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The Honorable Paul G. Gardephe United States District Court Southern District of New York 600 Pearl Street New York, NY 10007 January 15, 2021

VIA ECF

Re

Aviles, et al. V. de Blasio, et al.

20-CV-09829 (PGG)

Your Honor,

Pursuant to the Court's verbal request on January 14, 2021 for this supplemental briefing, Plaintiffs hereby present these additional legal authorities on fundamental rights to education and proof that Federal law on Emergency Use Authorization ("EUA") is case dispositive, requiring an immediate preliminary injunction in Plaintiffs' favor against mandatory consent forms as a requirement for in-person education.

The City may not condition in-person schooling on coerced consent to PCR testing.

The Court is understandably reluctant to take any tool out of the City's toolbox at this dangerous time in the coronavirus pandemic. However, since Defendants' mandate violates federal and state law, the Court has little choice but to steer Defendants back onto a lawful path.

PCR testing is not FDA approved. It is an EUA product that by its very nature is still experimental for detecting coronavirus. While we believe limitations in PCR testing make it

unfit for its current use, these concerns can and should be litigated at trial. At this preliminary injunction stage, we seek to free children from unlawful and unethical experimental medical testing in their schools.

EUA - Respectfully, it's a 'case closed' issue

It is undisputed by both parties that PCR tests are Emergency Use Authorization (EUA) products (Decl. Varma ecf 19 P.43.) Federal law confirms explicitly that an EUA product must be voluntary, because the federal statute requires literally, "the option to accept or refuse administration of the product." 21 USCS § 360bbb-3 ("Authorization for medical products for use in emergencies").

In a recent Federal case (*Doe v. Rumsfeld*, Civil Action No. 03-707 (EGS), 2005 U.S. Dist. LEXIS 5573 (D.D.C. Apr. 6, 2005)), an EUA anthrax vaccine could not even be mandated upon active duty soldiers. It was case dispositive (i.e., no need to discuss dangers of anthrax v. dangers of anthrax vaccine); rather, the only thing discussed was that the vaccine was indeed EUA, so by Federal law it could not be mandated. If military service cannot be conditioned on a forced EUA product, Plaintiffs' school attendance cannot be so conditioned either.

The reason Federal law governing EUA is case dispositive here is that the FDA and courts have found the federal preemption doctrine prevents States from going outside the bounds of the Emergency Use Authorization law. Defendants may argue an EUA anthrax vaccine is distinguishable from a EUA gentle nose swab. That is not the case. Both medical products are by their very designation experimental, and to mandate them violates federal and state law, which both rest on the first principle of the Nuremberg Code as codified in New York Public Health Law, which directly incorporates the Nuremberg Code, requiring that the human subject be "so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constrain or coercion." N.Y. Pub. Health Law § 2441. This is a bright line that cannot be blurred.

Federal Emergency Use Authorization

Plaintiffs' moving papers cite the CDC, which admits that it is illegal and unethical to mandate PCR testing in schools. (COVID-19 (Coronavirus Disease) ecf 11-2 Exh. 18. Page 3) Emergency Use Authorization means the PCR test must be voluntary, because the federal statute says so explicitly, "the option to accept or refuse administration of the product." 21 USCS § 360bbb-3 ("Authorization for medical products for use in emergencies").

Moreover, the States cannot mandate an Emergency Use PCR test because the FDA and courts have found the federal preemption doctrine prevents States from going outside the bounds of the Emergency Use Authorization law. See e.g., https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities ("FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564....In an emergency, it is critical that the conditions that are part of the EUA or an order or waiver issued pursuant to section 564A—those that FDA has determined to be necessary or appropriate to protect the public health—be strictly followed, and that no additional conditions be imposed.")

[&]quot;Emergency Use Authorization" (EUA) means that any product with this designation **must be voluntary**. Under 21 U.S.C. § 360bbb-3, "Authorization for medical products for use in emergencies":

⁽ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

⁽I) that the Secretary [of Health and Human Services] has authorized the emergency use of the product;

⁽II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

⁽III) **of the option to accept or refuse administration of the product**, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. [emphasis added]

This was also confirmed again last year at a CDC published meeting in August 2020 (called the Advisory Committee on Immunization Practices (ACIP)), where ACIP Executive Secretary Amanda Cohn, MD stated:

"I just wanted to add that, just wanted to remind everybody, that under an Emergency Use Authorization, an EUA, vaccines are not allowed to be mandatory. So, early in this vaccination phase, individuals will have to be consented and they won't be able to be mandated."

US Centers for Disease Control (September 2020), August 2020 ACIP Meeting - COVID-19 vaccine supply & next steps. https://www.cdc.gov/vaccines/videos/low-res/acipaug2020/Covid-19Supply-NextSteps 3 LowRes.mp4 (@1:14:40)

The law is clear that States are preempted from mandating an EUA product. And indeed, this fits the larger legal precedents of federal preemption. See e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 570-71 (2001) (overturning a State public health law because it was already the subject of a comprehensive Federal scheme to manage that public health matter); *Dep't of the Navy v. Egan*, 484 U.S. 518, 530 (1988). This matter is within the court's jurisdiction and case dispositive.²

