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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

JANE DOE, et al. Plaintiffs, vs. HOWARD ZUCKER, et al. Defendants.	Civil Action No.: 1:20 – CV – 0840 (BKS/CFH) **MEMORANDUM OF LAW**

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO STATE DEFENDANTS' MOTION TO DISMISS

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September 21, 2020

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27
28

TABLE OF CONTENTS

Table of Contents i

Table of Authorities ii

Preliminary Statement 1

Statement of Facts 3

Standard of Review 5

Legal Argument 6

I. POINT ONE: THE CONSTITUTIONAL CLAIMS ARE FACIALLY SUFFICIENT TO WITHSTAND DISMISSAL................................6

a. The right to a medical exemption where a child may be at risk of harm is a fundamental right and requires strict scrutiny…………………....7

b. The regulations and policies at issue place an undue burden on the fundamental right to a medical exemption for vulnerable children…..9

c. The challenged policies and procedures are not narrowly tailored to uphold a compelling state interest sufficient to outweigh the plaintiffs right to a medical exemption……………………………………………17

d. The challenged restrictions burden many additional fundamental constitutional rights………………………………………………………18

e. Deference Does Not Apply to Analysis of Fundamental Rights Infringements……………………………………………………………..20

II. POINT TWO THE REHABILITATION CLAIMS ARE FACIALLY SUFFICIENT TO WITHSTAND DISMISSAL……………………………21

III. CHD HAS STANDING TO SUE, AND DEFENDANTS ARE NOT IMMUNE FROM SUIT UNDER THE 11TH AMENDMENT PURSUANT TO EX PARTE YOUNG ……………………………………………........23

CONCLUSION 24

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
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23
24
25
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27
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TABLE OF AUTHORITIES

Cases

Adams & Boyle, P.C. v. Slatery,
956 F.3d 913 (6th Cir. 2020) 17

Ashcroft v. Iqbal,
556 U.S. 662 (2009) 6

Ayotte v. Planned Parenthood of N. New England,
546 U.S. 320 (2006) 2,9,11,12,16

B.C. v. Mount Vernon Sch. Dist.,
837 F.3d 152 (2d Cir. 2016) 21,22

D.A.B. v. N.Y.C. Dept of Educ.,
45 F. Supp.3d 400 (S.D.N.Y. 2014), ... 22

Doe v. Bolton,
410 U.S. 179 (1973) 1, 12

Easton v. Sundram, 947 F.2d 1011, 1015 (2d Cir. 1991)
947 F.2d 1011 (2d Cir. 1991) 6

Griswold v. Connecticut,
381 U.S. 479 (1965) 7

Gonzales v. Carhart,
550 U.S. 124 (2007) 11,21

Hayden v. County of Nassau,
180 F.3d 42 (2d Cir.1999) 6

Jacobson v. Massachusetts,
197 U.S. 11 (1905) 2,3,7,8,9,21,22

Keitt v. New York City,
882 F. Supp. 2d 412 (S.D.N.Y. 2011) 23

King v. Simpson,
189 F.3d 284 (2d Cir.1999) 6

Matter of Hofbauer,
47 N.Y.2d 648 (1979) 14,20

McElwee v. Cnty. of Orange,
700 F.3d 635 (2d Cir. 2012)..21

Neitzke v. Williams,
490 U.S. 319 (1989)..6

Nettis v. Levitt, 241 F.3d 186, 191 (2d Cir.2001)
241 F.3d 186 (2d Cir.2001)..6

Obergefell v. Hodges, 576 U.S. 644, 663 (2015)
576 U.S. 644 (2015)..7

Open Soc'y Int'l, Inc.,
651 F.3d 218 (2d Cir. 2011)..20, 23

Parham v. J.R.,
442 U.S. 584 (1979)..19

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505 U.S. 833 (1992)..10,11

Reno v. Flores,
507 U.S. 292, 293, 299 (1993)..7

Robinson v. Attorney General
957 F.3d 1171 (11th Cir. 2020) 14, 15

Stenberg v. Carhart,
530 U.S. 914 (2000)..2,10,11,17

State Employees Bargaining Agent Coal. v. Rowland,
494 F.3d 71 (2d Cir. 2007)..24

Sarmiento v. U.S.,
678 F.3d 147 (2d Cir.2012)..19

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530 U.S. 57 (2000)..19

Maioriello v. New York State Office for People with Developmental Disabilities, ,
2015 WL 5749879, at *19 (N.D.N.Y. Sept. 30, 2015) 24

Wallis v. Spencer,
202 F.3d 1126 (9th Cir. 2000) 19

Whalen v. Roe,
429 U.S. 589 (1977) 14

Whole Woman's Health v. Hellerstedt
136 S. Ct. 2292, 2298 (2016), as revised (June 27, 2016) 21

Statutes

N.Y. P.H.L. §2164[8] 6, 14

Federal Rules of Civil Procedure

Fed. R. Civ. P. 65 1

Other Authorities

LAWRENCE 0. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 126-28 (2d ed.2008) 8

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Plaintiffs respectfully submit this memorandum of law in opposition to State defendants' motion to dismiss dated August 24, 2020, *See* Dkt. No. 28.

PRELIMINARY STATEMENT

This suit challenges policies and practices promulgated and applied by defendants which violate fundamental constitutional rights of medically fragile children and their parents by placing arbitrary and undue burdens upon the availability of a medical exemption from vaccines. As a result of new policies which allow school principals to overrule treating physicians, hundreds of medically fragile children were removed from and school expulsion is imminent for many more even though New York licensed physicians certified that these children are at risk of harm from the vaccine at issue.

