IN THE UNITED STATES DISTRICT COURT DISTRICT OF COLUMBIA

VICTOR M. BOOTH, et al.,)	
	Plaintiffs,)	
v.)	No. 1:21-cv-01857-TNM
MURIEL BOWSER, et al.,)	
	Defendants.)	

AMICUS CURIAE BRIEF OF PHYSICIANS FOR INFORMED CONSENT IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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CERTIFICATE REQUIRED BY LOCAL RULES LCVR 7(o)(5) AND 7.1

Consistent with Fed. R. App. P. 29(a)(4)(A) and Local Rule 7(o)(5), I, the undersigned counsel of record for *amicus curiae* Physicians for Informed Consent ("PIC") certify that, to the best of my knowledge and belief: (1) PIC has no parent corporation; and (2) no publicly traded company owns stock in PIC. These representations are made in order that judges of this Court may determine the need for recusal.

Dated: February 16, 2022

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IDENTITY AND INTEREST OF AMICUS CURIAE

Amicus Curiae is Physicians for Informed Consent ("PIC"), a 501(c)(3) educational nonprofit organization focused on science and statistics. Representing hundreds of doctors, PIC delivers data on infectious diseases and vaccines, and unites doctors, scientists, healthcare professionals, attorneys, and families who support voluntary vaccination. In addition, its Coalition for Informed Consent consists of over 300 U.S. and international organizations.

This brief is submitted pursuant to leave requested by the unopposed accompanying motion. The parties have consented to this request.

INTRODUCTION

For the reasons set forth in the accompanying motion, *amicus curiae* PIC seeks leave to file this *amicus* brief in support of Plaintiffs' Motion for a Preliminary Injunction (ECF #33) and their Opposition (ECF #39) to Defendants' Motion to Dismiss (ECF #36). The challenged law, the District of Columbia's Minor Consent for Vaccinations Amendment Act of 2020, 2019 D.C. Adv. Leg. Serv. 532 (Dec. 23, 2020) (the "Minor Consent Act"), is unconstitutional and should be enjoined.

SUMMARY OF ARGUMENT

The Minor Consent Act fails every level of judicial scrutiny because it is arbitrary and irrational that the government would (1) completely override parental rights guaranteed by constitutional precedent, whilst (2) legalizing the worst-case scenario: behind closed doors an

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Consistent with Fed. R. App. P. 29(a)(4)(E) and Local Rule 7(o)(5), counsel for the *amicus curiae* authored the motion and brief in whole, and no counsel for a party authored the motion or brief in whole or in part, nor did any person or entity, other than the *amicus* and its counsel, make a monetary contribution to preparation or submission of the motion or brief.

https://code.dccouncil.us/us/dc/council/laws/23-193

adult stranger asks an 11-year-old girl to "consent" to his medical injection, which the child does not medically understand even after this stranger shares his information privately with her; she gets injured and her parents are ignorant *because of* the law. The Bill of Rights is surely present to protect against this ill-conceived legislation.³

Physicians who are fluent in obtaining informed consent would confirm that the Minor Consent Act would violate every level of judicial scrutiny. Physicians experienced in obtaining informed consent know it is not possible for 11-year-old children as a group to understand the risks of Covid-19, the relative durability of natural immunity, the risks and benefits of Covid-19 vaccination, the ingredients in vaccination, or the risks and benefits of Covid-19 therapies—all in the applied context of patient personal and family history, and all in the short time (if any) allotted for a Covid-19 vaccination during a medical appointment.

ARGUMENT

I. INFORMED CONSENT/REFUSAL IN VACCINATION IS A FUNDAMENTAL RIGHT TRIGGERING STRICT SCRUTINY.

Universally recognized by physicians, informed consent/refusal in vaccination is a fundamental right, as it is essential to the patient's life, liberty, and bodily integrity. *See*, *e.g.*,

Informed consent is a core component of the ethical clinical relationship. As with all forms of medical therapy, informed consent should precede vaccination administration.... If the patient declines, this informed refusal of recommended vaccination should be respected.... Patients who decline vaccination should continue to be supported with appropriate care options that honor their autonomous choices.

Citation: *Ethical issues with vaccination in obstetrics and gynecology*. (July 2021) Committee Opinion No. 829. American College of Obstetricians and Gynecologists. OBSTET GYNECOL

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 $[\]frac{3}{2}$ Amicus PIC concurs with plaintiffs and the amicus brief of Association of American Physicians and Surgeons (ECF #41-2).

2021;138:e16–23. https://www.acog.org/clinical/clinical-guidance/committee- opinion/articles/2021/07/ethical-issues-with-vaccination-in-obstetrics-and-gynecology.

Safeguarding informed consent/refusal is essential to a successful doctor-patient relationship. Vaccination carries risk of harm and is an invasive medical procedure.

The fundamental right of bodily integrity has been recognized in the United States. As this Supreme Court found in *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891), "No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *See also Washington v. Harper*, 494 U.S. 210, 229 (1990) ("The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty.")

