LIABILITY ISSUES WITH VACCINATIONS

JENNIFER R. ANNIS

ATKINSON, HASKINS, NELLIS,

BRITTINGHAM, GLADD & FIASCO



THE DEBATE BEGAN LONG AGO . . .



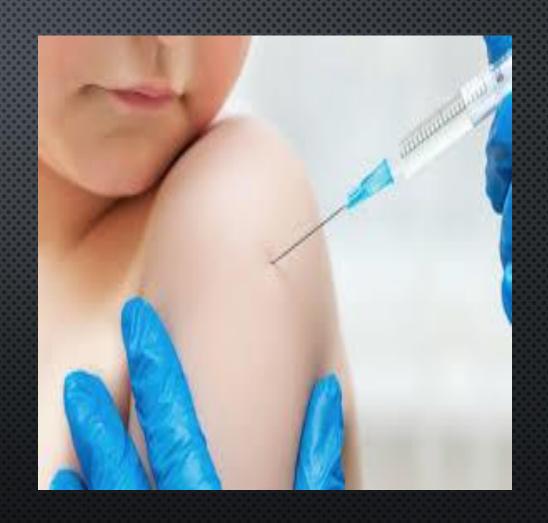
UP SWING IN LITIGATION IN THE 1970'S



NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 (NCVIA) 42 U.S.C. § 300AA-26

- RESPOND TO PUBLIC HEALTH CONCERNS ABOUT VACCINES
- REDUCE VACCINE LIABILITY
- PREVENT ANTICIPATED VACCINE SHORTAGES
- ESTABLISH FORUM FOR THOSE INJURED BY VACCINES
- COVERS ALL VACCINES RECOMMENDED BY CDC FOR ROUTINE ADMINISTRATION TO KIDS & ADULTS

- 1. DIPTHERIA
- 2. TETANUS
- 3. PERTUSSIS
- 4. MEASLES
- 5. MUMPS
- 6. RUBELLA
- 7. Polio
- 8. HEPATITIS A
- 9. HEPATITIS B
- 10. HAEMOPHILUS INFLUENZAE TYPE B (HIB)
- 11.INFLUENZA
- 12. PNEUMOCOCCAL CONJUGATE
- 13. MENINGOCOCCAL
- 14. ROTAVIRUS
- 15.HPV
- 16. VARICELLA (CHICKEN POX)



NCVIA REQUIREMENTS

MUST ADVISE ALL PARENTS AND PATIENTS OF THE RISKS AND BENEFITS VIA VACCINE INFORMATION STATEMENTS (VISS)

- Must do so for <u>EVERY DOSE</u> of <u>EVERY VACCINE</u>
 GIVEN!
- VISS ARE PRODUCED BY THE CDC AND CANNOT BE ALTERED,
 OTHER THAN TO ADD PRACTICE INFO

HTTP://WWW.CDC.GOV/VACCINES/PUBS/VIS/DEFAULT.HTM

OTHER NCVIA REQUIREMENTS

DOCUMENTATION OF:

- 1. Date administered
- 2. VACCINE MANUFACTURER
- 3. VACCINE LOT NUMBER
- 4. NAME AND BUSINESS ADDRESS OF ADMINISTERING HEALTHCARE PROFESSIONAL
- 5. VIS VERSION DATE
- 6. DATE THE VIS WAS PROVIDED TO THE PARENT/GUARDIAN

AAP ALSO RECOMMENDS:

- 1. SITE AND ROUTE OF ADMINISTRATION
- 2. VACCINE EXPIRATION DATE
- 3. STATEMENT THAT VIS WAS GIVEN AND DISCUSSED WITH PARENT/GUARDIAN



VISS FOR OTHER VACCINES NOT COVERED BY NCVIA

- 1. ADENOVIRUS (MILITARY USE ONLY)
- 2. ANTHRAX
- 3. CHOLERA
- 4. JAPANESE ENCEPHALITIS
- 5. PNEUMOCOCCAL POLYSACCHARIDE
- 6. RABIES
- 7. SHINGLES
- 8. TYPHOID
- 9. YELLOW FEVER

^{*} VISS ARE REQUIRED FOR THESE IF THE VACCINE IS PURCHASED UNDER CDC CONTRACT.

WHAT IF THERE IS AN ADVERSE REACTION?

should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7 | How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):

REFER THEM TO THE VCIP

VCIP

\$4.15 BILLION IN CLAIMS PAID SINCE 1988

- * BILLIONS OF VACCINE DOSES DISTRIBUTED TO HUNDREDS OF MILLIONS OF AMERICANS
- * 520 DEATH CLAIMS, MOSTLY FOR OLD WHOOPING COUGH VACCINE, NOT GIVEN IN THE LAST 20 YEARS
- * 6,600 CLAIMS PAID
- * 70% of payments for claims where there was not sufficient evidence that vaccines were at fault + The "no fault" alternative to traditional lawsuits.

