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HAND DELIVERED

September 2, 2021

Michele Lumbert, Clerk
Kennebec County Superior Court
Capitol Judicial Center
1 Court Street, Suite 101
Augusta, ME 04330

Dear Ms. Lumbert:

Please find enclosed herewith a Complaint (with Exhibits) in the matter of *Coalition for Healthcare Workers Against Medical Mandates, et al. v. Jeanne M. Lambrew, Commisioner of the Maine Department of Health and Human Services, and Nirav T. Shah, Director of the Maine Center for Disease Control and Prevention.*

Because of the important public policy question involved and the fact that September 17, 2021 is a critical date and is only two weeks away, I ask that this matter be brought to the Judge's attention as soon as possible.

Also attached are the following:

(1) A completed Civil Summary Sheet;
(2) Motion for Temporary Restraining Order and/or Injunctive Relief (with attachments);
(3) Motion for Exemption from Alternative Dispute Resolution;
(2) Draft Order; and
(3) My check in the amount of $175.00.

Sincerely,

David E. Bauer, Esq. (Maine Bar. No. 3609)

STATE OF MAINE
KENNEBEC, ss.

SUPERIOR COURT
CIVIL ACTION
DOCKET NO. _____

COALITION FOR HEALTHCARE WORKERS AGAINST MEDICAL MANDATES; MAINE STANDS UP; MAINERS FOR HEALTH AND PARENTAL RIGHTS; HEALTH CHOICE MAINE; AMANDA BROOKS; COREY BONNEVIE; REBEKAH LIBBY; and JANE and JOHN DOES, 1-100,	)
Plaintiffs	)
v.	)
JEANNE M. LAMBREW, in her official capacity as the Commissioner of the Maine Department of Health and Human Services,	)
and	)
NIRAV D. SHAH, in his official capacity as the Director of the Maine Center for Disease Control and Prevention,	)
Defendants	)

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs, by and through the undersigned attorneys, hereby file this Complaint for Declaratory and Injunctive Relief against Defendant Jeanne M. Lambrew, in her official capacity as the Commissioner of the Maine Department of Health and Human Services (the "Department"), and Nirav D. Shah, in his official capacity as the Director of the Maine Center for Disease Control and Prevention (the "Maine CDC"), and allege as follows:

NATURE OF THE CASE

1. This is an action to declare as illegal and unconstitutional 10-144 CMR Ch. 264, *Immunization Requirements for Healthcare Workers*, rule promulgated by the Department and effective August 12, 2021 (as further defined herein, the "Rule"). (Exh. A).

2. The Rule mandates that Maine's healthcare workforce be injected with one of the highly experimental COVID-19 "vaccines"[1] that have been released by the federal Food and Drug Administration ("FDA") pursuant to Emergency Use Authorization ("EUA")[2] granted under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq*. Maine's healthcare workers must be "fully vaccinated" by October 1, 2021. This deadline forces them to receive their injections no later than September 17, 2021. Healthcare workers that refuse to be injected must be excluded from the workplace, which will result in the termination of their employment, loss of income, housing and food insecurity, emotional distress and other consequential harm.

3. The COVID-19 vaccines currently being administered in Maine and across the United States and the world ***are all part of ongoing clinical trials***. Anyone who gets one of these vaccines is a test subject -- or, in the parlance of the scientific literature, a "participant" in the clinical trial.

4. Neither the Plaintiffs nor any other healthcare workers in Maine should be required to be *unwilling* participants in such a trial. Neither the Department nor Maine healthcare providers

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[1] Plaintiffs reject the application of the term "vaccine? to these medical interventions. They are more accurately described, as their manufacturers as described them, as a form of gene therapy.

[2] Pfizer-BioNTech COVID-19 Vaccine, EUA issued December 11, 2020 (*see* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine); Moderna COVID-19 Vaccine, EUA issued December 18, 2020 (*see* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine); Johnson & Johnson (Janssen) COVID-19 Vaccine issued February 27, 2021 (*see* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine)

should be permitted to make this decision for healthcare workers by requiring them to participate in a medical experiment in order to maintain their jobs. If the Rule is allowed to take effect, Maine's healthcare workers will face a terrible dilemma: take an experimental vaccine and risk injury and death, or forfeit their jobs and careers. And these individuals may well not even be able to move elsewhere to be gainfully employed in the fields to which they are dedicated and in preparing for which they have invested so many resources and so much time, because they face the prospect of similar mandates being imposed in other states.

5. The Rule violates the Maine Administrative Procedure Act, 5 M.R.S.A. §§ 8001 *et seq.* because it is a "major substantive rule" passed as an "emergency routine technical" rule, exceeds the Department's rulemaking authority under 22 M.R.S. § 802(2), and in other respects; but even if this were not true, the Rule is arbitrary, capricious, an abuse of discretion and/or otherwise not in accordance with law. The Rule violates the obligation to procure voluntary, informed consent for medical intervention, and the Plaintiffs' right to refuse unwanted medical treatment, as guaranteed by both the Fourteenth Amendment to the U.S. Constitution and the Maine Constitution. Finally, the Rule violates the requirement in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq*. that individuals to whom the EUA medical products are administered must have the right to accept or refuse them.

6. Accordingly, Plaintiffs seek the declaratory, preliminary and permanent injunctive relief requested herein.

JURISDICTION, VENUE AND STANDING

7. This Court has jurisdiction under the Maine Administrative Procedure Act because the Rule is final agency action affecting the rights, duties and privileges of the individual Plaintiffs and of the association Plaintiffs' membership. 5 M.R.S. § 8002(4); 5 M.R.S. § 11001(1).

8. This Court has jurisdiction to determine the "rights, status and other legal relations" among the parties under the Maine Uniform Declaratory Judgments Act, 14 M.R.S. § 5953.

9. This Court has jurisdiction to grant equitable relief under 14 M.R.S. § 6051(13).

10. This Court has concurrent jurisdiction with the federal courts to adjudicate Plaintiffs' claims arising under the U.S. Constitution. *Thiboutot v. State*, 405 A.2d 230, 235 (Me. 1975).

11. Venue is proper in this Court because the Defendant maintain headquarters in Kennebec County.

12. The association Plaintiffs have standing since their membership includes Maine healthcare workers who satisfy the definition of "employee" contained in the Rule, who are subject to its provisions, whose employment has been or will be terminated as a result of their unwillingness to submit to injection with the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine or Johnson & Johnson COVID-19 Vaccine, and who are suffering other immediate or threatened harm as a result of the challenged action. *DCCC and DSCC v. Me.*, 2020 Me. Super. LEXS 15 at *10-13.

13. The individual Plaintiffs have standing because they are healthcare workers who satisfy the definition of "employee" contained in the Rule, who are subject to its provisions, whose employment has been or will be terminated as a result of their unwillingness to submit to injection with the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine or Johnson & Johnson COVID-19 Vaccine, and who are suffering other immediate or threatened harm as a result of the challenged action.

PARTIES

Plaintiffs

14. Plaintiffs COALITION FOR HEALTHCARE WORKERS AGAINST MEDICAL MANDATES, MAINE STANDS UP, MAINERS FOR HEALTH AND PARENTALRIGHTS, and HEALTH CHOICE MAINE are associations, the membership of which is comprised, wholly or partly, of Maine healthcare workers who satisfy the definition of "employee" contained in the Rule, and who are subject to its provisions.

15. Emily Nixon, RN leads the Coalition for Healthcare Workers Against Medical Mandates (Nixon Decl., Exh. C, ¶ 5). The Coalition has a membership of 2,400 healthcare workers who meet the definition of "employee" in the Emergency Rule. Ms. Nixon states (¶ 5):

> *I have polled the [2,400] members [of the Coalition for Healthcare Workers Against Medical Mandates], and virtually all of them will refuse injection with any COVID-19 vaccine, and have been told they will be fired if they do not get injected with this experimental vaccine. They feel pressured, harassed and hostility coming from their employer. They do not agree or consent to being terminated. They will not resign. They are all facing termination of their employment, loss of income, housing insecurity, food insecurity, emotional distress and other harms.*

16. Plaintiff AMANDA BROOKS is a Physician Assistant employed by St. Joseph's Hospital, and a resident of Bangor, Maine. She is a member of Plaintiff Mainers for Health and Parental Rights. (Brooks Decl., Exh. D, ¶¶ 1-2). She satisfies the definition of "employee" contained in the Rule, is subject to its provisions, her employment has been or will be terminated involuntarily as a result of her unwillingness to submit to injection with the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine or Johnson & Johnson Vaccine, and is suffering other immediate or threatened harm as a result of the challenged action. Ms. Brooks states (¶ 3):

St. Joseph's Hospital has stated in Frequently Asked Questions posted on its website, that employees who are not vaccinated by the deadlines established by the Emergency Rule will be terminated. The FAQ states: "After 30 days of non-compliance, the employee will be deemed to have resigned from employment."

17. Plaintiff COREY BONNEVIE is an Emergency Management Technician-Paramedic employed by MaineHealth, and a resident of Rangeley, Maine. He is a member of Maine Stands Up and the Coalition for Healthcare Workers Against Medical Mandates. (Bonnevie Decl., Exh. E, ¶¶ 1-2). He satisfies the definition of "employee" contained in the Rule, is subject to its provisions, his employment has been or will be terminated involuntarily as a result of his unwillingness to submit to injection with the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine or Johnson & Johnson Vaccine, and he is suffering other immediate or threatened harm as a result of the challenged action. Mr. Bonnevie states (¶ 3):

Ms. Judith M. West, Chief Human Resources Officer at MaineHealth, has informed me and all healthcare workers employed by MaineHealth that unless we comply with the Emergency Rule and accept the COVID-19 injections by the deadline stated in the Emergency Rule, MaineHealth will terminate my employment. Her electronic letter [...] states: "If you are still non-compliant on October 1, your employment will be terminated.

