nerve damage
Flu (Influenza)	Death (thousands-tens of thousands a year) Pneumonia Encephalitis GBS
Hepatitis A	Death (rare) Liver damage Long period of illness

Disease we vaccinate against	Potential Complications
Hepatitis B	Death (about 5000 a year) Liver damage Liver cancer
HiB	Death (4 out of 100) Meningitis Blood stream infection <u>Epiglottitis</u>
HPV	Death (about 3000 a year) Cervical cancer Head and neck cancer Penile cancer Vulvar cancer
Measles	Death (1-2 out of 1000) Pneumonia Encephalitis

Disease we vaccinate against	Potential Complications
Meningococcal Disease	Death (3-4 out of 10) Loss of limbs Brain damage Pneumonia
Mumps	Meningitis Encephalitis Deafness Swollen testicles and infertility in men.
Polio	Death Paralysis (about one in 200)
Pneumococcal	Death Meningitis Pneumonia

Disease we vaccinate against	Potential Complications
Rotavirus	Deaths (20-60 a year pre vaccine) Dehydration
Rubella	Encephalitis Congenital Rubella Syndrome (CRS): in pregnancy, miscarriages and serious birth defects
Tetanus	Death (1 out of 10) Broken bones Pneumonia Difficulty breathing
Whooping Cough (Pertussis)	Death (mostly infants, 1 out of 500 people) Pneumonia Seizures

Additional sources on diseases:

- <http://www.chop.edu/service/vaccine-education-center/a-look-at-each-vaccine/>
- <http://www.cdc.gov/vaccines/vpd-vac/fact-sheet-parents.html>
- <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

When you vaccinate, you also protect others:

- Babies too young to vaccinate.
- Those with medical conditions that prevent vaccination.
- Those who suffered vaccine failure or whose immunity has worn off.
 - Typically, we don't know who falls into these two categories.
- Those left intentionally unvaccinated by their parents.



Community immunity is a matter of teamwork



I vaccinate my children to protect them
and to protect my neighbors

The Benefits of Vaccinating Outweigh the Risks of an Adverse Event

- All diseases have risks and most diseases can be fatal; some have higher fatality rates than others, but even those with low fatality rates leave families with holes where loved ones used to be. This is why we vaccinate against them.
- Serious reactions to modern vaccines can happen, but they are extremely rare. For example, in a study of patients in 4 health maintenance organizations between 1991 and 1997, there were 5 anaphylactic reactions (severe allergy reactions) out of 7,644,049 vaccine doses (.65cases/1,000,000 million doses).
- A 2013 Institute of Medicine Report examined the evidence and concluded: "Upon reviewing stakeholder concerns and scientific literature regarding the entire childhood immunization schedule, the IOM committee finds no evidence that the schedule is unsafe."

Local, state, national and international health authorities support vaccination.

- City of San Francisco: “Vaccines can prevent many infectious diseases. You should get some vaccinations in childhood, some as an adult, and some for special situations like pregnancy and travel. Make sure you and your family are up-to-date on your vaccinations.” <http://www.sfcdcp.org/yourvaccines.html>
- New York State: “Today's vaccines are among the 21st century's most successful and cost-effective public health tools for preventing disease and death. Thanks to immunizations, debilitating and often fatal diseases like polio, that were once common, are now only distant memories for most Americans.” <https://www.health.ny.gov/prevention/immunization/>
- The Centers for Disease Control and Prevention: “There's no greater joy than helping your baby grow up healthy and happy. That's why most parents choose immunization. Giving your baby the recommended immunizations by age two is the best way to protect him from 14 serious diseases, like measles and whooping cough.”
“<http://www.cdc.gov/vaccines/parents/index.html>”
- The World Health Organization: “Immunization is a proven tool for controlling and eliminating life-threatening infectious diseases and is estimated to avert between 2 and 3 million deaths each year. It is one of the most cost-effective health investments..”
<http://www.who.int/topics/immunization/en/>

Vaccines: Regulating the Product

Regulating Vaccines: The FDA's Role Part I



- Vaccines undergo extensive pre and post market testing and regulation.
- The Food and Drug Administration – FDA – is the regulatory agency responsible for overseeing the “safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products.”
- As a regulatory agency, the FDA writes rules governing the pharmaceutical industry, monitors for compliance and imposes penalties where there is non-compliance.
- The FDA oversees vaccines both before and after they arrive on the market. Vaccine manufacturers are subject to the detailed requirements that can be found in parts of the Code of Federal Regulations (C.F.R).
- The FDA mandates that all new vaccines undergo a lengthy and elaborate testing process that includes several phases of clinical trials. The FDA heavily regulates the clinical trial process. Before this complex process can even start, however, anyone attempting to license a vaccine needs to submit an Investigational New Drug (IND) application to the FDA. To do so, there must have already been animal and toxicology studies showing that the “product is reasonably safe for initial testing in humans.”

Regulating Vaccines: The FDA's Role II



- If a vaccine is shown safe and effective in clinical trials, the company needs to file a Biologics License Application, which is reviewed by the FDA. If agency staff deems it complete it goes for approval to the [Vaccine and Related Biological Products Advisory Committee](#), which includes experts and a consumer representative. The committee makes recommendations about vaccine licensing based on “safety, effectiveness and appropriate use,” according to its charter.
- The FDA carefully regulates the labeling – vial labels and inserts – of vaccines. The requirements can be found in [21 C.F.R. 201.57 and 21 C.F.R. 610.60](#). This regulation requires, for example, that all ingredients be listed (with very limited exceptions).
- The regulations also require both a list of “warnings and precautions” which lists the problems the vaccine may cause and a list of “adverse reactions” – problems reported after the vaccine but not necessarily caused by it.
- To prevent liability, company lawyers preparing the insert often include anything reported to them in the list of adverse events, whether or not there is evidence that it’s caused by the vaccine. Thus, there may be an extensive list of events, usually accompanied by language explaining that the events are listed regardless of causality).
- The FDA continues to monitor a vaccine after it’s on the market and has extensive powers to inspect manufacturing facilities and the production process, test samples, and more.

Regulating Vaccines: The FDA's Role Part III

- The FDA's role in ensuring vaccine safety does not end when the vaccine is approved for human use. It continues to monitor the vaccine even after it reaches the market.
- One way the FDA regulates vaccines is by participating in the [Vaccine Adverse Event Reporting System \(VAERS\)](#). VAERS is a national surveillance system that tracks all reports of suspected reactions to any vaccine. Actual causation is not required in order for a report to be made.
- FDA also participates in what is called "Phase IV studies," studies of vaccine safety after the vaccine is on the market.
- If violations or problems are found, the FDA has the authority to issue warning letters, to fine a company for some types of violations, to order retention, recall or destruction of a product, to order a company to stop manufacturing it, to fine a company, and in extreme cases it can criminally prosecute responsible individuals.

- A more detailed description of the FDA's role can be found [here](#).

VAERS Vaccine Adverse Event Reporting System

Report an Adverse Event | About VAERS | VAERS Data | Vaccine Resources | Information for Healthcare Professionals | Information for U.S. States and Territories | Information for Vaccine Manufacturers

Search web site: Search

Report an Adverse Event

[en Español](#)

Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.

The Vaccine Adverse Event Reporting System (VAERS) accepts all reports, including reports of vaccination errors. VAERS is primarily concerned with monitoring adverse health events and we encourage reporting of clinically significant adverse health events following vaccination. Using clinical judgment, healthcare professionals can decide whether or not to report a medical error at their own discretion. For example, a healthcare professional may elect to report vaccination errors that do not have an associated adverse health event, especially if they think the vaccination error may pose a safety risk (e.g., administering a live vaccine to an immunocompromised patient) or that the error would be preventable with public health action or education.

There are three ways to report to VAERS-

1. [Online](#)
2. [Fax](#)
3. [Mail](#)

Information identifying the person who received the vaccine and the person who filed the report is not made available to the public. You or your health care provider may be contacted for further information after your report is received.

Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

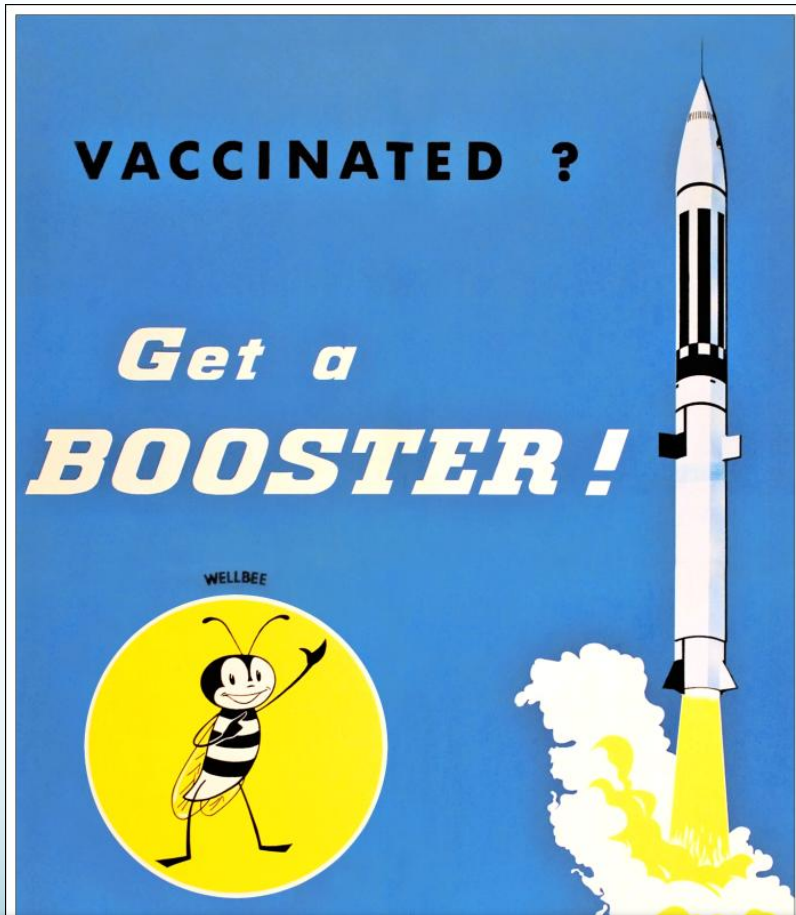
The US Food and Drug Administration has issued new regulations, "Postmarketing Safety Reports for Human Drug and Biologic Products; Electronic Submission Requirements", which describes requirements for electronic submission of Individual Case Safety Reports (ICSRs), ICSR attachments and periodic reports to FDA. For more information about electronic ICSR reporting to VAERS, refer to the FDA ICSR website: <http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm174963.htm> or contact the FDA Electronic Submissions Help Desk at: esgprep@fda.hhs.gov.

Report Online

- Complete a **VAERS On-Line Form** on this site.
- Before you begin review the [Instructions for Completing the VAERS On-Line Form](#). Please note that the VAERS On-Line form has a 20 minute limit to complete each of the steps. Your information will be erased if you timeout and you will be returned to Step 1; you will receive a warning after 15 minutes.

Protecting the Public Health, State and Federal Law

Disease Prevention: The CDC's Role



The "Wellbee" was used by the CDC in its comprehensive public health campaign. Here, it is used to remind people to get their booster shots, (photo credit: CDC 1964).

- Whereas the FDA is a regulatory agency, the Centers for Disease Control and Prevention (CDC) is not. The CDC does not oversee and regulate pharmaceutical companies directly. Its mission is to prevent disease of any kind.
- To fulfill that mission, the CDC, after a deliberative process with extensive expert input, recommends vaccine schedules that balance preventing diseases, vaccine safety, and cost-effectiveness.
- The CDC promotes those schedules and supports state in implementing vaccination programs, to reduce preventable diseases as much as possible.
- The CDC also co-manages the VAERS and does its own monitoring for vaccine safety.

Disease Prevention: The CDC's Recommended Schedule

- The CDC has a recommended vaccine schedule that is based on what experts determine will offer your child the earliest and safest effective protection against all the diseases against which it is cost-effective to vaccinate. The American Academy of Pediatrics (AAP) along with many other medical organizations recommends that health care providers adhere to the CDC's recommended schedule.
- The recommended schedule comes from the CDC's Advisory Committee on Immunization Practices (ACIP) which meets four times per year. The Committee's fifteen voting members include experts with extensive knowledge in infectious diseases, epidemiology, public health, health economics and other relevant fields and one consumer representative.
- The schedule is also approved by the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).
- Once approved by the CDC Director, ACIP recommendations become part of the official CDC recommendation and published in the CDC's Morbidity and Mortality Weekly Report (MMWR). While the director usually accepts the recommendation, it is not required and not all recommendations are accepted. This adds yet another layer of accountability.
- For more information on ACIP and its practices
 - <http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-child-immun-color-office.pdf>
 - <http://www.cdc.gov/vaccines/acip/committee/chapter.html>
 - <http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-acip-color-office.pdf>

School Immunization Requirements:

- Each state today requires children to be immunized against certain diseases before children can attend public school. Some states apply the requirements to day cares and private schools as well and a very small number of states also apply them to homeschooled children.
- Each state determines which vaccines are required before a child can attend school. Because states are not bound by the CDC's recommended childhood immunization schedule, the requirements in each of them differ somewhat. School immunization requirements are influenced by political factors and by what the state determines is necessary for school children to have to protect the public health.
- A state is not constitutionally required to offer non-medical exemptions (*Zucht v. King*, 260 U.S. 174, 177 (1922)).

At a glance:

All 50 states currently offer a medical exemption.

48 states offer non-medical exemptions – either a religious exemption, or a philosophical (also known as personal belief) one, or both.

States vary dramatically in how easy it is to obtain an exemption and in terms of the process.

- Some states also provide information about immunization and exemption rates in specific schools and/or daycares.

Religious Exemptions

- Although not constitutionally required to do so, if a state does offer a religious exemption, it needs to meet certain requirements:
 - The Exemption can't be limited to organized religion, because that discriminates against those with sincere beliefs that do not belong to an organized religion (*Dalli v. Board of Ed.* 358 Mass. 753, 754 (1971)).
 - The fact that a person's official religion does not oppose immunization – or even supports them – does not negate a person's sincere belief in opposition to vaccines. A person is allowed to hold their own version of their religion, and as long as they are sincere, that belief qualifies them for a religious exemption, if there is one: *Berg v. Glen Cove City School Dist.*, 853 F. Supp. 651, 655 (E.D.N.Y. 1994),.
 - Some states' statutes require a show of sincerity, and an exemption can be denied if an applicant cannot prove her sincerity.
 - If a state's statute does not require a show of sincerity at least some courts ruled that state officials cannot question an applicant's claims that their reasons are religious. . *LePage v. State of Wyoming Department of Health*, 18 P.3d 1177, 1180 (2001))
- More information on school immunization requirements can be found here:
- <http://www2a.cdc.gov/nip/schoolsurv/schlmmRqmt.asp>
- <http://www.immunize.org/laws/>
- <http://www.webmd.com/children/vaccines/news/20140211/states-may-be-getting-stricter-on-child-vaccine-exemptions>

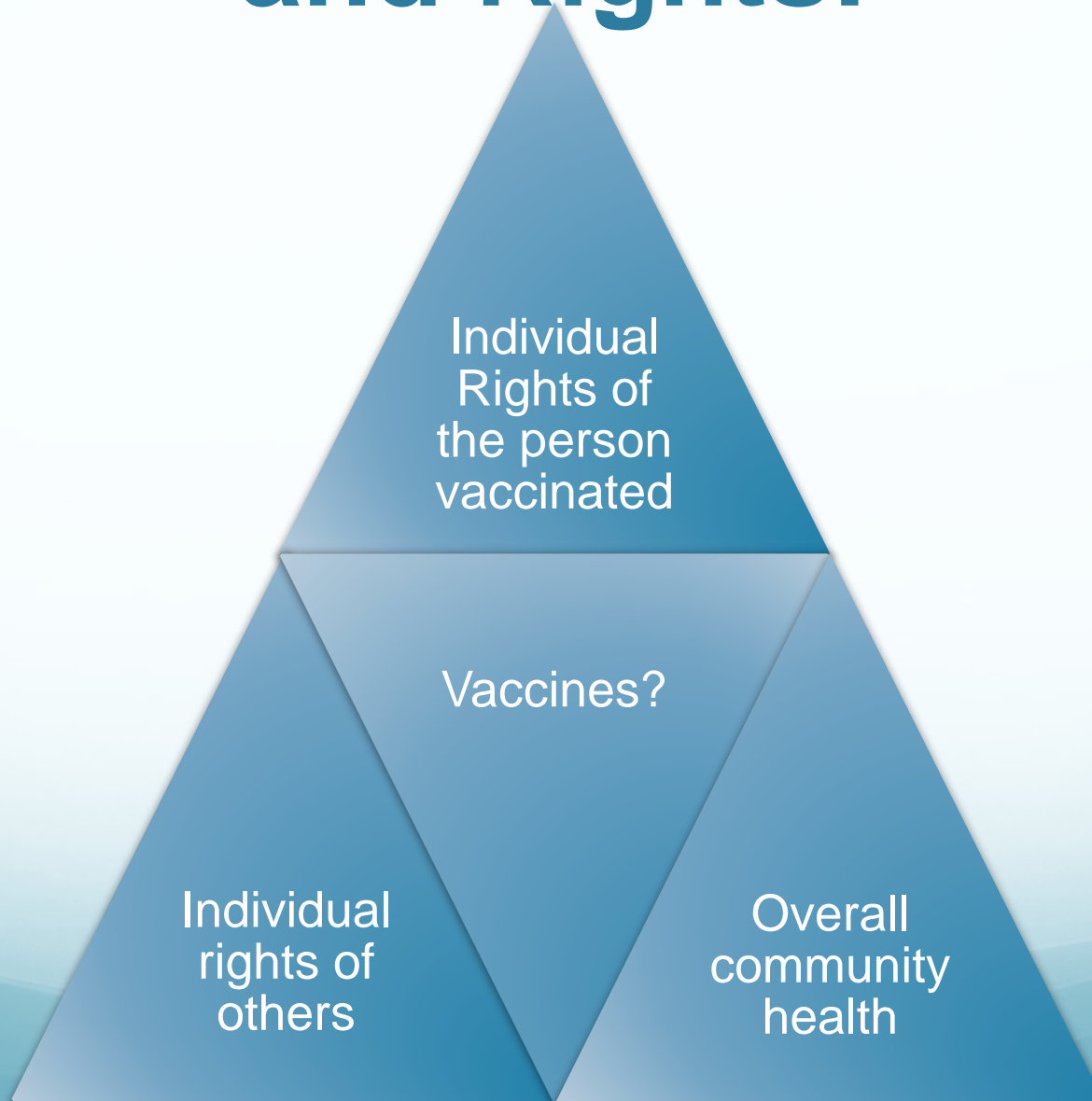


Individual Choice and Community Welfare

Several rights and interests affect what the law can do about vaccines:

- Individuals' autonomy to decide what medical treatment to accept or not for their bodies.
- Parents' right to make decisions for their children.
- Freedom of religion and thought.
- A child's right to health.
- The right of the community to act to protect the public health and prevent outbreaks.
- The rights of others to be free from preventable diseases.
- Costs to the public purse because of the harms of non-vaccinating.

Framework: Adult Vaccines and Rights:



Parental
Autonomy

Individual
Rights of
Others?

Vaccines
?

Child's
Rights

Overall
Community
Health

Community v. Individual

Achieving a balance of rights



- Our Supreme Court has long held that vaccine mandates are constitutional. When you live in society, your rights may be limited to prevent harm to others or to the general community. . The leading case was *Jacobson v. Massachusetts*, 197 U.S. 11, 25-27 (1905).
- While we respect individual rights, they are not absolute. Individual liberty does not “import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint.”
- Every individual’s rights need to be balanced against the rights of others, and the rights of the community as a whole. When public health and safety is involved, the government has authority to impose on individual liberty to protect the greater community.

Community v. Individual

Achieving a balance of rights – Cont.



- Religion:

- We care about religious freedom; but we also care about obedience to the law. The Supreme Court ruled that individuals must obey general laws even if they oppose them on religious grounds (Employment Division, Dep't of Human Resources of Oregon v. Smith, 494 U.S. 872 (1990)).
 - For vaccines, this means that there is no religious exemption required under 1st amendment. (Workman v. Mingo Board of Education (2011)).
 - So: a state may provide religious waivers from general laws – but it does not have to do so.
- However, this does not mean that individual rights are never protected.
 - In Jacobson the Supreme Court has suggested that individuals with valid medical reasons that prevent vaccinating cannot be required to vaccinate.

Community v. Individual

Achieving a balance of
rights – Cont.



In the employment context:

- Americans with Disability Act:
 - Employer must accommodate those with disability that prevents vaccinating unless it's a substantial hardship.
- Civil Rights Act 1964:
 - An employer cannot discriminate on religious ground, and must provide reasonable accommodation to those with sincere religious objections to a work practice.
 - Unless providing the accommodation imposes a burden on the employer – even a low burden.

Parental Rights

Reconciling parental rights with child's right to health

- Parental rights matter in our system. Parents have substantial freedom to determine education and care of child (*Troxel v. Granville*, 530 U.S. 57 (2000)).
- Parental rights are there partly to respect family autonomy and privacy and partly to allow parents to fulfill their responsibilities to a child.
- Children have rights too. Parental rights can be limited when they put a child at risk – for example, when by refusing to vaccinate, a parent leaves a child at risk of a dangerous disease (***Prince v. Massachusetts***, 321 U.S. 158 (1944)).
- A state has a responsibility to its most vulnerable members, including children. When parental actions place children at risk, the state may regulate.
- States have considerable freedom to balance parental rights and children's interests. The decision rests first with our democratically elected legislature, and secondly, with the courts interpreting statutes the legislature passed.



- In relation to vaccines, this means a state can choose what to require and when.
- For example, California requires vaccines against diphtheria, Hepatitis B, HiB, measles, mumps, pertussis, polio, rubella, tetanus, and varicella (chicken pox). Ohio does not require the HiB vaccine. Only a few states require vaccination against influenza.

Informed Consent for Vaccines

- Informed consent means that before a patient undergoes a medical treatment, they should have the risks and benefits of the treatment – and the alternatives to it – explained to them. Not properly informing of risks, benefits and alternatives is considered negligent.

- In the context of vaccines, patients deserve to be informed of –

- The risks of vaccinating.
- The risks of not vaccinating.

The Risks of Vaccinating:

- Under federal law, a provider is required to give a patient a Vaccine Information Sheet (VIS) that summarizes the known risks and benefits of the specific vaccine before vaccinating. The VIS provides information on the diseases we vaccinate against, who should get the vaccine, and the risks of the vaccine and how common they are. The VIS also includes information on what to do in case of a vaccine injury and how to be compensated in the very rare and unlikely case that someone suffers a serious vaccine injury.

- While some states may require more information to be given, the VIS probably covers the information that needs to be given to fulfill the requirements of informed consent when someone vaccinates.

VACCINE INFORMATION STATEMENT	
Tdap Vaccine (Tetanus, Diphtheria, and Pertussis) <i>What You Need to Know</i>	
<small>Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis</small>	
1 Why get vaccinated?	2 Tdap vaccine
<p>Tetanus, diphtheria and pertussis can be very serious diseases, even for adolescents and adults. Tdap vaccine can protect us from these diseases.</p> <p>TETANUS (Lockjaw) causes painful muscle tightening and stiffness, usually all over the body.</p> <ul style="list-style-type: none">• It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 5 people who are infected. <p>DIPHTHERIA can cause a thick coating to form in the back of the throat.</p> <ul style="list-style-type: none">• It can lead to breathing problems, paralysis, heart failure, and death. <p>PERTUSSIS (Whooping Cough) causes severe coughing spells, which can cause difficulty breathing, vomiting and disturbed sleep.</p> <ul style="list-style-type: none">• It can also lead to weight loss, incontinence, and rib fractures. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, which could include pneumonia or death.<p>These diseases are caused by bacteria. Diphtheria and pertussis are spread from person to person through coughing or sneezing. Tetanus enters the body through cuts, scratches, or wounds.</p><p>Before vaccines, the United States saw as many as</p>	<p>Tdap vaccine can protect adolescents and adults from tetanus, diphtheria, and pertussis. One dose of Tdap is routinely given at age 11 or 12. People who did <i>not</i> get Tdap at that age should get it as soon as possible.</p> <p>Tdap is especially important for health care professionals and anyone having close contact with a baby younger than 12 months.</p> <p>Pregnant women should get a dose of Tdap during <i>every</i> pregnancy, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.</p> <p>A similar vaccine, called Td, protects from tetanus and diphtheria, but not pertussis. A Td booster should be given every 10 years. Tdap may be given as one of these boosters if you have not already gotten a dose. Tdap may also be given after a severe cut or burn to prevent tetanus infection.</p> <p>Your doctor can give you more information.</p> <p>Tdap may safely be given at the same time as other vaccines.</p>
	3 Some people should not get this vaccine
	<ul style="list-style-type: none">• If you ever had a life-threatening allergic reaction after a dose of any tetanus, diphtheria, or pertussis

CDC Vaccine Information Sheet for Tdap
(5.9.2013)

Informed Refusal: The risks of not vaccinating

Refusal to Vaccinate							
Child's Name _____	Child's ID# _____						
Parent's/Guardian's Name _____							
My child's doctor/nurse, _____, has advised me that my child (named above) should receive the following vaccines:							
<table><thead><tr><th>Recommended</th><th>Declined</th></tr></thead><tbody><tr><td><input type="checkbox"/> Hepatitis B vaccine</td><td><input type="checkbox"/></td></tr><tr><td><input type="checkbox"/> Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine</td><td><input type="checkbox"/></td></tr></tbody></table>	Recommended	Declined	<input type="checkbox"/> Hepatitis B vaccine	<input type="checkbox"/>	<input type="checkbox"/> Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine	<input type="checkbox"/>	<ul style="list-style-type: none">■ That some vaccine-preventable diseases are common in other countries and that my unvaccinated child could easily get one of these diseases while traveling or from a traveler.■ If my child does not receive the vaccine(s) according to the medically accepted schedule, the consequences may include<ul style="list-style-type: none">- Contracting the illness the vaccine is designed to prevent (the outcomes of these illnesses may include one or more of the following: certain types of cancer, pneumonia, illness
Recommended	Declined						
<input type="checkbox"/> Hepatitis B vaccine	<input type="checkbox"/>						
<input type="checkbox"/> Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine	<input type="checkbox"/>						

