SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

MAGDALENA GARCIA, individually and on behalf of her minor child PS, CLEMENCE RASIGNI, individually and on behalf of her minor child NR, LYNN ROSENGER, individually and on behalf of her minor children MR and RR, MICHELLE CARROLL, individually and on behalf of her minor child EP, and GABRIELLE JAKOB, individually and on behalf of her minor children AG and DG,	No. 161484/2015
	Honorable Manuel J. Mendez
Plaintiffs-Petitioners,	
-against-	Motion # 001
THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE; THE NEW YORK CITY BOARD OF HEALTH; and DR. MARY TRAVIS BASSETT in her Official Capacity as Commissioner of the New York City Department of Health and Mental Hygiene,	
Defendants-Respondents.	

REPLY MEMORANDUM OF LAW IN SUPPORT OF VERIFIED ARTICLE 78 & DECLARATORY JUDGMENT PETITION

&

REPLY MEMORANDUM OF LAW IN SUPPORT OF PRELIMINARY INJUNCTION

&

OPPOSITION TO RESPONDENTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR CROSS-MOTION TO DISMISS

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Plaintiff-Petitioner respectfully submits this reply Memorandum of Law in support of plaintiffs-petitioners' Verified Article 78 and Declaratory Judgment Petition and -- in the event the foregoing is not decided on or shortly after November 25, 2015 -- in support of a preliminary injunction, *and* in opposition to defendant-respondents' cross-motion to dismiss.[1]

PRELIMINARY STATEMENT

This action is timely and laches are inapplicable since almost of the all plaintiffs didn't even have standing to assert their claims until literally days before the commencement of this proceeding. (*Infra* § I.) Defendants' attempt to rely on a one-hundred fifty year old local law regarding communicable diseases in general is improper because it was not included as a basis of statutory authority in its notice of proposed rule as required by the Charter (*Infra* § I(A)) and is misplaced because it *must* yield to later more specific State laws which expressly prohibit regulation mandating the flu shot (*Infra* § I(B)-(C)). In fact, these recent State laws, which even expressly require preschools to admit students that will receive all vaccines required by State law and prohibit regulation adding additional mandatory vaccines (including expressly the flu shot), render the flu shot dictate infirm under specific preemption and field preemption. (*Infra* §I(D).)

Most importantly, notwithstanding all of the foregoing, even if the DOH has the general authority to regulate regarding disease, the DOH's regulatory flu shot and vaccine regime plainly chooses between competing policy ends which the defendants have failed to specifically dispute, including failing to dispute that the defendants have made the policy choice to exclude smaller day care centers for economic reasons, that the defendants considered the economic impact on families from lost work days and out-of-cost expenses related to the flu, that the defendants chose to only

[1] Instead of submitting three memorandums of law (two replies and one opposition) with a total permitted length of 40 pages, a single combined memorandum of law with far less pages is respectfully submitted.

mandate the flu shot to babies and toddlers in order to protect the elderly, and that the defendants otherwise made the policy choice of choosing between merely encouraging the flu shot and requiring its injection into the human body under penalty of not being permitted to attend preschool. (*Infra* § I(E).) Defendants do not seriously, or in any manner, specifically contest they have made any of these and other policy choices discussed *infra* in enacting the flu shot dictate which the DOH enacted in direct conflict with the legislative policy to encourage the flu shot and which prohibited mandating the flu shot, and hence the DOH here has plainly crossed the line from permissible administrative rule-making to impermissible legislative policy making. (*Id.*)

To the extent the foregoing is ignored and the DOH's general authority to regulate regarding disease can be found to have permitted the Vaccine Powers Rule, it must be struck down as an unconstitutional delegation of legislative authority, because if such general authority to regulate regarding disease permits the DOH to adopt the flu shot and vaccine regime at issue here it would certainly also permit the DOH to regulate far less intrusive measures to control disease such as requiring every New Yorker to wear a mask and not shake hands at all times during flu season, eat less sugary foods to avoid heart disease, or immediately cease smoking to avoid lung disease. (*Infra* § III.) The real disease here to be concerned about is the spread of unchecked executive power and the illiberalism such excess has wrought on mankind through history. (*Id.*)

Finally, the DOH would have this Court ignore the recent on-point State laws regarding the flu shot and other vaccines, and ignore the founding bedrock principal of separation of powers, because the DOH swears in the affidavit of Dr. Barbot that the flu shot is safe and effective. *But not only is the safety and effective of the flu shot irrelevant to the question of whether the DOH could properly adopt its vaccine and flu shot regulation regime*, the DOH's claim regarding the safety and efficacy of the flu shot is at best misleading since the CDC's own data confirms the

efficacy of the flu shot is abysmal (apparently less effective than hand washing) and the U.S. Dep't of HHS data reveals the widespread serious adverse reactions to the flu shot. (*Infra* § IV.)

In fact, a meta-analysis of the influenza vaccine literature by the The Cochrane Collaboration, whose partners and funders include the World Health Organization ("WHO"), the National Institutes of Health ("NIH"), and health departments and universities from around the globe, published by Wiley in 2012, concluded that "at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications or community transmission of influenza," the influenza vaccine "in children aged two years or younger are no significantly more efficacious than placebo," that "[t]he lack of safety data for inactive vaccines in younger children [which is the only influenza vaccine licensed for children under five] is particularly surprising given that the inactive vaccine is now recommended for healthy children six months and older in the USA…", that "influenza vaccines were associated with serious harms such as narcolepsy and febrile convulsions," that "there is evidence of widespread manipulation of conclusions [in studies]…funded by industry," and that "National policies for the vaccination of healthy young children are based on very little reliable evidence." (*Id.*) But, again, the safety and efficacy of the flu shot is irrelevant as to whether the DOH could adopt the flu shot dictate.

I. PLAINTIFFS' CLAIMS ARE TIMELY & NOT BARRED BY LACHES

This proceeding was timely commenced and is not barred by laches.

A. Claims are Timely

This action was manifestly timely commenced as to plaintiffs' second cause of action seeking a declaratory judgment that Charter §§ 558 and 1043 violate the separation-of-powers doctrine and are unconstitutional to the extent they are found to have delegated and/or authorized

defendants to promulgate §§ 43.17(a)(2)(B) and 47.25(a)(2)(B) of the NYC Health Code. *See, Collateral Loanbrokers Ass'n of New York, Inc. v. City of New York*, 47 Misc. 3d 1225(A), 18 N.Y.S.3d 578 (Sup. Ct. Bronx County 2015) ("While generally, the statute of limitations for a declaratory judgment action involving a constitutional question is six years as prescribed by CPLR § 213(1), it is well settled that 'no period of limitation at all is applicable to an action for a declaratory judgment in cases involving a continuing harm, such as the application of an invalid statute.'") (citations omitted.)

