VACCINE REQUIREMENTS: A COMPARATIVE LEGAL ANALYSIS OF DIFFERENT JURISPRUDENTIAL AND REGULATORY INSTANCES IN THE U.S. STATES[*].

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1. Preface.

In 2021, various state and local entities instituted COVID-19 vaccination requirements to address the pandemic, particularly when the Delta variant began to cause spikes in COVID-19 cases across the country. Many public universities, for example, imposed vaccination requirements on their students and staff as a condition to be physically in the campus. Only few States have imposed statewide vaccination requirements and, when present, they are generally limited to health care workers. Two States, California and Louisiana, and the District of Columbia have announced plans in 2021 to add COVID-19 vaccination to their lists of mandatory vaccinations for students.[1] Except as is the case with several mandates regarding

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[1] California was the first federated state to announce mandatory COVID-19 vaccination requirements for schools starting Oct. 1, 2021. After implementing the first school masking and staff vaccination measures, California becomes the first state to announce plans to require vaccinations for students, adding the COVID-19 vaccine to the list of vaccinations required for school, such as measles, mumps and rubella vaccines. Students will have to be vaccinated to gain personal access to educational institutions effective when the Food and Drugs Administration grants full approval to the vaccine and for grades (7-12 and K-6). Governor Newsom announced, "The state already

state health care providers (as well as California's student vaccination requirements), which allow only exemptions based on medical reasons; most of these state and local vaccination requirements include both medical and religious exemptions.

It is therefore not surprising that many of these state mandatory vaccination requirements against COVID-19 have been the focus of several legal challenges.

The decisions of the Courts here analyzed have mostly upheld these requirements, especially where the relevant regulations allowed for both medical and religious exemptions.

Some of the common claims raised in these challenges include, for example, an alleged violation of plaintiffs' substantive rights to bodily integrity or the right to refuse unwanted medical treatment or an alleged violation of their equal protection rights.

Most Courts have rejected these claims, relying on the *Jacobson* case[2] and denying that fundamental rights or suspect classifications are introduced by vaccination mandates since they reasonably promote a legitimate governmental interest and are subject to review on a rational basis.

The main area of legal uncertainty regarding state vaccination requirements concerns 'if' and 'when' state vaccination requirements should provide for and allow for exemptions and the circumstances under which such exemptions may be granted or denied. It is precisely on this

requires that students be vaccinated against viruses that cause measles, mumps, and rubella - there's no reason why we wouldn't do the same for COVID-19. Today's measure, just like our first-in-the-nation school masking and staff vaccination requirements, is about protecting our children and school staff, and keeping them in the classroom", "Vaccines work. It's why California leads the country in preventing school closures and has the lowest case rates. We encourage other States to follow our lead to keep our kids safe and prevent the spread of COVID-19".

[2] In U.S. Supreme Court, 197 U.S. 11, *Jacobson v. Massachusetts*, 1905, the States' Supreme Court recognized the right of individual states to introduce mandatory vaccination laws. The case concerned 1902 regulation mandating vaccinations against smallpox, a growing disease that posed a present threat to the city of Cambridge during the early 1900s. The regulation in question provided for a medical exemption for children only while requiring individuals over the age of 21 to undergo the vaccinations in question or, alternatively, to pay a fine of five dollars. Mr. Henning Jacobson had refused the vaccine alleging that a vaccination received at a young age had made him seriously ill. For this, Jacobson was being criminally charged for not receiving the vaccination despite being over 21 years old and having free access to it. Jacobson claimed that the Massachusetts law, by mandating smallpox vaccination violated, *the spirit of the U.S. Constitution* and complained of the state's duty to uphold the Constitution through the Fourteenth Amendment. He also complained of an invasion by the law of his liberty in the part where it subjected him to a fine or imprisonment because of choosing not to vaccinate. According to Jacobson, this imposition was «hostile to the inherent right of every freeman to care for his own body and health in such a way as to him seems best», and he argued that the penalties provided for would constitute «an assault upon his person». However, the Supreme Court rejected the argument based on the Fourteenth Amendment noting how it was not a source of any substantive power of the U.S. government. After recognizing the state's authority to enact this statute as part of its police powers, the Court then examined the validity of a mandatory vaccination mandate. The Court then acknowledged that individual constitutional rights can be reasonably limited when necessary for the protection of the common good. In particular, the Court recognized how genuine freedom within an organized society can exist only when balanced against the harm that an individual's actions may cause to other individuals.

issue that there have been sharp disagreements among the Federal Appellate Courts, which have often reached conflicting results.

2. The most important jurisprudential cases about Covid-19 vaccination in the federated State of U.S.

2.1. Michigan.

In *Dahl v. Board of Trustees of Western Michigan University* (2021)[3], the District Court, on remand, suspended a state university's policy requiring student-athletes to be vaccinated in order to participate in team activities. The university's policy, which applied only to student-athletes and not the student body in general, stated that «[m]edical or religious exemptions and accommodations will be considered on an individual basis»[4]. Several student-athletes who were denied religious exemptions and were therefore excluded from activities instituted a lawsuit challenging this policy, alleging, among other claims, that it violated the free exercise of their rights. In considering the motion filed by the university to lift the preliminary injunction, the U.S. Court of Appeals for the Sixth Circuit held that the discretionary exemption process introduced by the university provided a *mechanism for individualized exemptions* (in line with what was affirmed in the Fulton case[5]) that thus precluded a blanket application of the policy by subjecting it to a stricter scrutiny. Delving into a closer examination, the Sixth Circuit concluded that student-athletes were more likely to succeed with reference to the *free exercise claim* because, while the university had a compelling interest *in fighting COVID-19*, the

[3] U. S. Court of Appeals, Sixth Circuit, *Dahl et al v. The Board of Trustees of Western Michigan University et al*, n. 21-2945, 2021.

[4] «medical or religious exemptions and further arrangements will be considered on an individual basis».

