

MEMORANDUM

TO: Health Law Section COVID-19 Task Force

FROM: Executive Committee, Food, Drug & Cosmetic Law Section

DATE: October 5, 2020

RE: Comments on COVID-19 Task Force’s Revised Resolution No. 3, “COVID-19 Vaccine and Virus Testing Legal Reforms

The Executive Committee of the Food, Drug & Cosmetic Law Section (the “FD&C Law Section”) of the New York State Bar Association (“NYSBA”) submits these comments (the “Comments”) on the Revised Resolutions of the NYSBA Health Law Section’s COVID-19 Task Force, dated September 18, 2020, which will be submitted to NYSBA’s House of Delegates for review, consideration and formal action on November 7, 2020. The Health Law Section has proposed these Revised Resolutions in connection with a revised report (the “Report”) issued by the Health Law Section’s COVID-19 Task Force, dated September 20, 2020.¹ The FD&C Law Section distributed an earlier version of the Report to its members for comment and received no comments.

The FD&C Law Section will address the Health Law Section’s proposed Revised Resolution No. 3, “COVID-19 Vaccine and Virus Testing Legal Reforms” (“Revised Resolution No. 3”) regarding vaccination, as FD&C Law Section members have a degree of expertise with respect to legal issues concerning vaccines. The FD&C Law Section believes that the remaining

¹ The COVID-19 Task Force issued the original Report on May 15, 2020 and a prior revised version of the Report was issued on July 1, 2020.

Resolutions proposed by the Health Law Section are not within the particular legal expertise of FD&C Law Section members and should be addressed by other Sections with more relevant expertise. Revised Resolution No. 3 is attached hereto as Appendix A.

The FD&C Law Section of the NYSBA appreciates the tremendous amount of work done under severe time constraints by the Health Law Section and its COVID-19 Task Force on the Report, and the amendments to the original draft Resolutions with respect to mandatory vaccinations. The FD&C Law Section wishes to express its thanks to the Task Force and, in particular, Hermes Fernandez, Esq., past Health Law Section Chair, and Mary Beth Quaranta Morrissey, Esq., the Task Force Chair, for the work done on the Report and Resolutions. In addition to preparing the Report, the Task Force held two dialogues regarding the Resolutions, and Dr. Morrissey repeatedly made herself available to discuss them.

The FD&C Law Section provides the comments below on Revised Resolution No. 3 and also proposes further revisions to Revised Resolution No. 3, which the FD&C Law Section believes are consistent with the Task Force's description of Revised Resolution No. 3 at the dialogue held on September 29, 2020. The proposed revisions to Revised Resolution No. 3 are attached hereto as Appendix B.

The Elimination of the Previously Proposed Vaccination Mandate Should be Made Clear

During discussions with the Task Force following the issuance of the Revised Resolutions, the Task Force made clear that the Revised Resolutions do not advocate enactment of a vaccination mandate, but instead seek to provide guidance setting forth issues that must be addressed before state and local government officials and public health authorities consider the possibility of a government mandate. The FD&C Law Section agrees with the NYSBA

Committee on Diversity and Inclusion that a resolution endorsing enactment of a vaccine mandate for the general population would have been premature since a COVID-19 vaccine has not yet been approved by the United States Food and Drug Administration (“FDA”) or been deemed to be safe and effective by the medical and scientific community. The FD&C Law Section also believes that NYSBA lacks the necessary scientific and medical expertise to recommend a mandatory vaccine when there is no existing vaccine that has been shown to be safe and effective, and that the NYSBA can make its most effective contributions to our nation’s efforts to combat the coronavirus pandemic by focusing on the wide range of legal issues involved, where NYSBA has relevant expertise.

The initial Report received significant media coverage for calling for nationwide mandatory vaccinations as soon as a COVID-19 vaccine becomes available. See, e.g., “State Bar Group Calls for ‘Mandatory’ COVID-19 Vaccinations, Regardless of Objections,” *New York Law Journal*, May 28, 2020;² “New York State Bar Committee Recommends Mandatory COVID Vaccine,” *National Review*, June 4, 2020.³ Particularly in light of the substantial publicity surrounding the initial Report, the FD&C Law Section believes it is important that Revised Resolution No. 3 make clear that the Health Law Section is no longer advocating a nationwide, state-wide or local vaccine mandate, but is instead proposing to set forth legal guidance as to the circumstances when it may be appropriate for state and local officials and public health authorities to consider the possibility of a government mandate.