As for petitioners' first cause of action pursuant to Article 78, it is also timely because the petitioners were not "clearly aggrieved" until they received notice from their respective preschools that their children would be excluded and such notice was not received until after the start of this school year -- less than four months before this proceeding was commenced. Petitioner Ms. Garcia, whose three year old son only began attending preschool for the first time ever in August 2015, only received notice in August/September 2015 that her son must receive the flu shot to continue attending his developmentally critical preschool and Head Start program; this notice stated:

> Department of Health and Mental Hygiene now mandates that all children attending Early Childhood programs receive the flu shot each year. The flu shot must be taken between September 1st through December 31st to be valid for the program year. All children that do not receive this vaccination by December 31st will be excluded from the program until the vaccination is received.

(Ex. B at 1-2.) Petitioner Ms. Rasigni also only received notice on October 6, 2015 from her child's school that:

> The Department of Health now requires children enrolled in preschool to have a flu shot by December 31st 2015. After this date, the DOH will begin issuing notices of violations to childcare facilities that fail to follow this mandate. .. Please make an appointment with your child's pediatrician to

> get the flu shot administered. We will need a doctor's note stating that your child has been vaccinated.

(Ex. B at 12.) Petitioners Ms. Rosenger, Ms. Jakob, and Ms. Carroll similarly only received similar notices on October 19, 2015, October 27, 2015 and on or about October 26, 2015, respectively. (Ex. B at 18, 19, and 22.) Hence, all of the petitioners' claims are timely since they all received notice of their child's exclusion from preschool within the last four months. As the court held in *Raffaele v. Town of Orangetown*:

> For a determination to be final 'upon the petitioner' it must be clear that the petitioner seeking review has been aggrieved by it. A determination generally becomes binding when the aggrieved party is 'notified.' … Accordingly, we find that the proceeding pursuant to CPLR article 78 was timely commenced insofar as it challenged the determination rendered on August 9, 1993 [when she was clearly told] … she would not be permitted to return to her former position

224 A.D.2d 430, 431 (2d Dep't 1996) *see also Adams v. Carrion*, 85 A.D.3d 1517, 1518 (3d Dep't 2011) ("A determination becomes final and binding for statute of limitations purposes when the party seeking judicial review is definitely impacted and aggrieved.")

Logically and sensibly it could not be otherwise. Plaintiffs-petitioners had no reason to challenge the dictate until it became applicable to them. Ms. Garcia, as well as other of the petitioners, didn't even have a toddler in child care last year and hence weren't just not aggrieved, *they simply did not even had standing to challenge the flu shot dictate until at the earliest after their child began attending preschool in August 2015 and they were provided notice that their child would be excluded without a flu shot*. (Ex. B at 3 and 22.) *See, e.g., McAllan v. New York State Dep't of Health*, 60 A.D.3d 464, 464 (2009) ("To have standing to challenge a governmental action, a party 'must show 'injury in fact,' such that he will actually be harmed by the challenged administrative action. As the term itself implies, the injury must be more than conjectural.

Furthermore, petitioners must show that they have suffered an injury ... distinct from that of the general public.") (citations and internal quotations omitted.)[2]

It is untenable that a petitioner can be barred from asserting a claim due to lack of standing and then later, when the petitioner has standing, to be barred by the statute of limitations. The law could not possibly countenance such an absurd result. It simply cannot be, as would result from respondents' position, that the statute of limitations to challenge the flu shot dictate has even run as to unborn and even yet to be conceived children; the law could not possibly have intended such as an absurd result. *See, e.g., Zappone v. Home Ins. Co.*, 55 N.Y.2d 131, 137 (1982) ("In the interpretation of statutes the absence of facial ambiguity is rarely, if ever, conclusive. Literal interpretation of the words used will not be accorded when to do so will occasion great inconvenience, or produce inequality, injustice or absurdity. It is, moreover, always presumed that no unjust of unreasonable result was intended and the statute must be construed consonant with that presumption.") (citations and internal punctuation omitted.)

Moreover, every act taken by the DOH to enforce its illegal flu shot dictate is yet another violation of law, which runs anew the four months limitations period. *See Town of Huntington v. Cty. of Suffolk*, 79 A.D.3d 207, 215 (2010) ("At the same time, where a municipality pursues a policy which the plaintiff claims violates a statute or regulation, each particular violation is subject to review pursuant to CPLR article 78 and starts the statute of limitations running anew. If a continuing wrong is alleged, the action is not time-barred because the cause of action continues to accrue anew, each day the wrong is perpetrated…"); *Tompkins v. State*, 7 N.Y.2d 906, 907 (1960)

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[2] Defendants' even appear to argue that plaintiffs will not have suffered an injury in fact until January 1, 2016: "As petitioners cannot show that their children have actually been denied entry into their respective regulated child care facilities, they cannot show irreparable harm as a matter of law." (MOL Opp. to PI at 10.) *See Mitchell v. New York Univ.*, 129 A.D.3d 542, 543 (1st Dep't 2015) (four months did not commence until plaintiff was informed by school "that he had been declared persona non grata").

(not time barred since "alleges a continuing wrong by the State in maintaining an improperly constructed highway"). Indeed, the Affidavit of Dr. Barbot makes plain that the DOH's enforcement and implementation of the flu shot dictate is ongoing, including that the DOH will "begin to issue citations in January 2016 for non-compliance" since the DOH is only starting "enforcement [of the flu shot dictate] beginning in January 2016," and even attaches DOH bulletin issued in November 2015 for the 2015-2016 flu season providing guidelines and instructions for its illegal flu shot dictate. (Affidavit of Oxiris Barbot ¶¶ 20, 25 and Exhibit C.)

In the event the Court chooses to commence the four months from January 2014 -- despite the fact that petitioners would not have even had standing to challenge the flu shot dictate -- then petitioners respectfully request that the Court extend the limitations period to two years as permitted by CPLR § 217(1) since this petition has also expressly been brought on behalf of the petitioners' minor children. *See* CPLR § 217(1) ("four months after the determination to be reviewed becomes final and binding upon the petitioner … or with leave of the court where the petitioner or the person whom he represents … was under a disability specified in section 208 [which includes a minor], within two years after such time.")

B. <u>Claims are Not Barred By Laches</u>

Defendants' cannot seriously assert laches against the plaintiffs who did not, at the earliest, even have standing to bring this proceeding (commenced on November 9, 2015) until October 27, 2015 for Ms. Jakob, October 26, 2015 (approximately) for Ms. Carroll, October 19, 2015 for Ms. Rosenger, October 6, 2015 for Ms. Rasigni and August 2015 for Ms. Garcia. (Ex. B at 1, 12, 18, 19, and 22.) This proceeding was thus literally filed within days of when almost all of the plaintiffs first had standing to challenge the flu shot dictate because until, as the least, receiving notice that their child would be excluded from preschool without a flu shot they did not have an "injury in

fact." (*Id.*) Defendants' even appear to argue that plaintiffs will only have an injury in fact when actually excluded from preschool on January 1, 2016. (MOL Opp. to PI at 10) ("As petitioners cannot show that their children have actually been denied entry into their respective regulated child care facilities, they cannot show irreparable harm as a matter of law.")