2006 – 2017:

- * 3.4 BILLION VACCINES DOSES DISTRIBUTED IN THE U.S.
- * ABOUT 700 CLAIMS MADE

\$25 MILLION IN LEGAL FEES PAID IN 2017 ALONE

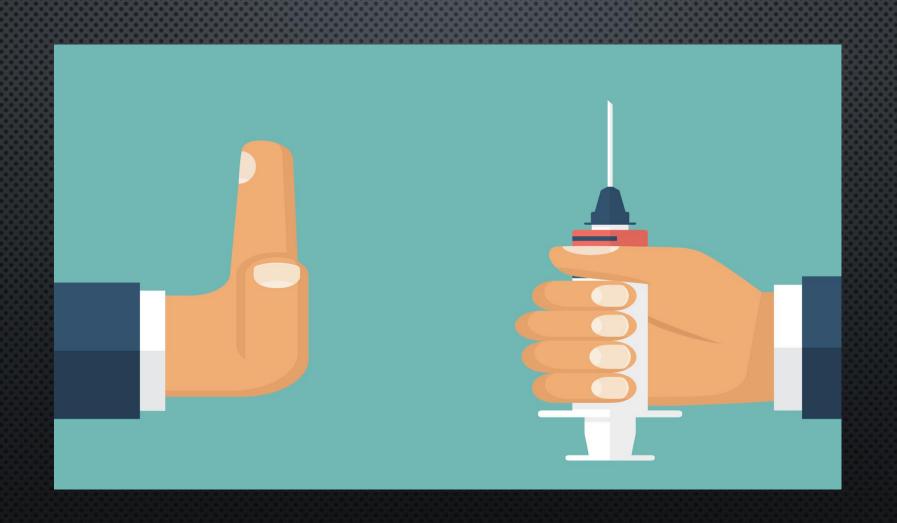
"VACCINE INJURY CLAIMS ARE FEW AND FAR BETWEEN." THE NEW YORK TIMES; JUNE 18, 2019

VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

CO-MANAGED BY THE CDC AND THE FDA

REPORT CAN BE DONE ONLINE: <u>WWW.VAERS.HHS.GOV</u>

AND NOW FOR THE TRICKY PART – REFUSAL.



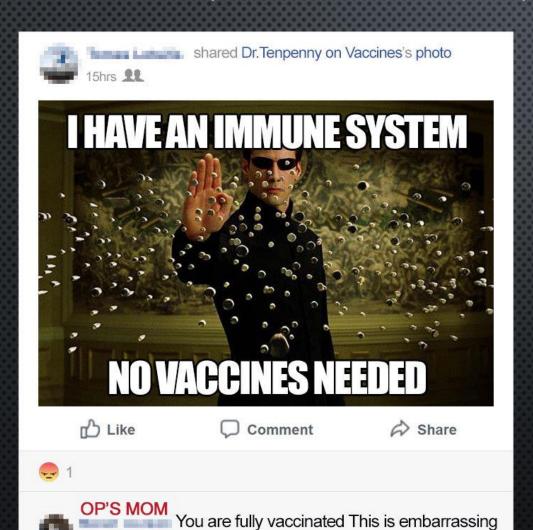
THE "ANTI-VAXXER" MOVEMENT





POSTING, AND POSTING, AND POSTING . . .

boredpanda.com





Shane Jay Post about it on Facebook. In any case DO NOT take them to a medical doctor. Facebook is the MOST RELIABLE source of medical information - particularly when it comes to Vaccine Science. #GodBless



AMA LETTER MARCH 13, 2019



"WITH PUBLIC HEALTH ON THE LINE AND WITH SOCIAL MEDIA SERVING AS A LEADING SOURCE OF INFORMATION FOR THE AMERICAN PEOPLE, WE URGE YOU TO DO YOUR PART TO ENSURE THAT USERS HAVE ACCESS TO SCIENTIFICALLY VALID INFORMATION ON VACCINATIONS, SO THEY CAN MAKE INFORMED DECISIONS ABOUT THEIR FAMILIES' HEALTH. WE ALSO URGE YOU TO MAKE PUBLIC YOUR PLANS TO ENSURE THAT USERS HAVE ACCESS TO ACCURATE, TIMELY, SCIENTIFICALLY SOUND INFORMATION ON VACCINES."

