

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT  
CIVIL ACTION NO. \_\_\_\_\_

TAMAR MASSOYAN-ARTINIAN, on behalf of  
her children, and MADISON SCHILTZ,

Plaintiffs,

v.

MONICA BHAREL, in her official capacity as  
Commissioner of the Massachusetts  
Department of Public Health and the  
MASSACHUSETTS DEPARTMENT OF  
PUBLIC HEALTH,

Defendants.

**JURY TRIAL DEMANDED**

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR  
EMERGENCY MOTION FOR PRELIMINARY INJUNCTION**

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Plaintiffs Tamar Massoyan-Artinian, on behalf of her children, and Madison Schiltz (collectively, “**Plaintiffs**”), by and through their attorneys, Siri & Glimstad LLP, respectfully submit this memorandum of law in support of their motion for a preliminary injunction against Monica Bharel in her official capacity as Commissioner of the Massachusetts Department of Public Health and the Massachusetts Department of Public Health (“**Defendants**”).

### **PRELIMINARY STATEMENT**

The Massachusetts Legislature has carefully considered which vaccinations should be mandatory for students attending both K-12 schools in the Commonwealth, and its world-renowned colleges and universities. For K-12 schools, the Legislature created a list of required vaccinations but then granted the Department of Public Health (“**DPH**”) authority to add additional vaccinations to that list through the usual process of adopting regulations. On the other hand, the Legislature required a different set of vaccinations for post-secondary students and did not give the DPH any authority to alter or enlarge that list.

The Legislature pointedly did not include the influenza vaccine in any of its lists. Nevertheless, on August 19, 2020, the DPH took it upon itself to issue a “press release” announcing it now required all children in K-12 schools, and all students attending colleges and universities to receive the influenza vaccine before December 31, 2020 (the “**Flu Shot Mandate**” or the “**Mandate**”). The problem is that the DPH has no authority to create a new vaccination mandate for students attending colleges and universities – only the Legislature can do that. Furthermore, all it did was issue a press release. It never took the steps needed to adopt a new regulation, such as providing prior notice or a public comment period. Thus, the Flu Shot Mandate is not a formal “regulation” and as such is unenforceable.

In addition to its other deficiencies, the DPH enacted the Flu Shot Mandate as a measure to prevent transmission of the flu and thereby decrease the burdens on the Commonwealth’s

healthcare system. However, over the past decade, multiple published surveys of all available medical studies have “found no evidence that vaccines prevent viral transmission” of influenza. This means that mandating the influenza vaccine does not serve to prevent its transmission. Further, independent reviews have repeatedly concluded that there is no reliable evidence that the influenza vaccine reduces the burden on healthcare resources. And since the DPH cannot support that the Flu Shot Mandate will prevent the spread of influenza or reduce the burden on the healthcare system, it has no rational basis or other grounds to vitiate the fundamental constitutional rights to bodily integrity, informed consent, parental choice, and substantive due process by forcing unwilling individuals to receive the influenza vaccine. Nor does it have grounds to so burden the right to an education enshrined in the Massachusetts Constitution.

Plaintiffs are an adult graduate student at Springfield College and a parent of two elementary school students in Waltham Public Schools. Each of these three students has received all the required vaccines to attend school but has not received the influenza vaccine. Nothing in the Commonwealth’s laws requires them to receive the influenza vaccine in order to exercise their constitutional right to an education. Nevertheless, the Flu Shot Mandate wrongfully threatens to prevent Plaintiffs from attending school on January 1, 2021, because they made the informed choice to not receive the influenza vaccine. Plaintiffs now bring this action seeking a declaration that the Flu Shot Mandate is invalid and *ultra vires* along with an injunction preventing its enforcement.

Plaintiffs do not question the need for robust public health tools to cope with the COVID 19 pandemic. However, the Flu Shot Mandate is neither legally adopted nor scientifically supported. If instead proper legislative and regulatory process had been followed, there would have been an opportunity to present to legislators and regulators powerful evidence that the Flu

Shot Mandate infringes on protected constitutional rights for no demonstrable public health benefit.

By granting the instant motion and enjoining the DPH from enforcing the Flu Shot Mandate, this Court will merely be maintaining the status quo. Plaintiffs do not oppose any individual choosing to receive the influenza vaccine. In fact, currently by employing non-coercive means, the DPH has achieved one of the highest levels of child influenza vaccination in the nation. Even with an injunction, the DPH will be free to continue to non-coercively encourage parents and students to receive the influenza vaccine just as it does now. Plaintiffs merely ask that they, and other students like them, be allowed to continue to attend their same schools during the pendency of this action without having to sacrifice their constitutionally protected rights in the process.