18. Plaintiff REBEKAH LIBBY is an Administrator at Berwick Estates, an assisted living facility, and is employed by New Communities, Inc. She is a resident of Berwick, Maine. She is a member of Mainers for Health and Parental Rights, Health Choice Maine and the Coalition for Healthcare Workers Against Medical Mandates. (Libby Decl., Exh. F, ¶¶ 1-2). She satisfies the definition of "employee" contained in the Rule, is subject to its provisions, her employment has been or will be terminated involuntarily as a result of her unwillingness to submit to injection with the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine or Johnson & Johnson Vaccine, and is suffering other immediate or threatened harm as a result of the challenged action. Ms. Libby states (¶ 3):

I am opposed to the new Emergency Rule, Immunization Requirements for Healthcare Workers, 10-144 Code of Maine Rules, Chapter 264 effective August 12, 2021 [ ]. My employer has announced that it will enforce the Emergency Rule in our workplace. If I am excluded physically from my workplace, I cannot perform my job. I will not consent to being injected with the COVID-19 vaccines.

19. Plaintiffs JANE AND JOHN DOES, 1-100, are Maine residents who satisfy the definition of "employee" contained in the Rule, are subject to its provisions, whose employment has been or will be terminated involuntarily as a result of their unwillingness to submit to injection with the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine or Johnson & Johnson Vaccine, and who are suffering other immediate or threatened harm as a result of the challenged action.

Defendants

20. Defendant JEANNE M. LAMBREW is the Commissioner of the Maine Department of Health and Human Services, and is being sued in her official capacity.

21. Defendant NIRAV D. SHAH is the Director of the Maine Center for Disease Control and Prevention, and is being sued in his official capacity.

STATEMENT OF FACTS AND LAW

Defendant's Rulemaking

22. On March 13, 2020, the President declared the ongoing Coronavirus Disease 2019 (COVID-19) pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, tribes, territories, and the District of Columbia pursuant to section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-5207 (the "Stafford Act").

23. On March 15, 2020, Governor Janet T. Mills proclaimed a "State of Civil Emergency" to authorize the use of emergency powers and expedite the State's response to the spread in Maine of the SARS-CoV-2 virus, which can cause the disease COVID-19. In her proclamation, the Governor also declared an "Extreme Public Health Emergency" pursuant to 22 M.R.S. § 802(2-A). The Governor renewed and amended the "State of Civil Emergency" many times, before it finally expired by order of the Governor as of midnight on June 30, 2021. The "Extreme Public Health Emergency" proclaimed by the Governor expired at the same time.

24. On June 30, 2021, the same day that the Governor's Proclamation of a "State of Civil Emergency" expired, the Defendant issued a declaration pursuant to 22 M.R.S. § 802(2) stating that a "health emergency" exists in the State of Maine "that poses a threat to the health and safety of Maine residents". (DHHS's COVID-19 Public Health Emergency Declaration, Exh. B). The Defendant's Declaration provides that it "shall remain in effect through the duration of the Public Health Emergency as declared by the Secretary of the U.S. Department of Health and Human Services". Id.

25. The federal government undertook "Operation Warp Speed" during 2020, and as a result, the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine or Johnson & Johnson COVID-19 Vaccine were developed and released for use in the general population more swiftly than any other vaccines in our nation's history. Further, this is only the second time in our history that a vaccine has been released pursuant to an EUA, the first being the Anthrax vaccine, which was released pursuant to an EUA for use in the U.S armed forces.

26. These COVID-19 vaccines have collectively been administered to millions of individuals in the United States, with 1,647,508 doses having been administered to individuals in the State of Maine as of September 1, 2021.

27. On August 12, 2021, the Department submitted documents to the office of the Secretary of State intended to formally promulgate amendments to 10-144 C.M.R. Ch. 264. The amended Chapter 264 was designated as an "Emergency Routine Technical Rule" effective August 12, 2021.

28. The amendments represent the exercise of significant agency discretion. They add COVID-19 to the list of diseases for which every Designated Health Care Facility in the State must require of all of its employees to present "proof of immunization or documented immunity". The amendments also provide that each Dental Health Practice and each Emergency Medical Services ("EMS") Organization in the State must also require a Certificate of Immunization against COVID-19 of all employees. The Rule includes a definition of "Designated Healthcare Facility" that carried over from the prior version of 10-144 C.M.R. Ch. 264; it includes licensed nursing facilities, residential care facilities, intermediate care facilities, hospitals, and home health agencies licensed by the Department. The amendments add definitions for the new terms "Dental Health Practice" and "Emergency Medical Services (EMS) Organization". The latter term includes EMS ground ambulance services, non-transporting EMS services, air ambulance services, EMS training centers, and emergency medical dispatch centers.

29. Some Maine employers defined as "Designated Healthcare Facilities" in the Rule, including but not necessarily limited to dental practices, have 20 or fewer employees and are therefore "small businesses" as that term is defined in 5 M.R.S. § 8052(5-A) (2021).

30. The Rule provides that with respect to the mandate to provide proof of immunization or documented immunity against COVID-19 (the "new mandate"), all affected employees must have been injected with their final dose of the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine or Johnson & Johnson COVID-19 Vaccine by September 17, 2021. 10-144 C.M.R. § 5(A)(7) (2021).

31. The Rule provides that a medical exemption from the new mandate is available to an employee who is exempt pursuant to 22 M.R.S. § 802(4-B), but it does not provide for an exemption on religious or philosophical grounds.[3]

32. The amendments can reasonably be expected to impose significant burdens on the public. The Rule defines "employee" to include "any person who performs any service for wages or other remuneration for a Designated Healthcare Facility, EMS Organization or Dental Health Practice" including independent contractors. 10-144 C.M.R. § 1(G). The United States Bureau of Labor Statistics estimates that 41,040 individuals are employed in Maine in jobs categorized as "healthcare practitioners and technical occupations", while 34,540 individuals are employed in Maine in jobs categorized as "healthcare support occupations", for a total of 75,580.

33. The Maine Department of Labor ("DOL"), Center for Workforce Research and Information, estimates that in calendar year 2018 (the most recent year for which this data is posted on the DOL's website), 84,842 individuals were employed in Maine in the field of health care.

34. Upon information and belief, a fierce public debate has been raging for months in the State of Maine, across the United States, and internationally on the questions of governmental responses to the pandemic in general,[4] and the safety and efficacy of COVID-19 vaccines in particular. The debate now taking place in the State of Maine with regard to COVID-related public policies has included to the new mandate imposed by the Rule.

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[3] 10-144 C.M.R. Chapter 264 formerly allowed for such an exemption, but the statutory authority for the exemption, 22 M.R.S. §802(4-B)(B), was repealed by PL 2019, c. 154, §9.

[4] *See, e.g.*, the Great Barrington Declaration, authored by Dr. Martin Kulldorff, a biostatistician and epidemiologist and a professor of medicine at Harvard University, Dr. Sunetra Gupta, an epidemiologist and professor at Oxford University, and Dr. Jay Bhattacharya, a professor at Stanford University Medical School, available at https://gbdeclaration.org (last visited August 25, 2021). The website banner provides this summary: "As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection." The Declaration has been signed by dozens of academic physicians and scientists from around the world.

35. The Rule imposes serious burdens on units of local government, notably local fire departments. On August 17, 2021, the Maine Fire Chiefs' Association publicly expressed its strong opposition to the Rule and the new mandate contained therein. It warned: "Enforcement of a COVID-19 Vaccination mandate on Maine's EMS agencies, both private and fire based, will have far reaching and long-lasting effects on the ability of EMS agencies to provide critical public safety services to the citizens of our communities." (Nixon Decl., Exh. C, ¶ 8, and Ex. 3 thereof).

36. The new mandate in the Rule also imposes serious burdens on broad segments of the public. First, it burdens tens of thousands of Maine residents who are now employed in the healthcare sector, and thousands more who are in the process of becoming credentialed, or who are considering employment in the sector. Thousands of Maine healthcare workers refuse to be injected with these experimental COVID-19 vaccines, and as a consequence are facing termination, unemployment, housing insecurity, food insecurity and emotional distress, in many cases after years of dedicated service, and have conducted peaceful protests in numerous cities.[5]

37. Secondly, the new mandate burdens the Maine businesses and organizations that employ healthcare workers in order to provide healthcare services to the public, placing the healthcare infrastructure the Defendants claim to want to protect under profound strain. The former Director of Maine CDC, now President and CEO of Androscoggin Home Healthcare and Hospice, warned in a letter dated July 7, 2021 that even the removal of a "religious or philosophical" exemption from the *pre-existing* vaccination mandates in the Rule was causing added problems for a healthcare delivery system in Maine that was already struggling under many pressures, including a diminishing workforce:

> *[H]ealthcare facilities will absolutely lose existing personnel as a result of this mandate. ...The nursing shortage in Maine and the United States is very real and profound. Frankly,*

[5] *See, e.g.*, Nixon Decl., Exh. C, ¶ 5; A. Brooks Decl., Exh. D, ¶¶ 3-5 and Ex. 1 thereof; C. Bonnevie Decl., Exh. E, ¶¶ 4-5 and Ex. 1 thereof; R. Libby Decl., Exh. F, ¶¶ 4-5, 8-9.

