Case Number: SU-2023-0066-A
Filed in Supreme Court
Submitted: 4/19/2023 10:31 AM
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Reviewer: Zoila Corporan

STATE OF RHODE ISLAND		SUPREME COURT
LAUREN NAGEL, Plaintiff/ Appellee	: :	
vs.	:	SU2023-0066-A
JOSHUA NAGEL, Defendant/Appellant	: :	

DEFENDANT/APPELLANT JOSHUA NAGEL'S MEMORANDUM IN SUPPORT OF MOTION PURSUANT TO RULE 28 FOR REMAND TO TRIAL COURT

On April 18, 2023, the Federal Drug Administration (FDA) issued a "Coronavirus (COVID-19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines" as follows:

> Today, the U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals. This action includes authorizing the current bivalent vaccines (original and omicron BA.4/BA.5 strains) to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations. The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.

(*See attached Exh. 1*). In essence, the original two-dose vaccine is no longer legal to administer in this Country. Instead, only the bivalent "booster" is emergency use authorized.

The same day, the Rhode Island Department of Health issued similar guidance to health care providers. In the "UPDATES TO COVID-19 VACCINE

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SCHEDULE", RIDOH states:

> We are also awaiting final CDC guidance on disposal of existing monovalent vaccine inventory. This guidance is expected April 19, 2023. Once this guidance is available, RIDOH will communicate it to providers. In the interim, please set aside any monovalent COVID-19 vaccine and mark as "Do Not Use."

(S*ee attached Exh. 2)*

In her testimony, the pediatrician, Dr. Powers, stated that she recommended that the children receive the original two-shot Covid-19 vaccine, and then five months later, that they receive the booster vaccine. (Tr. 11/1 at 36). Now that the FDA has changed the rules, it is illegal for the Nagel children to receive the first two-dose shot.

In the Order of the Trial Court, the final decision-making authority is given to Lauren Nagel only for the original series of the vaccine. The Court specifically states: "If those recommendations change when it comes time for a booster, then she can't authorize the booster unless the parties agree or she comes back to court." (Decision p. 9, ¶ 5)

Given this substantial change in circumstances, it would appear that the Trial Court Order is no longer effective. Instead, the parties must now confer again with the pediatrician to determine whether the booster is now recommended, and if it is, whether the parties will agree to the booster. If the parties cannot agree, the Trial Court has stated it will re-hear the matter.

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These changing circumstances are not unanticipated. As stated in our original Rule 12A statement, the federal government has stated that the public health emergency will end on May 11, 2023, and this leaves in question the future authorization of the Covid-19 vaccine. This latest amendment to the EUA for the Covid-19 vaccine further evidences the caution needed before rushing into forcing this vaccine on the two young girls in this case.

Under these present circumstances, this Court should consider that any ruling which would uphold the Trial Court's Order may not have any binding effect. Instead, the Court should consider remanding the matter to the Trial Court, which would be in a better position to consider any additional evidence as to what the pediatrician may recommend, what vaccine is actually now legally available, and whether it will still be in the best interests of these children to take the vaccine.

Finally, there remains no legitimate reason to lift the stay of the Trial Court order. Given the continuous changes in government recommendations and authorizations of the vaccine, the more prudent path is to allow the trial court to sort out these conflicting positions before forcing an experimental drug on these children.

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Respectfully submitted,
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CERTIFICATION

I hereby certify that I served this document through the electronic filing system on the following attorneys of record:

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