[5] U.S. Supreme Court, *Fulton v. City of Philadelphia*, 593 U.S., 2021: This was a case decided by the U.S. Supreme Court that was called to hear litigation alleging discrimination of local regulations based on the Free Exercise Clause and the Establishment Clause of the First Amendment of the U.S. Constitution. The specific case involved a religiously based foster care agency that had been denied a new contract by the city of Philadelphia, Pennsylvania, because of the agency's refusal, on religious grounds, to certify married same-sex couples as *foster parents*. "In a ruling adopted unanimously on June 17, 2021, the Court ruled that the city's refusal to enter into a new contract with the agency in question and based on the agency's adopted policy for same-sex couples violated the free exercise clause. The case was decided on a narrow basis contrasts with an earlier Supreme Court decision: U.S. Supreme Court, *Employment Division v. Smith*, 494 U.S. 872, 1190, in which the Court had ruled that neutral laws of general applicability could not be challenged for violation of *religious exemptions*. In contrast, in Fulton, the Court ruled that services such as foster care contracts did not constitute public agreements attributable to the Smith case and were therefore subject to strict scrutiny. Since the city of Philadelphia had allowed exceptions in its anti-discrimination policy for certifying foster care, the Court held that the city's policy had violated the foster care agency's free exercise of religion in accordance with what was affirmed in Smith.

vaccination policy had not been adequately applied to achieve this goal. This was because, first, non-athlete students were not required to be vaccinated, a circumstance that undermined the university's stated interest in wanting to prohibit behavior that could have resulted in health risks; moreover, the Court proposed comparisons with other university policies that, unlike the one at issue, allowed exemptions, and thus suggested that the vaccination policy adopted by the University of Michigan might have come across as unnecessarily burdensome.

2.2. Maine.

In *Does v. Mills (2021)*[6] , the U.S. Court of Appeals for the First Circuit was asked to review Maine's regulation that introduced COVID-19 vaccination into the list of required vaccinations for employees of licensed health care facilities. In 2019, the Maine legislature had eliminated all non-medical exemptions to the state's health care worker and student vaccination requirements, appealing to the recorded decline in vaccination rates and the need to protect those who were immunocompromised and thus dependent on others' vaccinations for their own protection.

In adopting the regulation in August 2021, the Maine *Department of Health and Human Services* and the *Center for Disease Control* stated that the rule introduced was necessary since: the highly contagious Delta variant had caused a 300 percent increase in COVID-19 cases between June and July 2021; health care facilities were particularly susceptible to outbreaks of infectious diseases such as COVID-19; such outbreaks hampered the state's ability to care for its residents with both COVID-19 and other diseases; alternatives to vaccination (such as regular testing or reliance on personal protective equipment) were not as effective alternatives; no health facility at the time, despite various efforts by States to promote voluntary vaccination, had achieved vaccination rates above 90 percent, a percentage that the State Public Health Agency said constituted the minimum rate required to prevent community transmission of Delta Variant. Many unvaccinated health care workers, faced with this regulation, decided to start a lawsuit challenging the regulation, claiming, among other allegations, that the COVID-19 vaccination requirement violated the *free exercise clause since no* religious exemption was allowed. In upholding the District Court's denial of issuance of a preliminary injunction, the

[6] U.S. Court of Appeals, First Circuit, *Does v. Mills*, n. 21-1826, 2021.

First Circuit Court concluded that the plaintiffs were unlikely to have their claim based on the *free exercise clause* granted. According to the Court, the vaccine regulation introduced in Maine constituted a neutral law of general applicability that did not «single out religious objections because of their religious nature»[7]. And «applie[d] equally across the board»[8] without requiring the state government «to exercise discretion in evaluating individual requests for exemptions»[9]. According to the First Circuit, making a general medical exemption available to employees who provided a written statement from a licensed physician attesting to the medical inadvisability of vaccination precluded the general applicability of the requirement. Unlike the exemption system at issue in the *Fulton* case, the medical exemption, according to the Court, constituted *a single objective exemption* that did not require discretionary evaluation, nor did it permit «secular conduct that undermines the government's asserted interests in a similar way» as a religious exemption would. On the contrary, according to the Court, exempting only those whose health would be endangered by vaccination strengthened the state's interests in protecting the health and safety of its residents, including those of the health workers and the most vulnerable who could not vaccinate for medical reasons. Since the medical exemption is significantly different from the religious exemption, the Court concluded that Maine's vaccination requirement had to be considered to be of general applicability and subject to rational review, which it would easily pass. Although the Court did not need to delve into the consideration of this issue, it noted that, the vaccination requirement under review would easily survive even the application of stricter scrutiny: Maine had a compelling interest in both stemming the spread of COVID-19 and in denying plaintiffs an exemption since exceptions to the requirement on non-health grounds threaten *the most vulnerable Mainers*. Even the vaccination requirement, according to the Court, was sufficiently narrow and proportional to what was necessary to achieve these interests, given that: Maine had considered alternatives such as testing, use of masks, and social distancing, but found them inadequate to achieve the state's goals, particularly in the face of the spread of the Delta variant; Maine «demonstrated that it ha[d] tried many alternatives to get its healthcare workers vaccinated short of a mandate»[10] but such efforts had failed to achieve the vaccination rate of at least 90 percent

[7] *Id.*, «[...] does not target religious exemptions merely because of their religious nature».
[8] *Id.*, «[...] applies uniformly in every sphere».
[9] *Id.*, «[...] to exercise its discretion in evaluating individual requests for exemption».
[10] *Id.*, «[...] demonstrated that it has tried to implement many alternatives to vaccinate its health workers short of a mandate».

needed to stop community transmission; and finally, the requirement was neither too narrow, in that it applied to all but those attesting to a medical contraindication nor too broad, in that it was limited to «the narrow sphere of healthcare workers...who regularly enter healthcare facilities»[11].

2.3. New York State.

In *We the Patriots USA, Inc. v. Hochul* (2021)[12], the U.S. Court of Appeals for the Second Circuit considered an emergency regulation adopted by the *New York Health Department*, N.Y.C.R.R. § 2.61, which ordered certain healthcare facilities in the state to require their employees to receive COVID-19 vaccines. Like Maine's emergency regulation, the vaccination requirement provided only for a medical exemption, which applied «only until such immunization is found no longer to be detrimental to [the employees'] health and must be supported by a certification from a licensed physician or nurse practitioner issued in accordance with generally accepted medical standards, including recommendations of the Advisory Committee on Immunization Practices»[13]. In the face of this regulation, several health care providers had decided to start a legal suit to challenge the rule in question, arguing that it violated the *free exercise clause*. The Court of Appeals for the Second Circuit had reaffirmed what the First Circuit had said: the claim could not be granted since the plaintiffs had not met their burden of proving that the New York rule, by allowing a medical but not a religious exemption, was not a neutral law of general applicability or that it would otherwise fail a scrutiny performed on a rational basis. In a similar vein to the First Circuit, the Second Circuit had observed how medical exemptions and religious exemptions could not be placed on the same footing with respect to what were the underlying governmental interests of the regulation (protecting the health of health care employees to avoid excessive shortages in the availability of personnel that could have compromised patient safety) this was because if medical exemptions promoted those interests religious exemptions would pose a threat to them.