> *we are rapidly approaching a crisis. ...Many Maine hospitals cannot fully staff their licensed beds for lack of staffing. Maine long-term care providers are only able to staff roughly 75% of their capacity based on workforce shortages. The ramifications are ample for Maine citizens. ...**While the vast majority of heath care workers in Maine have been vaccinated against COVID-19, those who have not are tensely monitoring for mandates and preparing employment strategies accordingly.** The untimely requirement for influenza vaccination is adding fuel to the fires of the more broad vaccination requirement discussions, which I fear will have a contrary result to what is intended with this regulation.*[6] (emphasis added)

38. The Board of Directors of the Maine Dental Association has stated that it was "misinformed" about the new mandate "and now fully recognizes how this mandate will negatively impact the ability of our colleagues across the state to provide safe and timely oral health care to our patients."[7]

39. The Maine Association of Community Service Providers, Maine Council on Aging, Alliance for Addiction and Mental Health Services, LeadingAge and the Behavioral Health Community Collaborative are opposed to the new mandate, because they have good reason to believe that they will need to "find replacement staff for those who will leave, and to create contingency plans for moving residents from facilities that need to close due to inadequate staffing."[8]

40. Finally, the new mandate burdens the consumers of healthcare services. For example, Plaintiff Bonnevie, a Paramedic employed by MaineHealth, states:

> *As a Northstar paramedic I can personally confirm the fact that we are regularly unable to meet acceptable response time standards. Frequently, we are dispatched to locations with patients who are over and hour and a half away. This is a direct result of staffing issues from a lack of workforce leaving ambulances unstaffed. The vaccine mandate, resulting in the termination of at least 10 of the providers within my organization will no doubt amplify the severity of the aforementioned operational concerns, and result in a reduction in the level of care being provided on each available ambulance, reducing advanced life support*

[6] Nixon Decl., Exh. C, ¶ 7, and Ex. 2 thereof.
[7] Nixon Decl., Exh. C, ¶ 9, and Ex. 4 thereof.
[8] Nixon Decl., Exh. C, ¶ 10, and Ex. 5 thereof.

care units, to basic medical taxis. And will result in a reduction of medical response and care for the members of the public whom we are intended to serve.[9]

The COVID-19 Vaccines Currently in Use in the U.S.

The Pfizer-BioNTech Vaccine and the BioNTech "Comirnaty" Vaccine

41. On December 11, 2020, the FDA issued an EUA for the Pfizer-BioNTech COVID-19 Vaccine for administration to individuals 16 years of age and older. (The statutory and regulatory framework surrounding the EUA process is described in detail beginning with Paragraph 64 below.)

42. The FDA's letter of authorization was revised and reissued on December 23, 2020, February 25, 2021, May 10, 2021, and August 12, 2021. The May 10, 2021 revision extended the EUA to individuals 12 through 15 years of age. The August 12, 2021 revision authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine in certain limited circumstances (individuals 12 years of age or older who have had an organ transplant or who are otherwise immunocompromised).

43. It has been widely reported that on August 23, 2021, the FDA formally approved the Pfizer-BioNTech COVID-19 Vaccine, with news media outlets reporting or at least implying that the Pfizer-BioNTech COVID-19 Vaccine would therefore no longer be administered under the emergency use provisions of federal law. The reality is not so straightforward. In fact, in a bold display of regulatory legerdemain, the FDA took two separate but related actions on August 23.[10] First, it approved the biologics license application submitted by BioNTech Manufacturing GmbH ("BioNTech"), headquartered in Mainz, Federal Republic of Germany. By this action BioNTech

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[9] Bonnevie Decl., Exh. E, ¶ 6.

[10] *See* FDA letter to Pfizer, Inc. dated August 23, 2021, from RADM Denise M. Hinton, Chief Scientist, available at https://fda.gov/media/150386/download (last visited August 27, 2021); and FDA letter to BioNTech Manufacturing GmbH dated August 23, 2021, from Mary A. Malarkey and Marion F. Gruber, PhD, available at https://www.fda.gov/media/151710/download (last visited August 27, 2021).

obtained the FDA's approval for the use in the U.S. of the company's "Comirnaty" COVID-19 vaccine in individuals 16 years of age and older.

44. Second, the FDA ***reissued and revised*** its most recent prior EUA for the Pfizer-BioNTech COVID-19 Vaccine, explicitly stating that the EUA for the Pfizer-BioNTech COVID-19 Vaccine ***remains in effect***. Moreover, the FDA stated that *even the Comirnaty vaccine* is also now covered by the EUA for certain uses not covered by the new license granted to BioNTech -- namely, when it is administered to individuals aged 12 through 15.[11]

45. As the FDA's August 23 letter to Pfizer clearly states, "the licensed vaccine [Comirnaty] has the same formulation as the EUA-authorized vaccine [the Pfizer vaccine] and the products can be used interchangeably…." In other words, while they are legally distinct and carry different labels, they are the same product with the same ingredients, administered in the same way and intended for the same purpose.[12]

46. Indeed, the FDA's August 23 letter to Pfizer noted that the FDA "Fact Sheet for Healthcare Providers Administering Vaccine" and "Fact Sheet for Recipients and Caregivers" have now been revised so that they reference both the Pfizer vaccine and the Comirnaty vaccine and apply to both products interchangeably.[13] The "Fact Sheet for Recipients and Caregivers" states: "You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2."

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[11] Or to provide a third dose to immunocompromised individuals.

[12] The FDA issued a Press Release on August 23 stating in part as follows: "The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, ***and will now be marketed as Comirnaty*** (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age…" (emphasis added).

[13] The FDA letter notes that the Fact Sheet for Healthcare Providers Administering Vaccine was also revised to update language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers had already been revised for this purpose coterminous with the EUA reissuance and revision of June 25, 2021; the current Fact Sheet is available at https://www.fda.gov/media/144414/download (last visited August 29, 2021).

47. Finally, buried in a footnote on Page 5 of the FDA's letter to Pfizer, is this critical sentence: "**Although COMIRNATY…is [now] approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population….**" (emphasis added).

48. It is thus apparent that the FDA's actions of August 23 were not what the public has been led to believe.

49. Some observers have concluded that the FDA's actions of August 23 represent a cynical ploy designed to allow the federal government to broadcast the fact that a COVID-19 vaccine has been fully approved in order to drive increased vaccination rates and the imposition of vaccine mandates.

50. Upon information and belief, no evidence has been made available to the public by FDA or anyone else that ***any*** doses of the Comirnaty vaccine are currently available for administration in Maine or indeed anywhere else in the United States.

51. In light of the above, it is reasonable to believe, and we must assume, that it is probable that at least for the time being the Pfizer-BioNTech COVID-19 Vaccine will continue to be administered in Maine -- under an EUA, rather than as a fully approved or licensed biologic -- and that the Comirnaty product will *not* be available for administration in this State.

52. As of the date of this filing, neither the State of Maine official online portal nor the Maine CDC website makes any mention of the Comirnaty vaccine.[14]

53. Presently, the estimated study completion date for the ongoing "Phase 1/2/3" clinical trial for the Pfizer-BioNTech COVID-19 Vaccine, formally entitled "Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in

[14] But interestingly, searches conducted on both websites on August 26 for the term "Comirnaty" did retrieve multiple pages prominently featuring the term "community".

Healthy Individuals", is ***May 2, 2023***[15]. These facts are not affected by the FDA's actions of August 23, 2021.

The Moderna Vaccine

54. On December 18, 2020, FDA issued an EUA to ModernaTX, Inc. for its newly-developed Moderna COVID-19 Vaccine. On June 25, 2021, the FDA revised the patient and provider fact sheets regarding the suggested increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination. On August 12, 2021, the FDA amended the Moderna EUA to allow for an additional dose to be given to certain immunocompromised individuals. The EUA allows the Moderna COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.

55. The EUA Fact Sheet for Recipients and Caregivers of the Moderna COVID-19 Vaccine states, "It is your choice to receive the Moderna COVID-19 vaccine."[16]

56. Presently, the estimated study completion date for the ongoing "Phase 2a" clinical trial for the Moderna COVID-19 Vaccine, formally entitled "Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of mRNA-12273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19" is ***November 1, 2021***[17]. A "Phase 3" trial is also now being conducted.

57. Moderna announced on August 25 that it has filed an application with the FDA for full approval of its COVID-19 vaccine.[18]

The Johnson & Johnson Vaccine

58. On February 27, 2021, FDA issued the only EUA for a single-shot vaccine in connection with the Johnson & Johnson Vaccine produced by Janssen Biotech, Inc. The EUA permits

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[15] *See* https://clinicaltrials.gov/ct2/show/NCT04368728 (last visited August 27, 2021).
[16] *See* https://fda.gov/media/144638/download (last visited August 24, 2021).
[17] *See* https://www.clinicaltrials.gov/ct2/show/NCT04405076 (last visited August 27, 2021),
[18] *See* https://investors.modernatx.com/node/12706/pdf (last visited August 27, 2021).

administration of the Johnson & Johnson Vaccine to individuals 18 years of age or older. This is the vaccine that currently unvaccinated healthcare workers in Maine will be forced to take no later than September 17, 2021 if they are to meet the terms of the new mandate set forth in the Rule.

59. The EUA Fact Sheet for Recipients and Caregivers of the Johnson & Johnson vaccine states, "It is your choice to receive the Janssen COVID-19 Vaccine."[19]

60. Presently, the estimated study completion date for the ongoing "Phase 1/2a" clinical trial for the Johnson & Johnson vaccine, formally entitled "Study of Ad26.COV2.S Adults (COVID-19)" is ***February 2, 2024***.

61. A "Phase 3" clinical trial was begun in June of 2020, but, as was widely reported at the time, it was paused on October 12, 2020 based on reports of severe blood clots after vaccination. A second "Phase 3" clinical trial, formally entitled "A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults (ENSEMBLE 2)" began on November 12, 2020. The estimated study completion date is ***May 31, 2023***.[20]

62. All of the COVID-19 vaccines are still undergoing clinical trials, and none of them have been subjected to long-term clinical studies that would expose long-term adverse consequences. The FDA uses the term "investigational product" to refer to all of the COVID-19 vaccines approved granted EUA status.[21]

63. In light of these facts, it is clear that every individual who receives one of the EUA COVID-19 vaccines is the subject of a medical experiment -- very possibly the largest experiment in human history.

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[19] *See* https://www.fda.gov/media/146305/download (last visited August 29, 2021).
[20] *See* https://clinicaltrials.gov/ct2/show/NCT04614948 (last visited August 27, 2021).
[21] *See*, e.g. *"Conduct of Clinical Trial of Medical Products During the COVID-19 Public Health Emergency, Guidance for Industry, Investigators, and Institutional Review Boards"*, page 2, issued March, 2020 and updated August 30, 2021, available at https://www.fda.gov/media/136238/download (last visited August 30, 2021).