Since plaintiffs proceeded as expeditiously as possible to bring this proceeding after obtaining standing, the doctrine of laches is inapplicable. *See Waste-Stream Inc. v. St. Lawrence Cty. Solid Waste Disposal Auth.*, 167 Misc. 2d 542, 548 (Sup. Ct. Lawrence County 1995) ("The defense of laches is unavailable in this case. Defendant has failed to demonstrate the 'delay' occasioned by Plaintiff once it learned of SWDA's purportedly *ultra vires* 'collection' activities. … Although Defendant urges it would suffer prejudice from the delay by virtue of its capital investment in equipment, this type of prejudice is of no moment because the investment, necessarily, had to have been made to engage in 'collection activities.' It was only when Defendant was able to, and did, engage in these activities that the Plaintiff was aggrieved and had standing to commence this declaratory judgment action.")

Furthermore, the claimed harm to the DOH is, in any event, illusory. The DOH is mandated pursuant to State law Section 613(1) of the Public Health Law to promote (and ironically not mandate) the influenza vaccine and hence the DOH would have, as it has done in every year prior to passing the flu shot dictate, engaged in a wide scale public campaign to promote the influenza vaccine, including to preschoolers. For example, Dr. Barbot as proof for his assertion that the "BOI spent $831,680 on flu vaccine promotion that included subway ads, radio print, social media, and wide dissemination of a City Health Information Bulletin with significant emphasis on this topic" *attaches only one exhibit* containing the City Health Information Bulletin for the 2015-2016 influenza season; however, this same bulletin in 2012-2013 (prior to the passage of the flu shot

dictate) contains nearly the same information, save for now stating that the flu shot is mandatory. (*Compare* Aff. Of Dr. Barbot Ex. 3 *with* Ex. C.) Similarly, the DOH is in any event mandated to conduct inspections of preschools around NYC and has done so for years prior to adopting the flu shot dictate to assure compliance with State mandated vaccinations. (PHL § 613(2).)

This action does not, in any way, seek to limit the DOH from promoting the flu shot; nor does it in any way seek to limit anyone's ability to obtain a flu shot; it merely asks that the DOH's illegal requirement that the flu shot be mandatory for children to attend preschool be enjoined. There is no need to remove any purported posters or ads. In fact, the DOH need merely send a notice to preschools *not* to kick out children that don't have the flu shot. Nothing more. This is neither arduous nor difficult as claimed by the DOH.

In contrast, children all over NYC will soon be kicked out of preschool based on an *ultra vires* and unconstitutional flu shot requirement adopted by unelected and unaccountable individuals at the DOH. It is noteworthy that since commencing this lawsuit the undersigned has received innumerable phone calls from parents across NYC that also have just recently received notice from their child's preschool that their children will be ejected on December 31, 2015 if they don't get the flu shot and these parents, often without the ability to leave work, adamantly refuse to inject their children with the flu shot, many of them because their own pediatrician has advised them it is unnecessary.

II. DOH'S RELIANCE ON LOCAL LAW § 17-109 AND CHARTER § 556 IMPROPER AND MISPLACED

DOH's reliance on Ad. Code § 17-109 and New York City Charter § 556 are improper and misplaced.[3]

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[3] Similarly, defendants' reliance on the Second Circuit decision in *Phillips v. City of New York*, 755 F.3d 538 (2d Cir. 2015) is misplaced because the Second Circuit's only ground for denying an injunction against

A. Cannot Rely on Ad. Code § 17-109 and Charter § 556

Section 1043 of the New York City Charter (the "**Charter**") requires that the DOH in its notice of proposed rule expressly state the statutory authority upon which it will adopt such proposed rule. (Charter § 1043) (*The "published notice [for the proposed rule] shall include ... the statutory authority, including the particular sections and subdivisions upon which the action is based*.") (emphasis added.) Here, the notice of the proposed rule for the flu shot dictate listed only two provisions -- Sections 558 and 1043 of the Charter. (Ex. D at 2.) Section 1043, ironically, contains the express requirement that the notice of proposed rule must provide "*the statutory authority, including the particular sections and subdivisions upon which the action is based*." (Charter § 1043(b)) (emphasis added.) Hence, having failed to include Ad. Code § 17-109 and Charter § 556 as a basis of statutory authority for adopting the flu shot dictate in its notice of proposed rule, it cannot now properly rely on these sections. (Charter § 1043)

B. Reliance on Ad. Code § 17-109 Is Misplaced

Even assuming the DOH could rely on Ad. Code § 17-109 (which was not listed in the notice of proposed rule) and further assuming this section authorized the DOH to mandate any vaccine it desired and create a regulatory regime for same (which it does not as discussed *infra*), the DOH's reliance on Ad. Code § 17-109 is misplaced because it is well settled that a prior general law must yield to a later more specific law and here the general (and until this lawsuit apparently long forgotten) ancient local law Ad. Code § 17-109 must yield to the recent and more specific State laws. *See, e.g., People v. Zephrin*, 14 N.Y.3d 296, 301 (2010) ("we have held on numerous occasions that a specific statutory provision governs over a more general provision"); *E. End Trust*

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the flu shot dictate there was because the plaintiff, whose child was not in preschool, "lack[ed] standing to challenge." (Exhibit E to the Affirmation of Mark W. Muschenheim.) The merits were never reached and hence this two sentence decision by the Second Circuit cannot have any preclusive effect here. *Id*.

Co. of City of Harrisburg, Pa., v. Otten, 255 N.Y. 283, 286 (1931) ("what is special or particular in the later of two statutes supersedes as an exception whatever in the earlier statute is unlimited or general"); *Schieffelin v. McClellan*, 135 A.D. 665, 669 (1st Dep't 1909) (same); *Wager v. Pelham Union Free Sch. Dist.*, 108 A.D.3d 84, 89 (2d Dep't 2013) ("general statutes…must yield to later, more specific statutes"); *People v. Avilas, Inc.*, 29 A.D.3d 764, 765 (2d Dep't 2006) ("a prior general statute must yield to a later more specific statute"); *Gen. Elec. Capital Corp. v. New York State Div. of Tax Appeals*, 301 A.D.2d 819 (3d Dep't 2003) *aff'd* 2 N.Y.3d 249 (2004) (later, more specific statute control over earlier, more general statute); *Erie Cty. Water Auth. v. Kramer*, 4 A.D.2d 545, 550 (4th Dep't 1957) *aff'd* 5 N.Y.2d 954 (1959) ("general statute yields to a later specific or special statute").