² Available at: <https://www.law.com/newyorklawjournal/2020/05/28/state-bar-calls-for-mandatory-covid-19-vaccinations-regardless-of-objections/>.

³ Available at: <https://www.nationalreview.com/corner/n-y-state-bar-committee-recommends-mandatory-covid-vaccine/>.

Clarification and Definition Required as to When a Vaccine is Deemed Safe and Effective

The FD&C Law Section applauds Resolution No. 3's clear recognition that "[a] vaccine must not only be safe and efficacious; it must be publicly perceived as safe and efficacious." Revised Resolution No. 3 provides that "trials also must follow rigorous protocols that will establish a vaccine's safety and efficacy through expert consensus of the medical and scientific communities." Revised Resolution No. 3 references "due consideration of the expert medical and scientific consensus regarding the safety and efficacy of a vaccine," including "evidence of properly conducted and adequate clinical trials." Yet neither the Report nor Revised Resolution No. 3 suggest where the "expert medical and scientific consensus" should come from. Thus, it is unclear whether permission to "allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN [Chemical, Biological, Radiological, Nuclear] threat agents when there are no adequate, approved, and available alternatives"⁴ pursuant to the FDA's Emergency Use Authorization ("EUA") process would constitute sufficient "due consideration of the expert medical and scientific consensus regarding the safety and efficacy of a vaccine" to provide a basis for enactment of a vaccination mandate under Resolution No. 3.

The FD&C Law Section believes that Revised Resolution No. 3 requires further clarification and definition on the critical issues of when a COVID-19 vaccine will be deemed to be safe and effective and which entities should be making that determination. Would the FDA's

⁴ Emergency Use Authorization, FDA, available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#abouteuas>.

normal vaccine approval process automatically be sufficient to permit state and local government officials and public health authorities to consider mandatory vaccination laws? Or would something more be required to establish a “medical and scientific consensus”?

The typical vaccine approval process is a three-part process as follows: During Phase I, small groups of people receive the trial vaccine. In Phase II, the clinical study is expanded and the vaccine is given to people with characteristics (such as age and physical health) similar to those for whom the new vaccine is intended. In Phase III, the vaccine is given to thousands of people and tested for efficacy and safety, after which the FDA review team will review all of the information submitted to evaluate whether the studies show that the vaccine is safe and effective for the proposed use.⁵ Multiple reports have indicated that the federal government and private companies have been working feverishly to expedite development, approval, and distribution of a COVID-19 vaccine as quickly as possible. The FDA has created a special emergency program for possible coronavirus therapies, the Coronavirus Treatment Acceleration Program (“CTAP”).⁶ This effort is certainly appropriate and laudable given the staggering loss of human life, with more than 200,000 Americans already dead from COVID-19. The FDA has indicated that a COVID-19 vaccine likely will be granted an EUA, which would allow such a vaccine to be administered to patients before completion of Phase III clinical trials. According to the FDA’s website, CTAP “uses every available method to move new treatments to patients as quickly as possible, *while at the same time finding out whether they are helpful or harmful*” (emphasis added). Thus, the FDA would allow a vaccine permitted under an EUA to be used on human

⁵ Available at <https://www.cdc.gov/vaccines/basics/test-approve.html>

⁶ Available at: <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap>.

patients before it makes a determination that the vaccine is helpful, ineffective or harmful (i.e., safe and effective).