FDA and Emergency-Use Authorization Generally

64. The federal Food, Drug and Cosmetic Act ("FDCA") generally prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" unless and until the FDA has approved the drug or biological product as "safe and effective for its intended use." FDCA §§ 301(a), 505(a), 21 U.S.C. §§ 331(a), 355(a); 42 U.S.C. § 262(a).

65 A vaccine is both a drug and a biological product under the FDCA. FDCA §201(g), 21 U.S.C. § 321(g); 42 U.S.C. § 262(i)(1).

66. Under the FDCA, the FDA oversees the review and approval of applications for all drugs, medical devices and biological products in the United States. The FDA is charged with the responsibility to ensure that drugs, medical devices and biological products are safe and effective for public use.

67. Section 564 of the FDCA, 21 U.S.C. § 360bbb-3, authorizes the FDA to issue an EUA for a medical drug, device or biologic, including a vaccine, under certain emergency circumstances, despite the fact that such products have not gone through the full FDA review process and therefore cannot be fully determined to be safe and effective. No other federal agency or entity and no State may deviate from or conflict with FDA's administration of EUA products.

68. Congress passed Section 564 in order to address a problem raised in emergency situations where the public could be at risk of exposure to a biological, chemical, radiological, or nuclear agent, and any disease caused by such agents, but where there may not be any previously approved or available countermeasures to treat diseases or conditions caused by such agents.

69. The purpose of Section 564 is to make available drugs, devices or biological products that have not gone through FDA's full approval process, in the event of a declared emergency. Section 564 permits a vaccine that has been granted EUA (an "EUA vaccine") to be introduced into interstate commerce and administered to individuals even when FDA has not approved the vaccine for more general distribution pursuant to its standard review process.

70. Section 564 of the FDCA vested the Secretary of the federal Department of Health and Human Services with permissive authority to "authorize the introduction into interstate commerce, during the effective period of a declaration of emergency, of a drug, device, or biological product intended for use in an actual or potential emergency..." 21 U.S.C. § 360bbb-3(a)(1).[22]

71. Specifically, Section 564 directs the FDA to impose certain "required conditions" on every EUA product that it allows to enter interstate commerce. Among the "required conditions" that the FDA must establish are "[a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed" of certain things, including "**the option to accept or refuse administration of the product.**" FDCA § 564(e)(1)(A)(ii)(III); 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) (emphasis added).

72. Coercion and compulsory COVID-19 vaccine mandates are entirely inconsistent, incompatible, and in direct conflict with these disclosure requirements, which require both healthcare workers administering EUA vaccines and vaccine recipients to be informed of the significant known and unknown benefits and risks of such use, and the choice to accept or refuse them.

73. Section 564 incorporates the principle that unlicensed medical products cannot be mandated by directing the FDA to ensure that all parties are aware of the "option to accept or

[22] With regard to the EUA process generally, *see* "Emergency Use Authorization of Medical Products and Related Authorities, Guidance for Industry and Other Stakeholders", issued by the FDA in 2017 and available at https://www.fda.gov/media/97321/download (last visited August 31, 2021).

refuse" administration of all EUA products, including EUA vaccines. FDCA § 564(e)(1)(A)(ii)(III). The following language appears in the Fact Sheet for Recipients and Caregivers that is required to be distributed to potential Moderna COVID-19 Vaccine and Johnson & Johnson COVID-19 Vaccine recipients: "It is your choice to receive or not receive [the vaccine]." This sentence does not appear in the Fact Sheet for the Pfizer and Comirnaty vaccines as of the date of this filing, but upon information and belief, it was found in the Fact Sheet for the Pfizer vaccine prior to August 23, 2021.

74. Congress included the requirement to inform recipients of the option to accept or refuse vaccination because individuals have a right under the Due Process Clause of the Fourteenth Amendment to voluntary, informed consent and to refuse unwanted medical treatment, especially as to unlicensed products that are still under investigation and therefore experimental.

75. Under the Due Process Clause, persons also have a right to voluntary, informed consent and to refuse unwanted medical treatment with licensed products if certain legal requirements are not met.

76. Under the Due Process Clause, the right to voluntary, informed consent and to refuse unwanted medical treatment cannot be circumscribed without legislative action that weighs the safety, efficacy, necessity, reasonableness, proportionality, and discriminatory nature of a particular vaccine mandate and permits an exemption to persons who can demonstrate that they possess a particular medical condition that makes them susceptible to harm, injury or death by the mandated vaccine.

77. To date, Congress has not enacted any amendment to 21 U.S.C. § 360bbb-3, authorizing the Secretary of HHS to mandate any emergency-use authorized drug, device, or biological product,

including any COVID-19 vaccine, or to otherwise permit coercion of any COVID-19 vaccine, or to delegate the authority and decision to do so to any State, or any public or private entity.

78. Additionally, prior to the appearance of COVID-19, FDA has made clear that, "In an emergency, it is critical that the conditions that are part of the EUA or an order or waiver issued pursuant to section 564A -- those that FDA has determined to be necessary or appropriate to protect the public health -- be strictly followed, and that no additional conditions be imposed."[23]

79. Upon information and belief, aside from the documents posted on its website, the FDA will not release to the public pursuant to the Federal Freedom of Information Act, 5 U.S.C. § 552 *et seq.*, its communications and exchanges of data or other information with COVID-19 vaccine manufacturers because it claims the vaccines are still under investigation. As a result, the American public is unable to review and consider all of the information and communications concerning these emergency-use authorized vaccines to make an informed decision about taking them.

Medical Freedom in the United States:
The Right to Voluntary, Informed Consent &
the Right to Personal Autonomy and Bodily Integrity

80. It is well established that customary international law includes a norm that requires voluntary, informed consent and prohibits non-consensual human medical experimentation. *Abdullahi v. Pfizer*, 562 F.3d 163, 174-188 (2nd Cir. 2009).

81. In August 1947, an International Military Tribunal ("IMT") sitting in Nuremberg, Germany convicted 15 Nazi doctors for crimes against humanity for conducting medical experiments without the consent of their subjects. "Among the nonconsensual experiments that the tribunal cited as a basis for their convictions were **the testing of drugs for immunization against**

[23] *See FDA, Emergency Use Authorization of Medical Products and Related Authorities – Guidance for Industry and Other Stakeholders*, January 2017, Page 41, available at https://www.fda.gov/media/97321/download (last visited August 27, 2021).

malaria, epidemic jaundice, typhus, smallpox and cholera." *Id.* at 178 (quoting *United States v. Brandt*, 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, 181-182 (1949) (emphasis added). The Nuremberg Code was created as part of the IMT's judgment, and it helps to define the contours of the customary international law norm. Its first Principle is that **"[t]he voluntary consent of the human subject is absolutely essential."** *Id.* at 179 (emphasis added). The Code elaborates on this first Principle as follows:

> *This means that the person involved should have legal capacity to give consent; should be so situated as to be **able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion**; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.* (emphasis added)

82. The Nuremberg Code has been adopted and amplified by numerous international declarations and agreements, including the World Medical Association's Declaration of Helsinki, the guidelines authored by the Council for International Organizations of Medical Services, Art. 7 of the International Covenant on Civil and Political Rights, the International Covenant on Human Rights, the Universal Declaration on Bioethics and Human Rights, and others.

83. "The history of the [voluntary, informed consent requirement] in United States law demonstrates it has been firmly embedded for more than 45 years and [ ] its validity has never been seriously questioned by any court." *Id.* at 182.

84. The voluntary, informed consent requirement is a critical part of the Declaration of Geneva,[24] the Declaration of Helsinki,[25] and the Belmont Report[26]. The principles of all of these

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[24] First adopted by the General Assembly of the World Medical Association in 1948.

[25] A set of ethical principles regarding human experimentation developed for the worldwide medical community by the World Medical Association in 1964, and widely regarded at the cornerstone document on human research ethics.

[26] Created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and issued on September 30, 1978. The Report was prompted by revelations regarding the Tuskegee Syphilis Study (1932-1972).

historic documents are encompassed in the "Common Rule", which guides all federally-funded research in the United States (and at most universities, even research that is not federally-funded). The Common Rule has been adopted by 20 agencies and department of the federal government, including the U.S. Department of Health and Human Services, of which the FDA is a part. The Common Rule is reflected in the rules enacted by each of these agencies and departments[27] and found in the Code of Federal Regulations.

85. The Fourteenth Amendment's Due Process Clause guarantees to every individual medical freedom in the form of the right to voluntary, informed consent, and the associated right to personal autonomy and bodily integrity.

86. In *Planned Parenthood v. Casey*, 505 U.S. 833, 857 (1992), the U.S. Supreme Court stated:

> *Roe, however, may be seen not only as an exemplar of Griswold liberty, but as a rule (whether or not mistaken) of personal autonomy and bodily integrity, with doctrinal affinity to cases recognizing limits on governmental power to mandate medical treatment or to bar its rejection. If so, our cases since Roe accord with Roe's view that a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims. Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 278, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990); cf., e. g., Riggins v. Nevada, 504 U.S. 127, 135, 118 L. Ed. 2d 479, 112 S. Ct. 1810 (1992); Washington v. Harper, 494 U.S. 210, 108 L. Ed. 2d 178, 110 S. Ct. 1028 (1990); see also, e. g., Rochin v. California, 342 U.S. 165, 96 L. Ed. 183, 72 S. Ct. 205 (1952); Jacobson v. Massachusetts, 197 U.S. 11, 24-30, 49 L. Ed. 643, 25 S. Ct. 358 (1905).*

To reiterate: "a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims." *See also Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) ("the 'liberty' protected by the Due Process Clause [of the Fourteenth Amendment] includes the right[] . . . to bodily integrity"); *Shillingford v. Holmes*, 634 F.2d 263, 265 (5th Cir.1981) ("the right to be free of state-occasioned damage to a person's bodily integrity is protected by the fourteenth

[27] With the exception only of the Central Intelligence Agency and the Office of the Director of National Intelligence.

amendment guarantee of due process."); *Doe v. Moore*, 410 F.3d 1337, 1343 (11th Cir. 2005) ("The Supreme Court has recognized that fundamental rights include those guaranteed by the Bill of Rights as well as certain 'liberty' and privacy interests implicit in the due process clause and the penumbra of constitutional rights. These special 'liberty' interests include 'the rights to marry, to have children, to direct the education and upbringing of one's children, to marital privacy, to use contraception, to bodily integrity, and to abortion.'").