Here, the later enacted PHL § 613(1) expressly and specifically directs that Commissioner of Health, with the participation of the DOH, to strongly encourage the flu shot with an express prohibition on regulation mandating the flu shot. As provided therein:

> The commissioner shall develop and supervise the execution of a program of immunization, surveillance and testing, to raise to the highest reasonable level the immunity of the children of the state against communicable diseases including, but not limited to, influenza... Municipalities in the state shall maintain local programs of immunization to raise the immunity of the children and adults of each municipality to the highest reasonable level, in accordance with an application for state aid submitted by the municipality and approved by the commissioner. Such programs shall include assurance of provision of vaccine….
>
> In connection with efforts to raise the immunity of children against influenza, the commissioner shall administer a program of influenza education to the families of children ages six months to eighteen years of age who attend licensed and registered day care programs, nursery schools, pre-kindergarten, kindergarten, school age child care programs, public schools or non-public schools. …. The … department of mental hygiene shall provide the commissioner with such assistance in carrying out the program... *Nothing in this subdivision shall authorize mandatory immunization of adults or children, except as provided in sections twenty-one hundred sixty-four and twenty-one hundred sixty-five of this chapter*.

(PHL § 613(1)) (emphasis added.) The legislative policy regarding the influenza vaccine could not be any clearer -- increase vaccination rates through education, not mandatory inoculation. (*Id.*) To assure the DOH's compliance with Section 613, the Commissioner of Health has even regulated that the DOH "shall maintain a program designed to minimize the occurrence and transmission of vaccine preventable disease" which "program shall include, at a minimum, activities to ensure … *compliance with all statutes and regulations concerning immunization applicable to local health departments, including but not limited to (1) Public Health Law section 613*." (10 CRR-NY 40-2) (emphasis added.)

In fact, and ensuring that there is no doubt regarding the policy to restrict regulation mandating the flu shot, Section 206(1)(l) of the Public Health Law expressly provides that the Commissioner of Health, with oversight authority over the DOH, shall:

> establish and operate such adult and child immunization programs as are necessary to prevent or minimize the spread of disease and to protect the public health. ... The commissioner may promulgate such regulations as are necessary for the implementation of this paragraph. *Nothing in this paragraph shall authorize mandatory immunization of adults or children, except as provided in sections twenty-one hundred sixty-four and twenty-one hundred sixty-five of this chapter.*

(Pub. Health Law § 206(1)(b), (1)(l)) (emphasis added.) The legislative policy is clear, Section 2164 of the Public Health Law embodies the legislative policy choice for which vaccines will be required to enter preschool and which vaccines are not required to enter preschool, and Sections 206 and 613 make plain that other vaccines, such as the influenza vaccine, are to be encouraged (not mandated) by the executive. (Pub. Health Law §§ 206(1), 613(1), and 2164.)

The foregoing statutory policy and requirements are expressly codified in 10 CRRNY 66-1.3 which provides that if a "child is in the process of receiving immunizations [defined to include only those vaccines listed in PHL § 2164 and does not include the influenza vaccine]" then "[a]

principal or person in charge of a school shall not refuse to admit a child to school [defined to include all preschools in NYC to which the flu shot dictate applies] based on immunization requirements." (10 CRRNY 66-1.3.) The law is clear -- any child in preschool in NYC cannot be denied admission if they will receive all vaccines required by Section 2164 of the Public Health Law and that section does not include the flu shot.

The broader and earlier adopted Ad. Code § 17-109 must yield to the later and specific statutorily dictated policy in PHL §§ 206(1), 613(1), and 2164 related to mandating versus encouraging the flu shot and other vaccines.

C. Reliance on Charter § 556 Is Misplaced

The DOH also improperly relies on Charter § 556(c)(2) which provides that the DOH shall "supervise the reporting and control of communicable and chronic diseases and conditions hazardous to life and health." As with Section Ad. Code § 17-109, even assuming the DOH could properly rely on Charter § 556(c)(2) (which it cannot, *see supra* § II(A)), whatever general authority the DOH believes it has to regulate communicable diseases therein must yield to the later and specific statutorily dictated policy regarding mandating the flu shot and other vaccines in PHL §§ 206(1), 613(1), and 2164.[4]

In any event, the Court of Appeals has held that Sections 556 and 558 of the Charter are essentially the enabling statutes that define the scope and powers of the DOH but do not grant it authority to pass laws; the DOH must still pass rules and regulations pursuant to some specific

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[4] Charter § 556(c)(2), in fact, does not specifically authorize the DOH to regulate regarding communicable diseases. The DOH leaves out and ignores the limiting term "supervise" in the authority to "supervise the reporting and control of communicable … diseases…" which limits the DOH to the supervision over the reporting and control of communicable diseases; this is far from a grant of authority to engage in rulemaking to control communicable diseases. In contrast, other areas over which the DOH is granted authority under Charter § 556 specifically grant the DOH the authority to "make policy" or "make rules and regulations," for example for providers of services for the mentally disabled. No such similar authority to set policy or make rules or regulations regarding communicable diseases is granted to the DOH in Charter § 556.

grant of legislative authority against which it can properly engage in interstitial rulemaking. For example, in the soda cup size ban case the DOH relied on this very same provision in Section 556 to assert that based on its mandate therein to regulate "chronic diseases" the DOH was permitted to pass the soda cup size ban to prevent the incidence of obesity, type 2 diabetes and other chronic diseases; here is what the Court of Appeals said about that in *Statewide Coalition*:

> It is true that the Board "may embrace in the health code all matters and subjects to which the power and authority of the [Department of Health and Mental Hygiene] extends" (N.Y. City Charter § 558 [c]) and that the Charter refers to the Board's supervision over "the reporting and control of communicable and chronic diseases and conditions hazardous to life and health" and "the abatement of nuisances affecting or likely to affect the public health" (N.Y. City Charter § 556[c][2]; *see also* § 556[c][9] [referring to Board's authority to "supervise and regulate the food and drug supply of the city and other businesses and activities affecting public health in the city"]). Nonetheless, the Charter contains no suggestion that the Board of Health has the authority to create laws. While the Charter empowers the City Council "to adopt local laws ... for the preservation of the public health, comfort, peace and prosperity of the city and its inhabitants" (N.Y. City Charter § 28[a]), the Charter restricts the Board's rulemaking to the publication of a health code, an entirely different endeavor.

23 N.Y.3d 681, 694 (2014). As discussed at length in plaintiffs' MOL in Support of Verified Petition, the permissible endeavor to engage in interstitial rulemaking requires that "the legislature must *specifically* delegate that power to him and must provide adequate guidelines and standards for the implementation of that policy." *Subcontractors Trade Ass'n v. Koch*, 62 N.Y.2d 422, 427-30 (1984) (emphasis in original). Furthermore, when engaging in interstitial rulemaking, as also discussed *infra* § II(E), such rulemaking may not violate the four factor test for determining whether the line between permissible administrative rule-making and impermissible legislative policy making has been crossed -- a line which the DOH here leapfrogs over as discussed *infra*.