### **FACTS**

#### **A. Statutory Framework for Requiring Influenza Vaccine for School**

The Massachusetts Legislature determined that in order to attend a K-12 school, absent an exemption, a child shall have been “immunized against diphtheria, pertussis, tetanus, measles, and poliomyelitis and *such other communicable diseases as may be specified from time to time by the department of public health.*” G.L. c. 76, § 15 (emphasis added). As for students attending colleges and universities in the State, the Legislature provided that all college students under thirty years of age, and all students in undergraduate or graduate health science programs need to have “been immunized against measles, mumps, rubella, tetanus and diphtheria,” and all college or university students who live in a dormitory must also be immunized against “meningococcal disease.” G.L. c. 76, §§ 15C, 15D. Thus, the Legislature chose a different set of vaccinations to apply to students in higher education settings as opposed to children in lower schools, and it did not grant the DPH authority to require additional immunizations for higher education students. *Compare* G.L. c. 76, § 15 *with* G.L. c. 76, § 15C.

The Massachusetts Administrative Procedures Act (“MAPA”), G.L. c. 30A, § 1 *et seq.*, provides the statutory scheme for an administrative agency to adopt regulations. Among other requirements, prior to adopting any regulation, MAPA requires an administrative agency, like the DPH, to provide notice to the public and a period of time during which the public has an opportunity to comment on the proposed regulations. G.L. c. 30A, § 3.

**B. The Flu Shot Mandate**

On August 19, 2020, without adopting a regulation, the DPH issued a press release entitled “*Flu Vaccine Now Required for all Massachusetts School Students Enrolled in Child Care, Pre-School, K-12, and Post-Secondary Institutions.*” (Ex. A.)<sup>1</sup> The press release declared that:

State public health officials today announced that influenza immunization will be required for all children 6 months of age or older who are attending Massachusetts child care, pre-school, kindergarten, K-12, and colleges and universities. ...

All students in K-12 must receive the seasonal influenza vaccine annually by December 31. ...

For older students, the flu vaccine requirement applies to all full-time undergraduate and graduate students under 30 years of age and all full- and part-time health science students. ... The only exception is for college and university students who exclusively attend classes online and never visit campus in person. College students who attend any classes or activities on campus, even once, must be vaccinated by December 31.

(*Id.*) The DPH also issued an FAQ which made clear that this requirement will apply perpetually henceforth. (Ex. B.)

At no point did the DPH adopt any regulation to codify this new purported requirement in this press release, nor were any of the MAPA requirements for adopting a regulation followed –

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<sup>1</sup> All exhibits referenced herein refer to exhibits appended to the Declaration of Elizabeth A. Brehm filed herewith.

no prior notice to the public, no public comment period, no business impact statement published, nor anything filed with the secretary of state regarding any proposed regulation.

**C. Plaintiffs Will Be Wrongfully Excluded from School or College on January 1, 2021**

Plaintiffs and their affected children have received all immunizations required to attend college or school pursuant to G.L. c. 76, § 15 and § 15 C. None of them, however, have received an influenza vaccine. It is on that basis alone that Plaintiffs or their children will be excluded from their public K-12 schools or from their graduate program on January 1, 2021.

Plaintiff Tamar Massoyan-Artinian is the mother of two children, R.A., age 7 and H.A., age 11. (*See* Affidavit of Tamar Massoyan-Artinian, hereinafter “**TMA Aff.**”, at ¶ 1.) Both of the children have received all of the vaccinations required to attend their public schools in Massachusetts as of December 11, 2020. *Id.* Both children have a history of allergies and adverse reactions to medications, including amoxicillin and influenza vaccines. (*Id.* at ¶ 2.)

Plaintiff Massoyan-Artinian’s older child previously experienced intense adverse reactions to the influenza vaccine. (*Id.* at ¶ 3.) This child developed asthma at a young age and the condition worsened over time. (*Id.*) Each year, after receiving the influenza vaccine, the child suffered complications including bronchitis, bacterial pneumonia, respiratory infections, and asthma attacks. Most of these reactions led to Emergency Room visits, and one led to a hospitalization at Boston Children’s Hospital. *Id.* Her younger child had adverse reactions to the influenza vaccine as well, including high fevers, rashes, and asthmatic tendencies such as requiring a nebulizer and steroids to stabilize breathing. (*Id.* at ¶ 4.)

After the last adverse response to the influenza vaccine, Plaintiff Massoyan-Artinian stopped having it administered to both of her children. (*Id.* at ¶ 5.) She inquired about a medical exemption to the influenza vaccine from her pediatrician based on her children’s prior experiences



but was told that the medical practice “decided that it will not provide exemptions for the flu vaccine.” (*Id.* at ¶ 6.)

If the DPH mandate is enforced, it will make Plaintiff Massoyan-Artinian face the Hobson’s Choice to either (i) comply against her judgment as their parent and risking her children’s’ health, or (ii) continue to refuse and have her children excluded from school. (*Id.* at ¶ 7.)