The challenged policies are arbitrary, capricious, and unjustified to further any legitimate state interest. Defendants admit that the goal of the new policies and procedures is to burden the medical exemption process so that fewer children can obtain them. To that end, they arbitrarily narrowed the definition of "what may cause harm" such that only a fraction of the known serious adverse reactions to vaccinations can now trigger the medical exemption. They vested school principals with the authority to overrule the children's treating medical providers. And they have placed additional burdens and roadblocks on the process which harm vulnerable children.

The challenged policies will not likely withstand judicial review. A sufficient medical exemption has been recognized as a constitutional prerequisite to any vaccine mandate for a hundred and fifteen years. *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905). Controlling precedent from the U.S. Supreme Court expressly forbids burdens on medical exemptions which subordinate the professional judgment of treating physicians. *Doe v. Bolton,* 410 U.S. 179, 199-200 (1973)(striking down restrictions on a medical exemption substantially similar to the ones at issue, holding that the patient's chosen medical provider must have

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discretion in decisions about what may constitute harm: "**[I]f a physician is licensed by the State, he is recognized by the State as capable of exercising acceptable clinical judgment").** *Doe* held that even requirements allowing other licensed physicians to overrule the treating provider on a medical exemption were unconstitutional. Certainly, allowing a school principal to overrule the parents' chosen physician is unlawful under this binding precedent.

Medical exemptions are given strict scrutiny, and even in cases where the possibility for harm alleged is only hypothetical and unlikely, the Supreme Court has deemed the exemption constitutionally insufficient. *Stenberg v. Carhart.* 530 U.S. 914, 937 (2000); *Ayotte v. Planned Parenthood of N. New England,* 546 U.S. 320, 325 (2006). The allegations in this case establish violations of other fundamental rights requiring strict scrutiny analysis as well – including the rights of parents to make medical decisions for their children in accordance with licensed physicians of their choice, the right to refuse medical treatment that could cause the child harm, and the right to be free from unconstitutional conditions requiring parents to forego fundamental constitutional rights if they want their child to receive an education at any private or public school in the state.

Rather than address the clear constitutional issues alleged, defendants engage in classic strawman tactics. Their central argument is that plaintiffs cannot prevail because the Supreme Court already decided that states may impose vaccine mandates in *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905). However, that is not the issue at all before the Court.

Plaintiffs do not challenge *Jacobson* or its holding that the state police power is broad enough to include vaccine mandates within limits. On the contrary, plaintiffs <u>rely</u> on *Jacobson,* which expressly held that a sufficient medical exemption is a necessary constitutional prerequisite to the state's police power to impose mandates, which determinations deserve the courts' strict scrutiny.

Defendants further fail to assert evidence of necessity for their draconian measures, arguing that *Jacobson* allows them *carte blanche* to operate without any scrutiny when vaccines are at issue.

Besides fundamentally misconstruing the issues, defendants cite to inapposite cases that do not extend state authority or judicial discretion nearly as far as they assert. Plaintiffs' complaint establishes multiple viable causes of action, appropriately names these parties, and should not be dismissed.

STATEMENT OF FACTS

For more than half a century, New York's existing statutory medical exemption provision has amply met the state's public health needs: "*If any physician licensed to practice medicine in this state certifies that such immunization may be detrimental to a child's health, the requirements of this section shall be inapplicable until such immunization is found no longer to be detrimental to the child's health."* NY PHL §2164[8].

The issue is defendants' adoption of additional policies and practices which, per their own admissions, intend to limit and burden the availability of medical exemptions for children who risk serious harm from vaccines. These regulations threaten to eviscerate the statute's necessary safety exemption meant to avoid medical harm to vulnerable people.

First, defendants arbitrarily narrowed the allowable reasons to obtain a medical exemption. New regulations removed the determination of "what may cause harm" from the judgment of informed treating physicians, substituting a narrow set of circumstances, pre-defined by the CDC's "ACIP guidelines," which are now the only basis to grant a medical exemption.

Clinical guidelines, such as the ACIP guidelines, however, are meant only to serve as a reference for treating physicians. The CDC itself acknowledges that the ACIP guidelines are not

an exhaustive list and cannot serve as a substitute for physicians' clinical judgment. Nor can the guidelines form the sole basis for the limits of a "valid medical exemption." Indeed, plaintiffs' complaint lists hundreds of additional conditions that vaccine manufacturers acknowledge as potential adverse events, yet defendants have arbitrarily excluded these serious conditions under the new criteria.

NYSDOH defendants do not refute plaintiffs' claims that the ACIP guidelines are not comprehensive and that it is irrational to use guidelines as an exhaustive list of permissible contraindications. Instead, they allege that the regulations are reasonable because they include an alternative, allowing a medical decision to be premised on "*other nationally recognized evidence-based standards of care.*" Plaintiffs complaint alleges that, in practice, defendants rendered this meaningless because they have routinely overruled any medical exemption that does not fall within a narrow reading of ACIP alone.

Second, the new regulations give school principals the power to overrule treating physicians. It does not cure the problem when principals consult a medical professional. School principals are no better qualified to decide between competing medical opinions than they are to second guess the treating physician in the first place.

Plaintiffs assert that these regulations pose enormous risks to their medically fragile children. Consulting doctors have no duty of care to the child, have never examined the child, do not have their full medical records, have no liability for malpractice or bad judgment, and often have financial incentives to deny as many medical exemptions as possible. It is not reasonable or even possible for a treating physician to document all the factors that go into his or her recommendation. A stranger to the child cannot reliably understand the full circumstances necessary to make an informed medical judgment to accept or deny the exemption. Certainly, to equate this opinion with that of a treating physician is arbitrary and capricious.

Defendants concede that they intend these and other challenged policies and practices to burden the medical exemption so that the number of students with exemptions dwindles.

Defendants stress that a measles outbreak in 2019 caused over 1,000 cases of measles in New York as an excuse. Yet they correctly do not suggest that medical exemption policy played any part.

