IADC COMMITTEE NEWSLETTER

PRODUCT LIABILITY

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IN THIS ISSUE

Pharmaceutical manufacturers have recently focused their research efforts on the development of vaccines to protect both mothers and their unborn children. As the administration of vaccines like the flu and Tdap vaccines to pregnant women becomes the standard of care in the United States, vaccine manufacturers face increased liability risks since both women and babies exposed in utero may be eligible to claim compensation for alleged vaccine-related harms. This article focuses on the public health benefits of maternal vaccination as well as the litigation risks for manufacturers when claims for in utero injuries are brought under the National Childhood Vaccine Injury Act.

Immunizing Pharma Liability: Maternal Vaccination and Manufacturer Risk

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Although pregnant women were routinely immunized with diphtheria, influenza, and polio vaccines in the 1950s, a lack of safety data coupled with sensationalized reports of failed clinical trials involving pregnant women in the 1960s led to a halt in maternal vaccination research.[1] Despite the life-saving potential of maternal vaccines, pharmaceutical companies have labeled pregnant women "off limits" for decades. Following several outbreaks and the increasing endorsement of maternal vaccinations by public health authorities like the Centers for Disease Control and Prevention (CDC) and the American Congress of Obstetricians and Gynecologists (ACOG), pharmaceutical manufacturers are beginning to dip their toes back into developing or expanding their vaccine platform to include efforts to protect unborn children. Boosters inoculating against common (and dangerous) childhood illnesses, like respiratory syncytial virus (RSV) and pertussis (or whooping cough) could become a routine part of pregnancy as well as a source of booming business – ultimately as large a market as the current market for pediatric vaccines – for pharmaceutical manufacturers.[2] This opportunity for market expansion will undoubtedly lead to increased liability risks for manufacturers as both women, and presumably, babies exposed *in utero*, may be eligible to claim compensation for alleged vaccine-related harms.

Benefits of Maternal Immunization

To date, the United States Food and Drug Administration (FDA) has not approved a vaccine specifically for the purpose of protecting unborn children, but researchers have identified advantages to vaccinating expectant mothers.[3] In particular, numerous studies have demonstrated that vaccinating pregnant women allows for the passage of protective antibodies from mother to baby.[4] The importance of these findings cannot be overstated. Infants are left in a vulnerable state in the first months and up to one year of life before they can receive many vaccinations directly, and the passage of maternal antibodies is viewed as a way to bridge the gap and provide protection until infants can be immunized.[5]

For that reason, numerous public health authorities currently recommend, and in many cases it has become the standard of care, that pregnant women receive vaccines against two common but potentially very harmful illnesses to infants: influenza and pertussis (also known as whooping cough). Beginning in 2009, the CDC recommended that pregnant women receive the flu vaccine,

[1] Janet A. Englund, *Overview of Maternal Immunization: Benefitting Mothers and Their Children* (2015), https://cdn2.sph.harvard.edu/wp-content/uploads/sites/32/2015/12/Janet-Englund.pdf.

[2] Cynthia Koons & Ketaki Gokhale, *Why Drug Companies Want to Sell Vaccines to Pregnant Women*, BLOOMBERG, June 30, 2016.

[3] *Id.*

[4] *Maternal Vaccines: Part of a Healthy Pregnancy*, CENTERS FOR DISEASE CONTROL AND PREVENTION, http://www.cdc.gov/vaccines/pregnancy/pregnant-women/index.html (last visited Nov. 22, 2016).