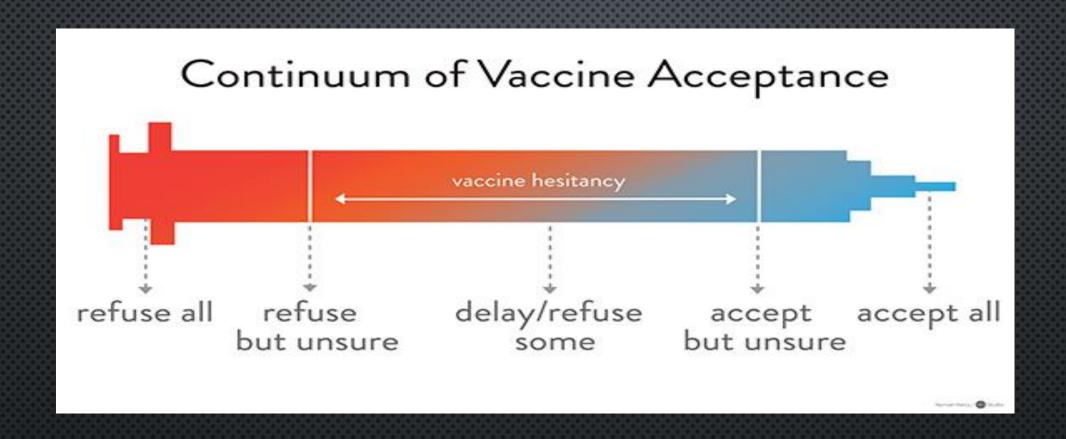
JAMES L. MADARA, M.D.

THE VCIP EFFECT

LAW FIRMS SPECIALIZE IN THE VCIP PROGRAM

- * DAY TIME COMMERCIALS
- * NUMEROUS WEBSITES OUTLINING PAYMENTS MADE

WHY WOULD OUR GOVERNMENT PAY OUT \$4.1 BILLION IN CLAIMS IF THE VACCINES REALLY ARE SAFE?



PER THE AAP, REFUSAL TO GET ONE OR MORE OF THE RECOMMENDED VACCINATIONS HAS JUMPED FROM 75% IN 2006 TO 88% IN 2013.

IS TERMINATION AN OPTION?

YES. FOLLOW THE PROPER STEPS:

- SCOPE
- NOTIFY OFFICE ADMIN AND SCHEDULING
- EMR RED FLAG
- CHECK HMO, PPO, MCO CONTRACTS
- SEND TERMINATION LETTER VIA CERTIFIED MAIL AND U.S. MAIL

TERMINATION LETTER

- PROFESSIONAL, NON-CONFRONTATIONAL
- DO NOT HAVE TO STATE THE REASON
 - HOWEVER, IF YOU DO, BE BRIEF AND OBJECTIVE
- CLEARLY STATE THE DATE TERMINATION IS EFFECTIVE
 - NOT THE SAME DATE AS THE LETTER
- CLEARLY STATE THE TIME TO PROVIDE EMERGENCY CARE ONLY (USUALLY 30 DAYS)
 - RURAL AREA?
- IDENTIFY SOURCE FOR REFERRAL INSURANCE NETWORK, MEDICAL SOCIETY, ETC.
- EXPLAIN THE PROCESS TO FORWARD MEDICAL RECORDS
 - ENCLOSE A HIPAA-COMPLIANT MEDICAL AUTHORIZATION

IF YOU DON'T TERMINATE, TWO THINGS YOU MUST DO:

DOCUMENT
"INFORMED REFUSAL"

FLAG THE PATIENT



INFORMED REFUSAL

BASIS FOR LAWSUIT:

"I DIDN'T UNDERSTAND THAT MY CHILD COULD DIE IF NOT VACCINATED."

WHILE OKLAHOMA DOES NOT HAVE A JURY INSTRUCTION FOR THIS, THE LEGAL CONCEPT HAS NOT BEEN EXPLICITLY REJECTED.

THE REQUIREMENTS ARE TO EXPLAIN & DOCUMENT:

- 1. THE PROPOSED TREATMENT
- 2. THE RISKS AND BENEFITS OF REFUSAL
- 3. ANTICIPATED OUTCOME WITH & WITHOUT THE TREATMENT
- 4. ALTERNATIVE THERAPIES, IF ANY

RESOURCES FOR INFORMED REFUSAL

- AAP HAS A FORM THAT CAN BE CUSTOMIZED.
 - http://www2.aap.org/sections/infectdis/resources.cfm

- MEDPRO GROUP ARTICLE
 - WWW.MEDPRO.COM

WHY FLAG THE PATIENT?



1. LIABILITY ISSUES RELATING TO URGENCY.

2. REMINDER TO REVISIT THE VACCINE DISCUSSION.

QUESTIONS?

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