- A trickier question is what constitutes informed consent for the decision not to vaccinate. Obviously, if a person does not come to the doctor they cannot be given information, but if a person comes, but refuses information, the same problem arises.
- The principal of “Informed Refusal” holds that the decision not to vaccinate should only be made after a person is provided the same accurate, vetted information as someone who chooses to vaccinate.
- One possible way to achieve truly informed refusal is to mandate that certain educational requirements be met before a parent could seek and obtain a non-medical exemption to school immunization requirements. For example, states would mandate that refusing parents receive accurate information about the risks and benefits of vaccines from a qualified source, preferably a health care professional.
- The AAP recommends such conversations with vaccine refusing parents because it gives the physician a chance to counter misinformation and potentially change the parents’ minds, leading to greater patient and community health. Even those with a religious objection to vaccination deserve to know the risk they are taking, so they can make an informed choice.
- The requirement of informed refusal interferes very minimally with parental autonomy. It is merely requiring education, does not impose or force a decision, and the potential benefit in terms of children’s health and the public health is very high.
- The AAP recommends that pediatricians document vaccine refusal using a Refusal to Vaccinate form as well as indicating parental refusal in the child’s chart. This recommendation is intended not only to protect the physician from potential liability, but is also suggested as a way to emphasize, to the parent, the importance the physician places on appropriate immunizations and to focus “parents’ attention on the unnecessary risk for which they are accepting responsibility.”

Increasing Immunization Rates

How can the law increase immunization rates?

What do we do, and what could we do?

Least
coercive

Most
coercive

Education

Incentives

Imposing
costs

Limiting
access

Criminal
Law

Forced
vaccination

Education:

- Several states require that parents taking advantage of a non-medical exemption receive education about vaccines' risks and benefits.
 - Washington and California require a signature from health care providers that the information was provided.
 - Oregon allows either signature from provider or completion of an online module.
 - Colorado's statute requires the Department of Health to create online educational materials, but does not require parents to view them.
- One other possible option is to pass a statute providing students – in high school or elementary school – with a mini module about vaccines as part of the curriculum, teaching them the facts early.

Government Funded Incentives and Subsidies

Patient Protection and Affordable Care Act

- The Affordable Care Act (ACA) encourages immunization in several ways.
- Under Section 2713, individuals insured under all applicable group and individual plans are to receive appropriate and recommended vaccines at no cost.
- Under Section 4204, the CDC can award states funds to be used in promoting and increasing vaccination coverage among adults and children. Funds can be used for, among other things, vaccine education, promotion, and cost-reduction to patients.
- Under Section 2705 (j) insurers may offer a rebate for participation in a wellness program, which should include vaccination. Whether insurers will actually offer such a rebate remains to be seen.

Subsidies cont.

Vaccines for Children Program

- Covers vaccines for children who would not otherwise be able to afford them (children on Medicaid or underinsured, or Native American or Alaskan children).
- <http://www.cdc.gov/vaccines/programs/vfc/about/index.html>

Section 317 Immunization Program

- As of October 1, 2012, covers:
 - Certain newborns receiving the birth dose of Hepatitis B vaccine prior to hospital discharge
 - Underinsured or uninsured adults
 - Fully insured individuals seeking vaccines during public health response activities including:
 - Outbreak response
 - Post-exposure prophylaxis
 - Disaster relief efforts
 - Mass vaccination campaigns or exercises for public health preparedness
 - Individuals in correctional facilities and jails
 - <http://www.cdc.gov/vaccines/imz-managers/guides-pubs/qa-317-funds.html>

Imposing Costs:

Civil lawsuits



- A tort is a civil wrong whereby a person injured by another can seek compensation from the wrongdoer.
- If an unvaccinated person contracts a preventable disease and infects another, there may be a tort suit to be had.
- While there have not yet been cases brought against unvaccinated people, there are decided cases holding people liable for negligence that caused another person to contract an infectious disease. (Smith v. Baker, 20 F. 709, 709–10 (C.C.S.D.N.Y. 1884); Stubbs v. City of Rochester, 124 N.E. 137, 138 (N.Y., 1919) Berner v. Caldwell, 543 So.2d 686 (Ala. 1989).
- Such a tort would have to fit under traditional tort principles. Demonstrating the existence of a duty and establishing causation in some specific cases are two potential barriers. They can, however, be overcome.
- Some additional potential civil lawsuits:
 - Unvaccinated Child v. Parent: In some states, parents have immunity: they cannot be sued by their child. In other states, however, a child left unvaccinated and harmed by a preventable disease could sue her parents.
 - Infected individual v. Anti-vaccine organization or doctor: Suit for negligent or intentional misrepresentation that causes physical harm may allow suing doctors and organizations that promote anti-vaccine misinformation.
 - Patient v. Doctor: Doctors that recommend against vaccination may be liable in medical malpractice to their patients, and maybe even third parties.
- There is potential for tort liability in this context. It simply has not been used yet.

Imposing Costs:

No-Fault Options



- Aside from personal injury lawsuits, additional legal avenues are available to limit the impact of unvaccinated individuals:
- Public Nuisance Laws: Non-vaccinating individuals who cause an outbreak may be sued under public nuisance laws. Under state statute or local ordinances, the appropriate government entity can sue for the behavior of one person that can, among other things, be injurious to health. When the harm affects a community, it's a public nuisance, and the state can sue.
- Public nuisance statutes have not yet been used to sue for outbreaks caused by non-vaccination, but they have been used to recover costs incurred from other types of behavior harmful to health. For example, at least two states have sued for harm caused by lead paint. The results have been mixed. In *State v. Lead Indus. Ass'n*, 951 A.2d 428, 443 (R.I. 2008), the court held that the manufacture and use of lead paint was not a public nuisance because it had not "interfered with a public right." However, in a more recent suit, a California court found against the lead paint manufacturers (*California v. Atl. Richfield Co.*, 2014 WL 280526 (Cal. Super)). *Richfield Co.*, 2014 WL 280526 (Cal. Super)).
- While not vaccinating is distinguishable from corporate behavior in lead paint cases, there is adequate precedent for bringing private nuisance suits against individuals as well as corporations.
- No-Fault Legislation : States might also consider passing legislation that imposes costs on non-vaccinating individuals in a variety of ways:
 - States could create a fund that will cover outbreaks and/or compensate individuals harmed by non-vaccination with no fault required, and fund it through a fee – or a tax – on those who do not vaccinate.
 - States can also pass laws allowing public health departments to bill those who do not vaccinate.
- Increase Premiums: At the federal level, the ACA could be changed to allow higher premiums to be collected from those who do not vaccinate.
 - More on this can be found here:
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2445610



Limiting Access

- Society has already agreed that it is reasonable to limit the access unvaccinated individuals have to certain community benefits.
- We already limit access to school through the use of mandatory immunization laws.

- Additionally, some states, and some employers, mandate that health care workers receive influenza vaccines.
- On health care workers and flu, see:
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3020194/>
http://hcpportalco20140422.pfizer.edrupalgardens.com/sites/g/files/g10013231f/publicaciones/2013_31_5_State-law-and-influenza-vaccination-of-health-care-personnel_827_832.pdf
https://www.massnurses.org/files/file/Health-and-Safety/H1N1/Legal_Landscape.pdf

Other ideas to limit access:

- Conditioning getting a passport on having the appropriate immunizations.
- Conditioning access to certain places – pools, parks, public transit - on immunization status.
- Requiring immunization for non-health care employees in professions where non-immunization is an issue, such as:
 - Teachers
 - Restaurant workers (e.g., hepatitis A)

Vaccine Refusal and Criminal Law



- In *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), the United States Supreme Court held that a criminal sanction – a fine – on an individual who refused to vaccinate was constitutional. While a lot of time has passed, this holding has not been overturned, and it may well be constitutional to impose a criminal sanction for non-vaccinating. Not all scholars, however, agree and some think that a case like *Jacobson* would be narrowed today.
- Criminal law can be used to punish non-vaccinating individuals in the context of someone who died from a preventable disease – the unvaccinated child, or someone she infects:
 - All states have manslaughter statutes. States vary on whether they require recklessness or just negligence to meet the required mental state for the statute.
 - Some states have criminal penalties as part of the statute governing parental duties, prohibiting child abuse and neglect. While not vaccinating can, conceivably, be seen as negligent – or as medical neglect – most cases of manslaughter for neglect or conviction for child neglect have involved much clearer cases of neglect than not vaccinating a healthy child when there is no ongoing outbreak.
- In some cases, criminal action might well be appropriate – e.g. if a child is harmed by not vaccinating during an outbreak, or not vaccinating against hepatitis B when the mother is hepatitis B positive.
 - For more information, see: <http://shotofprevention.com/2014/02/25/rights-of-the-unvaccinated-child-criminal-law/>



Force Vaccinating

- The most coercive option, of course, is forced vaccination.
- During an outbreak, it *may* be appropriate to vaccinate a child – by force if necessary – over parental opposition, to protect the child from the harms of a dangerous disease (*In re Christine M.*, 595 N.Y.S.2d 606, 616 (Fam. Ct. 1992)).
- However, under normal circumstances, it is probably inappropriate to do so.
 - See: <http://shotofprevention.com/2014/03/04/rights-of-the-unvaccinated-child-vaccinating-over-the-parents-will/>
- It is probably almost always inappropriate – and potentially unconstitutional – to force-vaccinate an adult of sound mind. Under our system, an adult may refuse treatment – even life-saving treatment. That is part of the principle that people have the autonomy to decide what will be done with their body. *Schloendorff v. Society of New York Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).
- There can, however, be other consequences to not vaccinating – for example, many states have laws allowing quarantining people who may infect others.