87. Further, the Supreme Court has stated that the protected liberty claims inherent in personal autonomy and bodily integrity include both the right *to be free from* unwanted medical intervention, and the right *to obtain* medical intervention:

> *As the joint opinion acknowledges, ante, 505 U.S. at 857, this Court has recognized the vital liberty interest of persons in refusing unwanted medical treatment. Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990). Just as the Due Process Clause protects the deeply personal decision of the individual to refuse medical treatment, it also must protect the deeply personal decision to obtain medical treatment, including a woman's decision to terminate a pregnancy.*

Casey, 505 U.S. at 927.

88. In the Supreme Court's seminal "right to die" case, *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261 (1990), the Court addressed whether an individual in a persistent vegetative state could require a hospital to withdraw life-sustaining medical care based on her right to bodily integrity. 479 U.S. at 265-69. Chief Justice Rehnquist noted that "[b]efore the turn of this century, [the Supreme Court] observed that 'no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.'" Id. at 269 (quoting *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251 (1891). He continued: "This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment," Id. at 269, "generally encompass[es] the right

of a competent individual to refuse medical treatment," Id. at 277, and is a right that "may be inferred from [the Court's] prior decisions." Id. at 278-79 (citing *Jacobson v. Massachusetts*, 197 U.S. 11 (1905); *Breithaupt v. Abram*, 352 U.S. 432 (1957); *Washington v. Harper*, 494 U.S. 210 (1990); *Vitek v. Jones*, 445 U.S. 480 (1980); *Parham v. J.R.*, 442 U.S. 584 (1979).).

89. In the words of Justice Sandra Day O'Connor, "[T]he liberty guaranteed by the Due Process Clause must protect, if it protects anything, an individual's decision to reject medical treatment...." *Cruzan*, 497 U.S. at 289.

90. The Law Court has also recognized that individuals have a fundamental liberty interest in refusing medical treatment. *Green v. Commissioner of the Dept. of Mental Health, Mental Retardation & Substance Abuse Services*, 2001 ME 86, ¶ 15, 776 A.2d 612.

91. The right to refuse medical treatment carries with it an implied right to the information necessary to make an informed decision about whether to refuse the treatment. Without crucial information about the risks and benefits of a procedure, the right to refuse rings hollow.

92. All individuals have the right to exercise informed consent and to refuse unwanted medical treatment voluntarily, and free from coercion by governments, employers, or anyone else.

Hi-Tech Vaccines, Questionable Efficacy and Safety, and Unknown Risks

93. Since COVID-19 vaccines employ novel technology never put into widespread use in healthy humans before, because they were only tested on humans for a limited period of time and particular people were intentionally excluded from those clinical trials (e.g. pregnant women and immunocompromised individuals), and because these vaccines are still under investigation in ongoing clinical trials which deem doses as "experimental," and have only been used by the public for less than a year, it is impossible to adequately assess their safety and efficacy. It is also

impossibly to assess whether their benefits outweigh their risks, because so much remains unknown about how, and if, they work, and what dangers they pose.

94. However, we do know more than ever now about the risks, dangers and waning efficacy of vaccination. In less than a year, the number of "adverse events" reported to the national Vaccine Adverse Event Reporting System ("VAERS") in connection with the COVID-19 vaccines, including serious injuries and deaths, has far exceeded the total combined number of adverse events reported in connection with all other federally recommended vaccines tracked in this system since its inception in 1990.[28]

95. Similarly, according to VAERS, COVID-19 vaccines have also caused more hospitalizations and more adverse health effects overall than all other vaccines administered combined since the U.S. Centers for Disease Control and Prevention (CDC) began tracking this information. These adverse events reported to VAERS include life-threatening anaphylaxis, myocarditis, pericarditis (heart inflammation), blood clotting disorders, cardiac disorders, miscarriages, Bell's Palsy, Guillain-Barré syndrome, and Multisystem Inflammatory Syndrome in children.

96. It is well known that VAERS, which notably is not a mandatory reporting system in many circumstances[29], captures only a fraction of the actual injuries caused by vaccines[30]. It is

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[28] VAERS is co-managed by the U.S. Centers for Disease Control and the U.S. Food and Drug Administration. *See* https://vaers.hhs.gov/. Between Dec. 14, 2020 and August 20, 2021, a total of 623,343 total adverse events were reported to VAERS, including 13,627 deaths. There were 84,466 reports of serious injuries, including deaths, during the same time period. *See also* the website maintained by the OpenVAERS Project at https://www.openvaers.com (last visited August 26, 2021). The European Union's European Medicines Agency maintains a similar vaccine injury reporting system known as the "EudraVigilance" system. It also shows unprecedented high levels of injuries reported in connection with administration of COVID-19 vaccines approved for use in EU member countries, which include all of the vaccines currently being administered in the U.S.

[29] Healthcare providers are required by law to report certain adverse events, "strongly encouraged" to report others, and simply "encouraged" to report yet others. Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.

entirely possible, therefore, that the COVID-19 vaccines might be responsible for hundreds of thousands or even millions of deaths in the United States in just eight months of use. If that number is accurate, COVID-19 vaccines could prove more deadly than COVID-19 itself.

97. Furthermore, the VAERS database is the only safety database to which the public has access. The government withholds extensive safety information from the public despite having at least ten additional data sources and expert consultants to analyze these data, according to Nancy Messonier, MD, Director of the National Center for Immunization and Respiratory Diseases.[31] These resources include databases maintained by the Centers for Medicare and Medicaid, the Veterans Administration, the Defense Department (DMSS), the Vaccine Safety Datalink, and the "Genesis" database, which is operated in cooperation with the National Institutes of Health and Brown University, and includes 250 long-term care facilities and 35,000 residents.

98. Recent data from the U.S. (in Massachusetts[32]) and abroad (for example, in Israel and the United Kingdom[33]) suggest that COVID-19 vaccines are failing to provide protection against COVID-19, that vaccinated and unvaccinated people are equally likely to carry and spread the

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[30] A study conducted by Harvard Pilgrim Healthcare, Inc. pursuant to a grant from the U.S. Department of Health and Human Services, and examining the period 12/01/07 - 09/30/10, concluded that *fewer than 1% of vaccine adverse events are reported* to VAERS; *see* "*Grant Final Report*" at https://www.openvaers.com/images/r18hs017045-lazarus-final-report-20116.pdf (last visited August 26, 2021).

[31] *See* FDA Meeting on COVID 19 and Emergency Use Authorization, Part 1 (Video), Dec. 10, 2020, available at https://www.c-span.org/video/?507053-1/fda meeting-covid-19-vaccine-emergency-authorization-part-1 (last visited August 24, 2021).

[32] *See* Catherine M. Brown, DVM; Johanna Vostok, MPH; Hillary Johnson, MHS et al., *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts*, CDC Morbidity and Mortality Weekly Report MMWR (July 2021) available at https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w#suggestedcitation (last visited August 24, 2021).

[33] *See* Nathan Jeffay, *Israeli, UK data offer mixed signals on vaccine's potency against Delta strain*, The Times of Israel (July 22, 2021), available at https://www.timesofisrael.com/israeli-uk-data-offer-mixed-signals-on-vaccinespotency-against-delta-strain/; Ian Sample, *Scientists back Covid boosters as study finds post-jab falls in antibodies*, The Guardian (July 22, 2021), available at https://www.theguardian.com/world/2021/jul/22/uk-scientists-back-covidboosters-as-study-finds-post-jab-falls-in-antibodies (both visited most recently August 24, 2021).

virus, and that viral variants, such as the Delta variant, appear to be infecting vaccinated and unvaccinated individuals in roughly equal numbers.

99. On May 1, 2021, the CDC changed its method for monitoring reported vaccine "breakthrough" cases, choosing to count only breakthrough cases that resulted in hospitalizations or death, thereby reducing the number of breakthrough cases counted for purposes of gauging the true effectiveness of COVID-19 vaccines and concealing the true vaccine failure rate from the public.[34]

100. Since there is insufficient evidence that these vaccines can prevent infection or transmission, they cannot promise to any inoculated population herd immunity against SARS-CoV-2 or its variants. Anyone reporting otherwise is misleading the public, because claims of efficacy are not supported by the clinical trials, emerging data or scientific analysis to date. Not surprisingly, the CDC is now stating that its goal is to see that individuals who have received all three COVID vaccines receive booster shots this fall,[35] and both the CDC and World Health Organization recommend that even fully vaccinated individuals continue to wear face masks.[36]

101. The COVID-19 "vaccines" do not function the way vaccines are expected to work by the public. As currently understood, the only effect these vaccines ***may*** have demonstrated in clinical trials is reduction of serious clinical disease; in other words, they may only lessen a

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[34] *See* Centers for Disease Control, *COVID-19 Vaccine Breakthrough Case Investigation and Reporting*, available at https://www.cdc.gov/vaccines/covid 19/health-departments/breakthrough-cases.html (last visited August 24, 2021).

[35] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html (last visited August 24, 2021). *See also* the August 18 *"Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots"*, available at https://www.fda.gov/news-events/press-announcements/joint-statement-hhs-public-health-and-medical-experts-covid-19-booster-shots (last visited September 1, 2021). The Joint Statement says that the Government's plan for booster shots is "subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines and CDC's Advisory Committee on Immunization Practices (ACIP) issuing booster dose recommendations based on a thorough review of the evidence." ACIP met on August 30, 2021 in part to discuss this question, but did not reach a definitive conclusion as to any possible booster recommendation. ACIP is scheduled to meet again October 20-21.