The FD&C Law Section recommends that Resolution No. 3 be further revised to identify a non-exhaustive list of recognized medical and scientific communities, such as the National Academies of Science, Engineering and Medicine, to which state and local government officials and public health authorities may look to determine whether a COVID-19 vaccine has been shown to be safe and effective. In light of reports of recent political pressure affecting COVID-19 guidelines and recommendations⁷, such assessments and determinations must be clearly untainted by political considerations. Aside from safety and efficacy concerns, this is important for the vaccine to attain public acceptance and consensus. While the FD&C Law Section appreciates the urgent need to develop a safe and effective vaccine, there is a clear tension between expediting delivery of a vaccine and ensuring that it is safe and effective and will not cause harmful side effects. The FD&C Law Section is unaware of a single instance in which the EUA process has ever been used to expedite mandated inoculation of the general population. Particularly in the current environment, the Report wisely recommends “deliberate, reasoned attention” to strategies to avoid mandating COVID-19 vaccines approved on the basis of limited or contested evidence of effectiveness which harm patients or prove to be ineffective. Consistent with this “deliberate, reasoned” approach, the FD&C Law Section believes that Resolution No. 3 should be further revised to clarify that issuance of an EUA by the FDA, standing alone, is not a sufficient basis upon which to consider imposition of a vaccination mandate in the absence of an

⁷ “White House Blocks New Coronavirus Vaccine Guidelines,” *New York Times*, October 5, 2020. Available at <https://www.nytimes.com/2020/10/05/us/politics/coronavirus-vaccine-guidelines.html?referringSource=articleShare>

expert consensus of the medical and scientific communities establishing the vaccine’s safety and efficacy, among a number of other factors which should also be considered.

Need for Greater Diversity in Clinical Trials

Revised Resolution No. 3 appropriately discusses the need to include “people of color” in the clinical trials. Scientists recommend that the patient population at least mirror the actual percentage of the population (indeed the National Institute of Health has suggested that the Black and Latino population should be overrepresented). This is especially important given that those communities have been found to be far more likely to be hospitalized with, and die from COVID-19 than other groups, and in light of the Report’s recommendation that those communities be given priority in receiving any approved vaccine.

Constitutionality of State and Federal Mandatory Vaccine Laws

There is a strong likelihood of massive litigation challenging the constitutionality of any vaccination mandate on various grounds. Indeed, individuals and groups filed legal and constitutional challenges to mask mandates and stay-at-home executive orders, and it is reasonable to anticipate additional challenges if a state or other regulatory authority enacts a vaccine mandate at any level. Given the current lack of any national consensus regarding a coronavirus vaccine, it is also reasonable to anticipate the possibility of protests and violent confrontations between those who refuse to get vaccinated and those who may be required to enforce any mandate, as the country has already seen with businesses seeking to enforce existing mask mandates.

The FD&C Section has reviewed existing case law on the constitutionality of state and local vaccination mandates and agrees with the Report that mandatory vaccinations have been

upheld as constitutional exercises of the state’s police power to protect public health, and that challenges to the exercise of that authority have been rejected by the courts. All fifty states have laws requiring certain vaccines for students, with exemptions for medical reasons. As the Report notes, in 2019, New York repealed the religious exemption for vaccinating school-attending children (Report at 65), although many other states continue to include a religious exemption in their existing vaccination mandates.

States have the right to enact mandatory vaccination laws to protect public health. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (upholding constitutionality of mandatory vaccination law for smallpox). The Court in *Jacobson* recognized that “the police power of a State must be held to embrace reasonable regulations enacted by the legislature to protect public health and safety,” *id.* at 25, and that individual liberties under the Constitution do “not import an absolute right in each person to be, at all times and in all circumstances, wholly free from restraint.” *Id.* at 26. The Court recognized that “a community has the right to protect itself against an epidemic of disease which threatens the safety of its members” and that “the rights of an individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand.” *Id.* at 29. A state law requiring mandatory vaccinations would be constitutional unless it “has no real or substantial relation to protecting public health” or is “a plain, palpable invasion of rights secured by the fundamental law.” *Id.* at 31. The mere fact that the vaccine is not fully effective for all and that it may cause side effects does not render mandatory vaccine laws unconstitutional. The Court in *Jacobson* concluded that mandatory vaccines are constitutional provided they contain an exception where vaccination would jeopardize a person’s health.

