

## INFORMED CONSENT MATTERS: OPPOSE HB2902 / SB2176

# STAND FOR HEALTH FREEDOM

*“Informed consent is based on the fundamental principle that every person has the right to control his/her own bodily integrity. The individual has a right to receive sufficient information to enable the individual to make an informed decision about whether to consent to or refuse the tests or treatments.”*

*Department of Children’s Services Administrative Policies and Procedures: 20.24<sup>1</sup>*

**Prior, uncoerced, fully-informed consent is even more critical when the manufacturer of the medical product and the individual administering it have been shielded by federal law from liability when the product causes injury or death.**

Included in this document:

1. Federal law critical to understanding informed consent and the vaccination of minors
2. Fact Check of Rep. Sabi “Doc” Kumar’s presentation of [HB2902](#), Amendment [017141](#), to full House Health Committee March 27, 2024

### **List of terms used in this document:**

NCVIA – The National Childhood Vaccine Injury Act of 1986<sup>2</sup>

VAERS – the Vaccine Adverse Event Reporting System<sup>3</sup>

INJURY TABLE – the federal Vaccine Injury Table<sup>4</sup>

PREP ACT – Public Readiness and Emergency Preparedness Act<sup>5</sup>

MMCA – N Mature Minor Doctrine Clarification Act of 2023<sup>6</sup>

VIS – Vaccine Information Sheet mandated by the NCVIA<sup>7</sup>

EUA FACT SHEET – Vaccine Fact Sheet mandated for Emergency Use Authorized vaccines<sup>8</sup>

PROVIDER - means a "health care provider" as defined in the NCVIA and means “any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.”

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<sup>1</sup> <https://files.dcs.tn.gov/policies/chap20/20.24.pdf>

<sup>2</sup> [42 USC 300aa](#)

<sup>3</sup> <https://vaers.hhs.gov/>

<sup>4</sup> <https://www.hrsa.gov/sites/default/files/hrsa/vicp/vaccine-injury-table-01-03-2022.pdf>

<sup>5</sup> <https://aspr.hhs.gov/legal/PREPAct/Pages/default.aspx>

<sup>6</sup> TN Code 63-1-165

<sup>7</sup> <https://www.cdc.gov/vaccines/hcp/vis/index.html>

<sup>8</sup> <https://www.cdc.gov/vaccines/covid-19/eua/index.html>

## **1. Federal law critical to understanding informed consent and vaccination**

Every PROVIDER who administers a vaccine covered under the NCVIA or the PREP ACT must follow the terms of the laws.

All vaccines included in the CDC's Child and Adolescent Immunization Schedule<sup>9</sup>, and all vaccines recommended to pregnant women<sup>10</sup>, fall either under the NCVIA or the PREP ACT no matter who receives the vaccine.

Under the NCVIA and PREP ACTS, vaccine makers and PROVIDERS are shielded from liability for injury or death caused by a vaccination<sup>11</sup>.

The NCVIA requires that a PARENT of a minor child must be given a federally drafted Vaccine Information Sheet (VIS) prior to every vaccine dose AND supplement that information as appropriate to fulfill the "informed" portion of "informed consent".

The NCVIA states:

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

The NCVIA is referenced in Tennessee's MMCA of 2023.

The full duties and responsibilities mandated on PROVIDERS in the federal NCVIA and PREP ACTS are not spelled out in the MMCA. Nevertheless, they apply, and every single PROVIDER should have been taught this in their medical training and incorporated the terms of the laws into their practice or business.

The "American Academy of Pediatrics Reducing Vaccine Liability: Strategies for Pediatricians" Guide<sup>12</sup> states:

"Provide Vaccine Information Statements – It's the Law!"

The NCVIA requires physicians to notify all parents and patients of the benefits and risks of vaccines through the use of Vaccine Information Statements (VISs). Despite this, only 62% of pediatricians indicated that they gave out a VIS with each dose of vaccine (Davis TC, et al. Pediatrics. 2001; 107:e17). According to AAP Periodic Survey#48, 6 out of 10 pediatricians report distributing VIS with every dose of each vaccine. About one-fourth do so with the first dose only, 10% sometimes do so, and fewer than 6% say they never distribute VIS."

The PREP ACT requires PARENTS be given prior receipt of a FACT SHEET and told of the option to refuse.

The MMCA was passed in 2023 by the General Assembly with the intent of protecting PARENTS and children by ensuring they received informed consent as is required by existing laws.