Defendants concede that the number of children who seek medical exemptions is far too low to impact herd immunity, which requires the already obtained 85-95% compliance for measles, less for other vaccines. Defendants do not refute that several of the vaccines required for school admission do not protect anyone except the recipient. Tetanus, for example, is not a communicable disease. It is not a matter of controversy that the "IPV" polio vaccine mandated in this country provides personal protection only and cannot stop replication and transmission of disease to protect the community. The previously favored live polio vaccine (OPV) could provide protection to others, but it was discontinued because too many children were getting polio from the vaccine and causing outbreaks of vaccine-derived polio. Vaccines for pertussis, diphtheria and meningitis fall into the same category as the IPV vaccines. They can provide personal protection from symptoms but cannot stop a child from catching the disease and becoming asymptomatic carriers capable of passing it on to others.

With apparent punitive intent, defendants announced that children whose medical exemptions have been denied cannot participate in school remotely through the 100% online learning options nor participate in any activity limited to "admitted" students, such as taking the Regents exam or SATs. These punitive measures place irrational and dangerous compliance above education and obviously have no rational connection to fear of contagion.

STANDARD OF REVIEW

Failure to State a Claim: "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Sarmiento v. U.S.,* 678 F.3d 147 (2d Cir.2012)(quoting *Ashcroft v. Iqbal,* 556 U.S. 662, 678, (2009)). A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (internal citations omitted).

In considering a motion to dismiss for failure to state a claim pursuant to Fed.R.Civ.P. 12(b)(6), the Court must accept all factual allegations of the complaint as true, and draw all reasonable inferences in favor of the nonmoving party." *Hayden v. County of Nassau,* 180 F.3d 42, 54 (2d Cir.1999); *Sarmiento v. United States,* 678 F.3d 147, 152 (2d Cir. 2012).

The Court may not dismiss the complaint unless it is certain that Plaintiffs can prove no set of facts that would entitle them to relief. *Neitzke v. Williams,* 490 U.S. 319,326-27 (1989); *Nettis v. Levitt,* 241 F.3d 186, 191 (2d Cir.2001). Therefore, the issue before the Court on such a motion "is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *King v. Simpson,* 189 F.3d 284, 287 (2d Cir.1999). This caution against dismissal applies with even greater force where plaintiffs complain of a civil rights violation. *Easton v. Sundram*, 947 F.2d 1011, 1015 (2d Cir. 1991).

LEGAL ARGUMENT

I. THE CONSTITUTIONAL CLAIMS ARE FACIALLY SUFFICIENT TO WITHSTAND DISMISSAL

Defendants' actions unduly burden many fundamental constitutional rights, and this Court should not dismiss the claims without sufficient judicial scrutiny of the facts.

Under the Due Process Clause of the Fourteenth Amendment, no state shall "deprive any person of life, liberty, or property without due process of law." The Fifth and Fourteenth

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Amendments' guarantee of "Due Process of law" includes "a substantive component, which forbids the government to infringe certain 'fundamental' liberty interests at all, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest." *Reno v. Flores*, 507 U.S. 292, 293, 299 (1993); *Griswold v. Connecticut,* 381 U.S. 479, 484–486, (1965); *Obergefell v. Hodges*, 576 U.S. 644, 663 (2015).

The first step in a substantive due process analysis is to carefully identify the right Plaintiffs allege to be infringed. *Washington v. Glucksberg,* 521 U.S. 702, 721 (1997). The standard of review governing the Court's analysis of the substantive due process claim arises from the nature of the infringed right.

The identification and protection of fundamental rights is an enduring part of the judicial duty to interpret the Constitution, but that responsibility has not been reduced to a formula. Rather, it requires that courts "exercise reasoned judgment identifying interests of the person so fundamental that the State must accord them its respect." *Obergefell* 576 U.S. at 664 (quoting *Poe v. Ullman,* 367 U.S. 497, 542 (1961)). If the right is fundamental, the Court must strictly scrutinize state infringements upon it, ensuring that the state action is narrowly tailored to serve its compelling interests that outweigh the infringement. *Id* at 663. The rights at issue in this case are all fundamental and, accordingly, their infringement triggers strict scrutiny.

a. The right to a medical exemption where a child may be at risk of harm is a fundamental right and requires strict scrutiny

The right to a medical exemption is itself an independent fundamental constitutional right requiring strict scrutiny analysis. The Supreme Court has recognized that provision of a medical exemption is a constitutionally required safeguard to any regime that mandates vaccines. Correlatively, strict scrutiny applies when reviewing them. *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 27, 36-39 (1905)(holding that the police powers of a state are broad

enough to impose vaccine mandates to protect the community at large within limits, but stressing the necessity of judicial review if a person is vulnerable to harm from the procedure).

This right to a medical exemption where the mandate may cause harm is of such fundamental importance that even the 1905 *Jacobson* decision emphasized it, substantially before modern substantive due process protections emerged. The decision advocated deference to lawmakers to decide general public health policies but expressly warned that Courts must not abandon rigorous judicial scrutiny of medical exemption claims. *Id.* Indeed, the Court stated that mandating a person to submit to a vaccine that may cause harm is "cruel and inhuman in the last degree":

> Before closing this opinion we deem it appropriate, in order to prevent misapprehension as to our views, to observe—perhaps to repeat a thought already sufficiently expressed, namely—that the police power of a state, whether exercised directly by the legislature, or by a local body acting under its authority, may be exerted in such circumstances, or by regulations so arbitrary and oppressive in particular cases, as to justify the interference of the courts to prevent wrong and oppression. Extreme cases can be readily suggested. Ordinarily such cases are not safe guides in the administration of the law. **It is easy, for instance, to suppose the case of an adult[1] who is embraced by the mere words of the act, but yet to subject whom to vaccination in a particular condition of his health or body would be cruel and inhuman in the last degree."** *Id* at 38–39 (emphasis added).