[5] *See Newborn Immune System*, WELLNESS, http://www.wellness.com/reference/allergies/newborn-immune-system (last visited Nov. 22, 2016).

after outbreaks of swine flu resulted in hospitalizations, premature labor, and delivery complications.[6] Similarly, starting in 2011, the Advisory Committee on Immunization Practices (ACIP), which provides guidance regarding the use of vaccines to the Director of the CDC, began to issue a serious of recommendations for the administration of the Tdap vaccine (protecting against tetanus, diphtheria, and pertussis) to all pregnant women in response to a substantial increase in cases of whooping cough among infants.[7] Infants account for 90% of all pertussis-related deaths because their immune systems are too undeveloped to handle a series of vaccines administered to older infants.[8] Therefore, newborns depend on maternal antibodies, which significantly increase in infants whose mothers receive the Tdap vaccine while pregnant.[9] ACOG now also recommends that pregnant women receive flu and Tdap vaccinations to protect both mothers and infants.[10] With the increased focus on the benefits of the passage of maternal antibodies, researchers have studied whether the flu or Tdap vaccines are associated with adverse fetal outcomes. The results to date have been reassuring.[11]

The flu and Tdap vaccines are currently available to physicians to administer to pregnant women; in fact, the administration of these vaccines has become the standard of care in the United States.[12] However, vaccine manufacturers are also seeking to develop new vaccines that are intended to protect infants through maternally-derived antibodies. For example, vaccines against Group B streptococcus and RSV are currently

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[6] *Pregnant Women and Influenza*, CENTERS FOR DISEASE CONTROL AND PREVENTION, http://www.cdc.gov/flu/protect/vaccine/pregnant.htm (last visited Nov. 22, 2016).

[7] *Updated Recommendations for Use of Tdap in Pregnant Women*, MORBIDITY AND MORTALITY WEEKLY REPORT (Feb. 22, 2013), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm.

[8] Flor M. Munoz et. al., *Safety and Immunogenicity of Tdap Immunization During Pregnancy in Mothers and Infants: A randomized Clinical Trial*, 311 JAMA 1760 (2014).

[9] *Id.*

[10] *The Flu Vaccine and Pregnancy*, ACOG, http://www.acog.org/Patients/FAQs/The-Flu-Vaccine-and-Pregnancy#does (last visited Dec. 8, 2016); *Committee Opinion No. 566: Update on Immunization and Pregnancy*, ACOG (June 2013), http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Update-on-Immunization-and-Pregnancy-Tetanus-Diphtheria-and-Pertussis-Vaccination.

[11] *See, e.g.,* Pedro L. Moro et. al., *Adverse Events in Pregnant Women Following Administration of Trivalent Inactivated Influenza Vaccine and Live Attenuated Influenza Vaccine in the Vaccine Adverse Event Reporting System, 1990-2009*, 204 AJOG 146 (2011); http://www.cdc.gov/flu/protect/vaccine/qa_vacpregnant.htm; *Updated Recommendations for Use of Tdap in Pregnant Women*, MORBIDITY AND MORTALITY WEEKLY REPORT (Feb. 22, 2013), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm.

[12] *Pregnancy*, IMMUNIZATION FOR WOMEN, http://immunizationforwomen.org/providers/pregnancy/pregnancy.php (last visited Dec. 8, 2016) (describing flu and Tdap vaccines as "routinely recommended during pregnancy"; *Recommended Adult Immunization Schedule United States 2016*, CDC, http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule.pdf.

in clinical development.[13][14] RSV infects nearly 70% of infants during their first year of life and is responsible for one-third of deaths resulting from lower respiratory infection.[15] And Group B strep results in 2.9 million neonatal deaths annually worldwide, significantly affecting infants in developing and poor countries.[16]

Hurdles in Developing Maternal Vaccines

Although acceptance of maternal vaccination has increased, both in the medical community and among the public, misconceptions about the dangers of vaccinations are still prevalent. For example, only about half of pregnant women received the flu vaccine in 2015-2016.[17] One 2011 study found that 29% of unvaccinated women stated that they were concerned about the vaccine's effect on the fetus.[18] Uptake of the Tdap vaccine has been similarly slow; a report in 2012 estimated that less than 3% of pregnant women received the vaccine.[19] Some of this hesitation in the United States may be due to the fact that FDA has yet to approve a specific indication for the use of vaccines in pregnant women to protect against illnesses in the infant.[20] In contrast, some foreign regulatory bodies have approved certain vaccines for administration during pregnancy with the purpose being to protect the infant.[21]