II. THE MINOR CONSENT ACT IS IRRATIONAL AND ARBITRARY.

Serious vaccination injury rarely manifests during the short window of minutes the patient is with the doctor or healthcare professional; vaccine injury most commonly manifests later (i.e., at home). The Minor Consent Act inherently disadvantages parents to identify adverse reactions and protect the child. This 'legally required parental ignorance' is a natural extension of the denial of parental rights.

From a constitutional perspective, the denial of the parental right of informed assent/refusal is dangerously unprecedented, and for good reason. Parental rights protect children from more than just the risks of Covid-19 vaccines, but also *every* pharmaceutical and medical intervention. In middle America there is a wise saying, 'never take down a fence until you know

why it was erected in the first place.'4

If this Court took the opportunity to appoint a special master to observe *Amici* AMA physicians attempting to prove their claim 'mature minor' with any randomly selected group of 11-year-olds, every lawyer and this Court would instantly see a group of helpless children asked to analyze pharmacology and biology concepts beyond their elementary school training. The impossibility of informed consent by these children would become obvious to the special master within minutes if not seconds. The Minor Consent Act is arbitrary and irrational because medical decisions require maturity and intellect. Under no real-world scenarios do informed consent discussions performed on randomly selected groups of 11-year-olds consistently meet the dictionary definition of informed consent with respect to the novel coronavirus. *See e.g.*,

Informed Consent. Voluntary agreement given by a person or a patients' responsible proxy (for example, a parent) for participation in a study, immunization program, treatment regimen, invasive procedure, etc., after being informed of the purpose, methods, procedures, benefits, and risks. The essential criteria of informed consent are that the subject has both knowledge and comprehension, that consent is freely given without duress or undue influence, and that the right of withdrawal at any time is clearly communicated to the patient. Other aspects of informed consent in the context of epidemiologic and biomedical research, and criteria to be met in obtaining it, are specified in International Guidelines for Ethical Review of Epidemiologic Studies (Geneva: CIOMS/WHO 1991) and International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva: CIOMS/WHO 1993).

Informed Consent, FARLEX PARTNER MEDICAL DICTIONARY (2012). https://medical-dictionary.thefreedictionary.com/informed+consent (accessed February 7, 2022).

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The Minor Consent Act is early similar to veiled and failed legislation in various populous states desiring to strip parental rights. One recent example was the 'Children's Bill of Rights' in California, a bill with a pleasant name but which was easily discredited (and never passed into law). Like that failed bill, the Minor Consent Act presumes arbitrarily and irrationally that all parents are unfit and therefore must be stripped of parental rights.

These obvious facts are supported also by the DC science and health curriculum for fifth graders, which contains zero references to vaccination or the immune system. In elementary school, these children are engaged in elementary learning of the basics of science and body (i.e., what things are called, general descriptions of how things work and how things relate to each other). Only in ninth grade do DC public school students begin their basic and highly simplified education about infectious disease and the immune system. Given the various aptitudes of public school students (with many never even reaching a ninth grade reading level), parental rights (and parental responsibility) are essential. It is arbitrary and irrational to discard parents from an equation that requires their participation at every other level.

The operative provision regarding informed consent in the Minor Consent Act is as follows:

For the purposes of this subsection, a minor shall be deemed to meet the informed consent standard if the minor is able to comprehend the need for,

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DC PUBLIC SCHOOLS (2014). Grade 5 Scope and Sequence Documents. https://dcps.dc.gov/publication/grade-5-scope-and-sequence-documents (accessed February 7, 2022). This is further confirmed by zero references to vaccination or the immune system in DC's official assessment of fifth grade student performance in science. See DISTRICT OF COLUMBIA, OFFICE OF THE STATE SUPERINTENDENT OF EDUCATION (2019). Assessment of the Next Generation Science Standards. https://osse.dc.gov/sites/default/files/dc/sites/osse/ publication/attachments/2019% 20DC% 20Science% 20Assessment% 20Design% 20and% 20Bluep mints%20Grade%205%2012.9.19.pdf (accessed February 7, 2022). See also DC SCIENCE. Next Generation Science Standards. Grade 5 Test Booklet. https://dc.mypearsonsupport.com/ resources/practice-tests/science/Grade% 205% 20Paper% 20Test.pdf (accessed February 7, 2022).

DC PUBLIC SCHOOLS. *P26 Health Education Scope and Sequence*. https://dcps.dc.gov/sites/default/files/dc/sites/dcps/publication/attachments/HealthSASP26.pdf (accessed February 7, 2022) ("This unit about anatomy focuses on disease prevention and world health issues. Students will identify behaviors that support optimal functioning of bodily systems (including the immune system) and learn about the effects of heredity and genetics on human growth and development. Students will also analyze how research and medical advances have influenced the prevention and control of many diseases, such as cancer and HIV/AIDS.").

BALLOTPEDIA. *NAEP scores by state* (2012-2013). https://ballotpedia.org/NAEP_scores_by_state ("District of Columbia ... NAEP Reading Percent Proficient and Above, Grade 8 – All Students ... 17%").

the nature of, and any significant risks ordinarily inherent in the medical care.