The *Jacobson* Court clarified that where a person alleges they are "*not at the time a fit subject of vaccination, or [for whom] vaccination by reason of his then condition would seriously impair his health*", the Judiciary is not only competent to strictly review the appropriate tailoring of the medical exemption, but must do so:

> We are not to be understood as holding that the statute was intended to be applied to such a case, or, if it was so intended, that the judiciary would not be

[1] "There being obvious reasons for such exception", children were exempt from the smallpox mandate. "*Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 30 (1905)("there are obviously reasons why regulations may be appropriate for adults which could not be safely applied to persons of tender years").

> **competent to interfere and protect the health and life of the individual concerned**. *Id.* (emphasis added)

Public health law scholars acknowledge this principle of harm avoidance as part of the foundational holding of *Jacobson.* See, e.g., LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 126-28 (2d ed.2008)(per *Jacobson,* public health regulations require five elements to be constitutional: (1) public health necessity, (2) reasonable means, (3) proportionality, (4) harm avoidance, and (5) fairness).

In abortion cases, the Supreme Court recognized held that the right to a medical exemption is a fundamental constitutional right independent of the right to an abortion. *See, e.g., Ayotte v. Planned Parenthood of N. New England,* 546 U.S. 320, 325 (2006)(complementing the general undue burden standard for reviewing abortion regulations, the Supreme Court has also identified a specific and independent constitutional requirement that an abortion regulation must contain an exception for the preservation of the pregnant woman's health). One would be hard pressed to imagine how courts would not strictly review state medical exemption cases, as the rights at issue -- self-defense, right to informed consent, right to bodily autonomy – are so fundamental. A medical exemption is not just a liberty interest – it goes to the very right to life itself.

b. The regulations and policies at issue place an undue burden on the fundamental right to a medical exemption for vulnerable children

It is not surprising, then, that courts give far less leeway to infringements on medical exemption than to infringements on other types of fundamental rights, even when the state has established a compelling interest.

As a floor, the Supreme Court has repeatedly held that the lack of a medical exemption robust enough to avoid the risk of serious harm, even if only to a very small number of hypothetical subjects, renders a regulation unconstitutional. *Ayotte* 546 U.S. 320, 325-327

1 (acknowledging that any regulation which did not contain a sufficient medical exemption would
2 be unconstitutional, whether the regulation burdened the right to a medical exemption facially
3 or as applied.) Under this standard, the Court holds medical exemption provisions
4 unconstitutional where states could even conceivably apply the regulation at issue in such a way
5 as to pose a serious health risk to any person.

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7 In *Stenberg v. Carhart,* the Supreme Court clarified that a medical exemption is so
8 fundamental that if a regulation was narrow enough that it might exclude anyone who needed it,
9 it would likely be unconstitutional. 530 U.S. 914, 937 (2000). The question was whether a ban
10 on partial birth abortions (which the Court held was an otherwise permissible regulation on post-
11 viability abortion) had a sufficiently broad medical exemption where it exempted only cases in
12 which the mother's life was in danger. The issue turned on the definition of what could be
13 considered "necessary, in appropriate medical judgment, for the preservation of the life or health
14 of the mother" pursuant to *Planned Parenthood of Southeastern Pa. v. Casey,* 505 U.S. 833
15 (1992). The *Stenberg* Court acknowledged that little science existed that could provide certainty
16 that a woman would ever even need to use the regulated method of abortion over other arguably
17 safe methods that remained available to protect her health. In fact, though some hypothetical
18 advantages of the banned procedure were advanced, no expert was able to provide even one clear
19 example where the lack of availability of the banned regulation might seriously impact a
20 woman's health (the case was a pre-enforcement facial challenge with no impacted plaintiffs
21 alleging actual harm). Even though the Supreme Court acknowledged there was little evidence
22 to support a strict reading of "necessity," it held the law unconstitutional for failure to provide a
23 robust medical exemption. The Court's analysis is instructive:

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27 > The word "necessary" in *Casey's* phrase "necessary, in appropriate medical judgment, for the preservation of the life or health of the mother," …cannot refer to an absolute necessity or to absolute proof. Medical treatments and procedures are often considered appropriate (or inappropriate) in light of estimated

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> comparative health risks (and health benefits) in particular cases. Neither can that phrase require unanimity of medical opinion. Doctors often differ in their estimation of comparative health risks and appropriate treatment. And *Casey's* words **"appropriate medical judgment" must embody the judicial need to tolerate responsible differences of medical opinion."** *Id.* at 937. (emphasis added)

In *Gonzales v. Carhart*, 550 U.S. 124 (2007) the Court affirmed that a law that poses significant risk to a woman's health would be unconstitutional but found insufficient evidence on the purely hypothetical facial challenge that the Act reviewed actually could pose such risk.

Like the *Stenberg* majority, *Gonzales* read *Casey's* "preservation of the mother's health" render unconstitutional medical exemption laws that "subject [women] to significant health risks." For Justice Kennedy, the question became whether women could ever experience adverse health risks as a result of the prohibition (the case was again a pre-enforcement hypothetical facial challenge). The Court decided that where it was uncertain that the law could ever present a health risk to women, even after rigorous analysis of arguments and expert testimony, the law could not be stricken on a facial insufficiency basis alone. Rather, specific challenges illustrating how the law caused a significant risk of harm would be necessary to strike the law as unconstitutional. *Id.* ("The Court assumes the Act's prohibition would be unconstitutional, under controlling precedents, if it "subject[ed] [women] to significant health risks…Whether the Act creates such risks was, however, a contested factual question…").