Other Issues

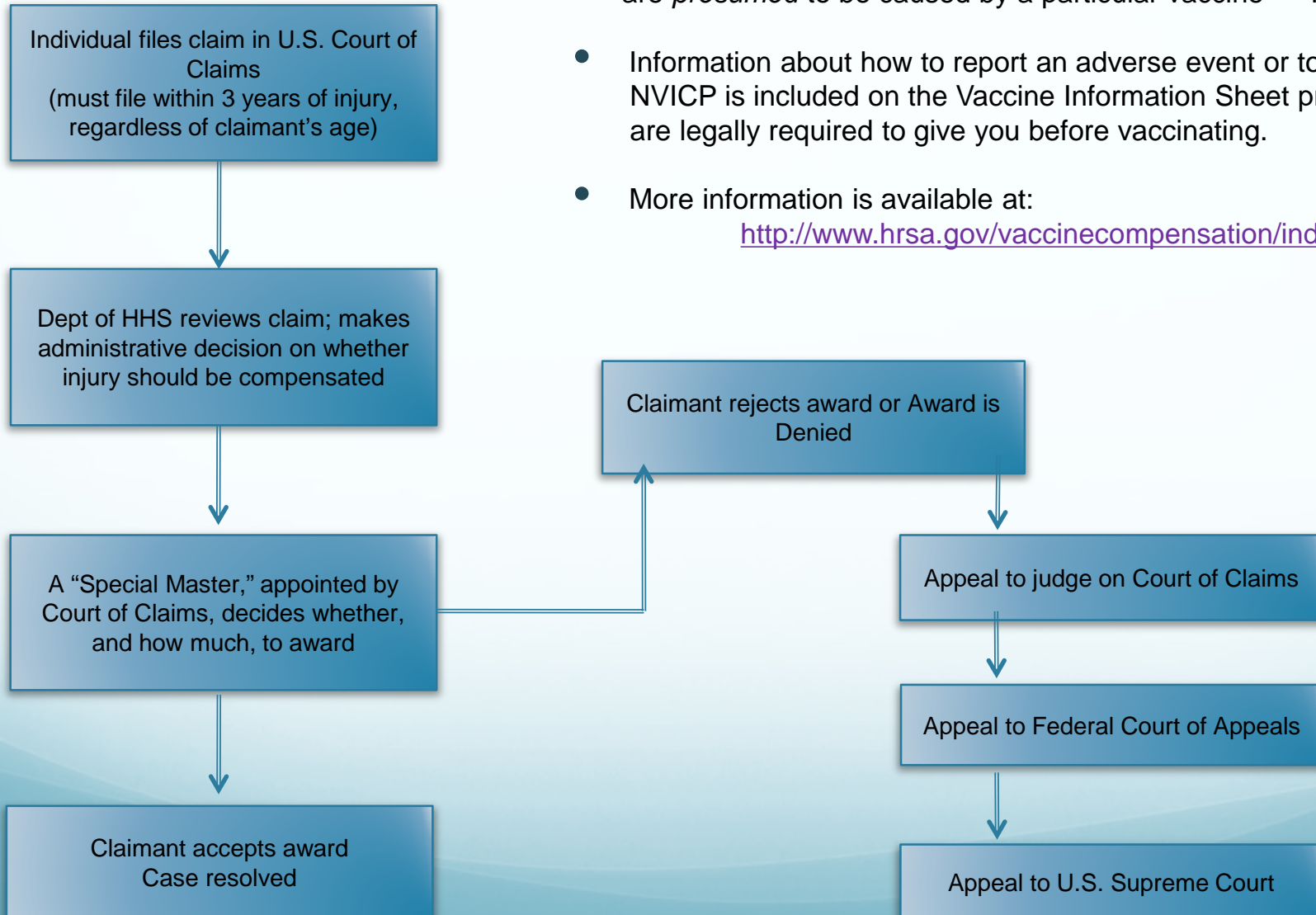
Vaccine Injuries:

Compensating the rare adverse event

- Vaccine injuries are very, very rare. The risks of an adverse reaction from a vaccine are much smaller than the risks of not vaccinating.
- Nothing is 100% safe; even food is potentially dangerous – you can choke or get food poisoning. However, realizing that vaccines can pose small risks, Congress put in place systems to investigate these rare events and a special system to compensate them.
- The National Childhood Vaccine Injury Act (NCVIA), 42 U.S.C. § 300aa- 1, et seq., made special arrangements for handling vaccine injuries.
- Under the NCVIA, doctors and vaccine manufacturers are required to report to the Department of Health and Human Services certain adverse events that happen after vaccinating (42 U.S.C. § 300aa-25).
- Parents and providers can also report such events to the Vaccines Adverse Events Reporting System. In fact, anyone can report at: <http://vaers.hhs.gov/index>.
- The NVCIA created a National Vaccine Injury Compensation Program (NVICP) which is funded by an excise tax - currently 75 cents - on each vaccine. This is a no-fault forum to recover harm, an alternative to going through the regular courts.
- The NVICP is designed to achieve two goals:
 - Assure vaccine supply by protecting manufacturers from liability.
 - Provide plaintiffs a quicker, less adversarial and easier to win in forum than the courts.

Vaccine Injuries: *The NVCIP*

- Under the NVCIP, there a list of injuries and reactions that are *presumed* to be caused by a particular vaccine – “Table Injuries.”
- Information about how to report an adverse event or to file with NVCIP is included on the Vaccine Information Sheet providers are legally required to give you before vaccinating.
- More information is available at:
<http://www.hrsa.gov/vaccinecompensation/index.html>



Vaccine Injuries:

NVICP v. the Courts

- The NVICP offers individuals with claims of vaccine-related injuries (“plaintiffs”) several advantages compared to a regular court:
 - Relaxed rules of evidence.
 - No need to show a design defect – or any defect.
 - If the petitioner is claiming an injury included in a special “Vaccine Injury Table,” causation is presumed. This makes it much easier for the plaintiff with a legitimate vaccine injury to get compensated.
 - To view the vaccine table
<http://www.hrsa.gov/vaccinecompensation/vaccinetable.html>.
 - Petitioners get lawyer fees and costs whether they win or lose, and the lawyers do not get part of the award (This is not typically the case in claims made in the traditional tort setting).
- The NVICP does not bar claims for injuries that are not recognized in the vaccine table. However, if the petitioner wants to claim an injury that is not on the table, he or she just needs to meet the regular standard of proof for a civil trial: they need to show that it’s more likely than not – more than 50% likely – that the vaccine caused the harm.

Vaccine Injuries:

NVICP v. the Courts Cont.

- Nor does the NVCIP bar suits against vaccine manufacturers outside of the NVCIP program, though all vaccine claims must initially begin under the NVCIP. If the plaintiff claims that the vaccine was not manufactured properly – a manufacturing defect – or that it was not accompanied with sufficient warnings, plaintiff can still sue in state courts if he or she is unhappy with the results in NVICP, but they have to go through NVICP first. However, if the plaintiff is claiming an injury from a design defect – because the vaccine was allegedly not designed safely enough – he or she cannot sue in state courts at all. (Bruesewitz v. Wyeth, 131 S.Ct. 1068 (2011)).
- The statute of limitations – the length of time during which you can file - is three years. Unlike in most states, it is not tolled – or stopped – for children. This is different than regular civil courts, where the statute of limitations is stopped for children: children can file throughout their childhood + the time of the statute. Note, however, that the statute of limitations is not tolled for other other claims against government either.
- The amount of money provided for a death is limited to \$250,000. That amount is low, and should probably be raised.
- In a recent decision, the Federal Circuit decided that parents cannot be compensated for lost earnings from a child if their child died before the age of 18. Tembenis v. Sec'y of Health & Human Servs., 733 F.3d 1190 (Fed. Cir. 2013) cert. denied, 13-902, 2014 WL 2921727 (U.S. June 30, 2014).

Are Vaccines “Unavoidably Unsafe”?