D. **Regulation Mandating Vaccines Is Preempted by State Law**

Notwithstanding all of the foregoing, State law has manifestly preempted regulation in regard to which vaccines are to be mandatory and which are to only be encouraged. The State legislature's prohibition on regulation mandating vaccines could not be any clearer when it provides in Section 206(1)(l) of the Public Health Law that the Commissioner of Health, with oversight authority over the DOH, shall:

> *establish and operate such adult and child immunization programs as are necessary to prevent or minimize the spread of disease and to protect the public health. ... The commissioner may promulgate such regulations as are necessary for the implementation of this paragraph. Nothing in this paragraph shall authorize mandatory immunization of adults or children, except as provided in sections twenty-one hundred sixty-four and twenty-one hundred sixty-five of this chapter.*

(Pub. Health Law § 206(1)(b), (1)(l)) (emphasis added.)

Apparently to drive home this point, Section 613(1) of the Public Health Law directs the Commissioner of Health, with the assistance of the DOH, is to "develop and supervise the execution of a program of immunization…to raise to the highest reasonable level the immunity of children of the state against communicable diseases including, but not limited to, influenza" but makes crystal clear that nothing in the foregoing grant of authority to promote and increase immunization rates "shall authorize mandatory immunization of adults or children, except as provided in sections [2164] and [2165] of this chapter." (Pub. Health Law § 613(1).) This section even provides that in conjunction with the DOH, "the commissioner shall administer a program of influenza education to the families of children ages six months to eighteen years of age who attend licensed and registered day care programs, nursery schools, pre-kindergarten, kindergarten, school age child care programs, public schools or non-public schools" but again makes crystal clear that nothing in this foregoing grant of authority "*shall authorize mandatory immunization of adults or*

children, except as provided in sections twenty-one hundred sixty-four and twenty-one hundred sixty-five of this chapter." (PHL § 613(1)) (emphasis added.)

And to assure the DOH's compliance with Section 613, the Commissioner of Health has even expressly regulated that the DOH "shall maintain a program designed to minimize the occurrence and transmission of vaccine preventable disease" which "program shall include, at a minimum, activities to ensure … *compliance with all statutes and regulations concerning immunization applicable to local health departments, including but not limited to (1) Public Health Law section 613*." (10 CRR-NY 40-2) (emphasis added.) The Commissioner of Health has, in recognition of PHL §§ 206, 613 and 2164, even regulated that if a "child is in the process of receiving immunizations [defined to include those listed in PHL § 2164 and does not include influenza]", then "[a] principal or person in charge of a school shall not refuse to admit a child to school [defined to include all preschools in NYC to which the flu shot dictate applies] based on immunization requirements." (10 CRRNY 66-1.3.) Thus, the law in this area could not be any clearer -- children complying with the vaccination requirements of PHL § 2164 (which does not include the flu shot) should not be excluded from school based on any regulation.

In fact, in recognition that the legislature has preempted the field of regulation seeking to mandate vaccinations, a bill was introduced in 2008 "*at the request of the Department of Health*" to amend Section 2164 of the Public Health Law to include additional vaccines recommended by the CDC, including the influenza vaccine (which was incidentally soundly rejected). (*See* Bill No. A10942 at 1, 4) (emphasis added); (*See* Bill No. A10942A (2008).)

It is also worth noting that the Public Health Law, no less than nine times, provides that broad sections of the Public Health Law "shall not apply to the city of New York," including excluding Sections 300 to 309, 311 to 399, 540 to 544, 1303 to 1307, 1500 to 1502, 2100 to 2108,

2120 to 2124, 2140 to 2145, 2150 to 2152, 4102, 4104 to 4134, 4136 to 4137, 3139 to 4173, and 4175 to 4178. (Pub. Health Law §§ 312, 545, 1309, 1503, 2110, 2125, 2146, 2153, and 4104.) However, as for PHL §§ 206, 613, and 2164, no such exception is provided and the DOH must adhere to these sections of the Public Health Law.

Permitting the DOH to mandate any vaccine it desires would not only "tend to inhibit" the policy directive in PHL §§ 206, 613, and 2164 by which the State legislature has prohibited regulation mandating additional vaccines, it would in fact directly conflict and eviscerate this policy choice. *See, e.g., Nyack v. Daytop Vill., Inc.*, 78 N.Y.2d 500, 505 (1991) ("This finding of preemption is justified by the belief that '[s]uch laws, were they permitted to operate in a field preempted by State law, would tend to inhibit the operation of the State's general law and thereby thwart the operation of the State's overriding policy concerns.' The Legislature's intent to so preempt a particular area can be inferred from a declaration of policy or from a comprehensive or detailed scheme in a given area.") (citations omitted) (cited by defendants.)

All of the examples of laws other than PHL §§ 2164 and 2165 mandating vaccines cited by defendants are inapposite since in each instance the vaccine requirement *was enacted by the State legislature* (save for two instances related to typhoid and smallpox adopted decades before PHL §§ 206 and 613 were enacted limiting regulation mandating vaccines); obviously, while the legislature prohibited regulation mandating additional vaccines, the legislature did not constrain itself from adding mandatory vaccines. [5] The fact that defendants cannot point to a single regulation mandating a vaccine adopted after the enactment of PHL §§ 206, 613 and 2164 is yet

[5] Defendants' reliance on 10 NYCRR § 2.42 (adopted no earlier than 1938) and the regulation discussed in *Pierce v. Bd. of Ed. of City of Fulton*, 30 Misc. 2d 1039, 1040 (Sup. Ct. Oswego County 1961) related to typhoid and smallpox, respectively, are inapposite because they were adopted decades before PHL §§ 206 and 613 were enacted limiting regulation mandating vaccines.

additional support that regulation mandating vaccines has been field preempted by the legislature. It is also worth noting that these statutory provisions were enacted by 213 legislators upon consensus after debate, public input, compromise, even partisanship because they are forced to hear each other out, and all the remaining safeguards in place for the passage of legislation; in contrast, the DOH's board is comprised of eleven unelected unaccountable individuals appointed by the mayor and should not be able to undo the clear policy choice in the field of mandatory vaccination made by the peoples' elected representatives.

Not only is there field preemption, there is also direct conflict preemption because mandating the flu shot directly conflicts with PHL §§ 206 and 613 which prohibit regulation mandating additional vaccines, including regulation mandating the flu shot. As the court in *Chwick v. Mulvey* (cited by defendants) explains:

> Under the doctrine of conflict preemption, a local law is preempted by a State law when a "right or benefit is expressly given ... by [ ] State law which has then been curtailed or taken away by the local law." Put differently, conflict preemption occurs … when a State Law prohibits what a local law explicitly allows. In determining the applicability of conflict preemption, we examine not only the language of the local ordinance and the State statute, but also whether the direct consequences of a local ordinance "render[s] illegal what is specifically allowed by State law."