In *Ayotte v. Planned Parenthood of Northern New England*, the Supreme Court addressed a facial challenge to a New Hampshire abortion act requiring advanced parental notification. 546 U.S. 320. The issue was whether the medical exemption was unconstitutional because it would not protect women whose health may be at risk from waiting the 48 hours necessary under the parental notification law. The state did not vigorously oppose the factual issue – that in some very small percentage of cases, pregnant minors, like adult women, would need immediate abortions to avert serious and often irreversible damage to their health. *Id.* at 328. The Supreme

Court thus found that the Act was unconstitutional because it required physicians to certify with impossible precision that an emergency abortion was "necessary" and because it impermissibly failed to protect the doctors' good faith medical judgment. *Id.* at 325. Rather than strike the law entirely, the Supreme Court remanded it for the District Court to determine whether any portion of the Act outside of the unconstitutional medical exemption could be saved.

In the present case, like in *Ayotte,* there is no controversy that the regulations will impose health risks for some children or that the medical exemption barriers require physicians to certify necessity with "impossible precision" and "fail to protect the doctor's good faith medical judgment."

Controlling precedent from the Supreme Court squarely forbids these infringements. In *Doe v. Bolton,* decided concurrently with *Roe v. Wade,* the Supreme Court examined restrictions on a medical exemption for an otherwise permissible law and declared unconstitutional nearly every practice defendants engage in here. 410 U.S. 179, 199-200 (1973).

First, the Court held that it was only constitutional to require that a physician determine that an abortion was "necessary" to protect the woman's health because the physician could consider a broad range of factors relevant to her clinical determination. "We agree with the District Court that the medical judgment may be exercised in the light of all factors—physical, emotional, psychological, familial, and the woman's age—relevant to the well-being of the patient. All these factors may relate to health. This allows the attending physician the room he needs to make his best medical judgment."

Thus, the Supreme Court clarified that a physician's determination of what may cause harm needs to be able to rest on any factor the physician finds relevant to a woman's health in their clinical determination. Under this standard, the challenged requirement that a physician limit her determination of "what may cause harm" only to the narrow ACIP guidelines would surely

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be unconstitutional. Though a state may have compelling reasons to limit medically unnecessary abortions to protect the life of the unborn, or to limit medically unnecessary exemptions to protect the community from contagion, the Supreme Court has repeatedly clarified that subjecting a person to risk of serious personal harm, is not an acceptable casualty in service of those needs. Thus, the determination of medical necessity cannot be made on narrow criteria.

Second, the Court struck down as unconstitutional a requirement that a hospital committee could review the treating doctor's determination of medical necessity before allowing the abortion to take place at that hospital. *Id.* at 199-200. The Court discussed at length why a hospital, which has an independent interest in ensuring that it is complying with law and standards of care, would want to review the grounds of the medical exemption. Nonetheless, the Court held that such review violated the patient's constitutional rights:

> Saying all this, however, does not settle the issue of the constitutional propriety of the committee requirement. Viewing the Georgia statute as a whole, we see no constitutionally justifiable pertinence in the structure for the advance approval by the abortion committee…**The woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview**." *Id.* at 192. "**We conclude that the interposition of the hospital abortion committee is unduly restrictive of the patient's rights and needs that, at this point, have already been medically delineated and substantiated by her personal physician.** To ask more serves neither the hospital nor the State. *Id.* at 197. *Emphasis added.*

Allowing school principals to review and override medical exemptions impermissibly infringes on the fundamental right to a medical exemption for the same reasons stated in *Doe.*

Lastly, the Court held that it was unconstitutional to require corroborating opinions from other state-licensed physicians. The Court's discussion of the corroborating opinion is particularly apposite to this case:

> The reasons for the presence of the confirmation step in the statute are perhaps apparent, but they are insufficient to withstand constitutional challenge. Again, no other voluntary medical or surgical procedure for which Georgia requires confirmation by two other physicians has been cited to us. **If a physician is licensed by the State, he is recognized by the State as capable of exercising acceptable clinical judgment**. If he fails in this, professional censure and deprivation of his license are available remedies.

> Required acquiescence by co-practitioners has no rational connection with a patient's needs and unduly infringes on the physician's right to practice. The attending physician will know when a consultation is advisable—the doubtful situation, the need for assurance when the medical decision is a delicate one, and the like. Physicians have followed this routine historically and know its usefulness and benefit for all concerned**. It is still true today that '(r)eliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he (the physician) possesses the requisite qualifications.**' *Dent v. West Virginia*, 129 U.S. 114, 122—123, 9 S.Ct. 231, 233, 32 L.Ed. 623 (1889). *See United States v. Vuitch*, 402 U.S., at 71, 91 S.Ct. at 1298. *Id.* at 199-200. (emphasis added.)

Defendants' argument that a school principal may overrule a treating physician because the district's consulting doctor disagrees must fail under this standard.

In this case, like in *Doe,* in enacting Public Health Law §2164(8), the New York State legislature already reached the limit of permissible restriction on medical exemptions. The fact that a physician licensed to practice in New York must certify the exemption is not merely sufficient; further regulation is unconstitutional. As the Supreme Court holds, "[i]f a physician is licensed by the State, he is recognized by the State as capable of exercising acceptable clinical judgment."

The Court reaffirmed *Doe* outside of the abortion context in *Whalen v. Roe,* 429 U.S. 589, 603 (1977)(under *Doe* it would be impermissible if access to controlled medications were "conditioned on the consent of any state official or third party" beyond the chosen licensed provider). See, also, *Matter of Hofbauer,* 47 N.Y.2d 648, 655–56, (1979)(citing *Doe* in denying a neglect proceeding against parents who chose to forego chemotherapy and holding that a parent must be able to follow any course of treatment "which is recommended by their physician and which has not been totally rejected by all responsible medical authority.")