The stumbling block that manufacturers have encountered in receiving a specific indication for administration during pregnancy might be due to the generally-accepted exclusion of

[13] Deborah Higgins et. al., *Advances in RSV Vaccine Research and Development: A Global Agenda* (2016), http://www.who.int/immunization/sage/meetings/2016/april/1_Advances_RSV_Vaccine_Research_Development_A_Global_Agenda.pdf.

[14] Tara Haelle, *Group B Step Vaccine for Pregnant Women Found Safe, Effective in Phase 2 Trial*, FORBES, Jan. 12, 2016.

[15] Deborah Higgins et. al., *Advances in RSV Vaccine Research and Development: A Global Agenda* (2016), http://www.who.int/immunization/sage/meetings/2016/april/1_Advances_RSV_Vaccine_Research_Development_A_Global_Agenda.pdf.

[16] *Maternal GBS Vaccine*, GSK (Sept. 7, 2015), http://www.who.int/immunization/research/meetings_workshops/12_Group_B_Strep.pdf?ua=1.

[17] RESULTS OF CDC'S 2015-2016 INTERNET PANEL SURVEY OF PREGNANT WOMEN, http://www.cdc.gov/flu/pdf/partners/flu-pregnancy-infographic-updated.pdf (last visited Nov. 22, 2016).

[18] Helen Ding, et. al., *Pregnant Women and Flu Shots*, (2011), http://origin.glb.cdc.gov/flu/pdf/fluvaxview/1112-pregnant-women.pdf.

[19] *Updated Recommendations for Use of Tdap in Pregnant Women*, MORBIDITY AND MORTALITY WEEKLY REPORT (Feb. 22, 2013), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm.

[20] Marion Gruber, *Regulatory Issues for Maternal Immunization*, NVAC (Sept. 9, 2014), https://www.hhs.gov/sites/default/files/nvpo/nvac/meetings/pastmeetings/2014/gruber_maternal_immunization_septnvac2014.pdf.

[21] For example, in November 2016, the German regulatory authority, Paul-Ehrlich-Institut, acting as the reference authority in Europe, approved GSK's updated Boostrix™ and Boostrix Polio™ vaccine labels with additional safety data in pregnant women. Boostrix™, indicated for booster vaccination against diphtheria, tetanus, pertussis (Tdap), and Boostrix Polio™, indicated for vaccination against poliomyelitis, are the first Tdap vaccines with safety data in pregnant women included in their labels. *GSK receives European approval for updated Boostrix™ and Boostrix Polio™ label to benefit pregnant women*, PHARMAVOICE, (Nov. 1, 2016), http://www.pharmavoice.com/newsreleases/gsk-receives-european-approval-updated-boostrix-boostrix-polio-label-benefit-pregnant-women/.

pregnant women from clinical trials. Although there is a growing body of research showing both the efficacy, *i.e.*, data establishing the passage of and effectiveness of maternal antibodies, as well as the safety of maternal vaccinations, the data are primarily from animal or epidemiologic studies. There have been limited well-controlled clinical trials of vaccines in pregnant women, but manufacturers are increasingly investigating ways in which to conduct these FDA-required clinical trials given the potential life-saving nature of maternal vaccinations. It remains to be seen how manufacturers will navigate the waters of recruitment of pregnant women or even approval from Institutional Review Boards that may be hesitant to approve a placebo-controlled study where the administration of the vaccine during pregnancy may be considered the standard of care, as in the case of Tdap and flu.

While the industry mindset seems to be evolving to recognize maternal immunization as a viable focus, the development and marketing of new vaccines may be impacted by resolution of an unsettled area of liability for vaccine manufacturers: will manufacturers be subject to liability for potential harm to children whose mothers were vaccinated during pregnancy, or will claims of that nature fall within the protections of the National Childhood Vaccine Injury Act ("Vaccine Act or Act")?