If the children are excluded from school, it will have devastating real-world effects on the family whether they leave or stay in the state. (*Id.* at ¶¶ 8-14.) They have many strong ties to their local cultural and religious communities. (*Id.* at ¶ 9.) Plaintiff Massoyan-Artinian’s husband’s parents live close to them, and they are the reason the family is living where they are. (*Id.*) Leaving their family and community would be devastating. (*Id.*)

On the other hand, if they stay in the state and are excluded from school other irreparable harm will result. (*Id.* at ¶¶ 10-12.) Both Plaintiff Massoyan-Artinian and her husband work. (*Id.* at ¶ 10.) If their children are excluded from school, they will be forced to homeschool the children. (*Id.*) This will come at great expense as one of them would likely have to give up his or her salary to stay home and educate the children. (*Id.*) Neither of the parents is trained as an educator and homeschooling is outside their life plans and abilities. (*Id.*)

Furthermore, if the children are excluded from their school in January, they will be devastated. (*Id.* at ¶ 11.) Like other students, they have already experienced upheaval due to the COVID-19 restrictions, but now as there is light at the end of the tunnel on COVID, they will be told they can never go back with their friends, or their teachers. (*Id.*) The children will suffer emotionally and will experience anxiety if this new dramatic change is foisted upon them, especially after the very challenging and trying year they have already experienced. (*Id.* at ¶ 12.)

Plaintiff Madison Schiltz is a 27-year-old student, teacher, and coach. (*See* Affidavit of Madison Schiltz, hereinafter “**MS Aff.**”, at ¶ 1.) She is fully vaccinated and has received every vaccine recommended to her by her doctors except for the influenza vaccine. (*Id.* at ¶ 2.) She is a master’s graduate student at Springfield College, pursuing a masters in strength and conditioning. (*Id.* at ¶ 3.) She is completing her third semester, has a 3.78 g.p.a. which she has worked hard for, and currently expects to graduate with her master’s degree in May 2021. (*Id.*)

Plaintiff Schiltz grew up getting vaccinated “on schedule.” (*Id.* at ¶ 5.) She understands the risks and benefits involved with her medical choices, including vaccines, and typically feels the benefit outweighs the risks. She has not reached that conclusion with regard to the influenza vaccine. (*Id.*) She has worked very hard to get where she is, and to know she may be unable to complete her education due to something she does not consent to is troubling. (*Id.* at ¶ 6.) Thus, the fact that her education is being threatened by an unlawful mandate has caused her mental and emotional distress. (*Id.*)

When Plaintiff Schiltz first heard about the DPH mandate, she took action. (*Id.* at ¶ 7.) She contacted her student body government, other students, and eventually the President of Springfield College to discuss her concerns and her objection to this mandate. (*Id.*) Plaintiff Schiltz was told that this was a mandate from the DPH and so the school’s hands were tied. (*Id.*)

When Plaintiff Schiltz was accepted at Springfield College, an influenza vaccine was not required. (*Id.* at ¶ 8.) She cannot comply with this mandate and will continue to stand up for what she believes in: informed consent, bodily autonomy, and her constitutional rights to liberty. (*Id.* at ¶ 9.) If she is merely excluded from campus, and forced to complete her degree remotely, that too will cause her numerous harms. *Id.* Specifically, as she is currently a Graduate Assistant she will lose that position and the thousands of dollars in free tuition and monthly stipend that comes with the position. (*Id.* at ¶¶ 4, 11.) Without these, she likely would be unable to afford to complete

her degree. (*Id.* at ¶ 11.) Therefore, if the mandate is enforced, Plaintiff Schiltz will be forced out of her school and will be unable to complete the degree that she has already expended significant time and resources to obtain. (*Id.* at ¶¶ 11-13.)

**D. The “Flu” and Influenza Vaccines**

The DPH repeatedly refers to influenza vaccines as an approach for dealing with the “flu.” (*See* Expert Affidavit of P. Doshi, T. Jefferson, P. Gotzsche, and C. Heneghan, hereinafter “**Doshi et al. Aff.**” at ¶ 7.) However, most cases of the “flu,” respiratory infections, and illnesses are not caused by influenza virus but rather by other viruses. (*Id.*) Every year, hundreds of thousands of respiratory specimens are tested across the United States and, on average, only 16% are found to be influenza positive. *Id.* Hence, the influenza vaccine, even if it were an effective product, could only address a small fraction of the “flu” cases in Massachusetts. (*Id.*)

The influenza vaccine also changes every year to target new strains of influenza virus. (*Id.* at ¶¶ 7-9.) One implication of this variation is that influenza vaccines are manufactured each year without knowing their efficacy or safety profile. (*Id.* at ¶ 10.) This can only be discovered after the fact. *Id.* Moreover, as discussed in the accompanying expert affidavits by world-renown scientists, there is no credible evidence these products reduce the incidence of hospitalization or mortality. (*Id.* at ¶¶ 14-16.) On the other hand, those same experts detail how influenza vaccines can cause serious injury and death, including various autoimmune and neurological disorders (*Id.* at ¶¶ 17-22) and can have serious unintended consequences including increasing susceptibility to other infections. (*Id.* at ¶¶ 23-26.)