A recent case from the Eleventh Circuit held that it is unconstitutional for a state to even suggest it might remove discretion from the treating physician in determinations about the need for a medical exemption despite the state's reliance on a public health emergency. *Robinson v. Attorney General* 957 F.3d 1171 (11th Cir. 2020)(upholding a TRO staying emergency

1 regulations restricting elective medical procedures due to *Covid-19*). Conflicting directives were
2 given about whether providers or the state would have "final say" over what qualified for a
3 medical exemption from these regulations. The court deemed the mere possibility that a treating
4 provider could be overruled in the determination of medical necessity unconstitutional, even
5 though defendants had powerful public health arguments argued that it was unlikely that the state
6 would ever choose to overrule a treating physician's medical determination of necessity. *Id.* at
7 1180. Nonetheless, that mere possibility led the Eleventh Circuit to uphold injunctive relief.
8
9 Moreover, if the hypothetical possibility of harm to a person is enough to render a medical
10 exemption unconstitutional, in this case, where the risk of harm is clear and articulated by multiple
11 named plaintiffs, the medical exemption cannot survive.
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13 Taking the plaintiffs' allegations as true and affording all favorable inferences to their
14 cause in this case, it is clear that the challenged policies and procedures are not only capable of
15 causing risk of harm, they already are causing significant harm to hundreds of medically fragile
16 children.
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18 As the complaint details, hundreds of evidence-based additional reasons exist which
19 could put some children at substantial risk of harm or death outside of ACIP. The long list of
20 precautions and adverse reactions in manufacturers' inserts, in Institute of Medicine Reports,
21 compensated by the Vaccine Injury Compensation Program and scores of peer reviewed studies
22 establish subpopulations at risk of serious harm. ACIP's narrow list of contraindications and
23 precautions do not cover adequately cover them.
24
25 In short, defendants' limiting definition is irrational and reckless. Guidelines are not
26 meant to replace treating physicians' clinical judgment or serve as an exhaustive list of
27 contraindications and precautions. Even the CDC admits that ACIP guidelines cannot define the
28 limits of a valid medical exemption and should not be used for that purpose.

Moreover, guidelines can be confusing and interpreted differently and, therefore, are too vague to use to overrule treating physicians. Defendants' decision to authorize and even pressure school principals to overrule medical exemptions if they do not agree that they fall within the ACIP guidelines is dangerous. Reasonable medical professionals trained to understand clinical guidelines disagree about how to interpret and apply ACIP. Certainly, a school principal, with no medical training or expertise in complex medical guideline interpretation and application, is not qualified to determine which of them is right when there is a difference of opinion. The good faith medical judgment of the treating provider cannot be infringed nor can treating physicians be required to certify necessity with such "impossible precision." *Ayotte* 546 U.S. 320.

The complaint contains lengthy factual discussion of the risks that these policies pose to medically fragile children including the named plaintiffs here. Some of these children have the same identified risk factors that led to their sibling's death from adverse vaccine reaction. Even though treating physicians certify that these children too are at risk of severe injury or death, current regulations deny them exemptions under the ACIP dogma. It shocks the conscious that according to defendant *Rausch-Phung*, the death of a sibling, even if recognized as occurring because of an adverse vaccine reaction, is not a sufficient reason for a medical exemption. *See* Dkt 1 (complaint) Par. 129 at page 23 of 73.

Many of these children themselves suffered serious adverse reactions to one or more vaccines; licensed medical professionals have documented them. Some of these children have produced not one, but three or more, certifications from well-regarded licensed physicians and even *specialists* that they are at risk of serious harm from one or more mandatory vaccines.

If the Court in *Stenberg* and *Ayotte* struck regulations that *might* cause risk of harm in hypothetical cases, certainly plaintiffs here, with proven records of harm, should prevail. On this ground alone, the Court should deny defendant's motion.

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c. The challenged policies and procedures are not narrowly tailored to uphold a compelling state interest sufficient to outweigh the plaintiffs right to a medical exemption

The risks to children here are the more unconscionable because defendants cannot justify the restrictions as necessary to achieve any compelling state interest. Taking the plaintiffs' factual allegations as true and affording them all reasonable inferences, the defendants' purpose cannot even survive a rational basis review, let alone the higher bar of strict scrutiny that medical exemption cases require.

The challenged policies bear no real and substantial relation to legitimate public health needs. *See Adams & Boyle, P.C. v. Slatery*, 956 F.3d 913 (6th Cir. 2020)(striking down *Covid-19* executive orders that burdened women's access to abortion where they lacked a real and substantial relationship to the pandemic).

Defendants admit explicitly and implicitly that the goal of their onerous and humiliating policies and procedures is to burden the medical exemption process limit the number given.

But limiting the number of children who can obtain a medical exemption at the potential expense of the health of medically fragile children is not a constitutional purpose. Here, defendants pursue their goal by arbitrarily expelling deserving children or exposing them to harm. Defendants thus defeat the state's compelling interest to protect life and instead cause irreparable harm. And the state forces parents to make this Hobson's choice without any evidence of medical exemption abuse.

To the extent that defendants assert the need to protect the community from contagious disease, the challenged policies, regulations, and procedures are not narrowly tailored to that end.

The half of one percent of children seeking medical exemptions cannot threaten herd immunity. Especially now that no non-medical exemptions exist, this number of medical exemptions is far too small to impact herd immunity for any relevant diseases. When Defendants'

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enacted the regulations, there had been no new measles cases for over six weeks. When they proposed it as permanent law, the measles outbreak had already been declared over, and there were no measles cases in New York. Furthermore, the legislature never established that any of the 1,000 people who contracted measles in 2019 had a medical exemption, let alone showed that the medical exemption had anything to do with the outbreak.

The risk of measles, while not to be discounted, is objectively low compared to the risk of harm asserted by these medically fragile children and their medical providers. In the last few decades, including during the latest outbreak, despite having had thousands more unvaccinated children in schools due to the religious exemption, there have been no measles deaths in New York even though there have been frequent outbreaks. Measles typically resolves in a week.