- Short answer: probably not, but if they were, it does not imply that they are unusually dangerous: quite the opposite.
- “Unavoidably unsafe” is a legal term of art. As such, it is used by lawyers to mean something different from the everyday conception of the term. For this reason, it can be easily misunderstood.
- Understanding “strict liability”: In the 1960s, the American Law Institute wrote section 402A of the Restatement (Second) of Torts. Under 402A, there would be a different standard of proof for cases involving product liability, “Strict liability” would be used in these cases, removing the burden on a plaintiff to show the manufacturer was negligent.
- Because the burden of proof on the plaintiff was now relaxed, there was worry that strict liability would chill the production of certain products that come with inherent risks but also important benefits. Accordingly, the drafters of 402A wrote “comment k” creating the category of “unavoidably unsafe” products.
- “Unavoidably unsafe” products are products whose benefits so far outweighed the risks that to win a product liability case against the manufacturer, you would have to show negligence. In other words, unavoidably unsafe products are more protected from liability – because they have substantial benefits.
- “Comment k” explained an unavoidably unsafe product: *“Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.”*
- One example of such a product was the old rabies vaccine, which had a much higher rate of complications than any modern vaccine, but because of the high risks of rabies – almost always fatal – its benefits still far outweighed those risks.
- Are vaccines unavoidably unsafe under this definition? Well, it depends on the state. Some states treat all pharmaceuticals as “unavoidably unsafe” and exempt all of them – drugs and vaccines – from strict liability. Others require a case by case determination that there isn’t a safer alternative design before exempting a product from strict liability. Some states are in between.
- In *Bruesewitz v. Wyeth*, the U.S. Supreme Court asked whether Congress was referring to the term “unavoidably unsafe” when setting up the National Vaccine Injury Compensation Program. A majority of the Supreme Court decided no: Congress was not trying to apply the “unavoidably unsafe” terminology to our childhood immunization schedule.

VFV: Mission Statement and functions

VFV: How to join

From: [Reiss, Dorit R.](#)
To: [Julie Murphy](#)
Cc: [Frank DeStefano \(fdestefano@cdc.gov\)](#); [Paul Offit \(paul.offit@gmail.com\)](#); [pickering007@bellsouth.net](#); [stanley.plotkin@vaxconsult.com](#)
Subject: Re: ACIP discussion - PLEASE HOLD THE DATE
Date: Friday, November 02, 2018 8:52:04 AM
Attachments: [image001.jpg](#)
[image002.jpg](#)

Done. Thinking if there's symbolism in it being Veterans Day.

Sent from my iPhone

On Nov 2, 2018, at 8:50 AM, Julie Murphy <Julie@immunize.org> wrote:

Hello,

Thank you for providing me with your availability for a conference call to discuss ACIP.

I am still waiting for a number of people to respond to my request, but it looks like **Monday, November 12, 2018, at 10 am CT/11 am ET** will work best.

Please tentatively hold this date/time and I hope to send a confirmation invitation within the next couple of days.

Let me know if you have any questions.

Kindest regards,
Julie

Julie Murphy, MA
Senior Administrator for Grants and Leadership
Immunization Action Coalition
651-647-9009

Free weekly immunization news? Read *IAC Express*
Sign up at www.immunize.org/subscribe/

[<image001.jpg><image002.jpg>](#)

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From: [Reiss, Dorit R.](#)
To: [Stanley Plotkin](#); Julie@immunize.org
Subject: Re: ACIP discussion - PLEASE HOLD THE DATE
Date: Friday, November 02, 2018 8:54:24 AM
Attachments: [image001.jpg](#)
[image002.jpg](#)

That would be fine for me, if that helps.

Sent from my iPhone

On Nov 2, 2018, at 8:53 AM, Stanley Plotkin <stanley.plotkin@vaxconsult.com> wrote:

Please, please change that to 10:30 am. Or I will be unable to attend.
Stanley

From: Julie Murphy [<mailto:Julie@immunize.org>]
Sent: Friday, November 02, 2018 11:51 AM
To: Frank DeStefano (fdestefano@cdc.gov); Paul Offit (paul.offit@gmail.com); pickering007@bellsouth.net; stanley.plotkin@vaxconsult.com; Dorit Reiss reissd@uchastings.edu
Cc: Julie Murphy
Subject: ACIP discussion - PLEASE HOLD THE DATE

Hello,

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<image001.jpg><image002.jpg>

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From: [Reiss, Dorit R.](#)
To: [Stanley Plotkin](#); "[Deborah L. Wexler](#)"
Cc: "[Amy Pisani](#)"
Subject: RE: Anyone who does pro-vaccine advocacy in France?
Date: Monday, June 02, 2014 9:34:51 AM

Thank you all very, very much.

Dorit Rubinstein Reiss
Professor of Law
UC Hastings College of the Law
415-5654844
reissd@uchastings.edu

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Monday, June 02, 2014 4:32 PM
To: 'Deborah L. Wexler'; Reiss, Dorit R.
Cc: 'Amy Pisani'
Subject: RE: Anyone who does pro-vaccine advocacy in France?

I am well aware of the controversy in France, where a surprising amount of antivaccination sentiment exists. I am going there tomorrow and will meet some of the people who participated in the May 22 debate. At the end of the week I can give some insight about it.
Stanley

From: Deborah L. Wexler [<mailto:Deborah@immunize.org>]
Sent: Monday, June 02, 2014 12:27 PM
To: Reiss, Dorit R.; Stanley Plotkin, MD
Cc: Amy Pisani (amyp@ecbt.org)
Subject: RE: Anyone who does pro-vaccine advocacy in France?

We can ask Stan Plotkin. I am going to cc him. He spends a fair amount of time in France. Stanley, can you help Dorit with her question?
Deborah

Deborah L. Wexler, MD
Executive Director
Immunization Action Coalition
deborah@immunize.org

From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]
Sent: Monday, June 02, 2014 11:06 AM
To: Deborah L. Wexler; Amy Pisani
Subject: Anyone who does pro-vaccine advocacy in France?

Hi Deborah and Amy,

Does either of you know any pro-vaccine advocate in France? This is making the rounds in the anti-vaccine community: <http://sanevax.org/france-aluminum-adjuvants-hpv-vaccines-debate/> and I'd like to get the real story and the meaning of it.

best,

Dorit Rubinstein Reiss
Professor of Law
UC Hastings College of the Law
415-5654844
reissd@uchastings.edu

From: [Reiss, Dorit R.](#)
To: [Stanley Plotkin](#)
Cc: [Deborah L. Wexler](#); [Amy Pisani](#)
Subject: RE: Anyone who does pro-vaccine advocacy in France?
Date: Monday, June 02, 2014 9:45:11 AM

I asked about this because it's coming up in social media and we are going to have to respond to it there. But if there's anything you think of that our social media group can do to help, please let us know.

Dorit Rubinstein Reiss
Professor of Law
UC Hastings College of the Law
415-5654844
reissd@uchastings.edu

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Monday, June 02, 2014 4:32 PM
To: 'Deborah L. Wexler'; Reiss, Dorit R.
Cc: 'Amy Pisani'
Subject: RE: Anyone who does pro-vaccine advocacy in France?

I am well aware of the controversy in France, where a surprising amount of antivaccination sentiment exists. I am going there tomorrow and will meet some of the people who participated in the May 22 debate. At the end of the week I can give some insight about it.
Stanley

From: Deborah L. Wexler [<mailto:Deborah@immunize.org>]
Sent: Monday, June 02, 2014 12:27 PM
To: Reiss, Dorit R.; Stanley Plotkin, MD
Cc: Amy Pisani (amyp@ecbt.org)
Subject: RE: Anyone who does pro-vaccine advocacy in France?

We can ask Stan Plotkin. I am going to cc him. He spends a fair amount of time in France. Stanley, can you help Dorit with her question?
Deborah

Deborah L. Wexler, MD
Executive Director
Immunization Action Coalition
deborah@immunize.org

From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]
Sent: Monday, June 02, 2014 11:06 AM
To: Deborah L. Wexler; Amy Pisani
Subject: Anyone who does pro-vaccine advocacy in France?

Hi Deborah and Amy,

Does either of you know any pro-vaccine advocate in France? This is making the rounds in the anti-vaccine community: <http://sanevax.org/france-aluminum-adjuvants-hpv-vaccines-debate/> and I'd like to get the real story and the meaning of it.

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UC Hastings College of the Law
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From: [Reiss, Dorit R.](#)
To: [Stanley Plotkin](#); "[Deborah L. Wexler](#)"
Cc: "[Amy Pisani](#)"
Subject: RE: Anyone who does pro-vaccine advocacy in France?
Date: Saturday, June 14, 2014 8:58:07 AM

Bad news indeed. Whether specific to HPV, or general.

Would it be appropriate to reach out to Dr. Autran and ask whether any of our social media groups can help, or at least offer support?

best,
Dorit.

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Friday, June 13, 2014 11:46 PM
To: 'Deborah L. Wexler'; Reiss, Dorit R.
Cc: 'Amy Pisani'
Subject: RE: Anyone who does pro-vaccine advocacy in France?