Liability Protection: The National Childhood Vaccine Injury Act

In response to increasing litigation and litigation costs relating to allegations of vaccine-related injuries – and the resulting vaccine shortage because manufacturers were disincentivized from developing and supplying vaccines[22] – Congress enacted the National Childhood Vaccine Injury Act of 1986.[23] The Vaccine Act served two primary functions. First, the Act established an extensive federal role in vaccine safety and development, including the establishment of the National Vaccine Advisory Committee to advise the Department of Health and Human Services (HHS) on research priorities and to study and recommend ways to encourage vaccine safety and availability. Second, the Act created the National Vaccine Injury Compensation Program (VICP) that provides for no-fault compensation for claimants alleging a vaccine-related injury. In exchange, vaccine manufacturers are afforded significant protection from liability for injuries allegedly arising from vaccines. In particular, the Vaccine Act mandates that claims for covered vaccine-related injuries must be brought under the VICP – in the United States Court of Federal Claims, or "Vaccine Court" – before proceeding in civil court.[24]

Claims that must be brought under the VICP are subject to more flexible rules of procedure

[22] Anna L. Jacobs, *Liability and Maternal Immunization: In Utero Injury Claims in the VICP*, 207 AJOG S63 (2012), available at http://www.ajog.org/article/S0002-9378(12)00730-2/fulltext.

[23] *See* 42 U.S.C. §§ 300aa-1 *et seq.*

[24] *See* 42 U.S.C. § 300aa-11(a)(1).

and evidence.[25] An injured party must file a petition in Vaccine Court and show by a preponderance of the evidence that he received a vaccine listed on the Vaccine Injury Table and suffered an injury that was caused by the vaccine.[26] Causation is presumed if the injury is listed on the Vaccine Injury Table and occurred within a specified time frame.[27] The VICP also provides a significant benefit to manufacturers: a manufacturer is afforded generous product liability protections because it is not a party to VICP claims and is thus shielded from the risk of a finding of liability and damages.[28] Petitions under the VICP are initially heard by a special master, whose decision may be reviewed by a judge in the United States Court of Federal Claims and in turn by the United States Court of Appeals for the Federal Circuit.[29] A petitioner may reject a judgment of the Court of Federal Claims and file a civil lawsuit against a vaccine manufacturer, subject to certain limitations under the Vaccine Act.[30]

The recent interest in the development of maternal vaccines has highlighted an issue that has received periodic attention in the Vaccine Court: does the Vaccine Act contemplate injuries caused *in utero* from a maternal vaccination. The court's analysis of that question has turned on the interpretation of the following language of the Vaccine Act:

> A petition for compensation under the Program for a vaccine-related injury or death shall contain…an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died…***received a vaccine*** set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine[31]

Decisions in Recent Cases Involving Alleged *In Utero* Vaccine Injury

The Federal Claims Court has struggled to interpret the term "receive" in cases involving claims for alleged *in utero* injury. Because the Federal Circuit has not weighed in on the issue, the law remains unsettled. The majority of cases addressing compensation for *in utero* injuries under the VICP in the early 1990s and 2000s held that a child may not recover under the Act because the child itself had not received the vaccine.[32] The special masters in these early cases focused on Congress' intent