[36] *See* https://www.cnet.com/health/cdc-and-who-recommend-fully-vaccinated-should-wear-masks-indoors-heres-the-latest/ (last visited August 30, 2021).

person's symptoms from COVID-19. They are ***not*** designed primarily to stop infection or prevent vaccinated persons from spreading the virus even while they are asymptomatic. Whether COVID-19 vaccines work effectively at preventing infection or transmission, or even reducing symptoms, remains an open question; rates of COVID-19 today are following the same pattern they followed last year, when COVID-19 vaccines were not available. COVID-19 vaccines have not been shown to be responsible for any observed reduction in infections or hospitalizations when rates are compared between this year and last year. According to current data, COVID-19 vaccines are failing against the Delta variant. Consequently, COVID-19 vaccines may offer a false sense of security, and constitute a poor public health initiative, rushed through development ("at warp speed"), touted and marketed prematurely, for financial gain, to an unsuspecting and fearful public. A COVID-19 vaccine has the potential to be marketed to and even coerced into every human body on the planet. And no other product in the world holds such financial potential.

102. Moreover, the effectiveness of COVID-19 vaccines has been vastly overstated, with the presentation to the public of misleading figures that do not account for differences between *relative risk reduction* and *absolute risk reduction* ("ARR") for different members of the population.[37] In studying the effectiveness of a medical intervention in randomized controlled trials (often called the gold standard of study design), the most useful way to present results is in terms of ARR. ARR compares the impact of treatment by comparing the outcomes of the treated group and the untreated group. In other words, if 20 out of 100 untreated individuals had a negative outcome, and 10 out of 100 treated individuals had a negative outcome, the ARR would be 10% (20 - 10 =

[37] *See* Les Irwig; Judy Irwig, et al., *Relative and Absolute Risks, Smart Health Choices: Making Sense of Health Advice* (2008) available at https://www.ncbi.nlm.nih.gov/books/NBK63647/ ("Absolute risk reduction (ARR) – also called risk difference (RD) – is the most useful way of presenting research results....").

10). **According to a study published by the National Institutes of Health, the ARR for the Pfizer Vaccine is a mere 0.7%, and the ARR for the Moderna Vaccine is only 1.1%.**[38]

103. One can calculate based on ARR the Number Needed to Vaccinate ("NNV"), which signifies the number of people that must be injected before even one person benefits from the vaccine. The NVV for the Pfizer Vaccine is 119, meaning that 119 people must be injected in order to observe the reduction of a COVID-19 case in one person. The highly reputed journal the *Lancet* reports data indicating that the NVV may be as high as 217. The NVV to avoid hospitalization exceeds 4,000. The NVV to avoid death exceeds 25,000.

104. Meanwhile, the possibility of antibody dependent enhancement – the likelihood that COVID-19 vaccine mediated antibodies could actually make a person more susceptible to infection or exacerbate their disease – has not been adequately acknowledged or studied.[39]

105. COVID-19 vaccines have undergone no testing for genotoxicity, mutagenicity, teratogenicity, and oncogenicity. In other words, it is unknown whether or not COVID-19 vaccines will change human genetic material, cause birth defects, reduce fertility, or cause cancer.

106. COVID-19 vaccines are considered gene-based vaccines or vaccines produced from gene therapy molecular platforms, whose safety and efficacy has not been fully assessed. This is unlike all other vaccines, where there is a set amount of antigen or a dead or live-attenuated virus in the vaccine. Referring to the "mRNA technology" in its Moderna COVID-19 Vaccine, Moderna admits the "novel and unprecedented nature of this new class of medicines", and further admits that the FDA classes its vaccine as a form of "gene therapy", in its Securities and Exchange

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[38] *See* R. Brown, *Outcome Reporting Bias in COVID-19 mRNA Vaccine Clinical Trials*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996517/

[39] *See* Wen Shi Lee; Adam K. Wheatley; Stephen J. Kent; Brandon J. DeKosky, *Antibody dependent enhancement and SARS-CoV-2 vaccines and therapies*, Nature Microbiology 5, 1185-1191 (2020), available at: https://www.nature.com/articles/s41564-020-00789-5?fbclid=IwAR0MTDI0qIQgLkqnjaYI7vyr-H4Wj2IcNiAQT1hWboXDk0YIIdwaCVgr5xg (last visited August 24, 2021).

Commission filings.[40] This radical new technology has never previously been administered to human beings.

107. The risks of taking these mRNA vaccines are not well-known or fully understood. These vaccines were only tested on human subjects for six (6) months before being released to the public; there is absolutely no knowledge whatsoever of their long-term efficacy or long-term safety. Clinical trials for these vaccines are scheduled to continue through 2023, and FDA literature and the clinical studies themselves continue to refer to these biologics as "investigational" or "experimental."

108. COVID-19 vaccines use mRNA to force human cells to produce the spike protein of SARS-CoV-2 in order to trigger an immune response. Scientists are now learning that the spike protein *is itself* toxic to the human body. As far as we know, the process initiated by these vaccines is irreversible; the body's production of the toxic spike protein of SARS-CoV-2 cannot be turned off and could harm or kill a person if the body does not react as intended, or if the body is overcome by the unnatural production of spike protein. The spike protein has been demonstrated to injure vital organs such as the brain, heart, lungs, as well as damage blood vessels and directly cause blood clots. Furthermore, because these vaccines enter cells within these organs, the generation of spike protein within heart and brain cells in particular, causes the body's own immune system to attack these organs. This is abundantly apparent with the burgeoning number of cases of myocarditis or heart inflammation among individuals below age 30.

109. These mRNA injections are more appropriately categorized as gene therapies that do not fulfill a single criteria or definition of a standard vaccine. These nucleic acid vaccines send the

[40] *See* www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm (last visited August 31, 021).

body instructions to produce pieces of the virus with the expectation that the body's immune system mounts a response to the pieces of the virus made by the body.

110. Tragically, data recorded in the CDC's Vaccine Adverse Event Reporting System ("VAERS") reveal unprecedented levels of death and other adverse events since the FDA first issued EUAs for the three COVID-19 vaccines.

Evolving Scientific Knowledge

111. The typical vaccine development process takes between 10 and 15 years, and consists of the following sequential stages - research and discovery (2 to 10 years), pre-clinical animal studies (1 to 5 years), and finally clinical human trials in four phases (typically 5 years). Phase 1 of the clinical human trials consists of healthy individuals and is focused on safety. Phase 2 consists of additional safety and dose-ranging in healthy volunteers, with the addition of a control group. Phase 3 evaluates efficacy, safety and immune response in a larger volunteer group, and requires two sequential randomized controlled trials. Phase 4 is a larger scale investigation into longer-term safety. Vaccine developers must follow this process in order to be able to generate the data the FDA needs in order to assess the safety and effectiveness of a vaccine candidate.

112. This 10 to 15-year testing process has been abandoned for purposes of the COVID-19 vaccines. The first human-to-human transmission of the SARS-CoV-2 virus was not confirmed until January 20, 2020, and less than a year later the COVID-19 vaccines had EUAs, and for the first time in history this novel mRNA technology was being injected into millions of human beings.

113. All of the stages of testing have been compressed in time, abbreviated in substance, and are overlapping, which dramatically increases the risks. Upon information and belief, pharmaceutical companies did not independently verify the genome sequence that China released on January 11, 2020. Upon information and belief, the COVID-19 vaccines were studied for only

56 days in macaques, and 28 days in mice, and then animal studies were halted. Upon information and belief, the pharmaceutical companies discarded their control groups receiving placebos, squandering the opportunity to learn about the rate of long-term complications, how long protection against the disease lasts and how well the COVID-19 vaccines inhibit transmission. A number of studies were deemed unnecessary and not performed prior to administration in human subjects, including single dose toxicity, genotoxicity, carcinogenicity, prenatal and postnatal development, offspring, local tolerance, teratogenic and postnatal toxicity and fertility. The American public has not been properly informed of these dramatic departures from the standard testing process and the risks they generate.

114. Thus the COVID-19 vaccines remain under investigation and are still undergoing clinical trials. The long-term safety and efficacy of all COVID-19 vaccines therefore remains completely unknown. But as physicians and scientists are continue to study these vaccines, much of what they are learning is extremely alarming.

115. A Pfizer Biodistribution Study recently obtained by Dr. Byram Bridle, MD, a viral immunologist (through Japan's equivalent of a public records request) showed that lipid nanoparticles from the vaccine did not stay in the deltoid muscle where they were injected, as the vaccine's developers claimed would happen, but instead circulated throughout the body and accumulated in large concentrations in organs and tissues, including the spleen, bone marrow, liver, adrenal glands and -- in "quite high concentrations" -- in the ovaries.[41]

[41] *See* Children's Health Defense Team, *Watch 1-Hour Version of Censored Interview with Inventor of mRNA Vaccine Technology*, The Defender (July 8, 2021) available at https://childrenshealthdefense.org/defender/censored-dark horse-podcast-bret-weinstein-robert-malone-inventor-mrna-vaccine-technology/ (last visited August 24, 2021).

116. The Pfizer Biodistribution Study, which upon information and belief may also be in the possession of the FDA, reveals the various organs and tissues of the body where the Pfizer vaccine was detected following vaccination.[42]

117 The latest data from Israel and the United Kingdom suggest that COVID-19 vaccine-induced immunity is waning rapidly in those countries.[43]

118. Pfizer has already sought authorization for a booster shot to its COVID-19 vaccine for certain groups.[44]

119. Epidemic spread of COVID-19, like all other respiratory viruses, is driven by symptomatic persons who can self-isolate or quarantine from the general population. Asymptomatic spread is trivial and inconsequential. According to a meta-analysis of contact tracing studies published in the Journal of the American Medical Association, asymptomatic COVID-19 spread was only 0.7%.[45]

120. A rational and ethical prevention measure to reduce the spread of COVID-19 is a simple requirement, as part of formal policies, that persons with active symptomatic, febrile (feverish) respiratory illnesses, like COVID, should isolate themselves.