**ARGUMENT**

**I. PLAINTIFFS ARE ENTITLED TO A PRELIMINARY INJUNCTION**

Given the December 31, 2020 deadline established by the DPH, Plaintiffs are forced to seek a preliminary injunction to stay enforcement of the Flu Shot Mandate so as to avoid the

irreparable harm of being precluded from attending school. To be awarded an injunction, the Plaintiffs must satisfy the familiar three-part test: “(1) a likelihood of success on the merits; (2) that irreparable harm will result from denial of the injunction; and (3) that, in light of the [moving party's] likelihood of success on the merits, the risk of irreparable harm to the [moving party] outweighs the potential harm to the [nonmoving party] in granting the injunction.” *Loyal Order of Moose, Inc., Yarmouth Lodge #2270 v Bd. of Health of Yarmouth*, 439 Mass. 597, 601 (2003) (quotations omitted). “When a party seeks to enjoin governmental action, a judge is also required to determine that the requested order promotes the public interest, or, alternatively, that the equitable relief will not adversely affect the public.” *Id.* (quotations omitted)

“A preliminary injunction ordinarily is issued to preserve the status quo pending the outcome of litigation.” *Doe v. Superintendent of Sch. of Weston*, 461 Mass. 159, 164 (2011). That is all that Plaintiffs seek here, to preserve their ability to receive an education while the court adjudicates the DPH’s mandate.

## **II. PLAINTIFFS HAVE A HIGH LIKELIHOOD OF SHOWING THAT THE FLU SHOT MANDATE IS INVALID AND UNENFORCEABLE**

Plaintiffs are highly likely to succeed in the instant action because the Flu Shot Mandate is invalid and unenforceable for three separate reasons. First, the DPH lacked authority to apply the Mandate to post-secondary students and did so *ultra vires*. Second, for K-12 students, the DPH failed to comply with the MAPA procedures, making the Mandate unenforceable. Third, the Mandate is unconstitutional.

### **A. The DPH Lacked Authority To Adopt The Mandate For Post-Secondary Students**

#### **1. The Legislature Chose Not To Grant DPH Discretion to Mandate Any New Vaccines for College Students**

It is settled law that “an administrative agency has no authority to promulgate rules or regulations that conflict with the statutes or exceed the authority conferred by the statutes by which

the agency was created.” *Massachusetts Mun. Wholesale Elec. Co. v. Energy Facilities Siting Council*, 411 Mass. 183, 194 (1991); *Goldberg v. Board of Health of Granby*, 444 Mass. 627, 633 (2005) (if a court “conclude[s] that the statute is unambiguous, [it] give[s] effect to the Legislature’s intent”).

With regard to requiring immunizations for attending K-12 school, the Legislature provided a list of required vaccinations, but then also permitted “such other communicable diseases as may be specified from time to time by the” DPH. G.L. c. 76, § 15. However, it made a different choice for immunizations required to attend colleges and universities. *Compare* G.L. c. 76, § 15 *with* § 15C. There, the Legislature did not grant the DPH any role in selecting the required vaccinations. Instead, it identified a finite list of required vaccinations. Specifically, the Legislature mandated that post-secondary students need to have “been immunized against measles, mumps, rubella, tetanus and diphtheria,” and “meningococcal disease” if they live in a dormitory. G.L. c. 76, §§ 15C, 15D.

It is axiomatic that a statute should be read in accordance with its plain meaning in light of the whole statutory scheme. *ENGIE Gas & LNG LLC v. Dep’t of Pub. Utils.*, 475 Mass. 191, 199, (2016). Clearly the Legislature knew full well how to grant the DPH authority in Chapter 76 to expand the list of required vaccinations through duly promulgated regulations and did so for K-12 students in Section 15. The fact that Section 15D is silent as to the DPH’s involvement, necessarily means that the Legislature intended to *not* empower the DPH to require additional immunizations to attend colleges and universities. Without such authorization to act, the DPH lacked authority to enact the Flu Shot Mandate for post-secondary students, and Plaintiffs will be able to establish that the Mandate cannot be enforced against such students.

## **2. The Legislative History Further Makes Plain the DPH's Lack of Authority to Mandate the Flu Shot to College Students**

The vaccine requirements for a “child” to attend K-12 “school” in Section 15 was last amended in 1972. (1972 Mass. Acts 77.) When the Legislature, in 1985, wanted to require immunizations for attending college, it promulgated a new Section 15C. (1985 Mass. Acts 98.) At that time, bills were introduced to grant the DPH similar authority under Section 15C as it already enjoyed under Section 15. *See* MA H.B. 6099 (1984) and MA H.B. 222 (1985) (seeking to have Section 15C include in the list of required vaccines “such other communicable diseases as may be specified from time to time by the department of public health.”). But such language did not make it into the final bill. Thus, the Legislature’s choice to withhold authority from the DPH in this latter statute was not an oversight, but rather a deliberate choice.

Furthermore, during the thirty-five years since its enactment, the Legislature has had numerous opportunities to amend Section 15C to again grant the DPH a role in selecting the required vaccines. Numerous bills have been introduced to amend Section 15C to adopt language similar to Section 15, but each bill has failed to pass. For example, MA H.B. 180, introduced January 1, 1992, proposed amending Section 15C to add that the required vaccinations would include “other such communicable diseases, in accordance with regulations of the department of public health.”<sup>2</sup>

Given the Legislature’s unambiguous choice to withhold authority from the DPH regarding vaccinations for college students, that agency cannot now simply appropriate to itself the authority long denied it. For this reason, the Court must hold that the DPH cannot now be allowed to apply the Flu Shot Mandate to post-secondary students.