[11] *Id.*, «[...] the restricted sphere of health care workers who regularly enter health care facilities».
[12] U.S. Court of Appeals, Second Circuit, *We the Patriots USA, Inc. v. Hochul*, n. 21-2179, 2021.
[13] *Id.*, «[...] Only until such immunization is no longer detrimental to the health [of employees] and must be supported by certification by a licensed physician or nurse practitioner and issued in accordance with generally accepted medical standards, including the recommendations of the Advisory Committee on Immunization Practices».

Similarly to what the First Circuit's has stated, the Second Circuit found that the medical exemption in the regulation at issue did not create a system of individualized exemptions under *Fulton*[14] because the rule «provide[d] for an objectively defined category of people to whom the vaccine requirement does not apply»[15], i.e., those who present a suitable certification issued by a licensed physician and conforming to generally accepted medical standards. Since the plaintiffs, according to the Court, had not shown that § 2.61 lacked neutrality or general applicability, the Court had applied a *rational-basis review*. A standard adopted in an emergency requiring employees of health care facilities to be vaccinated in the face of a particularly contagious variant of the virus, which had claimed the lives of more than 750,000 U.S. residents and some 55,000 New Yorkers, the Court observed, *easily met that standard*. In sum, the *Dahl* case on the one hand, and the *Does case* and the *We the Patriots* case on the other, highlight some of the unresolved issues raised by Fulton as they too address vaccination requirements and the circumstances under which States may be constitutionally required to provide or grant religious exemptions. While the *Dahl* case suggests that the provision of a medical exemption with respect to a vaccination requirement may be sufficient to preclude it from having general applicability and thus allow it to be subject to *rational-basis review*; the *Does case* and the *We the Patriots case* hold that, at least in the context of health care employment, a vaccination requirement that provides only a medical exemption is generally applicable and thus subject to rational-basis review. The Supreme Court rejected the requests to suspend the application of the emergency rules introduced by Maine and New York and litigated in *Does* and *We the Patriots*, allowing their implementation.

3. Powers of the executive branch in relation of to the introduction of vaccination requirements: the case of the moratorium on eviction and the related jurisprudence.

Prior to the outbreak of the COVID-19 pandemic, federally mandated vaccination requirements related primarily to immigration, the military, and to some federal health care employment settings.

[14] See note 5.
[15] *Id.*, «[...] provided an objectively defined category of people to whom the vaccination requirement does not apply».

At the onset of the COVID-19 pandemic, and even before the pandemic, some commentators believed that a likely source of authority for the issuance of federal public health orders, including those related to vaccination requirements, might have been found in section 361(a) of the Public Health Service Act (PHSA), the *Centers for Disease Control's* moratorium on evictions, and related litigation. This provision, codified at 42 U.S.C. § 264(a), grants to the Secretary of HHS the authority, delegated in part to the *Centers for Disease Control and Prevention* (CDC) to introduce and enforce regulations necessary «to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession»[16]. In accordance with this provision, Section 361 (a) states: «[f]or purposes of carrying and enforcing such regulations», the agency «may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in [its] judgment may be necessary»[17]. Based on this statute, it was argued that through a broad interpretation of the authority described by Section 361 (a) it would be possible to allow CDC to issue regulations requiring vaccination under circumstances that would prevent foreign or interstate transmission of COVID-19.

Before COVID-19 vaccines became available through the Emergency Use Authorization (EUA) during the Trump administration, the CDC then invoked Section 361 of the PHSA to issue a national moratorium on evictions in September 2020. The CDC justified this moratorium by asserting that evictions threatened to increase the spread of COVID-19 as they forced people to live in new shared housing or congregate environments.

As a result of this moratorium on evictions, numerous legal challenges were brought. In June 2021, the U.S. Court of Appeals for the District of *Columbia Circuit* (D.C. Circuit) and the Sixth Circuit, in reviewing procedural motions to stay or lift the stay of the District Courts' preliminary injunction orders, had reached different conclusions about the CDC's asserted statutory authority to issue the order in question. The D.C. Circuit, adopting a broad interpretation of Section 361, concluded that «the CDC's eviction moratorium f[ell] within the

[16] «[...] prevent the introduction, transmission or spread of communicable diseases from foreign countries into the States or possessions, or from one state or possession to any other state or possession».

[17] Section 361 (a), *Public Health Service Act* (PHSA): «[...] For the purpose of the introduction and enforcement of such regulations», the agency «may put in place such inspection, fumigation, disinfection, sanitation, extermination of pests, destruction of animals or objects found infected or contaminated so as to be sources of infection dangerous to humans, and other measures, as in [its] judgment may be necessary».

plain text of 42 U.S.C. § 264(a)»[18]. The Sixth Circuit, on the other hand, had characterized the measures listed in Section 361(a) as *property interest restrictions* and concluded that the eviction moratorium was *radically unlike* those restrictions and therefore «f[ell] outside the scope of the statute». The litigation over the eviction moratorium has introduced much legal uncertainty about the scope of CDC's authority under PHSA Section 361(a), including the agency's authority to issue regulations relating to public health measures, such as vaccinations, that are likely to affect infectious disease control more directly than eviction moratoriums. Uncertainty about the scope of Section 361(a) was compounded after August 2021, when the Supreme Court, in granting a procedural motion to lift a stay on the eviction moratorium in *Alabama Ass'n of Realtors v. Department of Health and Human Services (2021)*[19], noted that plaintiffs challenging the eviction moratorium would be likely to succeed with respect to their legal claim. And it described the measures listed by Section 361(a) as measures «directly relate[d] to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself», the Court concluded that the moratorium on evictions «relate[d] to interstate infection far more indirectly», and the scope of the CDC's purported authority discouraged an interpretation by the government. The government has since voluntarily dropped its appeal and no final decision on the merits has been made in the case. In short, while the eviction moratorium litigation suggests that CDC's authority under Section361(a) does not extend to the issuance of eviction moratoriums, it does leave unresolved the precise scope of the agency's authority, conferred on it by that provision, to take other measures to prevent the spread of communicable diseases. To address the spread of the Delta variant in 2021, the President and several executive agencies, including the *Centers for Medicare and Medicaid Services* (CMS) and *the Occupational Safety and Health Administration* (OSHA), have engaged several other statutory authorities to issue COVID-19 vaccination mandates related to employment or workforce for civilians. These vaccination requirements include those that apply: to most Medicare and Medicaid certificate providers (*CMS's Medicare/Medicaid provider mandate*); employers with 100 or more employees (*OSHA's large-employer vaccination and testing mandate*); civilian employees of the federal executive agency (*Federal employee mandate*); federal contractors for executive departments, agencies, and bureaus (*Federal contractor*

[18] *Id.*, «[...] the CDC's moratorium on evictions is contained in the plain text 42 U.S.C. § 264(a)».
[19] U.S. District Court, District of Colombia, *Alabama Ass'n of Realtors v. Department of Health and Human Services*, n. 20-cv-3377, 2021.

mandate); and Head Start program personnel who provide comprehensive early childhood education and developmental services for low-income children (*Head Start mandate*). Subject to exemptions required by federal law for medical reasons or related to religious beliefs, these employment-based mandates directly require certain employees to receive COVID-19 vaccinations or direct certain employers to impose a vaccination or testing requirement on their employees and staff.[20]

3.1. Centers for Medicare & Medicaid Services Medicare/Medicaid provider mandate: The CMS mandate provided for Medicare/Medicaid providers.