81 A.D.3d 161, 167-68 (2d Dep't 2010) (citations omitted.) Here, the flu shot dictate which renders it illegal to attend preschool without a flu shot is directly at odds with PHL §§ 206 and 613 which prohibits regulating adding mandatory vaccines; it is also directly at odds with State law which pursuant to PHL § 2164 provides that such a child, as long as they have all other State required vaccines, can attend preschool; this policy choice is also reflected in, as discussed *supra*, 10 CRRNY 66-1.3 which prohibits preschools in NYC from refusing admission to children that will receive all vaccines required under PHL § 2164. Furthermore, the flu shot dictate unravels the

benefit conferred on the people of this State by PHL §§ 206 and 613 which assure that a legislative enactment, not an executive regulation, is required to mandate additional vaccines.

E. ***All Other Arguments Aside*, The Vaccine Powers Rule Must be Declared *Ultra Vires* Pursuant to the *Boreali* Test**

Most importantly, (i) assuming defendants could rely on Ad. Code § 17-109 and Charter § 556 (which would render meaningless the requirement in Charter § 1043(b)(1) to list the statutory authority upon which the rule is based), (ii) further assuming the earlier and broader local law Ad. Code § 17-109 and Charter § 556 did not need to yield to the more recent and specific PHL §§ 206, 613, and 2164, and (iii) finally assuming there is no specific or field preemption, even under all of these assumptions the Vaccine Powers Rule plainly crosses the line between permissible administrative rule-making and impermissible legislative policy making.

As for the first Boreali factor, defendants utterly fail to address any of the policy choices made by the DOH discussed in plaintiffs' MOL in Support of Verified Petition. For example, defendants simply ignore the fact that in choosing to require the influenza vaccine rather than to merely encourage the influenza vaccine, the DOH was forced to choose between competing ends of health and privacy concerns.[6] *Rivers v. Katz*, 67 N.Y.2d 485, 494 (1986) ("fundamental right to make decisions concerning one's own body").[7] Defendants also do not dispute the fact or evidence present that DOH considered non-health concerns such as avoiding missed school days and economic factors such as avoiding missed work days. (MOL in Support of Verified Petition

[6] As DOH's Deputy Health Commissioner Dr. Jay Varma stated: "That is a constant struggle between the rights of people to determine what goes in and out of their body, but also those rights have limits to them... Vaccination requirements are one area in which the health and benefit of the community trumps individual civil liberties." *See http://www.nydailynews.com/blogs/dailypolitics/updated-board-health-votes-require-mandatory-flu-shots-kids-blog-entry-1.1697448*

[7] A list of the ingredients in influenza vaccines, as published by the CDC, is provided in footnote 5 of plaintiffs' MOL in Support of Verified Petition.

at 20.) In fact, the Affidavit of Dr. Barbot expressly admits these were considering when she states that "the total annual economic burden of influenza infection in the Unites States estimated to be over $10 billion in direct medical costs and over $87 billion in total costs," that it is "estimated that for every 100 children with the flu, their parents miss 195 days of work," that "[o]ne case of influenza in a child under five years of age causes out of pocket costs of $52 to $178 and parental lost wages of between $222 and $1,456" and that "each year…38 million school days are missed due to influenza illness." (Aff. of Dr. Barbot ¶¶ 6, 7.) Defendants' affidavit could thus not make it any clearer that non-health considerations factored into the DOH's flu shot dictate.

The DOH further does not specifically dispute that it made the policy choice to only apply the flu shot dictate to children 6 to 59 months (no age corollary for vaccination exists in N.Y. law) including in order to safeguard the elderly population and because it would be far harder to enforce compliance against the elderly; that it made the political, economic and social policy choice of permitting day care centers to pay a fine, up to $2,000 per child, instead of excluding children that have not receiving the influenza vaccine (only exclusion is possible under N.Y. law); and that it made the policy choice of only applying the flu shot dictate to approximately a quarter of the 11,000 licensed and registered child care facilities in NYC, excluding, for example, smaller licensed and registered home based day care facilities to lessen the economic burden on such facilities (no corollary exists in any N.Y. vaccination law).

Every one of the foregoing undisputed policy choices involved choosing between competing policy ends of privacy, health and economic concerns, including when the DOH decided to grant themselves the authority to decide which vaccines shall be mandatory, what aged individuals in NYC must receive these vaccines, what establishments would be made to shoulder the burden of enforcing these new dictates by force of expulsion or otherwise pay a steep fine,

choosing which establishments would be exempt from this burden economic burden, and otherwise requiring that parents inject a substance into their child under duress of expulsion. The first *Boreali* factor therefore decidedly tips in favor of finding the Vaccine Powers Rule was *ultra vires.*

The only case cited by defendants to support their empty argument regarding the first *Boreali* factor was a decision upholding the Taxi and Limousine Commission's requirement that taxi drivers use a specific vehicle; it is respectfully submitted that this provides no analogy to requiring the injection of a foreign substance into the human body of babies and toddlers using the coercive penalty of excluding them from preschool. *See Greater New York Taxi Ass'n v. New York City Taxi & Limousine Comm'n*, 25 N.Y.3d 600, 610 (2015). Moreover, in that case there was a statutory grant of authority to regulate regarding the "safety, and design, comfort, convenience, noise and air pollution control and efficiency in the operation of vehicles." *Id.* at 609. A similar specific grant of authority to decide which vaccines to mandate is glaringly absent here and in fact, as discussed *supra*, there is ample State law prohibiting regulation to add additional mandatory vaccines.

As for the second Boreali factor, the defendants' only response to the points raised in plaintiffs' MOL in Support of Verified Petition as to the second *Boreali* factor is to cite to Ad. Code § 17-109; however, this ignores, as discussed *supra*, the well settled rule that the general (and until this lawsuit apparently long forgotten) ancient local law in Ad. Code § 17-109 must yield to the later more specific State laws codified in PHL §§ 206(1)(l), 613(1), and 2164 which expressly and specifically direct the Commissioner of Health, with the participation of the DOH, to strongly encourage the flu shot with an express prohibition on mandating the flu shot. These sections also provide which vaccines shall be required for entry into preschool in this State and the influenza vaccine is simply not on the list. The defendants' analysis of the second Boreali factor

in their opposition completely ignores these later more specific statutory enactments to which Ad. Code § 17-109 must yield.

Defendants are also mistaken that this case is somehow different from *Boreali* since here Section 556(c)(2) permits regulation for the "control of communicable…disease" but that no such corollary existed for the Commissioner of Health to regulate chronic diseases caused by smoking; in fact, the Commissioner of Health in *Boreali* similarly had the authority to regulate for the "control of disease" as well as "supervise and regulate the sanitary aspects of camps, hotels, boarding houses, public eating and drinking establishments, swimming pools, bathing establishments and other businesses and activities affecting public health." (Pub. Health Law § 201(c), (m).) Nonetheless, this far more specific grant of authority to the Commissioner of Health was not enough to save the smoking ban because, *inter alia*, the State legislature had already spoken by creating a list of the public places in which smoking was already prohibited. *Boreali v. Axelrod*, 71 N.Y.2d 1, 6-7 (1987). Similarly, here, the legislature has already spoken by making a list of the vaccines required for entry into preschool in this State (and has even gone one step further by expressly stating that regulations cannot add to this list). (PHL §§ 206, 613 and 2164.)