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[42] Megan Redshaw, *'We Made a Big Mistake' — COVID Vaccine Spike Protein Travels From Injection Site, Can Cause Organ Damage*, The Defender (June 3, 2021), available at https://childrenshealthdefense.org/defender/covid-vaccine-spike protein-travels-from-injection-site-organ-damage/ (last visited August 24, 2021).

[43] Nathan Jeffay, *Israeli, UK data offer mixed signals on vaccine's potency against Delta strain*, The Times of Israel (July 22, 2021) available at https://www.timesofisrael.com/israeli-uk-data-offer-mixed-signals-on-vaccines potency-against-delta-strain/ (last visited August 24, 2021); Ian Sample, *Scientists back Covid boosters as study finds post-jab falls in antibodies*, The Guardian (July 22, 2021)

[44] Michael Erman, Julie Steenhuysen, *Pfizer, BioNTech to seek authorization for COVID booster shot as Delta variant spreads,* Reuters.com (July 9, 2021), available at https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer ask-fda-authorize-booster-dose-covid-vaccine-delta-variant-spreads-2021-07-08/ (last visited August 24, 2021).

[45] *See* Zachary J. Madewell, PhD; Yang Yang, PhD; Ira M. Longini Jr, PhD; Elizabeth Halloran, MD, DSc; Natalie R. Dean, PhD, *Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis*, JAMA Network Open, available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102 (last visited August 24, 2021).

121. There is good reason to believe that by requiring Maine's healthcare workers to be injected with the COVID-19 vaccines, the Defendants are actually increasing the risks to vulnerable patients, not reducing them. The prestigious Oxford University Clinical Research Group recently published a paper in the premier British medical journal, *The Lancet*, documenting their finding that individuals injected with the COVID-19 vaccines carry 251 times the load of COVID-19 virus in their nostrils compared to the unvaccinated.[46]

122. The vaccinated also shed the toxic spike proteins manufactured by their bodies, and transmit them to the unvaccinated, who may be injured by them. Page 67 of the Pfizer EUA application refers to shedding and transmission of the toxic spike protein by the vaccinated, to the unvaccinated. It describes the possibility of **the passive "vaccination" of the unvaccinated through proximity to the vaccinated**, including inhalation or skin contact. Pursuant to the referenced document, each person getting the Pfizer-BioNTech COVID-19 Vaccine had to consent to the possibility of exposing pregnant women through inhalation or skin contact (note that pharmaceutical companies can only disclose actual, not purely speculative, risks). According to the document, an "exposure during pregnancy" event that must be reported to Pfizer within 24 hours occurs if:

> *A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.*
>
> *A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:*
>
> *A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.*

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[46] *See* Nguyen Van Vinh Chau and Nghiem My Ngoc, *Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers*, Vietnam, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733 (last visited September 1, 2021).

Further, an "exposure during breastfeeding" event occurs if "[a] female participant is found to be breastfeeding while receiving or after discontinuing study intervention."

123. Additionally, there is now strong evidence that persons who have been infected with SARS-CoV-2 and recovered from COVID-19 are protected from future reinfection for over a year, and potentially have lifelong immunity -- unlike vaccinated persons for whom boosters are already being proposed.[47] Individuals who have recovered from a prior infection of COVID-19 have a negligible risk of reinfection. The full extent of natural immunity includes antibodies, B-cells, plasma cells, T-helper cells, T-presenting cells, natural killer cells, and a host of innate defenses against the virus. Natural immunity is robust, durable, and complete against all strains of SARS-CoV-2. If there was any significant risk of reinfection, there would be millions of such cases by this time.

124. More recently, medical professionals have begun to raise concerns that vaccinating those recently infected can lead to serious injury or death by causing antigen-specific tissue inflammation in any tissues harboring viral antigens.[48]

125. SARS-CoV-2 causes infection in humans that results in robust, complete, and durable immunity.

126. Natural immunity is superior to vaccine-induced immunity.

127. Epidemiological studies have demonstrated to a reasonable degree of medical certainty that natural immunity following infection and recovery from the SARS-CoV-2 virus provides

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[47] *See* Yair Goldberg; Micha Mandel, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three month nationwide experience from Israel*, medRxiv (April 20, 2021), available at https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1 (last visited August 24, 2021). See also Jackson S. Turner; Wooseob Kim, et al., *SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, Nature 595 (pp. 421-425) (May 24, 2021).

[48] *See* Hooman Noorchashm, MD, *An Urgent Warning to Rutgers University: On a Potential Safety Hazard and Liability in Your COVID-19 Vaccine Mandate* (March 25, 2021), available at https://noorchashm.medium.com/an-urgent-warning-to_rutgers-university-on-a-potential-safety-liability-in-your-covid-19-vaccine 82e10e1e1fb (last visited August 24, 2021).

robust and durable protection against reinfection, at levels equal to or better than the *most effective* vaccines currently available.[49]

128. It is medically unnecessary for persons who have recovered from COVID-19 and present evidence of natural immunity to undergo vaccination for SARS-CoV-2. Coercing such persons to do so would subject them to an elevated risk of adverse side effects.

Alternatives to Experimental Immunization

129. There are now well-studied, safe and reliable alternatives to vaccination to prevent and treat COVID-19, including, but not limited to, monoclonal antibody infusion, Ivermectin, Methylprednisolone, Fluvoxamine, Hydroxychloroquine, Vitamin C, Vitamin D3, Zinc, Melatonin, Aspirin, corticosteroids and other accessible therapies. Randomized-controlled trials and observations by front line medical practitioners have confirmed that COVID-19 is preventable and treatable, especially at early onset with medicines and practices that have proved safe for decades. As a result, the pandemic can end now without vaccines, based upon current scientific knowledge and understanding. Vaccines are not necessary to defeat COVID-19.

130. The treatment for COVID-19 infection has improved tremendously since its advent. Studies have shown several different treatment methods which have proven safe and effective. For example, a combination of medications, supported by the Association of American Physicians and Surgeons, for a minimum of five days, and acutely administered supplements used for the initial ambulatory patient with suspected and confirmed COVID-19 (moderate or greater probability) has proven effective.[50]

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[49] *See, e.g.* N. Kojima; A. Roshani, et al., *Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 Infection among previously infected or vaccinated employees*, medRxiv (July 3, 2021), available at https://www.medrxiv.org/content/10.1101/2021.07.03.21259976v2

[50] *See* Brian C. Procter; Casey Ross; Vanessa Pickard; Erica Smith; Cortney Hanson; Peter A. McCullough, *Clinical outcomes after early ambulatory multidrug therapy for high risk SARS-CoV-2 (COVID 19)*

131. Even more significantly, the FLCCC has developed the most comprehensive prevention and treatment protocols for COVID-19 to date.[51] This organization is composed of some of the most well-established and widely-published physicians in the world who are actually treating patients in hospitals. In particular, they are best known for their evaluation, use and championing of Ivermectin as a solution to end the COVID-19 pandemic based on numerous scientific studies demonstrating its dramatic prophylactic and treatment capabilities.[52]

132. Ivermectin has been used over-the-counter for COVID in many countries and regions with excellent reported treatment success. The drug's safety has been established with at least a billion doses used, and the drug is on the World Health Organization's list of essential drugs.

133. Upon information and belief, many medical professionals suspect FDA's feigned ignorance about Ivermectin was a prerequisite to issuing EUAs for COVID-19 vaccines, given the EUA requirement that no approved drug may be available for the same indication. Ivermectin and hydroxychloroquine, both of which have extremely long biological half-lives, can be given periodically but infrequently as an effective prophylaxis for COVID-19.

134. Hydroxychloroquine, chloroquine, or Ivermectin have been used weekly to prevent COVID-19. Many clinical trials have documented the benefits of these drugs for COVID-19 prevention. Yet FDA has remained silent about these benefits, even though the efficacy of these preventive treatments probably supercedes that of COVID vaccines.

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infection, Reviews in Cardiovascular Medicine (December 30, 2020), available at https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.260 (last visited on August 24, 2021).

[51] *See* FLCCC's prevention and treatment protocols for COVID-19 available at https://covid19criticalcare.com/covid-19-protocols/ (last visited August 24, 2021).

[52] *See* Kory, Pierre MD; Meduri, Gianfranco Umberto MD; Varon, Joseph MD; Iglesias, Jose DO; Marik, Paul E. MD, *Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19*, American Journal of Therapeutics (May/June 2021) available at https://journals.lww.com/americantherapeutics/Fulltext/2021/06000/Review_of_the_Emerging_Evidence_Demonstrating_the.4.aspx (last visited on August 24, 2021).

135. The Department has innumerable options available to it in fulfilling its mission to protect the health and safety of Maine residents, Maine healthcare workers, and patients in Maine healthcare facilities, that do not involve the coercive administration of an experimental vaccine.

136. From all appearances, the Department did not access or consider any of the vast amount of relevant information and data outlined above before issuing the Rule. The Maine Administrative Procedure Act requires the Department to summarize the relevant information considered during the development of the rule[53], but ***the only such information cited by the Department[54] is the COVID guidance provided by the CDC and the "experience and knowledge" of its own employees.***[55] This is shocking and frankly intolerable. The Department should not be permitted to promulgate a rule that so clearly violates the fundamental rights of the individual Plaintiffs and other healthcare workers in Maine without considering all available relevant evidence and making a proper showing that the Rule is narrowly tailored to serve a compelling State interest.

137. The Maine Administrative Procedure Act was also violated by the Department when it promulgated the Rule as an emergency "routine technical rule". The new mandate, if it is to be enacted, should be either (A) statutorily enacted by the Legislature; (B) promulgated as an emergency rule by the Department if and when 22 M.R.S. 802(2) has been amended by the Legislature to authorize it; or (C) promulgated by the Department as a non-emergency major substantive rule so that the Legislature has the opportunity to consider the matter and hear testimony from the public.

CLAIMS FOR RELIEF

COUNT I

The Rule is Invalid Under State Law Because It Was Promulgated as an Emergency Rule

[53] 5 M.R.S. § 8057-A(1)(E)
[54] In the "Rulemaking Fact Sheet" submitted by the Department to the Secretary of State.
[55] Specifically, staff employed by the Maine Center for Disease Control, which is part of the Department.