<sup>9</sup> <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

<sup>10</sup> <https://www.cdc.gov/vaccines/pregnancy/index.html>

<sup>11</sup> <https://www.law.cornell.edu/uscode/text/42/300aa-11>

<sup>12</sup> [https://downloads.aap.org/AAP/PDF/immunization\\_reducingvaccineliability.pdf](https://downloads.aap.org/AAP/PDF/immunization_reducingvaccineliability.pdf)

## 2. Fact Check of Rep. Sabi Kumar's presentation of [HB2902](#), Amendment [017141](#), to full House Health Committee March 27, 2024

*The national nonprofit organization Stand For Health Freedom has more than 12,500 Tennessee members. Three thousand of those have joined since the beginning of this legislative session. Parental rights and informed consent are chief among their concerns, and they are looking to the General Assembly to uphold their rights. The information presented by the House sponsor of HB2902 that led to the passage of the bill in the House Health Committee contained errors of fact that must be addressed. No disrespect to Rep. Kumar is intended. This fact check is provided with the intention of serving the people of the state who deserve to be part of the legislative process and engage in rebuttal when necessary.*

Rep. Kumar: "Last year we passed the Mature Minor Act, that was House Bill 1380. It asserted parental rights and all of us voted that important dictum. The major change with last year's bill was that parental consent was required for all vaccinations. Before that, it had been a part of the routine medical care given by family physicians and pediatricians and parental consent was not required."

### **False.**

- Informed consent or informed refusal prior to a medical treatment is a fundamental human right. There is no exception for "routine medical care." There are various ways that medical providers obtain and document informed consent or refusal to routine care.
- The administration of a vaccine is unique because of the NCVIA and the PREP ACT.
- Prior to the NCVIA, when vaccine manufacturers and those who administered them could be held liable for injury or death caused by vaccines, PROVIDERS took care to provide proper informed consent since that afforded them a measure of legal protection if the patient experienced an adverse reaction.
- When Congress was drafting the NCVIA, they and President Ronald Reagan were afraid that when they removed liability from vaccine makers and PROVIDERS, informed consent would cease because there would be no financial incentive for providers to take the time to give parents the necessary information needed for informed consent. To remedy this, they created the Vaccine Information Sheet (VIS) and required it to be given to the PARENT of the child prior to vaccine administration.
- The PREP ACT carries similar requirements that PROVIDERS must give EUA FACT SHEETS to vaccine recipients or their PARENTS prior to vaccine administration. The PREP ACT additionally requires recipients be told they have the right to refuse the vaccine.

Rep. Kumar: "Today, if a child in foster care breaks an arm or needs heart surgery, the foster parent can sign consent form for them, but they cannot sign for vaccination because they are not a biological parent."

### **Half False.**

Before and after passage of the MMCA:

- Breaking an arm or needing heart surgery (unless surgery could be safely delayed while parental informed consent sought), fall under the state's emergency laws where prior parental informed consent is not required.
- The MMCA does not say that an individual must be a "biological parent" to give informed consent. MMCA names parents or legal guardians.
- Prior to MMCA, DCS's form CS-0206 "Authorization for Routine Health Services for Minors" included immunizations. Since MMCA took effect, DCS separated consent to immunizations with form CS-4246. Soon after a child is taken into custody and before a child is put in foster care, these "consent" forms are presented to parents whose children have been taken into custody and require a signature.

- DCS is the “legal custodian” of children placed in their custody which gives them “the right to physical custody of the child; the right to determine the nature of the care and treatment of the child, including ordinary medical care; and the right and duty to provide for the care, protection, training, education and physical, mental and moral welfare of the child. Such rights and duties are, however, subject to the conditions and limitations of the order granting legal custody and to the remaining rights and duties of the child's parent(s);” Tenn. Code Ann. § 37-5-103 (underline added)
- DCSs “Healthcare Consent Guidelines for Youth in DCS State Custody” tells providers: “Unless the parents’ rights have been terminated, DCS is merely the legal custodian – not the youth’s legal parent or guardian. The parent(s) or guardian(s) have the legal authority to determine healthcare when their youth is in DCS custody.” <https://files.dcs.tn.gov/policies/chap20/HealthConsentGuide.pdf>
- Unfortunately, DCS forms are for “consent” only, and it is uncertain if parents are “informed” before giving consent. It is also uncertain if parents are given a federally mandated VIS prior to every dose of every vaccine given to their child, as per NCVIA, which does not make exceptions for parents whose children are in DCS custody.

Rep. Kumar: “The bill created essentially two problems, one of them was small, and that was since parental consent was required, working parents could not just send their child with a sibling or a grandparent to get their vaccinations, they had to sign a consent.”

**False.**

- Parental informed consent was required prior to the passage of the MMCA.
- The NCVIA mandated that PROVIDERS give a VIS to PARENTS and to supplement with other information as appropriate, prior to the administration of each and every dose of vaccine and document receipt of the VIS in the child’s medical record.
- The PREP ACT mandates PARENTS be given an EUA FACT SHEET and told they have the right to refuse.
- The MMCA does not prevent a parent from having another individual transport their minor child to get a vaccination, however, the federal 1986 and PREP ACTS must be followed regarding the PROVIDER giving the PARENT a VIS and other information as needed, obtaining informed consent, and documenting such in the child’s medical record.
- With vaccine makers and PROVIDERS shielded from liability for injury or death caused by the administration of qualifying vaccines, PARENTS are on their own protecting the children, which is why Congress mandated VISs and documentation that every required step was taken.
- PROVIDERS must ensure that if they set up convenience policies that allow a non-PARENT to bring a minor to a vaccination appointment, all aspects of federal and state law are adhered to so that the PARENT is properly informed as by law. The PROVIDER must document the required information, how it was delivered, and how consent was given and verified.
- SB2176 / HB2902 violates the NCVIA and the protective clarifying language of the MMCA.