On Nov. 4, 2021, the *Centers for Medicare & Medicaid Services* (CMS) published an *Interim Final Rule* (IFR), effective Nov. 5, 2021, requiring Medicare and Medicaid providers to introduce and enforce a policy requiring, subject to exceptions required by law, all eligible staff to receive the first dose of COVID-19 vaccine and two doses or one dose of a single-dose COVID-19 vaccine by Dec. 6, 2021 and to complete the vaccination series by Jan. 4, 2022. This requirement applies to 15 types of providers participating in the Medicare and Medicaid programs, including hospitals, long-term care facilities and rural health clinics. The requirement does not apply to other health care entities such as physician practices, organ procurement organizations and portable x-ray providers.

The vaccination policy for providers involved in the RFI, must apply to all staff who directly provide any care, treatment or other services for the facility and/or its patients, including employees of the Congressional Research Service (including administrative staff and facility leadership); licensed professionals; students, interns and volunteers; and individuals who provide care, treatment or other services for the facility and/or its patients under contract or other arrangement (including cleaning and food services). Individuals who provide services 100 percent remote from patient care sites and away from staff working at care sites, such as telemedicine or fully remote payroll services, are not subject to immunization requirements. CMS states that providers who fail to comply with these requirements will be subject to the application of remedies based on the level of noncompliance and relative readiness, which may

[20] Cmp. W.W. Shen, *State and Federal Authority to Mandate COVID-19 Vaccination*, in *Congressional Research Service*, 2022.

include civil monetary penalties; denial of payment for new admissions; and termination of Medicare/Medicaid programs. At least 24 states, on behalf of some of their state health facilities likely to be subject to such immunization requirements, filed lawsuits challenging the IFR shortly after it was issued. The cases are still in their early stages, but the legal issues that District Courts have been asked to consider relate to whether CMS had a *good cause* to waive the applicable regulatory requirements. Courts may also consider whether or not the vaccination requirements imposed exceed CMS's statutory authorities applicable to a particular service provider.

3.2. OSHA's large-employer vaccination and testing mandate: vaccination and Emergency Temporary Standard (ETS) for employers with 100 or more employees.

On the same day CMS released its IFR, *the Occupational Safety and Health Administration* (OSHA) issued an Emergency Temporary Standards (ETS) requiring private employers with 100 employees or more to introduce and enforce a policy requiring all employees: to receive the COVID-19 vaccination, subject to exceptions required by law, or requiring employees as an alternative to the COVID-19 vaccination to regularly provide proof of COVID-19 testing and wear a face cover when indoors or occupying a vehicle with another person. Based on the ETS, employees who are not fully vaccinated, including those who have been granted exemptions, must undergo a COVID-19 test at least once every seven days if they attend a workplace where other workers are present. Employees who do not attend the workplace at least once every seven days must take a test within seven days before returning to the workplace. Employees exempt from ETS requirements are employees who work remotely or at a site where no other people are present and employees who work exclusively outside. Involved employers may, but are not obligated to, pay any costs associated with testing and must ensure that employees with paid leave are able to receive and catch up on vaccination requirements. The vaccination requirements under the ETS are based on OSHA's authority provided in Section 6(c) of the *Occupational Safety and Health Act*[21] of 1970. The provision authorizes the

[21] The Occupational *Safety and Health Act* of 1970 is a U.S. labor law governing federal occupational health and safety in the private sector and federal government in the United States. It was enacted by Congress in 1970 and was signed into law by President Richard Nixon on December 29, 1970. Its main objective is to ensure that employers provide employees with an environment free of recognized hazards, such as exposure to toxic

agency to issue an ETS that takes effect immediately upon publication in the *Federal Register*[22], without submitting to APA regulation[23] in the event it establishes «that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and that such emergency standard is necessary to protect employees from such danger».

OSHA then decided to issue the ETS noting how unvaccinated workers faced a grave danger from exposure to SARS-CoV-2 in the workplace, since: COVID-19 had killed more than 725,000 people in the U.S. in less than two years; that unvaccinated individuals of exposed to a much higher risk of serious health outcomes; and that evidence demonstrated the transmissibility of the virus in the workplace and there was a prevalence of infection in employee populations.

On the same day the ETS was issued, numerous petitioners, including employers, States, and religious groups decided to challenge the mandate in several federal Appellate Courts. In response to one such petition filed by several affected employers and four States, the Fifth Circuit suspended enforcement of the ETS the day after it was issued. On November 12, 2021, the Court upheld the suspension, largely based on its conclusion that the ETS «grossly exceeds OSHA's statutory authority». In addition, the Court concluded that COVID-19 does not constitute a required *serious danger* of Section 6(c), since the agency cannot prove that all workplaces affected by the regulation are exposed to COVID-19, and since the effects of COVID-19 may be mild and the status of the spread of the virus has changed over time. The ETS, according to the Court, was not even *necessary* to protect unvaccinated workers given its «staggering[] overb[readth]», such that its application was on the one hand too inclusive (since it was to apply to employers and employees in virtually all industries and workplaces in

chemicals, excessive noise levels, mechanical hazards, heat or cold stress, or unsanitary conditions. The law gave birth to the Occupational *Safety and Health Administration* (OSHA) and the *National Institute for Occupational Safety and Health* (NIOSH).

[22] The *Federal Register* is the official journal of the U.S. federal government that contains government agency rules, proposed rules and public notices. It is published every weekday except on federal holidays. Final rules promulgated by a federal agency and published in the Federal Register are then reorganized by subject and codified in the *Code of Federal Regulation* (CFR), which is updated annually. The *Federal Register is* compiled by the *Office of the Federal Register* (within the *National Archives and Records Administration*) and printed by the *Government Publishing Office*. There are no copyright restrictions on the *Federal Register*: as a work of the U.S. government, it is in the public domain

[23] *The Administrative Procedure Act* (APA, 1946) is the U.S. federal statute that governs how administrative agencies of the U.S. federal government may propose and establish regulations and grants U.S. Federal Courts oversight over all agency actions. The APA applies to both federal executive departments and independent agencies. The text of the APA can be found under Title 5 of the U.S. Code, beginning with Section 500.