[25] 42 U.S.C. § 300aa-11(a)(1).
[26] 42 C.F.R. Part 100.3.
[27] Anna L. Jacobs, *Liability and Maternal Immunization: In Utero Injury Claims in the VICP*, 207 AJOG S63 (2012), available at http://www.ajog.org/article/S0002-9378(12)00730-2/fulltext.
[28] *History of Vaccine Safety*, CDC, http://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html (last visited Dec. 12, 2016); NVAC, THE NATIONAL VACCINE ADVISORY COMMITTEE: REDUCING PATIENT AND PROVIDER BARRIERS TO MATERNAL IMMUNIZATIONS 36 (2014).
[29] 42 U.S.C. § 300aa-12(c)-(f).
[30] 42 U.S.C. § 300aa-11(a)(2)(A).
[31] 42 U.S.C. § 300aa-11(c) (emphasis added).
[32] *Melton v. Sec'y of Dep't of Health & Human Servs.*, No. 01-105V, 2002 WL 229781, *1 (Fed. Cl. Jan. 25, 2002); *Di Roma v. Sec'y of Health & Human Servs.*, No. 90-3277, 1993 WL 496981, *3 (Fed. Cl. Nov. 18, 1993); *Van Houter v. Sec'y of Dep't of Health & Human Servs.*,

to exclude fetuses from the VICP, evidenced by the Vaccine Act's clear indication that an injured party must have "received a vaccine…or if such person did not receive a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine."[33] Congress made only one exception – for parties who contracted polio from another person who received a polio vaccine – to the requirement that an injured person receive a vaccine, and, the special masters reasoned, fetuses clearly fell outside the bounds of this exception.[34]

Recent VICP cases, however, have held that a child injured *in utero* resulting from a vaccine given to the pregnant mother may recover.[35] For example, in 2013, the special master in *Schultz v. Sec'y of Health & Human Servs.*[36] determined that a child's injury allegedly resulting from his premature birth after his mother received a flu vaccine was compensable under the VICP. The special master looked to the plain meaning of the term "receive," reasoning that a fetus receives or acquires things from his mother *in utero*, and is therefore capable of receiving a vaccine through his mother.[37] In contrast to the narrow interpretation of the term by earlier courts, the special master noted that the Vaccine Act is a broad remedial statute that should "be construed in a manner that effectuates that underlying spirit and purpose."[38]

Cases, like *Schultz*, that permit compensation under the VICP for *in utero* injuries allegedly resulting from vaccines promote the goal of compensating rare injuries while ensuring that vaccine manufacturers continue to research and develop vaccines. The Act reduces the burden of civil litigation on manufacturers, thus encouraging continued vaccine research and development, because the manufacturer is shielded from claims in Vaccine Court; petitions are filed against the Secretary of HHS as the respondent.[39] Moreover, compensation under the VICP is funded by a $.75 excise tax on vaccines recommended by the CDC for routine administration to children.[40]

No. 90-1444V, 1991 WL 239056, *2 (Cl. Ct. Oct. 30, 1991).

[33] 42 U.S.C. § 300aa-11(c).

[34] *See Melton,* 2002 WL 229781, *1; *Di Roma*, 1993 WL 496981, *3; *Van Houter*, 1991 WL 239056, *2.

[35] *Sumner v. Sec'y of Health & Human Servs.*, No. 99-946V, 2015 WL 5173644, *7 (Fed. Cl. Aug. 13, 2015) (holding that petitioner could recover for *in utero* injury caused by vaccine administered to mother if she could prove the vaccine caused her injury); *N.H. ex rel. Castaneda v. Sec'y of Dep't of Health & Human Servs.*, No. 11-749V, 2012 WL 1722346, *6 (Fed. Cl. Apr. 24, 2012) (denying respondent's motion to dismiss because petitioner could have received vaccine *in utero*); *Rooks v. Sec'y of Dep't of Health & Human Servs.*, 35 Fed. Cl. 1, 12 (1996) (Court of Federal Claims vacated special master's decision and held that a child whose mother received the MMR vaccine while pregnant was eligible for compensation under the Vaccine Act).

[36] No. 12-234V, 2013 WL 5314595, *1 (Fed. Cl. Aug. 30, 2013)

[37] *Schultz*, 2013 WL 5314595, *1.

[38] *Id.*

[39] Anna L. Jacobs, *Liability and Maternal Immunization: In Utero Injury Claims in the VICP*, 207 AJOG S63 (2012), available at http://www.ajog.org/article/S0002-9378(12)00730-2/fulltext.