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<sup>2</sup> The following bills also attempted to add the above language to Section 15 C: MA H.B. 192 (1993); MA H.B. 204 (1994); MA H.B. 170 (1997); MA H.B. 123 (1999); MA H.B. 133 (2001); MA H.B. 74 (2003).

## **B. The Flu-Shot Mandate Is Invalid Because The DPH Did Not Comply With MAPA**

In order for the Flu Shot Mandate to apply to K-12 students, DPH should have enacted a “regulation” promulgated pursuant to the procedure required by the MAPA. G.L. c. 30A, § 1 *et seq.* However, DPH chose to not enact the Flu Shot Mandate as a regulation. It failed to provide prior notice to the public, an opportunity for the public to comment, and it never entered the Flu Shot Mandate into the Code of Massachusetts Regulations (“**CMR**”), all steps required by the MAPA. The DPH’s failure to follow such procedures means that the Flu Shot Mandate is nothing more than an *ultra vires* fiat with no legal force.

### **1. DPH Was Required to Follow the MAPA**

When the provisions of the agency’s enabling legislation “prescribe a mode and method for the procedure for the promulgation of rules or regulations,” the agency must follow those procedures. *New England Milk Dealers Ass’n v. Department of Food & Agric.*, 33 Mass. App. Ct. 935, 936 (1992). “But where no mode and method of procedure for rulemaking are provided, the provisions of the Massachusetts Administrative Procedure Act are generally applicable.” *Id.*

G.L. c. 76, § 15 is the enabling legislation by which the DPH is authorized to regulate which additional immunizations – beyond those already required by that section – shall be required to attend K-12 school in Massachusetts. Because this enabling legislation does not specify the “mode and method” for adopting a regulation to require an additional immunization for school attendance, the DPH was bound to abide by the procedures contained in the MAPA before adopting the Flu Shot Mandate. *See New England Milk Dealers*, 33 Mass. App. Ct. at 936.

### **2. The Flu Shot Mandate is a Regulation**

The MAPA, broadly defines a “regulation” as “the whole or any part of every rule, regulation, standard or other requirement of *general application and future effect*, including the amendment or repeal thereof, adopted by an agency to implement or interpret the law enforced or

administered by it.” G.L. c. 30A, § 1 (5) (emphasis added); *Carey v. Comm'r of Correction*, 479 Mass. 367, 371 (2018) (“Given the purpose of the APA, we interpret its definition of regulation broadly.”). Just because an agency chooses not to call something a regulation does not mean the requirements of the MAPA do not apply to it, rather a court must determine for itself whether the agency’s action falls within the definition of a regulation. *Carey*, 479 Mass. at 371 (holding that contrary to the commissioner’s contention, enacting a policy regarding visitors to prisons had to conform to the MAPA’s rules).

Even though the DPH only released it as a press release, the Flu Shot Mandate squarely falls within the definition of a “regulation” as defined by the MAPA. *Id.* It is a rule or standard of “general application and future effect,” and thus the DPH was required to comply with the procedures in the MAPA before adopting the Flu Shot Mandate. *See, e.g., Id.; Kneeland Liquor, Inc. v. Alcoholic Beverages Control Comm’n.*, 345 Mass. 228 (1962) (finding that alcohol price schedules that require agency approval set down public policy with legal consequences and thus are regulations under the MAPA); *Allied Theatres of New England, Inc. v. Commissioner of Labor & Indus.*, 338 Mass. 609, 611 (1959) (holding that labor department’s order setting minimum wages was a regulation under the MAPA).

### **3. Public Comment was a Prerequisite to Adopting the Flu Shot Mandate**

The MAPA requires that “[p]rior to the adoption, amendment, or repeal of any regulation ... the agency shall ... afford interested persons an opportunity to present data, views or arguments in regard to the proposed action orally or in writing” and “[i]f the agency finds that oral presentation is unnecessary or impracticable, it may require that presentation be made in writing.” G.L. c. 30A, § 3. These notice and comment procedures are not mere formalities. Indeed, failure to abide by these requirements results in the invalidation of the regulation. *See, e.g., Carey*, 479 Mass. at 371 (holding that notice and hearing procedures under the MAPA are required to be



followed prior to adopting a new policy and deeming the new regulation unenforceable until it was reenacted by following the MAPA's procedures).

Here, the DPH never provided notice that it intended to adopt the Flu Shot Mandate, nor did it provide an opportunity for comment on the mandate prior to its adoption. These procedural lapses, among others, are fatal to the Flu Shot Mandate because, by failing to abide by the MAPA procedures, the Flu Shot Mandate was *never* properly adopted and so it is invalid.

Consequently, the Flu Shot Mandate does not carry the force of law as a "regulation." As explained by the Supreme Judicial Court, rules issued by an administrative agency without following procedures under the MAPA "do not have the same status as regulations adopted pursuant to the [MAPA]. . . . they do not carry the force of law." *Global NAPs, Inc. v. Awiszus*, 457 Mass. 489 (2010); *see also Evans v. Mayer Tree Service, Inc.*, 89 Mass. App. Ct. 137, 149 (2016) (agency protocols not formally promulgated do not carry force of law); *Massachusetts Gen. Hosp. v. Rate Setting Comm'n.*, 371 Mass. 705, 707 (1977) (finding that non-regulation agency guidance does not "have the binding force attributable to full-blown regulation").