Relying on *Jacobson*, the Supreme Court has previously concluded it is within the police power of a state to provide for compulsory vaccinations, rejecting constitutional challenges. *Zucht v. King*, 260 U.S. 174 (1922). The Supreme Court has upheld the state’s power to issue laws protecting public health even where such laws restrain individual rights and religious liberties. *See, e.g., Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944) (noting that “the right to practice religion freely does not include liberty to expose the community to communicable disease”).

Jacobson remains good law. Chief Justice Roberts cited *Jacobson* earlier this year, concurring in declining a religious institution’s attempt to enjoin, on First Amendment free exercise grounds, a California executive order issued to address the coronavirus pandemic, which restricted large public gatherings, including religious services. *South Bay United Pentecostal Church v. Newsom*, 590 U.S. ___, 140 S.Ct. 1613 (2020). Chief Justice Roberts gave great deference to State officials, noting that “[w]hen those officials ‘undertake[] to act in areas fraught with medical and scientific uncertainties,’ their latitude ‘must be especially broad.’” *Id.* at ___, 140 S.Ct. at 1613,

Significantly, the decision in *South Bay United Pentecostal Church* was 5-4, with Justice Ruth Bader Ginsburg in the majority declining to enjoin the executive order. Given the high probability that coronavirus litigation will again make its way to the Supreme Court, the scope of *Jacobson v. Massachusetts* may well be addressed by the Supreme Court again soon, with a newly-confirmed Supreme Court Justice as the swing vote. It is possible that the Supreme Court may be more receptive to challenges to vaccination mandates that fail to include a religious exemption.

There are some significant potential distinctions between the vaccination mandate upheld in *Jacobson* in 1905 and any potential vaccination mandate that may be considered today, which could have an impact on any efforts to apply *Jacobson* to any COVID-19 vaccination mandate that may be enacted. The smallpox vaccine at issue in *Jacobson* had been “accepted by the mass of the people, as well as by most members of the medical profession... and in most civilized nations for generations.” *Jacobson*, 195 U.S. at 34-35. By contrast, a premise of the Report -- that a majority of Americans will want a COVID-19 vaccine when it becomes available (Report at 64) -- may no longer be accurate today, just a matter of months after the Report was first written. A recent study indicated that the percentage of people who said they would get the vaccine if it were available today is now just over 50 percent. Pew Research Center, “US Public Now Divided over Whether to Get COVID-19 Vaccine.”⁸

In addition, the penalty for non-compliance with the vaccine mandate in *Jacobson* was a \$5 fine, equivalent to roughly \$150 today. Neither the Report nor Revised Resolution No. 3 address how any COVID-19 vaccination mandate might be enforced. The FD&C Law Section assumes that Revised Resolution No. 3 does not contemplate a vaccination mandate that would be enforced by forcible physical compulsion, and that enforcement might take the form of a fine, as in *Jacobson*, or conditioning participation in education or government programs upon compliance or creation of other incentives for compliance.

Revised Resolution No. 3 refers to the possibility of state and local governments mandating vaccinations for unspecified “populations identified by the state and local health authorities.” Elsewhere, Revised Resolution No. 3 states that “[h]ealth care workers and other

⁸ Available at: <https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine>.

essential workers most endangered by COVID-19 and populations at highest risk must be afforded priority access to a vaccine.” There is a substantial difference between affording vulnerable segments of the population priority access to a vaccine and mandating that they receive it. Particularly in the absence of a strong consensus as to the safety and efficacy of a vaccine, imposing a mandatory vaccine on certain communities could cause additional complications in enforcement, raising potential ethical issues and providing bases for additional legal challenges.

The Report alludes to the possibility of a federal vaccination mandate, stating that “the gravity of COVID-19 presents compelling justification for State legislatures *and Congress* to mandate a COVID-19 vaccination.” Report at 65 (emphasis added). Although the Report addresses the constitutionality of a vaccine mandate under a State’s police power, the Report does not discuss the constitutionality of a potential federal vaccine mandate.