[40] *About the National Vaccine Injury Compensation Program*, HEALTH RESOURCES AND SERVICES ADMINISTRATION, https://www.hrsa.gov/vaccinecompensation/about/ (last visited Dec. 12, 2016).

Claims outside of the jurisdiction of the Vaccine Act are dismissed and may be refiled in civil court against the vaccine manufacturer.[41] Therefore, when a special master finds that a claim alleging an *in utero* vaccine-related injury is outside the subject matter jurisdiction of the Vaccine Act because the fetus did not receive a vaccine, the petitioner may then impose liability against the manufacturer in civil court. Because of the broad implications for manufacturer liability and public health, it is vital that courts addressing claims for *in utero* injury follow the modern interpretation of the term "receive" under the Act. By reasoning that alleged victims whose pregnant mothers were administered a vaccine did, in fact, receive a vaccine, courts compensate rare injuries and protect manufacturers from tort claims filed in civil court.

The courts are not alone in tackling whether *in utero* injuries should fall within the ambit of the Vaccine Act. The National Vaccine Advisory Committee (NVAC) charged by the Assistant Secretary for Health with reviewing the current state of maternal immunizations to identify barriers to the implementation of current recommendations, has cited the lack of definitive protection for vaccine manufacturers as a potential obstacle to the development of vaccines specifically designed to protect pregnant women and babies.[42] For that reason, the NVAC recommends allowing claims of alleged vaccine-related *in utero* injuries to be pursued under the VICP to provide settled liability protection to vaccine manufacturers and administrators.[43] The NVAC advances several potential avenues for the HHS Secretary to implement this recommendation, including: 1) supporting a statutory amendment to the Vaccine Act to include language that specifies coverage for live-born infants of mothers vaccinated during pregnancy; 2) pursuing administrative rule-making to adopt a broader interpretation of the Act; or 3) supporting a litigation strategy to seek a binding decision on *in utero* coverage through the U.S. Court of Appeals.[44]

In December 2014, four members of Congress who authored and co-sponsored the Vaccine Act urged HHS to move forward with the NVAC's recommendations.[45] In a letter to the Secretary of HHS, Congressional members noted that the Act was created to establish a "dynamic framework to facilitate the advancement of vaccine science and technology" like advancements in maternal immunization and passive immunity to newborns.[46] The Congressmen called on HHS to expand VICP coverage to specifically include maternal immunizations, thereby

[41] *Melton*, 2002 WL 229781, at *1 (special master dismissed complaint alleging injuries child received *in utero* after mother received MMR vaccine for lack of subject matter jurisdiction under the Vaccine Act).

[42] NVAC, THE NATIONAL VACCINE ADVISORY COMMITTEE: REDUCING PATIENT AND PROVIDER BARRIERS TO MATERNAL IMMUNIZATIONS 36 (2014), http://www.hhs.gov/sites/default/files/nvpo/nvac/reports/nvac_reducing_patient_barriers_maternal_immunizations.pdf.

[43] *Id.*at 37.

[44] *Id.*

[45] Letter from Rep. Henry Waxman, Sen. Orrin Hatch, Sen. Ron Wyden, & Sen. Edward Markey to Hon. Sylvia Burwell, Sec. of HHS (Dec. 11, 2014).

[46] *Id.*

promoting the goal of developing new vaccines and providing compensation to those injured by them.[47]

Conclusion

Until a decision by the Federal Circuit or a Congressional statutory amendment clarifies the language of the Vaccine Act, vaccine manufacturers face uncertain risks associated with developing maternal vaccinations for the purpose of protecting unborn babies. As manufacturers have begun to realize the life-saving potential of maternal vaccination for both mothers and infants, decreasing liability risks related to the few injuries allegedly caused by vaccines could be crucial to the advancement of public health.

[47] *Id.*

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