Rep. Kumar: “This bill makes it possible that parents can sign a standing consent at the doctor’s office that would apply until canceled. Once that consent is in the physician’s medical records, then family members can take children for vaccination, especially to help the working parents.”

**Misleading.**

- “Standing consent” for vaccination conflicts with the mandated requirements of the 1986 and PREP ACTS, the tenets of informed consent, and medical due diligence.

- The tenets of informed consent include information pertinent to safety and necessity of the product, alternatives to receiving the product, and the child's medical status and fitness to receive the product on the day of administration. This information cannot be known many weeks, months, or years prior to the product administration.
- PROVIDERS must ensure that when they set up convenience policies that allow a non-PARENT to bring a minor to a vaccination appointment, all aspects of federal, state law, medical ethics, and medical due diligence are adhered to.

### Per the CDC's VIS Frequently Asked Questions<sup>13</sup>:

#### **Q: How early can VISs be provided to parents/legal representatives prior to vaccination?**

A: The National Childhood Vaccine Injury Act requires that a current VIS be provided to parents/legal representatives prior to vaccination. Although the Act does not specify the amount of time allowed between VIS provision and vaccination, they must be provided as close to the time of vaccination as is programmatically feasible and reasonable, keeping in mind that VISs are designed to inform vaccine recipients (or their parents/legal representatives) about the risks and benefits of specific vaccines, as well as medical eligibility, prior to vaccine receipt. For example, providing VISs several weeks prior to a scheduled school-located vaccination clinic may be reasonable. However, providing VISs several months prior to vaccination (e.g., providing them in July for a January vaccination clinic or at the end of one school year for a vaccination clinic the next school year) is not acceptable as parents/legal representatives may not have retained the VISs to review just prior to vaccination, the VIS may have since been revised, and a student's medical eligibility may have changed during that time.

Rep. Kumar: "The second major problem with our last year's bill was that there are 8,800 children in the state of Tennessee in foster care. Six hundred are under DCS care, and 8,200 are in foster care. Because last year's bill said parental consent is required for vaccination, that was not possible with these children, because parents are difficult to find. That's why children are in foster care. So DCS does not have the resources to get court orders for these 8,800 children, therefore this bill that we are proposing will grandfather those children prior to this law so children who were getting their vaccinations under the previous system will continue to get that care . . . the main purpose of this bill is to grandfather those children who were previously getting their vaccinations and at this time not impose on our system to get 8,800 court orders."

#### **False and Misleading**

- DCS does not need need a court order for all 8,800 children.
- Prior to the passage of the MMCA, DCS was fully aware of parental rights and informed consent requirements. For example, DCS form 050608, which predates the MMCA states:
  - "Unless the parents' rights have been terminated, DCS is merely the legal custodian –not the youth's legal parent or guardian. The parent(s) or guardian(s) have the legal authority to determine healthcare when their youth is in DCS custody."
- DCS has always had policies and forms about parental / legal guardian informed consent. How many parents had already given consent to vaccination when MMCA went into effect? And how many since?
- How many of the children are between the ages of 0-18 months, 5-6, 11-12? Those are the ages when daycare and school required vaccines are administered.
- How many of the children entered the system already up-to-date with daycare / school vaccines?
- How many parents claim a religious religious exemption to vaccination?

<sup>13</sup> <https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html>

- How many of those children have parents that lost their medical decision authority through due process of law, leaving DCS with the legal right to assume medical decision authority?
- For how many children has DCS already acquired a court order allowing them to vaccinate?

NCVIA and PREP Act PROVIDER requirements pertain to parents and legal guardians of children in DCS custody who retain their medical decision making authority.

Regarding Rep. Leatherwood's question about the portion of the bill that would allow parents to provide consent for all future vaccinations:

Rep. Kumar replied: "Definitely the consent that has given is for future vaccinations on a continued basis when a child needs three shots to complete the course, it will not apply to new vaccination because you cannot have an informed consent on a vaccination that has not yet come into the market so the side effects and indications for those are not yet known. It will only apply to existing vaccinations, as you said."

**Misleading.**

The language of the bill does not limit the vaccines to existing products or those given in a series. The bill says "all future vaccinations." Besides new vaccines, there are often new formulations and brands that enter the market and replace vaccines already on the pediatric schedule. There are dozens of vaccines in the industry product pipeline, some of them intended to replace traditional products with mRNA formulations. Blanket consent to future vaccination is medically unethical and violates the MMCA and NCVIA.

INFORMED CONSENT MATTERS.

It is a fundamental human and parental right.

OPPOSE HB2902 / SB2176

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