America without an attempt to account for differences in exposure to COVID-19); and on the other hand too un-inclusive since it overlooked workplaces with 99 or fewer employees. In addition to its analysis based on the statute, the Court also noted how the ETS likely oversteps the authority granted to the federal government by the *Commerce clause* of the U.S. Constitution. After characterizing the regulated activity as *mandatory vaccination*, the Fifth Circuit then expressed the view that the ETS impermissibly «regulates noneconomic inactivity that falls squarely within the States' police power»[24].

3.3. Executive Order 14,043 Federal employee mandate.

Executive Order 14,043, issued September 9, 2021, requires each executive agency to implement a program to require vaccination against COVID-19 for all federal employees and that allows for exceptions required by law, including those based on a disability, medical condition, or sincerely held religious belief. The intended mandate for federal employees (Federal Employee Mandate) calls on the *Safer Federal Workforce* Task Force (Task Force)[25] to develop guidelines for implementing this requirement. The mandate is based on the President's statutory authority provided by U.S.C. §§ 3301, 3302, and 7301.22. These provisions give the President general authority to prescribe rules and/or regulations for executive branch employees. Based on guidelines developed by the Task Force, federal employees must have completed a course of vaccination (i.e., two weeks must have elapsed since the administration of a single-dose vaccine or a two-dose vaccine series) or have obtained an exception by Nov. 22, 2021. Employees who refuse to be vaccinated or provide proof of vaccination and have neither an exception nor a request for an exception as mentioned above, are subject to disciplinary action, up to and including removal or dismissal. Based on the guidelines, any removal or termination must be preceded by a brief period of education and

[24] *Federal COVID-19 Vaccination Mandates and Related Litigation: An Overview*, in *Congressional Research Service*, 2021.

[25] The *Safer Federal* Workforce Task Force (Task Force) was established by Section 4 of Executive Order 13991 on the Protection of the Federal Workforce and the Requirement to Wear a Facemask, dated January 20, 2021. The task force is co-chaired by the White House COVID-19 Response Coordinator, the Administrator of General Services, and the Director of the Office of Personnel Management. Task force memebers include the Director of the Office of Management and Budget (OMB), the Director of the Federal Protective Service, the Director of the U.S. Secret Service, the Administrator of the Federal Emergency Management Agency, the Director of the Centers for Disease Control and Prevention (CDC), and the Secretary of Veterans Affairs.

counseling and a period of suspension generally up to 14 days. In the face of this measure, several federal employees and at least one employee union have instituted lawsuits challenging the *Federal Employee Mandate*. A variety of claims have been raised in these lawsuits, including some common allegations of challenges to state vaccination requirements. However, the Courts have generally rejected these claims.

3.4. Office of Head Start IFM, Head Start mandate: the mandate for Head Start programs.

On November 30, 2021, *the Office of Head Start* within *HHS's Administration for Children and Families* issued an IFR that imposed both vaccination and masking requirements for Head Start program recipients. Established in 1965, the Head Start program directly awards funds to public and private nonprofit and for-profit organizations, government agencies, and schools to promote the school readiness of infants, toddlers, and preschoolers from low-income families who meet certain federal performance standards. The IFR is in addition to federal performance standards to require all employees of Head Start programs, as well as contractors and volunteers who have contact with or provide direct services to children to receive administration of a single-dose COVID-19 vaccine or a two-dose vaccine series by Jan. 31, 2022, subject to legally required exceptions based on a disability, medical condition, or sincerely held religious belief. Those granted exemptions are required to undergo weekly COVID-19 testing.

In addition, the IFR requires universal masking, with some exceptions, for all individuals two years of age and older when indoors. For those who are not fully vaccinated, the IFR also requires outdoor masking if the environment is crowded or involves close contact with others. According to *the Office of Head Start*, the Head Start mandate is based on the HHS Secretary's determination, adopted after consultation with child health experts and CDC and FDA recommendations, that additional health and safety standards are needed to ensure the reduction of SARS-CoV-2 transmission; avoid serious illness, hospitalization and death among program participants; and reduce the risk of program disruption, which would result in multiple hardships to children and families who rely on the program to meet their health, nutrition and early learning needs. The Secretary's determination notes that COVID-19 vaccines are the safest and most effective way to protect individuals and the people with whom they live and

work from serious infections and diseases and the risk of hospitalization. It goes on to add that since most participants in Head Start programs are too young to be vaccinated, the introduction of additional health and safety standards, in the form of masking and mandatory vaccination, imposed on all who are eligible to meet them, are the best defenses against COVID-19, especially in light of the spread of Delta and other variants. The Head Start mandate is based on the Secretary's authority under Section 641A of the *Head Start Act* to «modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs»[26], including «administrative and financial management standards»[27]; «standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate) for such agencies, and programs»[28]; and «such other standards as the Secretary finds to be appropriate»[29]. Following the issuance of the IFR, 25 states, in two separate lawsuits, filed suit challenging the Head Start mandate.

4. The constitutionally recognized authority of Congress to introduce mandatory vaccination requirements.

4.1. Spending clause and commerce clause: vaccination mandates.

As noted in the preceding pages, although the States have traditionally exercised most of the authority in public health matters, including the area of vaccination, Congress shares with them some competing powers in this area, descended from the *emunerated powers (*Art. 1 Sec.8) provided by the Constitution. This congressional authority derives specifically from the *spending clause* (Art. 1, Sec. 8, Cl. 1) and the *commerce clause* (Art. 1, Sec. 8, Cl. 3) of the Constitution, which can be used by Congress to clarify existing statutory authorities with respect to vaccination requirements, or to create additional sources of authority or limitations on them. The spending *clause* authorizes Congress to tax and spend money on the *general welfare*.

Based on this authority, which is subject to various limitations, Congress can offer federal funds

[26] «[...] amend, if necessary, program performance standards by regulation applicable to Head Start agencies and programs».
[27] «[...] rules of administrative and financial managemen».
[28] «[...] standards for conditions and location of facilities (including indoor air quality assessment standards, where applicable) for such agencies and programs».
[29] «[...] other standards that the Secretary deems appropriate».

to non-federal entities and prescribe the terms and conditions under which the funds are to be accepted and used by the recipients.

Applying its *spending authority* in the context of an immunization mandate, Congress could, for example, encourage States to enact an immunization mandate that meets certain federal requirements by imposing this as a condition for receiving certain federal funds.