Furthermore, the lack of public comment had substantive consequences here because it allowed the DPH to act based on faulty assumptions about the effects of the influenza vaccine, including that it would reduce hospitalization and the transmission of the flu. However, as discussed below, Plaintiffs' experts' reports show that these assumptions are not supported by scientific studies, a fact that could have been brought to the DPH's attention if it allowed the public to comment. (*Infra* § C.1.)

#### **4. DPH Failed to Follow Procedures for Adopting an Emergency Regulation**

The DPH's press release announcing the Flu Shot Mandate stated that "[t]he new vaccine requirement is an important step to reduce flu-related illness and the overall impact of respiratory

illness during the COVID-19 pandemic.”<sup>3</sup> However, even assuming *arguendo* the DPH was entitled to a waiver from the formal deliberative processes of notice, hearing and public comment required by MAPA, due to the ongoing COVID-19 public health emergency, the DPH failed even to comply with requirements of the MAPA applicable to issuing emergency regulations.

Pursuant to sections 2 and 3 of the MAPA, an administrative agency may dispense with the notice, hearing, and public comment phases in the process of adopting an “emergency regulation” so long as “the agency’s finding and a brief statement of the reasons for its finding [are] incorporated in the emergency regulation as filed with the state secretary under section five” and any emergency regulation “shall not remain in effect for longer than three months.” G.L. c. 30A, §§ 2-3. The DPH did not comply with any of these when adopting the Flu Shot Mandate. It did not include a brief statement of the reasons to support an emergency regulation, did not file any such statement with the secretary of state, nor did it in fact promulgate any regulation, emergency or otherwise, to incorporate into the CMR. Moreover, the DPH provided that the mandate would continue indefinitely, well beyond the three-month time limit provided for an emergency regulation.

For all these reasons, Plaintiffs are highly likely to show that the Flu Shot Mandate cannot be enforced because it was not adopted pursuant to any of the requirements of the MAPA.

### **C. The Flu Shot Mandate Is Unconstitutional**

Even if the DPH had enacted the Flu Shot Mandate pursuant to the rules required by MAPA, and it had the authority to regulate vaccinations for post-secondary students, neither of which it did, the Flu Shot Mandate must still be struck down as unconstitutional under the

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<sup>3</sup> <https://www.mass.gov/news/flu-vaccine-now-required-for-all-massachusetts-school-students-enrolled-in-child-care-pre>.

Massachusetts and United States Constitutions. When the DPH chose to condition the provision of an education on their injection of an influenza vaccine, the agency invalidated Plaintiffs' informed medical decisions, and impinged upon Plaintiffs' fundamental constitutional rights to bodily integrity, informed consent, parental choice, and the substantive due process rights under the United States Constitution and the Massachusetts Constitution.

### **1. Plaintiffs' Have Valid Constitutionally Protected Reasons to Refuse the Influenza Vaccine**

While not necessary to decide that the Flu Shot Mandate is unconstitutional, Plaintiffs' decisions to not receive the influenza vaccine are entirely reasonable and rational. With virtually all pharmaceutical products, there are risks and benefits. Vaccines are no exception. (*See* Expert Affidavit of P. Aaby and C. Stabell Benn, hereinafter "**Aaby and Benn Aff.**" at ¶ 8; *see also* Doshi et al. Aff. at ¶¶ 17-26.) This is why the cornerstone of medical ethics is informed consent, a principle which is also a long recognized fundamental, civil, and human right. (*Aaby and Benn Aff.* at ¶ 5.) Informed consent requires conveying the risks and benefits of a medical procedure or pharmaceutical product to a patient and obtaining un-coerced consent. *See, e.g., Shine v. Vega*, 429 Mass. 456, 463 (1999) (reiterating the fundamental right to informed consent to "decide whether a particular medical treatment is in [the patient's] best interests"). Nonetheless, in enacting the Flu Shot Mandate, the DPH took away this right to informed consent for the influenza vaccine from all students in the Commonwealth.

It is a well-established fact that influenza vaccines can cause serious injury and death, as well as various harmful unintended consequences. (*Doshi et al. Aff.* ¶¶ 17-26; *Aaby and Benn Aff.* at ¶ 8.) Because of the dangers posed by vaccines, Congress enacted the National Childhood Vaccine Injury Act of 1986 (the "**1986 Act**"), which granted vaccine manufacturers (and any medical personnel that administers a vaccine) blanket immunity from liability for injuries caused

by these products.<sup>4</sup> Vaccines are the only medical products in the U.S. with such immunity. This immunity creates a moral hazard for those promoting these products because product liability lawyers, one of the other pillars of how the U.S. ensures the safety of its drug supplies, play no role in the safety of vaccines.