As for the third Boreali factor, the defendants claim that "petitioners cite to a handful of proposed bills" to support the third *Boreali* factor which considers whether the legislature has tried but failed to reach agreement. In fact, Plaintiffs' MOL in Support of Verified Petition states that "the legislature has not only reached agreement with regard to the legislative policy concerning the influenza vaccination and vaccines in general, it has made this policy explicit in N.Y. law" and details the guidance and policy set by the State legislature in Pub. Health Law §§ 206(1)(l), 613(1), and 2164 regarding mandating the flu shot in particular and other vaccine in general. This analysis won't be repeated herein as it already discuss in the plaintiffs' MOL in Support of Verified Petition

as well as *supra*. Suffice to say that the DOH here did not merely act in an area in which the legislature has tried, but failed, to reach agreement. Far worse. The DOH acted in direct contravention to the policy directive and law enacted by the legislature which directs the executive to encourage the flu shot and other vaccines not already mandated by State law and otherwise prohibits regulation adding additional required vaccines.

As for the fourth Boreali factor, defendants do not contest that no specialized expertise was required to grant itself the authority to mandate any vaccine it desires, nor does it seriously contest that there is any special or technical expertise in requiring that certain aged children receive the influenza vaccine -- the DOH merely parroted the CDC's suggestion and adopted the age range set in New Jersey and Connecticut for preschooler vaccination. (Aff. of Dr. Babot ¶¶ 13, 15.)

The DOH's argument essentially is that the flu shot is safe and effective and hence the DOH should be given free rein to require it be injected into babies, toddlers and children in NYC. Putting aside that DOH's description of the safety and efficacy of the flu shot is misleading at best (*infra* § IV), the safety and efficacy of the flu shot and its benefit to the public health are irrelevant to the issue of whether the DOH can violate plain State policy prohibiting regulation mandating the flu shot and other vaccines, and create an elaborate regulatory regime for same making policy choices along the way such as excluding smaller day care centers for economic reasons. Indeed, while safeguarding children and adults from the diseases resulting from inhaling second hand smoke in public places is an important health initiative, the Court of Appeals in *Boreali* struck this regulation for the same reasons the Vaccine Powers Rule must be struck down here:

> [W]e stress that this case presents no question concerning the wisdom of the challenged regulations, the propriety of the procedures by which they were adopted or the right of government in general to promulgate restrictions on the use of tobacco in public places. The degree of scientific support for the regulations and their unquestionable value in protecting those who choose not to smoke are, likewise, not pertinent except as background information.

> Finally, there has been no argument made concerning the personal freedoms of smokers or their "right" to pursue in public a habit that may inflict serious harm on others who must breathe the same air. The only dispute is whether the challenged restrictions were properly adopted by an administrative agency acting under a general grant of authority

71 N.Y.2d 1, 8-9 (1987) (emphasis added) *see also American Kennel Club, Inc. et al. v. City of New York et al.*, Index No. 13584/89, slip op. (Sup. Ct. N.Y. County Sept. 19, 1989) (while preventing children from being mauled or killed by limiting the ownership of pit bulls in NYC is an important safety initiative, this too was struck down because the DOH's authority to protect the safety of NYC residents could not support this regulation).

III. DOH'S HEALTH CONCERNS CANNOT ANNUL SEPARATION OF POWERS

Defendants' claim that the second cause of action must be dismissed is without merit. Even assuming that defendants can properly rely on anything other than the statutory authority actually listed in its notice of proposed rule (*see supra* § II(A), and further assuming local law Ad. Code § 17-109(a) regarding communicable diseases in general did not need to yield to later more specific State statutes prohibiting regulation mandating the flu shot (*see supra* § II(B)), and further assuming the DOH is correct that it can ignore all other Statutory guidance in the PHL, and derivative State regulation, regarding regulating the flu shot and vaccines in general (*see supra* § II(B)-(D)), the DOH is nonetheless still left with a general authority to regulate public health and disease, and hence the question is whether such a broad unbounded delegation without any guidelines is constitutional?

If this delegation is constitutional, then there is no reason the DOH cannot require that every NYC resident wear a facial mask at all times during the flu season or prohibit all NYC residents from shaking hands during the flu season. In fact, both of these requirements are far less constitutionally offensive than mandating the flu shot which requires government intrusion into

the right to bodily integrity and parental choice by requiring the affirmative act of having ones child injected with a foreign man-made substance or else face the punitive penalty of having them excluded from childcare. This should be a right that is only taken away by elected legislative representatives, either directly or through express statutory authority to engage in interstitial rulemaking to "fill in the blanks" to a statute mandating the flu shot.

It is respectfully submitted that there is no responsibility given to this Court greater than assuring that the basic separation of powers between the branches of government -- the bedrock of our democracy -- is maintained. As John Adams, in his Thoughts on Government, stated: "A question arises whether all the powers of government, legislative, executive, and judicial, shall be left in this body? I think a people cannot be long free, nor ever happy, whose government is in one Assembly." The concentration of power in one executive, such as a king, emperor, or dictator, and the illiberalism it has wrought on mankind, is precisely why executive power was split into three branches, with the task of creating laws placed in the hands of the peoples' elected representatives in the legislative branch. Time has shown the wisdom of checking the executive power's inevitable self-expansion by the judiciary. It really is simple -- we live in a city, state and country in which elected representatives of the legislature passes laws, not the executive.

Defendants implore this Court to ignore the foregoing and cast aside the bedrock principal of our democracy because the DOH "knows best" and hence should be permitted to self-regulate that "*All children shall have such additional immunizations as the Department may require*" and further mandate the flu shot for all children in New York City aged 6 months and 5 years attending only certain typically larger day care centers. The DOH has manifestly forgotten its place in our system of government.

If Defendants' logic if adopted would permit the DOH to adopt literally any regulation that has the aim of reducing disease among NYC residents. Such an approach would do violence to the separation of powers and its assurance of limiting executive overreach. Consider that if the DOH can self-regulate that "All children shall have such additional immunization as the Department may require" why can't it self-regulate "All children and adults shall wear surgical masks at all times during the flu season or at other times as the Department may require" since wearing surgical masks is apparently more effective at reducing the spread of the flu than the flu shot. (*Compare* Ex. E, CDC Report that flu shot had an overall effectiveness rate of 19% for the 2014-2015 flu season *with* Ex. F, Healthline Report that wearing masks reduces likelihood of being diagnosed with flu by 80%.) Respectfully, the real disease here that must be feared here is that of executive creep into the domain of the legislature and the slow death to the separation of powers doctrine.