Questions exist as to whether Congress’s enumerated powers include the power to require vaccination. Indeed, the Supreme Court has held that “the regulation of health and safety matters is primarily, and historically, a matter of local concern.” *Hillsborough Cnty. v. Automated Med. Labs.*, 471 U.S. 707, 719 (1985). Congressional authority to regulate interstate commerce does not permit Congress to compel individual action. *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (Commerce Clause does not give Congress the power to command individuals to purchase insurance). Federal regulatory agencies cannot act beyond Congressional authority. The FDA does not have authority to mandate vaccines or to require states to mandate vaccines. While the Centers for Disease Control’s Advisory Committee on Immunization Practices may make recommendations about vaccines, it does not have the authority to mandate vaccines. Inasmuch as Revised Resolution No. 3 does not propose a federal

mandate and the Report does not address the issue of a federal mandate in detail, we do not believe a detailed analysis of the constitutionality of a potential federal mandate is necessary here.

The FD&C Law Section appreciates the opportunity to provide these comments on Revised Resolution No. 3 and also appreciates the Task Force's consideration of the proposed Revisions to Revised Resolution No. 3, attached hereto as Appendix B.

Appendix A

Resolution #3

COVID-19 Vaccine and Virus Testing Legal Reforms

The authority of the State to respond to a public health threat and public health crisis is well-established in constitutional law and statute. In balancing protection of the public's health and civil liberties, the Public Health Law recognizes our interdependence, and that a person's health, or her/his/their lack of health, can and does affect others. This is particularly true for communicable and infectious diseases. Since the discovery of the smallpox vaccine in 1796, vaccines have played a crucial role in preventing the spread of dangerous and often fatal diseases. The New York Public Health Law mandates several vaccinations for students at school-age up through post-secondary degree educational levels, and for health care workers. The Public Health Law also mandates treatment for certain communicable diseases, such as tuberculosis.

The New York State Bar Association recommends:

A vaccine must not only be safe and efficacious; it must be publicly perceived as safe and efficacious. Diverse populations, including people of color, older adults, women, and other marginalized groups, must be represented in clinical trials. The trials also must follow rigorous protocols that will establish a vaccine's safety and efficacy through expert consensus of the medical and scientific communities.

State Government to:

A.1. Ensure Access to Virus Testing: Establish a coordinated statewide plan for Virus Testing to ensure:

A.1.(a) frontline health care workers are prioritized in access to rapid diagnostic testing; and

A.1.(b) the most vulnerable individuals from health status and essential business/employee standpoint have equitable access to rapid diagnostic testing.

A.2. Adopt Ethical Principles Guiding Equitable Allocation and Distribution: Once available, a vaccine should first be equitably allocated and distributed based upon widely accepted ethical principles including: maximizing benefit to the society as a whole through reducing transmission and morbidity and mortality; recognizing the equal value, worth and dignity of all human persons and human lives; mitigating suffering, health inequities and disparities; and ensuring fairness and transparency in decision making. Health care workers and other essential workers most endangered by COVID-19 and populations at highest risk must be afforded priority access to a vaccine.

A.3. Encourage Public Acceptance and Educational Programs: Efforts must be made to encourage public acceptance. Public health authorities should build on existing systems and infrastructures including community-based organizations and networks. The campaign must

Resolution #3 (continued)

acknowledge distrust in communities of color from a history of medical exploitation. Efforts should include linguistically and culturally competent educational and acceptance programs, and stakeholder community engagement strategies, to build public trust, widely encouraging vaccine uptake and addressing vaccine hesitancy.

A.4. Take Steps to Protect the Public's Health, and As May Be Necessary, Consider Vaccine Mandate to Reduce Risks of Transmission and Morbidity and Mortality:

Our state and nation have suffered terrible losses from COVID-19. As of September 3, 2020, 186,000 Americans, including 26,000 New Yorkers, have lost their lives. Unemployment has been at the highest levels since the Great Depression. Numerous businesses have closed.

Should the level of vaccination be deemed insufficient to check the spread of COVID-19 and reduce morbidity and mortality, after due consideration of the expert medical and scientific consensus regarding the safety and efficacy of a vaccine and the need for required inoculation, including i) evidence of properly conducted and adequate clinical trials, ii) reasonable efforts to promote public acceptance, and iii) fact-specific assessment of the threat to the public health in populations and communities, appropriate action as warranted would need to be taken to permit the state and local governments to mandate vaccination for populations identified by state or local public health authorities, subject to exception for personal medical reasons.