Those injured by the influenza vaccine must file a claim against the U.S. government in the Vaccine Injury Compensation Program, administered in the United States Court of Federal Claims. (Doshi et al. Aff. ¶¶ 20-21.) Over \$4 billion has been paid out by this program for vaccine injury claims and influenza vaccines represent over 50% of these claims. (*Id.* at ¶ 21.) Injuries from influenza vaccines for which compensation has been paid include Anaphylaxis (severe allergic reaction), Bell's Palsy, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Complex Regional Pain Syndrome (CRPS), Cardiac Arrest, Death, Fibromyalgia, Guillain-Barre Syndrome (GBS), Multiple Sclerosis (MS), and Transverse Myelitis (TM), among many others. (*Id.*)

Moreover, in the last ten years, the Vaccine Adverse Events Reporting System (VAERS), administered by the CDC and FDA, has received reports of the following serious events following receipt of an influenza vaccine: 1,527 deaths; 3,327 permanent disabilities; 12,692 hospitalizations; and 40,040 emergency room and/or medical office visits. (*Id.* at ¶ 20.) A report from researchers at Harvard Medical School, including the Director of Bioinformatics, funded by an agency within the U.S. Department of Health and Human Services, stated that “fewer than 1% of vaccine adverse events are reported” to VAERS. (*Id.*)

The assumptions and advertised views about influenza vaccine products have stifled the ability for most people – even otherwise intelligent and analytical individuals – to rationally and

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<sup>4</sup> See <https://www.law.cornell.edu/uscode/text/42/300aa-1>.

objectively consider these products. This issue is compounded by the fact that many consider it off limits to even request to see the evidence which underpins claims regarding influenza vaccines. In a court, public health officials cannot justify their policies and statements regarding the influenza vaccine without evidence. Plaintiffs, therefore, respectfully ask that all preconceived notions regarding these products be set aside. That only proven statements be considered. And that the Court, if it reaches the constitutional issues in this case, cautiously examine the proof for any claim regarding influenza vaccines made by either party.

## **2. The DPH Did Not Have A Compelling Interest to Enact the Mandate**

Having impinged on these constitutional rights, the DPH has the burden to prove it has a compelling state interest to exclude adults from college and children from K-12 school, and that exclusion is the least restrictive means to achieve the compelling interest.

Courts have recognized that the desire to control the spread of an infection can constitute such a compelling state interest. However, **that compelling interest to control influenza spreading from student-to-student is absent with regard to the influenza vaccine because studies have repeatedly concluded that there is no evidence to support that the influenza vaccine prevents transmission of the influenza virus.** (Doshi et al. Aff. at ¶¶ 11-13.)

As detailed in the accompanying expert report, Cochrane is an independent scientific body that conducts systematic reviews of available scientific studies to assess the current state of knowledge on questions of interest. (*Id.* at ¶ 11.) Its partners and funders include the National Institutes of Health (NIH) and the World Health Organization (WHO). *Id.* The process Cochrane undertakes to conduct a systematic review involves a thorough search and critical assessment of all the published articles on a given clinical topic. *Id.* By reviewing all existing studies, Cochrane's systematic reviews aim to reduce bias when appraising the scientific literature and help

protect against “cherry picking.” *Id.* Systematic reviews are widely regarded as the most trustworthy sources of information, sitting atop the Evidence-Based Medicine Pyramid. *Id.*

In 2010, Cochrane published a systematic review entitled “Vaccines for preventing influenza in healthy adults” which, after a review of the published randomized clinical trials and comparative studies for the influenza vaccine, “found no evidence that vaccines prevent viral transmission” of influenza. (*Id.* at ¶12.) In 2014, Cochrane updated this systematic review with 41 new trials and in 2018 it updated it again with 52 additional trials comprising over 80,000 additional individuals. (*Id.*) These updates did not change the conclusion it reached in 2010 that there is no evidence that influenza vaccines prevent viral transmission of influenza. (*Id.*)

In 2018, Cochrane conducted the same systematic review of all published clinical trials and studies with regard to influenza vaccination and children entitled “Vaccines for preventing influenza in healthy children.” (*Id.* at ¶ 13.) It concluded that “we could find no convincing evidence that vaccines can reduce ... community transmission of influenza.” (*Id.*)

Furthermore, Plaintiffs are submitting with this brief expert affidavits from world-renown experts on the influenza vaccines. Those experts affirm that “at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza.” (*Id.* at ¶ 15.)

In addition to preventing transmission in school settings (for which the evidence is lacking, as noted above), the DPH has also asserted that a goal of the Flu Shot Mandate was to “save lives and preserve healthcare resources.”<sup>5</sup> And in its press conference, Commonwealth officials cited in support of the Flu Shot Mandate statistics for emergency room visits and deaths associated with the “flu.”

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<sup>5</sup> <https://www.mass.gov/news/flu-vaccine-now-required-for-all-massachusetts-school-students-enrolled-in-child-care-pre>.