Many health regulations might be noble and important, and that is why the people have elective representatives to create laws to govern the conduct of society, including adopting or refusing to adopt laws. To permit the DOH to pass literally any law that would appear to safeguard against disease is an infection into the powers of the legislature that must be stopped before spreading unchecked. The New York branch of the ACLU (*see* Ex. G) and the Rhode Island branch of the ACLU (*see* Ex. H) appear to agree with the foregoing analysis, and at least one NYS assemblyman also agrees the DOH should not have adopted the flu shot dictate (*see* Ex. I).

IV. **THE SAFETY AND EFFICACY OF THE FLU SHOT IS IRRELEVANT**

The DOH submits a long affidavit and spends numerous pages otherwise touting the safety and efficacy of the flu shot; *not only is this analysis irrelevant to the question of whether the DOH had the authority to adopted the Vaccine Powers Rule*, the DOH's analysis is misleading. As for

the efficacy of the flu shot, it is abysmal. According to the CDC (whose mandate includes encouraging and promoting the flu shot), the flu shot's "overall VE [vaccine effectiveness] estimate was 19%" in the 2014-12015 flu season. (Ex. E.) Hand washing is apparently more effective at preventing the flu and it has no known side effects. (Ex. J) ("use of hand-sanitizing gel reduces absenteeism rates by 33-50 percent").

In fact, The Cochrane Collaboration, whose partners and funders include the World Health Organization ("WHO"), the National Institutes of Health ("NIH"), and health departments and universities from around the globe (*see http://www.cochrane.org/about-us/our-partners-and-funders/our-funders*), conducted a meta review of the published studies related to the influenza vaccine totaling 300,000 observations in 2012 entitled "Vaccines for preventing influenza in healthy children (Review)," which was published by John Wiley & Sons, Ltd. and funded by *inter alia* the UK National Institute for Health Research, <u>and which concluded that "at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications or community transmission of influenza</u>." (Ex. A at 1, 18 and 20.) The Cochrane study pointed out that other similar reviews have reached the same conclusion. (Ex. A at 19.)[8]

Moreover, the Cochrane study meta review also concluded that the influenza vaccine "in children aged two years or younger are no significantly more efficacious than placebo." (Ex. A at 2.) Yet, despite this finding, the DOH's flu shot dictate applies to this age range and the DOH even lists "[c]hildren aged 6 though 59 months, *especially those younger than 2 years of age*" as an important group to receive the flu shot. (Aff. Dr. Barbot Ex. C at 2) (emphasis added.) Putting aside that the DOH therefore does not appear to be engaged in science based policymaking, it has

[8] In fact, the CDC itself admits that most of the statistics it publishes regarding, *inter alia*, its estimate of the number of deaths caused by influenza, including many of the statistics relied upon by Dr. Barbot in her affidavit, rest on speculation and conjecture. *See http://www.cdc.gov/flu/about/disease/us_flu-related_deaths.htm*

mandated without any representation by the people that these children bear the known risks associated with the flu shot without any concomitant benefit. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 131 S. Ct.1068, 1089, 179 L. Ed. 2d 1 (2011) (Federal law provides almost complete immunity from liability to vaccine manufacturers on the ground that vaccines are "unavoidably unsafe," even if properly prepared and manufactured in compliance with FDA standards.)

As for the flu shot's safety for children aged 6 months to 5 years, the Cochrane study found that:

> We were surprised to fine only one safety study of inactivated vaccine in children under two years was carried out nearly 30 years ago in 35 children. The lack of safety data for inactive vaccines in younger children [which is the only influenza vaccine licensed for children under five] is particularly surprising given that the inactive vaccine is now recommended for healthy children six months and older in the USA…"

(Ex. A at 18.) The study also stated that "influenza vaccines were associated with serious harms such as narcolepsy and febrile convulsions." (Ex. A at 2.) Indeed, health care providers, on a voluntary basis, can report adverse reactions to vaccines they administer to the Vaccine Adverse Events Reporting System ("VAERS") operated by the U.S. Department of Health and Human Services and co-sponsored by the CDC and FDA. (*See https://vaers.hhs.gov/index*). VAERS contains reports of the following adverse events for children aged 6 months to 5 years following the flu shot: 124 reports of death, 135 reports of permanent disability, 753 reports of emergency rooms visits, and 1,604 reports of being hospitalized. (*Id.*) And it is widely believed that only a tiny fraction of vaccine adverse events are ever reported to VAERS, which is a *voluntary* reporting system. (*See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3547435/*) ("a confidential study

conducted by Connaught Laboratories, a vaccine manufacturer, indicated that 'a fifty-fold underreporting of adverse events' is likely").[9]

Amazingly, the foregoing damning conclusions in the Cochrane study were reached despite the fact that it included studies "funded by industry" for which the Cochrane study states there is "evidence of widespread manipulation of conclusions":

> This review includes trials funded by industry. An earlier systematic review of 274 influenza vaccine studies published up to 2007 found industry-funded studies were published in more prestigious journals and cited more than other studies independently from methodological quality and size. Studies funded from public sources were significantly less likely to report conclusions favourable to the vaccines. The review showed that reliable evidence on influenza vaccines is thin but there is evidence of widespread manipulation of conclusions and spurious notoriety of the studies. The content and conclusions of this review should be interpreted in the light of this finding.

(Ex. A at 2.) Nonetheless, and despite including these studies in its review, the Cochrane study concluded, in addition to the findings noted above, that "National policies for the vaccination of healthy young children are based on very little reliable evidence." (Ex. A at 20.)

Of course, even if the flu shot was the most safe and effective pharmaceutical product on the market it would be completely irrelevant because, among the other reasons discussed above, the DOH's Vaccine Powers Rule is *ultra vires* as discussed *supra* §§ II, III.

CONCLUSION

WHEREFORE, Petitioners-Plaintiffs request that this Court enter an Order: (1) permanently enjoining and restraining defendants-respondents and any of their agents, officers and employees from implementing or enforcing §§ 43.17(a)(2)(B) and 47.25(a)(2)(B) of the NYC Health Code and declaring them invalid on the basis that they are unlawfully *ultra vires*; (2)

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[9] Additionally, the Vaccine Injury Compensation Program, part of the U.S. Federal Court of Claims, has compensated 1,262 individual injured by the flu shot out of a total of 4,333 individuals compensated totaling over $3 billion dollars.

alternatively, declaring that §§ 558 and 1043 of the NYC Charter violate the separation-of-powers doctrine and are unconstitutional to the extent they are found to have delegated and/or authorized defendants-respondents to promulgate §§ 43.17(a)(2)(B) and 47.25(a)(2)(B) of the NYC Health Code; (3) *alternatively*, preliminarily enjoining and restraining defendants-respondents and any of their agents, officers and employees from implementing or enforcing §§ 43.17(a)(2)(B) and 47.25(a)(2)(B) of the NYC Health Code; and (4) granting such other and further relief as this Court deems just, proper and equitable.

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