Appendix B

Proposed Revisions to Revised Resolution #3

COVID-19 Vaccine and Virus Testing Legal Guidelines

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The authority of the State to respond to a public health threat and public health crisis is well-established in constitutional law and statute. In balancing protection of the public's health and civil liberties, the Public Health Law recognizes our interdependence, and that a person's health, or her/his/their lack of health, can and does affect others. This is particularly true for communicable and infectious diseases. Since the discovery of the smallpox vaccine in 1796, vaccines have played a crucial role in preventing the spread of dangerous and often fatal diseases. The New York Public Health Law mandates several vaccinations for students at school-age up through post-secondary degree educational levels, and for health care workers. The Public Health Law also mandates treatment for certain communicable diseases, such as tuberculosis.

The New York State Bar Association recommends:

To protect public health, it would be useful to provide guidance, consistent with existing law, to assist state and local elected officials and public health authorities in identifying conditions that must be met before it may be appropriate for them to consider the possibility of enacting a vaccine mandate. A vaccine must not only be safe and efficacious; it must be publicly perceived as safe and efficacious. Diverse populations, including people of color, older adults, women, and other marginalized groups, must be represented in clinical trials. The trials also must follow rigorous protocols that will establish a vaccine's safety and efficacy through expert consensus of the medical and scientific communities as may be reflected in the assessments and determinations of recognized organizations of medical and scientific experts such as the National Academies of Science, Engineering and Medicine. Permitting an Emergency Use Authorization by the U.S. Food and Drug Administration, standing alone, is not a sufficient basis upon which to consider imposition of a vaccination mandate in the absence of an expert consensus of the medical and scientific communities establishing the vaccine's safety and efficacy, among other factors which should be considered.

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A.2. Adopt Ethical Principles Guiding Equitable Allocation and Distribution: Once available, a vaccine should first be equitably allocated and distributed based upon widely accepted ethical principles including: maximizing benefit to the society as a whole through reducing transmission and morbidity and mortality; recognizing the equal value, worth and dignity of all human persons and human lives; mitigating suffering, health inequities and disparities; and ensuring fairness and transparency in decision making. Health care workers and other essential workers most endangered by COVID-19 and populations at highest risk must be afforded priority access to a vaccine.

A.3. Encourage Public Acceptance and Educational Programs: Efforts must be made to encourage public acceptance. Public health authorities should build on existing systems and infrastructures including community-based organizations and networks. The campaign must acknowledge distrust in communities of color from a history of medical exploitation. Efforts should include linguistically and culturally competent educational and acceptance programs, and stakeholder community engagement strategies, to build public trust, widely encouraging vaccine uptake and addressing vaccine hesitancy.

A.4. Take Steps to Protect the Public's Health, and As May Be Necessary, Consider Vaccine Mandate to Reduce Risks of Transmission and Morbidity and Mortality:

Our state and nation have suffered terrible losses from COVID-19. As of September 3, 2020, 186,000 Americans, including 26,000 New Yorkers, have lost their lives. Unemployment has been at the highest levels since the Great Depression. Numerous businesses have closed.

Should the level of immunity be deemed insufficient by expert medical and scientific consensus to check the spread of COVID-19 and reduce morbidity and mortality, a potential mandate should be considered only after the following conditions are met:

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j) evidence of properly conducted and adequate clinical trials;

ii) reasonable efforts to promote public acceptance;

iii) fact-specific assessment of the threat to the public health in populations and communities,

iv) the expert medical and scientific consensus (as may be reflected in the assessments and determinations of recognized organizations of medical and scientific experts such as the National Academies of Science, Engineering and Medicine) regarding the safety and efficacy of a vaccine and the need for immunization, and

v) consideration of potentially less intrusive alternatives.

State and local governments may then consider whether or not it may be appropriate to take action as warranted to mandate vaccination for populations identified by state or local public health authorities, subject to exception for personal medical reasons. Enforcement of any vaccination mandate that may be enacted would never be through the use of physical compulsion, but could be achieved through various means, including fines for non-compliance, conditioning participation in education upon compliance or creation of incentives for compliance.

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