The exercise of this authority descended from the *spending clause*, assuming it materializes within the limits marked by *general welfare*, is permissible as long as: Congress provides clear notification to the States involved concerning the vaccination mandate that they (or other recipients of funding) are to enact or implement; the mandate is related to what are the purposes for which the federal funds are appropriated; the conditional granting of these funds is not, in other ways, precluded by the Constitution; and the amount of federal funds must not be «so coercive as to pass the point at which pressure turns into compulsion». As for the *commerce clause*, Congress relied on it to enact some of the first federal health laws designed to protect the public from contagion and products that, in general, could lead to health problems. As the federal government increased its role in public health, Congress then relied on the *commerce clause* to pass more organic national health regulations, beginning with the *Food and Drug Act* of 1906.

While certainly Congress's authority under the commerce *clause* is far-reaching, the Supreme Court in a majority decision in *National Federation of Independent Business (NFIB) v. Sebelius* (2012)[30] agreed there is a limit to this authority: by appealing to it, Congress, cannot force people to engage in commercial activities. According to Chief Justice John Roberts, the *commerce clause* does not give Congress the power «to regulate individuals precisely because they are doing nothing».

Although it is uncertain whether this Court decision sets binding precedent, it is important in that it suggests that a federal mandate directed at requiring individuals to administer a vaccine is susceptible to challenge in that this type of mandate can be understood to compel individuals *doing nothing*, thus not engaged in any activity, to engage instead in a commercial activity consisting, in this case, of receiving a specific health care service. On the other hand, the Court noted that a federal mandate that identifies vaccination as a condition for engaging in existing

[30] United States Supreme Court, *National Federation of Independent Business (NFIB) v. Sebelius*, 567 U.S. 519, 2012.

economic activities, such as employment or interstate travel, raises fewer constitutional concerns.

Although vaccination mandates are among the *emunerated powers* that the Constitution confers on Congress, other constitutional provisions may constrain government action. In the context of public health regulations, the main constraints are those based on federalism and the protection of individual rights. For example, the Supreme Court has provided its own interpretation of the *Tenth Amendment* such that it prevents the federal government from commandeering or requiring States or localities to adopt or enforce federal policies. In the context of vaccination, this principle prevents Congress from directly requiring States or localities to pass mandatory vaccination laws or implement federal vaccination laws but does not prevent Congress from using the authority given to it by the *Spending Clause* to incentivize States to do so, as long as the amount offered to them is not so significant as to actually compel them to issue the mandate. Regarding the protection of individual rights, the Courts have recognized that there are few constraints on individual rights descended from the authority to impose mandatory vaccination requirements. As explained above, the Courts have largely dismissed complaints based on the alleged violation of the *due process clause* and the *equal protection clause by* mandatory vaccination requirements in accordance with *Jacobson* and *Zucht*. As with state vaccination requirements, the main area of legal uncertainty regarding federally mandated requirements concerns 'whether' and 'under what circumstances' the state must allow religious exemptions from a vaccination requirement. Undoubtedly, vaccination mandates are a legal tool available to governments to increase COVID-19 vaccine uptake, if Congress determines that the executive branch's exercise of these authorities (including the provisions of the Procurement Act, SSA, and OSH Act) adequately reflects the intent of Congress, Congress itself, within constitutional limits, may intervene to clarify the scope of these statutory provisions with respect to vaccination requirements. To the extent that Congress determines that a federal vaccination mandate may be necessary to address the evolving pandemic, it could also impose a vaccination mandate through other legislative action. Any such legislation, however, must be consistent with the authority the Constitution gives Congress and must respect constitutional *due process and* religious liberty guarantees.

4.2. FDA Emergency Use Authorization and Covid-19 Vaccines.

The process of developing and testing a COVID-19 vaccine is designed to be significantly shorter than the normal timeline required for routine vaccine development. Shortening this process at times can make it difficult to detect potential adverse events that occur only after a medium to long period of time and not immediately. In addition, since the review process needs to be shorter than the typical 6-10 months required to perform a review under a *Biologics License Application* (BLA), FDA scientists, have had much less time to review the safety and efficacy data for COVID-19 vaccines. In light of concerns reported by the public about the safety and efficacy of these rapidly developed vaccines, FDA officials sought to clarify that any candidate vaccine "will be reviewed according to the established legal and regulatory standards for medical products"[31].

In addition, FDA officials assured that the quantity and quality of safety and efficacy data needed to support the issuance of an EUA are the same as those required for the issuance of a BLA.

The level of evidence required by law for the issuance of an EUA is different from that needed for the issuance of a BLA, although both processes involve the submission of safety and efficacy data to the FDA. For a license to be issued under a BLA, it must be demonstrated that the vaccine is safe, and substantial evidence in this regard must be provided. Where a vaccine is first made available under an EUA, substantial evidence of efficacy is not required by law. However, it is necessary that the totality of the available scientific evidence suggests that the vaccine can be effective in preventing COVID-19 and that the known and potential benefits of the vaccine outweigh its known and potential risks.[32]

Prior to the COVID-19 pandemic, all vaccines subject to government mandates were licensed under a Biologics License Application (BLA) through which vaccines are typically introduced into interstate commerce.

Contrary to this practice, as of December 2021, only one COVID-19 vaccine, Pfizer's

[31] «Will be examined according to established legal and regulatory standards for medical products».

[32] Cmp. K. Dekar and A. Dabrowska, *Vaccine Safety in the United States: Overview and Considerations for COVID-19 Vaccines*, in *Congressional Research Service*, 2020.

Comirnaty, has been licensed by the FDA under a BLA. Several other COVID-19 vaccines have been authorized through an *Emergency Use Authorization that* complies with the EUA provision of the FD & C Act (*Federal Food, Drug, and Cosmetic Act*) discussed in previous pages.

Before the FDA authorized Pfizer's COVID-19 vaccine, some commentators raised a single legal issue related to COVID-19 vaccination mandates. Specifically, they argued that Section 564(e)(1) of the EUA prevents entities, including government entities, from mandating COVID-19 vaccines.

Section 564 (e) (1) provides that the Secretary of HHS, when issuing an EUA for a medical product, must impose conditions necessary to protect the public health, including appropriate conditions designed to inform individuals «of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks»[33]. Since each individual must be provided with the *option to accept or refuse*, some commentators have argued that the provision «suggests that mandates are categorically prohibited»[34].