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² "When Congress intends federal law to 'occupy the field, state law in that area is preempted." ABC Charters, Inc. v. Bronson, 591 F. Supp. 2d 1272, 1303-04, 1312 (S.D. Fla. 2008 (granting preliminary injunction for plaintiffs seeking to invalidate State law re travel to Cuba, because "there is a substantial likelihood that the Travel Act Amendments will be found unconstitutional under ... the Supremacy Clause." See also Shaw v. Delta Air Lines, 463 U.S. 85, 96 n.14, 103 S. Ct. 2890, 2899 (1983) ("It is beyond dispute that federal courts have jurisdiction over suits to enjoin state officials from interfering with federal rights. See Ex parte Young, 209 U.S. 123, 160-162 (1908). A plaintiff who seeks injunctive relief from state regulation, on the ground that such regulation is pre-empted by a federal statute which, by virtue of the Supremacy Clause of the Constitution, must prevail, thus presents a federal question which the federal courts have jurisdiction under 28 U. S. C. § 1331 to resolve. See Smith v. Kansas City Title & Trust Co., 255 U.S. 180, 199-200 (1921); Louisville & Nashville R. Co. v. Mottley, 211 U.S. 149, 152 (1908); see also Franchise Tax Board, ante, at 19-22, and n. 20; Note, Federal Jurisdiction over Declaratory Suits Challenging State Action, 79 Colum. L. Rev. 983, 996-1000 (1979). This Court, of course, frequently has resolved pre-emption disputes in a similar jurisdictional posture. See, e. g., Ray v. Atlantic Richfield Co., 435 U.S. 151 (1978); Jones v. Rath Packing Co., 430 U.S. 519 (1977); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963); Hines v. Davidowitz, 312 U.S. 52 (1941).")

<u>Levels of Scrutiny – Education as a Fundamental Right</u>

A poor, migrant mother may not speak English. A young mother who doesn't even have a high school diploma may not be able to foster her child's education. Several family members, several generations, or several different families living in a small apartment cannot provide adequate opportunities.

Remote learning segregates, harms the most vulnerable and implicates equal protection. If students are forced into remote learning by refusal to submit, an inequality exists based on the differences in learning environment based on socio-economic status and, unfortunately, race. The disparity between learning environs is striking. A small apartment on a noisy street is not equal to learning spaces afforded the genteel. Defendants create a virtual Jim Crow school. In-school versus remote learning are *de facto* separate educational facilities that the Supreme Court has declared unconstitutional.

"Segregation with the sanction of law, therefore, has a tendency to [retard] the educational and mental development of Negro children and to deprive them of some of the benefits they would receive in a racial[ly] integrated school system."

Brown v. Bd. of Educ., 347 U.S. 483, 494 (1953).

The court found the Negro school inferior in physical plant, curricula, and transportation, and ordered the defendants forthwith to provide substantially equal curricula and transportation and to "proceed with all reasonable diligence and dispatch to remove" the inequality in physical plant.

Brown v. Bd. of Educ., 347 U.S. 483, 486

Education is not a fundamental right, but it is at least a "quasi" fundamental right subject to intermediate scrutiny. Under *Plyler v. Doe*, "infringements on certain 'quasi-fundamental' rights, like access to public education, also mandate a heightened level of scrutiny." *United States v. Harding*, 971 F.2d 410, 412 n.1 (9th Cir. 1992) (emphasis added). And the New York Constitution, Art. XI, § I, ¶ 1 provides for the Maintenance and Support of a thorough and efficient system of free public schools.

While we acknowledge that the Constitution does not grant the right to a public education, San Antonio Independent School Dist. v. Rodriguez, 411 U.S. 1, 35 (1973), neither is it merely some governmental "benefit" indistinguishable from other forms of social welfare legislation. Both the importance of education in maintaining our basic institutions, and the lasting impact of its deprivation on the life of the child mark the distinction. The "American people have always regarded education and [the] acquisition of knowledge as matters of supreme importance." Meyer v. Nebraska, 262 U.S. 390, 400 (1923). We have recognized "the public schools as a most vital civic institution for the preservation of a democratic system of government," Abington School District v. Schempp, 374 U.S. 203, 230 (1963) (BRENNAN, J., concurring), and as the primary vehicle for transmitting "the values on which our society rests." Ambach v. Norwick, 441 U.S. 68, 76 (1979).

"In addition, education provides the basic tools by which individuals might lead economically productive lives to the benefit of us all. Education has a fundamental role in maintaining the fabric of our society. We cannot ignore the significant social costs borne by our Nation when select groups are denied the means to absorb the values and skills upon which our social order rests."

Denial of education to isolated groups of children affronts the goals of the Equal Protection Clause: the abolition of governmental barriers presenting unreasonable obstacles to advancement on the basis of individual merit. Paradoxically, by depriving children of any disfavored group of an education, we foreclose the means by which that group might raise the level of esteem in which it is held by the majority.

What [the Supreme Court] said 28 years ago in Brown v. Board of Education, 347 U.S. 483, 493 (1954), still holds true:

"Today, education is perhaps the most important function of state and local governments. ...In these days, it is doubtful that any child may reasonably be expected to succeed in life if he is denied the opportunity of an education. Such an opportunity, where the state has undertaken to provide it, is a right which must be made available to all on equal terms."

Plyler v. Doe, 457 U.S. 202, 221-223 (1982)

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The State is constrained to recognize a student's legitimate entitlement to a public

education as a property interest which is protected by the Due Process Clause and which may not

be taken away without adherence to the minimum procedures required by that Clause.

Plaintiffs do recognize the Covid-19 emergency and thank the Court for its commitment

to protect New Yorkers and respect Constitutional rights; Plaintiffs agree that we all want the

best for New York Public Health. Ultimately though, the pandemic can never change the case

dispositive issue that Emergency Use Authorization products cannot be mandated under Federal

law.

Further, Defendants cannot continue with the disparate impact of in-person learning

conditioned on unlawful consents.

We thank you for your kind attention and consideration.

Respectfully yours,

/s/ James G. Mermigis

/s/ Ray L. Flores II

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