The situation is indeed bad. After discussion with French vaccinologists, it appears that they are in disarray as there is no government support of vaccination, which has become political, and few people willing to speak out in favor of science. There is an organization called Corevac, headed by Dr. Brigitte Autran brigitte.autran@psl.aphp.fr, but they have not been able to do much. The current government is unpopular and unlikely to take a strong stand. I was to meet the head of the French technical committee akin to the ACIP, but he failed to show up at the pro-vaccine meeting where I spoke and where he was supposed to speak, which gives you an idea of the situation.
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To: Reiss, Dorit R.; Stanley Plotkin, MD
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Immunization Action Coalition
deborah@immunize.org

From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]

Sent: Monday, June 02, 2014 11:06 AM

To: Deborah L. Wexler; Amy Pisani

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Dorit Rubinstein Reiss

Professor of Law

UC Hastings College of the Law

415-5654844

reissd@uchastings.edu

From: [Reiss, Dorit R.](#)
To: [Stanley Plotkin](#)
Subject: RE: Anyone who does pro-vaccine advocacy in France?
Date: Saturday, June 14, 2014 9:27:39 AM

Done.

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Saturday, June 14, 2014 4:07 PM
To: Reiss, Dorit R.
Subject: RE: Anyone who does pro-vaccine advocacy in France?

Can't hurt

From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]
Sent: Saturday, June 14, 2014 11:58 AM
To: Stanley Plotkin; 'Deborah L. Wexler'
Cc: 'Amy Pisani'
Subject: RE: Anyone who does pro-vaccine advocacy in France?

Bad news indeed. Whether specific to HPV, or general.

Would it be appropriate to reach out to Dr. Autran and ask whether any of our social media groups can help, or at least offer support?

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From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
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To: 'Deborah L. Wexler'; Reiss, Dorit R.
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Subject: RE: Anyone who does pro-vaccine advocacy in France?

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best,

Dorit Rubinstein Reiss
Professor of Law
UC Hastings College of the Law
415-5654844
reissd@uchastings.edu

From: [Reiss, Dorit R.](#)
To: [Stanley Plotkin](#)
Subject: Re: letter to the editor
Date: Thursday, May 31, 2018 5:12:32 PM
Attachments: [image001.png](#)

Thank you for doing this.

Sent from my iPhone

On May 31, 2018, at 5:11 PM, Stanley Plotkin <stanley.plotkin@vaxconsult.com> wrote:

I will try for the AAP News
Stanley

From: First, Lewis R [<mailto:lewis.first@med.uvm.edu>]
Sent: Tuesday, May 29, 2018 10:55 PM
To: stanley.plotkin@vaxconsult.com
Cc: Plemmons, Mark
Subject: RE: letter to the editor

Dear Dr. Plotkin,

Thank you for your email inquiring as to whether we would publish your letter in our journal. As Mr. Plemmons noted, our editorial board's policy regarding letters is only to publish letters that are initially comments posted online in regard to responses to an article we have published. Thus publishing a letter like yours, though important, opens a door to many others who also want to alert pediatricians as to what is going on in regard to other groups that are out to convince families to disregard scientific evidence on a variety of issues relevant to child health. Thus I would recommend you consider one of the following options:

1. Publish your letter in AAP News instead, where letters like yours can appear.
2. Wait until we have a vaccine study published or vaccine hesitancy study—and submit your letter as an online comment in regard to that article (that could become a published Letter to the Editor)
3. Convert your letter into an unsolicited commentary (a "Pediatric Perspectives" piece) which would require peer review but would if accepted appear in our journal.

I hope you find at least one of these options helpful.

Best,

Lewis First

Lewis R. First, MD, MS
Editor-in-Chief, *Pediatrics*
Professor and Chair
Department of Pediatrics

University of Vermont
Larner College of Medicine
Chief of Pediatrics
University of Vermont Children's Hospital
Given Courtyard S-250
Burlington, Vermont 05405
O: 802-656-0027
Fax: 802-656-2077
Email: lewis.first@uvm.edu

From: Plemmons, Mark <MPlemmons@aap.org>
Sent: Tuesday, May 29, 2018 2:04 PM
To: First, Lewis R <lewis.first@med.uvm.edu>
Subject: FW: letter to the editor

Dr. First,

Please see the attached comment and emails below. If you'd like me to respond to him further, let me know.

Sincerely,

Mark Plemmons || Publications Editor
American Academy of Pediatrics
Division of Journal Publishing
345 Park Blvd, Itasca, IL 60143
Phone: 630-626-6347

<image001.png>

Stay Connected On The New Clinical Research and News Network
Gateway.aap.org || [Blog](#)

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Tuesday, May 29, 2018 1:00 PM
To: Plemmons, Mark <MPlemmons@aap.org>
Subject: RE: letter to the editor

I take it that you will send the letter to Dr. First. I would appreciate it if you would transmit this attachment in order that he understands the value of the letter to Pediatrics.

Thank you,
Stanley Plotkin

From: Plemmons, Mark [<mailto:MPlemmons@aap.org>]

Sent: Tuesday, May 29, 2018 1:26 PM
To: Stanley Plotkin
Subject: RE: letter to the editor

Hi Dr. Plotkin,

Comments can only be posted in response to an article. We don't have anywhere to post comments that stand alone apart from an article. Was there a specific article this was in response to?

The "Letters to the Editor" feature in the *Pediatrics* journal published some online comments that have been chosen by the editors. Very few comments are chosen to be published in the journal; selection depends upon what the editors feel is timely and significantly contributes to the conversation regarding the article/topic. If your posted comment were selected, we'd be in touch to acquire a copyright release form before publication.

Sincerely,

Mark Plemmons || Publications Editor
American Academy of Pediatrics
Division of Journal Publishing
345 Park Blvd, Itasca, IL 60143
Phone: 630-626-6347

<image001.png>

Stay Connected On The New Clinical Research and News Network
Gateway.aap.org || [Blog](#)

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Tuesday, May 29, 2018 12:00 PM
To: Plemmons, Mark <MPlemmons@aap.org>
Subject: letter to the editor

Dear Dr. Plemmons:

I have had great difficulty in navigating the Pediatrics website in order to submit a letter to the Editor on a subject that should interest AAP members. I attach the letter and I realize it might be published only online but would still request your help to do so, as I think it carries some importance to the membership.

Thank you,
Stanley Plotkin

From: [Reiss, Dorit R.](#)
To: [Stanley Plotkin](#)
Subject: Re: michigan
Date: Wednesday, December 12, 2018 9:01:06 PM

Dear Stanley,

I apologize for the delay in answering. I reached out to a couple of colleagues with expertise in civil procedure, and the (less than satisfactory) answer is that it really depends on the locality and area, and there may not be any rules setting timing - and my colleagues are not sufficiently familiar with the specific rules that apply to that court. I can dig deeper or reach out to the lawyer, but it will take a few days.

best,
Dorit.

Dorit Rubinstein Reiss
Professor of Law
UC Hastings College of the Law
415-5654844
reissd@uchastings.edu

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Wednesday, December 12, 2018 9:17 PM
To: Reiss, Dorit R.
Subject: michigan

Dear Dorit:

I've asked you this before, but how long can the judge in Michigan stall without giving a decision?

Stan

From: [Reiss, Dorit R.](#)
To: [Offit, Paul](#); [Stanley Plotkin](#)
Subject: Re: Op-ed on vaccines
Date: Wednesday, May 30, 2018 4:39:30 AM

Small headshot. They put it next to the piece. Like what you use for conferences.

Sent from my iPhone

On May 30, 2018, at 4:16 AM, Offit, Paul <OFFIT@email.chop.edu> wrote:

Edits are fine. What pictures do you want?

From: Reiss, Dorit R. <reissd@uchastings.edu>
Sent: Tuesday, May 29, 2018 5:46 PM
To: Offit, Paul; Stanley Plotkin
Subject: Fw: Op-ed on vaccines

- A. Are the edits okay?
- B. Do you have pictures you can send - either to Ben directly, or to me and I will forward?
- C. I think my signature covers all of us, but will let you know if that's not the case.

best,
Dorit.

Dorit Rubinstein Reiss
Professor of Law
UC Hastings College of the Law
415-5654844
reissd@uchastings.edu

From: Ben Armistead <Ben_Armistead@dailyjournal.com>
Sent: Tuesday, May 29, 2018 9:17 PM
To: Reiss, Dorit R.
Subject: RE: Op-ed on vaccines

Thanks Dorit! Minor edits attached. Do you have photos of each author we can use?
(Have ours on file.)

Also, our freelance agreement is [here](#).

Best,

Ben

From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]
Sent: Tuesday, May 29, 2018 11:59 AM
To: Ben Armistead <Ben_Armistead@dailyjournal.com>
Subject: Re: Op-ed on vaccines

Dear Ben,

Please see attached my piece. As you will see, it's a multi-author piece. Please tell me if it fits the Daily Journal, or if it would fit after specific changes.

I appreciate your help in this, once again.

best,

Dorit.