On the other hand, medically fragile children are at substantial risk of harm if denied a medical exemption. In addition to the deaths of some of the named plaintiffs' siblings, there are verified deaths from adverse vaccine reactions that occur each year, not to mention thousands of injuries. Vaccines may be safe and effective for most, but not for all. This is what science clearly shows.

And, the challenged regulations apply to all vaccines, not just measles vaccines, even the vaccine that are not designed to protect against contagion. As detailed in the complaint, many of the vaccines on the mandatory schedule cannot provide protection to anyone except the recipient and thus cannot impact herd immunity at all. This is not contested science. Many of these children are only missing vaccines in this latter category. The state would be hard-pressed to even advance a rational purpose for the restrictions on medical exemptions for these vaccines.

d. The challenged restrictions burden many additional fundamental constitutional rights

In addition to violating the Constitutionally protected right to a medical exemption, defendants have infringed other Constitutionally protected fundamental rights.

Parents have a fundamental right to direct the care and upbringing of their children, and medical decisions fall squarely within that liberty interest. *See Troxel v. Granville*, 530 U.S. 57, 58 (2000)("There is a presumption that fit parents act in their children's best interests" and thus "there is normally no reason for the State to inject itself into the private realm of the family to further question fit parents' ability to make the best decisions regarding their children."); *see also Parham v. J.R.*, 442 U.S. 584, 604 (1979)("Simply because the decision of the parent…involves risks does not automatically transfer the power to make that decision from the parents to some agency or officer of the state. The same characterizations can be made for a tonsillectomy, appendectomy, or other medical procedure…Parents can and must make those judgments.")

It is constitutionally impermissible for defendants to usurp these decisions on the basis of a disagreement between the licensed treating physician and a consultant that a school principal happens to employ, a person who has never examined the child and who is inherently less qualified. It is also against the child's best interest. Parents are in the best position to determine a course of action to protect their medically fragile child's health where there are differing medical opinions. Parents of medically fragile children typically spend years working with providers, diving deep into the literature, and gaining first-hand experience with their particular child's reactions to various medical interventions and triggers. They love their children and they are best equipped to ask the appropriate questions, evaluate and make the final determination in the child's best interests where differences of medical opinion exist.

These rights adhere not only to the parent but to the child as well. "The right to family association includes the right of parents to make important medical decisions for their children, and of children to have those decisions made by their parents rather than the state." *Wallis v. Spencer*, 202 F.3d 1126, 1141 (9th Cir. 2000).

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"While this right is not absolute inasmuch as the State, as *parens patriae*, may intervene to ensure that a child's health or welfare is not being seriously jeopardized by a parent's fault or omission, great deference must be accorded a parent's choice as to the mode of medical treatment to be undertaken and the physician selected to administer the same." *Matter of Hofbauer,* 47 N.Y.2d 648, 655–56, (1979)(a parent and child's constitutional rights demand parents be able to make medical treatment decisions in cases where there is a conflict of medical opinion, so long as the parent has sought the advice of licensed professionals and follows a plan "which is recommended by their physician and which has not been totally rejected by all responsible medical authority.")

Plaintiffs also assert here the fundamental rights to refuse medical treatment and to exercise informed consent. As fundamental rights, their infringement requires factual review with strict scrutiny analysis.

Defendants misconstrue plaintiffs' claim regarding education. There may be an independent constitutional right to an education, particularly where defendants preclude not only a free public education but the right to go to school at all, public or private. But either way, it violates the "unconstitutional conditions doctrine," for the government to place a burden on a benefit or subsidy that infringes on the recipient's constitutionally protected rights, even if the government has no obligation to offer the benefit in the first instance. *Open Soc'y Int'l, Inc.,* 651 F.3d 218 (2d Cir. 2011). Courts review unconstitutional conditions under strict scrutiny analysis regardless of whether the benefit is a "fundamental right" on its own. *Id.*

e. Deference Does Not Apply to Analysis of Fundamental Rights Infringements

Defendants suggest that principles of deference require this Court to abstain from any scrutiny of the facts or arguments regarding Plaintiffs' harms or burdens against the state's needs. But deference does not govern review of medical exemptions. In fact, quite the opposite is true.

1 In *Gonzales, supra,* the Supreme Court clarified that whether a medical exemption
2 restriction might cause harm is a factual determination, and the Court should not merely defer
3 to legislative or agency determinations:
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5 > The Attorney General urges us to uphold the Act on the basis of the congressional findings alone… Although we review congressional factfinding under a deferential standard, we do not in the circumstances here place dispositive weight on Congress' findings. **The Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake.** See *Crowell v. Benson,* 285 U.S. 22, 60, 52 S.Ct. 285, 76 L.Ed. 598 (1932) ("In cases brought to enforce constitutional rights, the judicial power of the United States necessarily extends to the independent determination of all questions, both of fact and law, necessary to the performance of that supreme function"). *Id* at 165. (emphasis added)
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11 In *Whole Woman's Health v. Hellerstedt,* the Supreme Court clarified when addressing
12 medical need or burden, deference of the kind the defendants suggest is not appropriate.
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14 > The Fifth Circuit's test also mistakenly equates the judicial review applicable to the regulation of a constitutionally protected personal liberty with the less strict review applicable to, *e.g.,* economic legislation. And the court's requirement that legislatures resolve questions of medical uncertainty is inconsistent with this Court's case law, which has placed considerable weight upon evidence and argument presented in judicial proceedings when determining the constitutionality of laws regulating abortion procedures." *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2298 (2016), as revised (June 27, 2016).
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19 As discussed in detail above, *Jacobson* itself clarified that deference does not apply to
20 review of medical exemptions. *Jacobson* 197 U.S. 11 (1905).
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22 **II. THE REHABILITATION CLAIMS ARE FACIALLY SUFFICIENT TO WITHSTAND DISMISSAL**

23 Plaintiffs sufficiently pleaded viable claims under the Rehabilitation Act.
24 The ADA and Section 504 both protect "qualified individual[s] with a disability" from
25 discriminatory denial of benefits. *See* 42 U.S.C. § 12132 (ADA); 29 U.S.C. § 794(a)(Section
26 504); *B.C. v. Mount Vernon Sch. Dist.*, 837 F.3d 152, 158 (2d Cir. 2016)."Because the
27 standards adopted by the two statutes are nearly identical, [courts] consider the merits of these
28 claims together." *McElwee v. Cnty. of Orange*, 700 F.3d 635, 640 (2d Cir. 2012).