4.3. Some interpretative profiles of section 564(e)(1) of the EUA.

Although no Court has dealt with the interpretation of this provision, the first segment of it would suggest that vaccination requirements are categorically prohibited, since each person must have «the option to accept or refuse». However, a different result would be reached where one assumed that the second part of the provision is functional to qualify the first. Under this interpretation, the provision as a whole could be interpreted to mean that although a person has the option to refuse an EUA product, his or her refusal can always have «consequences». It follows that the legality of a vaccine mandate depends on the meaning one decides to attach to the term «consequences»: a meaning that will have to be reconstructed in light of the overall context of the statute. According to a first interpretation, the term «consequences» would refer to health consequences, since the entire section merely details the conditions of authorization

[33] Article 564(e)(1), *Emergency Use Authorization* (EUA): «[...] of the possibility of accepting or refusing to administer the product, of the possible consequences of refusing to administer the product, and of the alternatives to the product available and their benefits and risks».
[34] *Id*., «[...] suggests that warrants are completely prohibited».

of EUA medical products, including the need to assess and disclose known risks and benefits and the need to monitor and report adverse events while making no reference to obligations or waivers of consent. According to another interpretation, the phrase «consequences» should be understood in a broader sense such that it encompasses any adverse action capable of occurring in the face of vaccine refusal: «consequences» could then include both health risks and adverse consequences related to employment, access to education, use of public transportation, ability to store in a store, board an airplane, and more. In practice, such a broad interpretation would also open the possibility for public and private entities to institute vaccine requirements and would require that people be informed, before deciding whether or not to accept an EUA medical product, of all possible health and non-health consequences of their choice. However, it seems unlikely that Congress intended to impose this broad disclosure requirement on health care providers who administer products under an EUA. Moreover, should the second part of the provision be allowed to give access to vaccine obligations, it would at the same time empty the option introduced in the first part («option to accept or refuse») of meaning. But this, according to the canons of statutory interpretation is not possible: the provisions of a statute must always be interpreted to be mutually consistent and compatible. In sum, the interpretation that the mandatory disclosures mentioned in Section 564(e)(1) are limited to the health risks of rejecting an EUA product during a public health emergency must be preferred; a choice also supported by the legislative history of the bill that later led to the introduction of the EUA. The context in which the EUA pathway was first created and used supports the interpretation that vaccine mandates should be considered excluded from the law. The EUA protocol was introduced as part of a challenge[35] brought against the Department of Defense's (DoD) *Anthrax Vaccine Immunization Program (*AVIP). Anthrax, also called *anthrax* (from the black color of the skin lesions that develop in victims of this infection), is an acute infection caused by the bacterium *Bacillus anthracis*. Of anthrax, there are several forms that differ in spread and danger and are classified according to the route of entry: *cutaneous*, the most frequent form; *pulmonary*, rare; and *gastrointestinal*, very rare. The vaccine in question had been approved by the FDA as prophylaxis for cutaneous anthrax, but the Department of Defense had also sought to impose it among military service members as a form of protection against pulmonary anthrax. This decision had then qualified as off-label use of the vaccine, and service members had therefore brought a lawsuit to stop its administration. Since the AVIP program involved the off-

[35] U.S. Court of Appeals, District of Columbia Circuit, *Rempfer v. Sharfstein*, 583 F.3d 860, 2009.

label use of a vaccine for military personnel, the law required everyone's informed consent or a presidential waiver of informed consent. From the introduction of AVIP in 1997 to the time the lawsuit was briefed in 2003, neither President Clinton nor President Bush had issued such a waiver. On December 22, 2003[36], a Federal Court halted AVIP because of DoD's failure to comply with informed consent requirements. Eight days later, the FDA stepped in to expand the product label to include prevention from pulmonary anthrax. Service members challenged FDA's decision on procedural grounds, arguing that the agency had not followed its own regulations regarding label changes.

When it became clear that the Court would rule against the FDA, the *Project BioShield Act was* created[37]. In October 2004, a District Court had ruled in favor of military service members by overturning the FDA decision, but by then the bill had passed and President Bush had signed it into law. In December 2004, the Department of Defense, based on the newly introduced EUA program, had then submitted an EUA for anthrax vaccine, and within weeks the FDA had then issued an EUA that included pulmonary anthrax prevention. Subsequently, the DOD resumed anthrax vaccinations, but only on a voluntary basis. Vaccinations remained voluntary until December 19, 2005, when the FDA approved a label expansion for the anthrax vaccine, and then DoD resumed mandatory vaccinations for some military personnel. This series of events lends credence to the theory that vaccine mandates should not be considered covered by EUA provisions.

4.4. Jurisprudential pronouncements under the EUA.

After some state and private agencies began mandating COVID-19 vaccinations in 2021, some plaintiffs filed appeals complaining that COVID-19 vaccination requirements violated Section 564(e) of the FD & C Act. Courts have generally rejected this claim, holding that Section 564

[36] U.S. District Court, District of Colymbia, *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 2004.

[37] The *Project Bioshield Act was* passed by the U.S. Congress in 2004 and provided for the allocation of $5 billion for the purchase of vaccines that would be used in the event of a bioterrorist attack. It was a 10-year program aimed at acquiring medical countermeasures adverse to biological, chemical, radiological and nuclear agents for civilian use. The key element of the law was the recognized ability to proceed with the storage and distribution of vaccines that had not been tested for safety or efficacy in humans because of ethical concerns. The efficacy of such agents cannot be tested directly in humans without also exposing them to the relevant chemical, biological or radioactive threat the tests were being conducted on the basis of the FDA Animal Rule used to test for full animal efficacy. The *Project BioShield Act of 2004* among other provisions, established the comprehensive Emergency Use Authorization program.

(e) only imposes an informed consent requirement on medical providers who administer vaccines for the purpose of informing potential recipients of the related risks and their right to refuse administration. Accordingly, Courts have generally concluded that the provision does not prohibit various entities from requiring individuals, duly informed by their medical providers, to be vaccinated. After the FDA fully licensed the *Comirnaty* vaccine, legal challenges to COVID19 vaccination requirements based on the EUA statute are largely moot. In *Valdez v. Grisham* (2022)[38] the Tenth Circuit Court of Appeals upheld a District Court decision that kept in place New Mexico's vaccination requirements for health care workers. A New Mexico nurse had challenged a state public health order requiring health care workers in hospitals and congregate care facilities to vaccinate against COVID-19. The order allowed exemptions only for medical and religious reasons. The nurse asserted that the public health order violated the *Equal Protection Clause* of the U.S. Constitution and the substantive principles of the *Due Process of Law Clause*, and therefore requested that the order be blocked. The District Court approached had refused to block the order, however, since the nurse had not shown that the vaccination could cause him irreparable harm and that the public interest outweighed the request to block the vaccination requirements. The Tenth Circuit had then upheld this decision finding that the lower Court had not abused its discretion in holding that the nurse would not succeed on the merits of his claims. The case *Bridges v. Houston Methodist Hospital* (2021)[39] concerns a policy announced on April 1st, 2021, by Houston Methodist Hospital that required employees to be vaccinated against Covid-19 by June 7, 2021. Jennifer Bridges and 116 other employees had sued the hospital to block the injection requirement, claiming that the hospital was in fact illegally forcing its employees to be injected with one of the available vaccines, since layoffs were being contemplated as an alternative.