Even if this definition were not hopelessly vague, nothing in this definition or the remainder of the Act would actually protect an 11-year-old child from a misplaced *presumption* ("deemed") of consent. The stranger who vaccinates does not know this child and is not in a position to adjudge their comprehension. This is another example where parents are essential to provide a safeguard against abuse. It is irrational and arbitrary for government to completely remove parents from a vaccine equation in which they are present at every other healthcare decision (including decisions following vaccine injury).

Consider an 11-year-old reading the CDC's FAQ page for Covid-19 vaccines: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html, such as:

"Your child may have some <u>side effects</u>... Contact a doctor or healthcare provider:

- If the redness or tenderness where the shot was given gets worse after 24 hours
- If the side effects are worrying or do not seem to be going away after a few days

If you or your child get a COVID-19 vaccine and you think you or they might be having a severe allergic reaction after leaving the vaccination site, seek immediate medical care by calling 911. Learn more about COVID-19 vaccines and rare severe allergic reactions."

Every CDC link will link to still more pages, such as this one that describes in detail what to do, which is wholly unrealistic to thrust upon 11-year-olds:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html.

Amicus PIC has special experience preparing educational documents to reach all audiences, and therefore knows firsthand that 11-year-olds as a group are not equipped to understand sufficient vaccinology and biology science to provide informed consent to Covid-19

vaccination. For example, PIC prepared its educational documents⁸ on Covid-19 to reach the largest audience possible (every reachable age), but 11-year-olds (as a group) are not within the reachable age group to understand even the basics of this science.

Consider for example an 11-year-old hearing evidence that the clinical trials for the Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines were not designed to observe asymptomatic infection with SARS-CoV-2 or the effect of the vaccine on the transmission of COVID-19.

Will the 11-year-old understand that in its briefing document for each vaccine, the U.S. Food and Drug Administration (FDA) states that "it is possible that asymptomatic infections may not be prevented as effectively as symptomatic infections" and "data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination." Furthermore, "additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection." Citations:

- U.S. FOOD AND DRUG ADMINISTRATION, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: Pfizer-BioNTech COVID-19 vaccine. Vaccines and Related Biological Products Advisory Committee Meeting: December 10, 2020. https://www.fda.gov/media/144245/download.
- 2. PHYSICIANS FOR INFORMED CONSENT. *Pfizer COVID-19 vaccine: short-term efficacy and safety data*. Dec 2021. https://www.physiciansforinformedconsent.org/COVID-19-vaccines.
- 3. U.S. FOOD AND DRUG ADMINISTRATION, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: Moderna COVID-19

PHYSICIANS FOR INFORMED CONSENT (2022). Education: *SARS-CoV-2 and COVID-19 Vaccines*. https://physiciansforinformedconsent.org/covid-19/.

- vaccine. Vaccines and Related Biological Products Advisory Committee Meeting: December 17, 2020. https://www.fda.gov/media/144434/download.
- 4. PHYSICIANS FOR INFORMED CONSENT. Moderna COVID-19 vaccine: short-term efficacy and safety data. Apr 2021. https://www.physiciansforinformedconsent.org/COVID-19-vaccines.
- 5. U.S. FOOD AND DRUG ADMINISTRATION, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: Janssen Ad26.COV2.S vaccine for the prevention of COVID-19. Vaccines and Related Biological Products Advisory Committee Meeting: February 26, 2021. https://www.fda.gov/media/146217/download.
- 6. PHYSICIANS FOR INFORMED CONSENT. Janssen (Johnson & Johnson) COVID-19 Vaccine: Short-Term Efficacy & Safety Data. May 2021. https://www.physiciansforinformedconsent.org/COVID-19-vaccines.

Consider how an 11-year-old would process the information that in July 2021, in a Barnstable County town in Massachusetts, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town and 346 (74%) occurred in fully vaccinated persons. Of the five hospitalized cases, four were vaccinated. The CDC also concluded, "Cycle threshold values were similar among specimens from patients who were fully vaccinated and those who were not," which suggests vaccinated and unvaccinated persons can equally spread SARS-CoV-2 and there is no scientific basis for discrimination based on vaccination status. Another CDC statement highlighting this, "... preliminary evidence suggests that fully vaccinated people who do become infected with the Delta variant can spread the virus to others."

Brown CM, Vostok J, Johnson H, et al. *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings*— *Barnstable County, Massachusetts*, July 2021. MMWR MORB MORTAL WKLY REP 2021;70:1059-1062. https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm.

CDC. Interim Public Health Recommendations for Fully Vaccinated People. Covid-19, Vaccines. Updated July 28, 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.

CONCLUSION

The Minor Consent Act fails every level of judicial scrutiny because it is arbitrary and irrational to separate 11-year-olds from their fit parents in the hope that a stranger will protect them in the short time (if any) allotted for a Covid-19 vaccination appointment.

Dated: February 16, 2022 Respectfully submitted,

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