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As the Second Circuit explained in *B.C. v. Mount Vernon School District*: "To establish a prima facie case of discrimination under either the ADA or Section 504, a plaintiff must show the following: (1) plaintiff is a "qualified individual with a disability;" (2) plaintiff was "excluded from participation in a public entity's services, programs or activities or was otherwise discriminated against by [the] public entity;" an (3) "such exclusion or discrimination was due to [plaintiff's] disability." *B.C.*, 837 F.3d at 158 (citations omitted).

In connection with the second prong: "(e)xclusion or discrimination may take the form of disparate treatment, disparate impact, or failure to make a reasonable accommodation." *Id*.

Plaintiffs make two claims – (1) due to their disabilities, defendant districts have excluded medically fragile children from participation in services that they are otherwise entitled to receive, and (2) that they were discriminated against under theories of disparate treatment, disparate impact and failure to make a reasonable accommodation.

Defendants argue that the plaintiffs cannot prevail because they cannot show that they are excluded from participation in benefits due to their disabilities.

Defendants rely on *D.A.B. v. N.Y.C. Dept of Educ*., 45 F. Supp.3d 400 (S.D.N.Y. 2014) for the proposition that vaccination requirements cannot constitute discrimination based on disability. However, *D.A.B.* specifically relied upon the availability of sufficient exemptions – including a medical exemption – to conclude that the challenged regime would not be likely be deemed discriminatory.

In *D.A.B.,* the court did not decide the issue of whether the vaccine requirement constituted discrimination in that case (the child had not applied to or been rejected by the school but elected for other reasons – particularly dissatisfaction with the services offered – to attend private school). The court did speculate in dicta, however, that the vaccine requirement was

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unlikely to be found discriminatory as there was a medical exemption available if the child could not safely take the vaccine due to his disability. *D.A.B.,* 45 F. Supp. 3d at 407.

Here, plaintiffs allege that the new regulations narrow the medical exemption so that most of the acknowledged potential harms are no longer covered. Thus, those with disabilities that fall outside of the non-exhaustive ACIP contraindications are discriminated against and denied benefits to which they are otherwise entitled. Plaintiffs have made a *prima facie* case that the restrictions are overly narrow and plausibly unlawful. If that is so, then the restrictions also discriminate and disparately impact medically fragile children with certain disabilities.

III. CHD HAS STANDING TO SUE, AND DEFENDANTS ARE NOT IMMUNE FROM SUIT UNDER THE 11TH AMENDMENT PURSUANT TO EX PARTE YOUNG

Standing: Defendants challenge the standing of Children's Health Defense (CHD) to appear as a plaintiff. An Association has standing to bring suit on behalf of its members when (1) at least one of the association's members would otherwise have standing to sue in its own right, (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *All. for Open Soc'y Int'l, Inc. v. U.S. Agency for Int'l Dev.*, 651 F.3d 218 (2d Cir. 2011), aff'd sub nom. *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.,* 570 U.S. 205 (2013). CHD has asserted that many of its members have standing, that the interests – protecting children from harm and challenging unlawful regulations that will place them at risk of harm – are germane to its purpose, and that the suit does not require participation of the individual members of CHD, as the requested relief is prospective injunctive relief against unconstitutional policies and practices that impact all families seeking a medical exemption.

Immunity: Defendants allege that the Constitutional claims against the Department of Health are improper under the Eleventh Amendment. Plaintiffs agree and do not bring

Constitutional claims against DOH. The State officials named in their official capacities are the intended parties in these claims. It is well settled pursuant to *Ex Parte Young* that a plaintiff may sue a state official acting in his official capacity, notwithstanding Eleventh Amendment sovereign immunity, for prospective, injunctive relief from violations of federal law. *State Employees Bargaining Agent Coal. v. Rowland*, 494 F.3d 71 (2d Cir. 2007).

The DOH is named as a defendant in the Rehabilitation claims along with defendant *Zucker* and defendant *Rausch-Phung* in their official capacities. Defendants agree *DOH* can be properly sued under the Rehabilitation Act but suggest that the Rehabilitation Act claims against the officials should be dismissed. As they are named in their official capacities, the Rehabilitation Act claims should not be dismissed against the named defendants. *Keitt v. New York City*, 882 F. Supp. 2d 412, 425 (S.D.N.Y. 2011)(rehabilitation claims against state agency and high level state employees in their official capacities were proper – suits against officers in their individual capacities is not proper under the Rehabilitation Act); *Maioriello v. New York State Office for People with Developmental Disabilities*, No. 1:14-CV-0214 GTS/CFH, 2015 WL 5749879, at *19 (N.D.N.Y. Sept. 30, 2015)("Individuals in their personal capacities are not proper defendants on claims brought under the ADA or the Rehabilitation Act, although individuals can be sued in their official capacities under these statutes."). *Ex Parte Young* extends to naming individual state actors sued in their official capacities as defendants in Rehabilitation claims where the suit against them does not seek punitive damages but rather prospective equitable relief, as here. *Id.*

CONCLUSION

Wherefore, plaintiffs respectfully request that this Court deny the defendants' motion to dismiss.

Respectfully submitted,

/s Sujata S. Gibson

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