Dorit Rubinstein Reiss

Professor of Law

UC Hastings College of the Law

415-5654844

reissd@uchastings.edu

From: Ben Armistead <Ben_Armistead@dailyjournal.com>

Sent: Tuesday, May 29, 2018 5:10 PM

To: Reiss, Dorit R.

Subject: RE: Op-ed on vaccines

That'd be great.

From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]

Sent: Tuesday, May 29, 2018 10:03 AM

To: Ben Armistead <Ben_Armistead@dailyjournal.com>

Subject: Re: Op-ed on vaccines

Hi Ben,

Thank you! I can send you a draft either today or tomorrow?

best,

Dorit.

Dorit Rubinstein Reiss

Professor of Law

UC Hastings College of the Law

415-5654844

reissd@uchastings.edu

From: Ben Armistead <Ben_Armistead@dailyjournal.com>
Sent: Tuesday, May 29, 2018 4:03 PM
To: Reiss, Dorit R.
Subject: RE: Op-ed on vaccines

Hi Dorit –

Sure, that'd be great! When do you think you can have it by?

Best,

Ben

From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]
Sent: Monday, May 28, 2018 9:48 PM
To: Ben Armistead <Ben_Armistead@dailyjournal.com>
Subject: Op-ed on vaccines

Dear Ben,

I wonder if you would be interested in an op-ed describing a problem that came up in family law cases where one parent wants to vaccinate and another does not, and a new resource prepared to respond to that?

best,

Dorit.

Dorit Rubinstein Reiss

Professor of Law

UC Hastings College of the Law

415-5654844

reissd@uchastings.edu

From: [Reiss, Dorit R.](#)
To: [Stanley Plotkin](#)
Subject: Re: Op-ed on vaccines
Date: Thursday, May 31, 2018 5:11:24 PM

Thank you!

Sent from my iPhone

> On May 31, 2018, at 5:05 PM, Stanley Plotkin <stanley.plotkin@vaxconsult.com> wrote:

>

>

>

> From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]

> Sent: Tuesday, May 29, 2018 5:46 PM

> To: Paul Offit ; Stanley Plotkin

> Subject: Fw: Op-ed on vaccines

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> A. Are the edits okay?

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> reissd@uchastings.edu

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> From: Ben Armistead <Ben_Armistead@dailyjournal.com>

> Sent: Tuesday, May 29, 2018 9:17 PM

> To: Reiss, Dorit R.

> Subject: RE: Op-ed on vaccines

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> Thanks Dorit! Minor edits attached. Do you have photos of each author we can use? (Have ours on file.)

>

>

>

> Also, our freelance agreement is here<<https://na3.docusign.net/Member/PowerFormSigning.aspx?PowerFormId=a092b7b2-cfe0-4455-a164-50b503bc82d7>>.

>

>

>

> Best,

>
> Ben
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> reissd@uchastings.edu<<mailto:reissd@uchastings.edu>>

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> Sent: Tuesday, May 29, 2018 4:03 PM

> To: Reiss, Dorit R.

> Subject: RE: Op-ed on vaccines

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> Best,

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> Ben

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> From: Reiss, Dorit R. [<mailto:reissd@uchastings.edu>]

> Sent: Monday, May 28, 2018 9:48 PM

> To: Ben Armistead <Ben_Armistead@dailyjournal.com<mailto:Ben_Armistead@dailyjournal.com>>

> Subject: Op-ed on vaccines

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> 415-5654844
>
> reissd@uchastings.edu<<mailto:reissd@uchastings.edu>>
> <photo Plotkin 1013.jpg>

From: [Reiss, Dorit R.](#)
To: [Stanley Plotkin](#); "Paul Offit"
Subject: Re: Potential Submission to the Family Advocate
Date: Friday, June 01, 2018 9:32:06 AM

I'll get it rolling.

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Friday, June 1, 2018 4:29 PM
To: Reiss, Dorit R.; 'Paul Offit'
Subject: RE: Potential Submission to the Family Advocate

I agree, we want to get the word out to the largest audience.
Stan

From: Reiss, Dorit R. [mailto:reissd@uchastings.edu]
Sent: Friday, June 01, 2018 9:39 AM
To: Paul Offit ; Stanley Plotkin
Subject: Fw: Potential Submission to the Family Advocate

So, the Family Advocate is the more fitting outlet, I think - we do not have a full law review article planned - but it's a long process. My inclination is to start it anyway, because this is a population we want to reach (family lawyers), while working to get the word out in other ways. But if a year ahead seems too long to you, I won't bother.

Thoughts?

Dorit

From: lisa_comforty@comforty.com <lisa_comforty@comforty.com>
Sent: Friday, June 1, 2018 11:54 AM
To: Reiss, Dorit R.
Subject: RE: Potential Submission to the Family Advocate

Hello, Dorit:

Thank you very much for your inquiry. As you may know, *Family Advocate* is the Section's magazine—articles are short (2,500 words), not footnoted, conversational in tone, and oriented towards the practitioner. The legal analysis is still, of course, required to be rigorous and accurate. *Family Law Quarterly*, on the other hand, is our law journal, with the typical footnoted and more academically oriented (though still practical) format. Articles are often 10,000 words or so. It would seem that you could write for either, of course.

That said, *Family Advocate* is planned very far in advance and in accordance with specific themes--authors have to wait a year or two sometimes just to be assigned a place in an issue. *FLQ* slots are a bit more flexible. I could put you in touch with either of the editors in chief. Do you have a preference?

Lisa

Lisa V. Comforty
Lisa Comforty Consulting, LLC

Managing Editor
Family Advocate/Family Law Quarterly
ABA Section of Family Law
Email: lisa_comforty@comforty.com
Telephone: 224-425-6833

From: Reiss, Dorit R. <reissd@uchastings.edu>
Sent: Thursday, May 31, 2018 10:10 PM
To: lisa_comforty@comforty.com
Subject: Potential Submission to the Family Advocate

Dear Ms. Comforty,

I am a professor of law in UC Hastings College of the Law. Over the past five years my focus has been on law and policy related to vaccines. In that role I have been watching and communicating with family lawyers in cases in which the parents debate whether to vaccinate or not.

I would like to write an article about the legal situation in such cases and the potential pitfalls, with some advice. Does that sound like something that might be of interest? I am not a lawyer. But I have received multiple queries over the years from family law lawyers wanting to discuss it.

best,
Dorit.

Dorit Rubinstein Reiss
Professor of Law
UC Hastings College of the Law
415-5654844
reissd@uchastings.edu

From: [Reiss, Dorit R.](#)
To: [Stanley Plotkin](#)
Subject: Re: [VACSAFETY] New Hooker analysis
Date: Wednesday, December 12, 2018 8:59:14 AM

I'm glad it helped, Dr. Plotkin. I find Orac's work very helpful in many contexts.

Since Ms. Kroner is looking for people for a new effort, it's good for the people on the list to be warned, too.

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Wednesday, December 12, 2018 3:05 PM
To: Reiss, Dorit R.
Subject: FW: [VACSAFETY] New Hooker analysis

Dear Dorit:

Thank you for this, which led me to Orac, which enabled me to read his comments on Shannon Kroner, who is trying to get me to participate in a debate on vaccines and autism, which I will not do.

Stan

From: Vacsafety [mailto:VACSAFETY@LISTSERV.IMMUNIZE.ORG] **On Behalf Of** Reiss, Dorit R.
Sent: Wednesday, December 12, 2018 9:27 AM
To: VACSAFETY@LISTSERV.IMMUNIZE.ORG
Subject: [VACSAFETY] New Hooker analysis

Hi All,

In case people need a rebuttal, Orac went through this paper.

<https://respectfulinsolence.com/2018/12/12/brian-hookers-antivaccine-pseudoscience-has-risen-from-the-dead-to-threaten-children-again/>

"As for the analysis, unsurprisingly Hooker finds what he describes as a statistically significant correlation between MMR vaccination and autism diagnosis, but it depends on age of first MMR vaccination. For instance, for receipt of first MMR dose at 18 months or earlier, there is no statistically significant relationship. At 24 months, there is a weakly statistically significant ($p=0.03$) relationship with an odds ratio of 1.82. However, there were only 23 cases, which is a small number for a case-control study like this. At 36 months, the odds ratio was 3.86, but this is based on only 7 cases. You can see the problem with this. It's the same problem that Hooker had with his previous result and the same reason that DeStefano et al didn't think the correlation was real; the numbers are so small that this is almost certainly a spurious result, particularly given that it

wasn't seen in any other subgroup and there is no biologically plausible mechanism why MMR would increase the risk of autism in only African-American males who received the MMR after 24 months.

...

In other words, it sounds as though Hooker, faced with annoying potential corrections for confounders (covariates), simply dispensed with correcting for them in his reanalysis. "

best,
Dorit.

Dorit Rubinstein Reiss
Professor of Law
UC Hastings College of the Law
415-5654844
reissd@uchastings.edu

To unsubscribe from the VACSAFETY list, click the following link:

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