However, this premise is not supported by the available science. Randomized clinical trials have not demonstrated that administration of influenza vaccines reduces the risk of hospitalization or mortality, a failing clearly set forth in the Cochrane review on this topic. (Doshi et al. Aff. at ¶¶ 14-16.) In 2018, the Cochrane review of influenza vaccines in healthy children reached the conclusion that “at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza.” (*Id.* at ¶15.) As for adults, in 2018 Cochrane concluded that “We found low-certainty evidence that hospitalization rates and time off work may be comparable between vaccinated and unvaccinated adults, although the confidence interval around the effect for hospital admission is wide and there was substantial variation in the direction of effect on time off work.” (*Id.*) In other words, there was no compelling evidence of benefit in a reduction in hospital admission or time off work. (*Id.*) Other systematic reviews focusing on randomized controlled trials have reached similar conclusions regarding the lack of a reduction in hospitalization and mortality from influenza vaccines. (*Id.*)

In fact, there are randomized trials which report findings that raise questions about the ability of influenza vaccines to **increase** the risk of non-influenza flu-like symptoms. (*Id.* ¶ 16.) In one such study, conducted by the Centers for Disease Control and Prevention, the authors wrote: “During the 1997-1998 influenza season, vaccine recipients reported significantly more ILI-related [ILI = influenza like illness] sick days, lost workdays, and lost work hours for physician visits than placebo recipients.” (*Id.*)

For these reasons, the DPH cannot assert a compelling interest to impinge upon Plaintiffs’ constitutional rights. All that remains is a naked infringement on these rights, which is unconstitutional.

### **3. The DPH Had No Rational Basis for the Flu Shot Mandate**

The Flu Shot Mandate cannot survive the strict scrutiny analysis that applies where, as here, fundamental rights are infringed. However, even apart from a strict scrutiny analysis, for the same reasons discussed *supra*, the Flu Shot Mandate cannot even survive the more lenient “rational basis” test. Indeed, the DPH’s stated reasons for the Flu Shot Mandate are so inadequate and so scientifically unsound that the Flu Shot Mandate is not even rationally related to a legitimate governmental purpose. It does not, and cannot, meet the policy objectives the DPH has proposed.

The purported purpose of the flu shot mandate is to “reduce flu-related illness and the overall impact of respiratory illness during the COVID-19 pandemic.” (Ex. A.) DPH’s reasoning that the spread of influenza or hospitalization rates might decrease with an increase in influenza vaccine uptake is not founded in fact or science. *See* Section C.2., *supra*.

### **III. PLAINTIFFS WILL SUFFER IRREPARABLE HARM, WHICH WILL OUTWEIGH ANY DELAY IN ENFORCING THE FLU SHOT MANDATE**

An irreparable harm is one that “cannot be vindicated” by an award of damages if the moving party prevails in the case. *Doe vs. Yunits*, No. 001060A, 2000 WL 33162199 (Mass. Super. Oct. 11, 2000) (applying the irreparable harm standard in an educational setting) (Ex. C.) Here the plaintiffs, and numerous other students in the Commonwealth, are all facing the prospect of being denied their right to an education, or at the very least being denied the right to receive that education in their chosen schools. By being excluded from school, plaintiffs are not only missing educational opportunities, but are also “being denied the benefits of attending school with [their] peers, learning in an interactive environment, and developing socially.” *Id.* In such situations, Massachusetts courts have previously had no problem finding that the student missing school will suffer irreparable harm. *Id.* (finding irreparable harm where a student was being forced to be home schooled because “the doctrine of ‘separate but equal’ has no place” in education (internal



quotations omitted)); *see also Doe v. Worcester Pub. Sch.*, 484 Mass. 598, 604 (2020) (affirming the conclusion that that a student who is suspended from school would suffer irreparable harm). Alternatively, if Plaintiffs do not receive an injunction, and are forced to choose to receive the influenza vaccine against their will, that is not an act that can be undone.

With regard to the relative burdens faced by the parties, Plaintiffs are merely asking that the Court preserve the current status quo, as it has stood for years. As the DPH press release noted, the Flu Shot Mandate is a new requirement, one that neither the Legislature nor the DPH had previously seen fit to require. Even though the state is still experiencing the COVID-19 pandemic, as discussed in the accompanying expert affidavits, there is little support for the idea that the Flu Shot Mandate will reduce either transmission or hospitalizations. (Doshi et al. Aff. ¶¶ 11-16.) And many other states and countries have chosen to *not* enact such a mandate in the face of the pandemic. (*E.g.*, Aaby and Benn Aff. at ¶¶ 7.) As such, the evidence is that the effect on the Commonwealth’s pandemic response will be minimal if the proposed injunction is granted. Thus, this is “a case where the status quo should be maintained to minimize the harm that final relief cannot redress ... by creating or preserving, ... a state of affairs such that after the full trial, a meaningful decision may be rendered for either party.” *Loyal Order of Moose, Inc.*, 439 Mass. at 603.

Lastly, it is unquestionably in the public’s interest to prevent a state agency, like the DPH, from acting outside of the authority granted to it by the Legislature, especially whereas here, allowing such actions will irreparably impinge on important constitutional rights. Plaintiffs do not oppose any individual receiving the influenza vaccine, and even with an injunction the DPH will be free to encourage people to receive the influenza vaccine (without forcing them to receive it).

**CONCLUSION**

Wherefore, Plaintiffs respectfully request the court grant their motion and issue a preliminary injunction prohibiting the DPH from enforcing the Flu Shot Mandate during the pendency of this action.

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Respectfully submitted,

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