The federal Court had rejected the arguments, however, asserting that Texas law only protected employees from being fired for refusing to commit criminal acts mind undergoing the COVID-19 vaccination did not constitute an illegal act. Moreover, the hospital was not forcing employees to receive the vaccine: employees could have chosen to refuse. Furthermore, with respect to the language used in the *Federal Food, Drug, and Cosmetic Act*, the Court held that Section 546(e) «confers certain powers and responsibilities to the Secretary of Health and

[38] U.S. Court of Appeals, Tenth Circuit, *Valdez v. Grisham*, n. 21-2105, 2022.
[39] U.S. District Court, Southern District of Texas, *Bridges v. Houston Methodist Hospital*, 2021.

Human Services in an emergency»[40], such that «it neither expands nor restricts the responsibilities of private employers»[41]. Concluding that «section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements»[42].

6. Conclusions.

This paper concludes with a quick reflection on the renewed interest sparked by the recent pandemic with respect to the importance of vaccine prevention for the lives of various state systems and individuals.

The pandemic caught most jurisdictions unprepared with respect to the type of measures to be taken, the ability of their health systems to handle the emergency, and the suitability of their regulations and legislative processes to provide rapid and adequate responses. In the field of pharmacology, never would one have imagined that despite the great advances made by scientific research we would find ourselves unprepared to deal with a new infectious threat, with a severe shortage of specific drug therapies. A major lag in anti-infectious drug research and development processes compared to other areas of medicine emerged, and the consequent need for increased investment to fund the fight against infectious diseases.

The pandemic has brought to light worrying skepticism harbored by the population with respect to the reliability and unavoidability of medicine and vaccine science, highlighting an alarming indifference and lack of confidence in science and progress: it has been forgotten that evidence to support clinical decisions is a key element in making choices.

In addition, as far as the world of regulation is concerned, the pandemic was able to bring out a great elasticity of regulatory agencies: the strong pressure on them encouraged a streamlining of bureaucratic procedures, demonstrating that it is possible to manage exceptional situations without losing sight of the safety and efficacy of medicines. During the Covid-19 pandemic, new vaccines and drugs were approved, new regulatory innovations were witnessed, and

[40] *Id.*, «[...] grants certain powers and responsibilities to the Secretary of Health and Human Services in the event of an emergency».
[41] *Id.*, «[...] neither expand nor limit the responsibilities of private employers».
[42] *Id.*, «Section 564 specifies only that certain information must be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements».

pharmacosurveillance activity was particularly active and in the public spotlight: the speed with which vaccines and new drugs could be developed and approved demonstrated that, using the criteria of scientificity and safeguarding the safety of citizens, research is capable of changing the course of events on a global scale. The pandemic revealed an undoubted inadequacy of public health with respect to digital evolution by highlighting how new technologies, artificial intelligence and big data represent important opportunities not only in the fight against the current pandemic, but also against future threats to public health. There is a need to invest in the digitization of healthcare to increase communication between professionals and manage all patient clinical data in a more homogeneous and coordinated way.

Another mistake made during the pandemic undoubtedly involved the dissemination of information: the advance of the virus brought with it a tsunami of misinformation, which created distrust and concern among citizens. This has led to difficulties in disentangling information about the efficacy and safety of vaccines, both of which have been repeatedly questioned. Thus, the importance of helping citizens understand that they should avail themselves only of up-to-date information from authoritative and reliable sources emerged. Another sore point was insufficient investment: the Covid-19 pandemic underscored the importance of strengthening the Health System: the lack of processes to digitize administrative and clinical data made clinical and therapeutic management of patients complex and difficult. Placing faith in the adage that every cloud has a silver lining, we must observe that although in the reality of these last few years negative feelings, problems and difficulties have prevailed; the experience that has concerned us has been useful in making the various orders responsible, at least in power, with respect to the type of initiatives and interventions to be undertaken in the future not only to prevent and cope with calamities of this kind, but also to improve the well-being and lifestyle of its citizens. The experience was useful in emphasizing the importance that investments in scientific research and the health care system have for the well-being and growth of the future population; in reiterating the centrality and relevance that education and information have for the formation of citizens capable of making informed and sustainable choices; and in clarifying that fanaticism and idolatry lead to nothing but the triumph of misinformation.

Abstract: The work here presented describes the approach of some Courts of federated States and of the Supreme Courts about the exceptions to mandatory vaccine requirements in order to

contrast the Covid-19 pandemic. About the tools of comparative law, analyzing the different approach of the state's Court we can define a paradigm used in most of the western State. Moreover, due to the scarcity of time to evaluate the decisions taken by the executive bodies we can also trace a model of reaction to crisis of the constitutional State. In this paper are analyzed and discussed the main jurisprudence cases of Michigan, Maine and the State of New York. In the latter part the decision taken by the executive branch are analyzed, specially that one related to the moratory on evictions. This paper concludes with a quick reflection on the renewed interest sparked by the recent pandemic with respect to the importance of vaccine prevention for the lives of various state systems and individuals.

Abstract: Il lavoro qui presentato descrive l'approccio di alcuni Tribunali degli Stati federati e delle Corti Supreme in merito alle eccezioni all'obbligo di vaccino per contrastare la pandemia di Covid-19. Con gli strumenti del diritto comparato, analizzando i diversi approcci delle Corti statali si può definire un paradigma utilizzato nella maggior parte degli Stati occidentali. Inoltre, data la scarsità di tempo per valutare le decisioni prese dagli organi esecutivi, possiamo anche tracciare un modello di reazione alla crisi dello Stato costituzionale. In questo lavoro vengono analizzati e discussi i principali casi giurisprudenziali del Michigan, del Maine e dello Stato di New York. In quest'ultima parte vengono analizzate le decisioni prese dal ramo esecutivo, in particolare quella relativa alla moratoria sugli sfratti. Il documento si conclude con una rapida riflessione sul rinnovato interesse suscitato dalla recente pandemia rispetto all'importanza della prevenzione vaccinale per la vita dei vari sistemi statali e degli individui.

Key words: vaccine – covid-19 – vaccine requirements – vaccine exceptions – health workers.

Key words: vaccino – covid-19 – requisiti vaccinali – eccezioni vaccinali – salute dei lavoratori.