138. Plaintiffs reallege and reincorporate by reference all prior paragraphs of this Complaint and the paragraphs in the counts below as though fully set forth herein.

139. 22 M.R.S. § 802 addresses the authority of the Department to address communicable, environmental, and occupational diseases. Subsection 1 provides that the Department may (A) designate and classify such diseases; (B) establish requirements for reporting and other surveillance methods for measuring the occurrence of such diseases, and the potential for epidemics; (C) investigate cases, epidemics and occurrences of such diseases; and (D) establish procedures for the control, detection, prevention and treatment of such diseases, including public immunization and contact notification programs.

140. 22 M.R.S. § 802(2) provides that the Department has the authority to declare that a "health emergency" exists; as noted above, the Department did so on July 1, 2021. Subsection 2 also authorizes the Department to adopt an emergency rule for the protection of public health, but the rule must "relat[e] to" three specific procedures or actions: (A) procedures for the isolation and placement of infected persons; (B) procedures for the disinfection, seizure or destruction of contaminated property; and (C) establishment of temporary facilities for the care and treatment of infected or exposed persons. The statute does not authorize the Department to undertake emergency rulemaking for any other purposes.

141. The new mandate does not fall within any of the categories for emergency rulemaking set forth in 22 M.R.S. § 802(2).

142. The "Statutory Authority" provision at the end of the Rule formerly cited "22 MRS §802". This provision of the Rule has now been amended to cite §802, subsections (1) and (3), thereby omitting the only part of the statute that actually authorizes the promulgation of emergency rules. This despite the fact that the Rule itself, in Section 1, Paragraph L (formerly Par. J), the text

of which has not been amended, explicitly (and correctly) notes that DHHS may adopt emergency rules "pursuant to 22 MRS § 802(2)".

143. All emergency rulemaking must comply with the provisions of 5 M.R.S. § 8054. Section 8054(2) provides that "[a]ny emergency rule must include, with specificity, the agency's findings with respect to the existence of an emergency...." The Rule does not contain such emergency findings. While the "Basis Statement"[56] submitted by the Department to the Secretary of State as part of the rulemaking process does contain "Findings of Emergency", the statute clearly requires that such findings must be included in the text of the rule.

144. Since it was not promulgated in accordance with the controlling Maine statute, Plaintiffs seek a Declaratory Judgment that the Rule is unlawful and invalid under 5 M.R.S. § 8058.

COUNT 2

The Rule is Invalid Under State Law Because It Was Promulgated as a "Routine Technical" Rule

145. Plaintiffs reallege and reincorporate by reference all prior paragraphs of this Complaint and the paragraphs in the counts below as though fully set forth herein.

146. The Maine Administrative Procedure Act provides that all rules adopted after January 1, 1996 fall into one of two separate categories: "routine technical rules" and "major substantive rules".

147. "Routine technical" rules are "procedural rules that establish standards of practice or procedure for the conduct of business with or before an agency and any other rules that are not major substantive rules as defined in paragraph B". 5 M.R.S. § 8071(2)(A). "Major substantive" rules are initially adopted only provisionally and are subject to heightened legislative review.

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[56] The Basis Statement, like the Rule itself, cites for its authority 22 M.R.S. §§ 802(1) and (3), with no mention of sub-§(2).

Section 8071(2)(B) provides that "major substantive rules" are rules that in the opinion of the Legislature:

> (1) Require the exercise of significant agency discretion or interpretation in drafting; or
>
> (2) Because of their subject matter or anticipated impact, are reasonably expected to result in a significant increase in the cost of doing business, a significant reduction in property values, the loss of significant reduction of government benefits or services, the imposition of state mandates on units of local government...***or other serious burden on the public*** or units of local government. (emphasis added)

148. 22 M.R.S. §§ 802(1) and 802(3) are cited by the Department as the statutory authority for the Rule both in the Rule itself and in the supporting documentation submitted to the Secretary of State. Subsection (1) does not provide statutory authority for the new mandate; rather, it speaks only of the powers of the Department to "designate"; "classify"; "investigate"; and establish "reporting requirements" and "procedures". It cannot possibly be construed as authorizing the new mandate, with its serious implications for the lives of Plaintiffs' member and other healthcare workers in Maine.

149. Subsection (3), in relevant part, simply provides a general grant of rulemaking authority to the Department in connection with carrying out its duties under Title 22, Subtitle 2, Part 3, Chapter 250, and states that rules adopted pursuant to Subsection (3) are routine technical rules unless otherwise indicated. Read in context, this provision can only mean that the Department's rules adopted under Chapter 250 are meant to be either non-emergency

routine technical rules, or emergency rules promulgated for the limited purposes set forth in Subsection (2) (the circumstances "otherwise indicated").

150. This conclusion is supported by the notable failure of the Rule and of the Department's supporting documentation to cite 22 M.R.S. § 802(2) as providing authority for the Rule. As noted above, this provision of the statute is the only provision that mentions a declaration by the Department of a public health emergency, and it understandably authorizes only emergency rules -- ***but not*** the new mandate found in the Rule, as the Department clearly recognizes.

151. In these circumstances, the Court should recognize that when the Department wants to promulgate a rule that is not a proper subject for emergency rulemaking under 22 M.R.S. § 802(2) but that also cannot properly be considered a routine technical rule under the Administrative Procedure Act, the proper course for the Department is to promulgate a non-emergency "major substantive rule".

152. In fact the new mandate clearly falls within the definition of "major substantive rule" provided by 5 M.R.S. § 8071(2)(B): it clearly requires the exercise of significant agency discretion or interpretation in drafting, and more importantly, because of its subject matter and anticipated impact, it can reasonably be expected to result in both (A) the imposition of a state mandate on units of local governments, notably local fire departments; and (B) a serious burden on significant segments of the public, namely (i) the tens of thousands of Maine residents who are now employed in the health care sector, or who are considering such employment in the future, (ii) the Maine businesses and organizations that employ healthcare workers in order to provide healthcare services to the public, and (iii) the consumers of healthcare services.

153. Conversely, it cannot reasonably be maintained that the new mandate found in the Rule really constitutes a "routine" and purely "technical" rule.

154. Since it was not promulgated in accordance with the controlling Maine statute, Plaintiffs seek a Declaratory Judgment that it is unlawful and invalid under 5 M.R.S. § 8058.

COUNT 3

The Rule is Invalid Under State Law Because the Department Did not Consider All Relevant Information Available to It

155. Plaintiffs reallege and reincorporate by reference all prior paragraphs of this Complaint and the paragraphs in the counts below as though fully set forth herein.

156. 5 M.R.S. § 8052(4) provides that an agency "shall consider all relevant information available to it, including, but not limited to, economic, environmental, fiscal and social impact analyses and statements and arguments filed, before adopting any rule."

157. The Department did not consider all relevant information to it before promulgating the Rule. As noted above, by the Department's own admission, the only information that it considered was the COVID guidance provided by the CDC and the "experience and knowledge" of its own employees.

158. Since it was not promulgated in accordance with the controlling Maine statute, Plaintiffs seek a Declaratory Judgment that the Rule is unlawful and invalid under 5 M.R.S. § 8058.

COUNT 4

The Rule is Invalid Under State Law Because the Department Did not Prepare an Economic Statement

159. Plaintiffs reallege and reincorporate by reference all prior paragraphs of this Complaint and the paragraphs in the counts below as though fully set forth herein.

160. Some of the Designated Healthcare Care Facilities affected by the new mandate imposed by the Rule have 20 or fewer employees and are therefore small businesses as defined by 5 M.R.S. § 8052(5-A). The new mandate imposed by the Rule may have an adverse economic impact on these small businesses.

161. 5 M.R.S. § 8052(5-A) provides that prior to the adoption of any proposed rule that may have an adverse economic impact on small businesses, an agency of the State of Maine must prepare an economic impact statement that includes (A) an identification of the types and an estimate of the number of the small businesses subject to the proposed rule; (B) the projected reporting, record-keeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record; (C) a brief statement of the probable impact on affected small businesses; and (D) a description of any less intrusive or less costly, reasonable alternative methods of achieving the purposes of the proposed rule.

162. The Department did not prepare an economic impact statement as required by 5 M.R.S.A. § 8052(5-A).

163. Since it was not promulgated in accordance with the controlling Maine statute, Plaintiffs seek a Declaratory Judgment that the Rule is unlawful and invalid under 5 M.R.S. § 8058.

COUNT 5

The Rule is Unlawful Because it Violates the Substantive Due Process Right to Voluntary, Informed Consent and Personal Autonomy and Bodily Integrity, Including the Right to Refuse Medical Treatment, Guaranteed by the Fourteenth Amendment to the U.S. Constitution and by Article 1 of the Maine Constitution

164. Plaintiffs reallege and reincorporate by reference all prior paragraphs of this Complaint and the paragraphs in the counts below as though fully set forth herein.

165. The Fourteenth Amendment to the United States Constitution provides that no State shall "deprive any person of life, liberty, or property, without due process of law."

166. Under the Due Process Clause, a competent person has a constitutionally protected liberty interest in bodily integrity. *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997). A competent person also has a constitutionally protected liberty interest in to be free from unwanted medical intervention. *Planned Parenthood v. Casey*, 505 U.S. 833, 927 (1992).

167. The right to refuse medical treatment carries with it an implied right to the information necessary to make an informed decision about whether to refuse the treatment.

168. Without crucial information about the risks and benefits of a procedure, the right to refuse rings hollow.

169. Together, the rights to refuse or accept treatment and to information constitute informed consent, guaranteed by the Fourteenth Amendment.

170. The Due Process Clause requires balancing between an individual's liberty interest in refusing treatment and the state's interest in requiring it.

171. Presumably, Defendants formulated and adopted the new mandate contained in the Rule in order to minimize outbreaks of COVID-19 among the public in the State of Maine; to prevent or reduce the risk of transmission of COVID-19 among members of the public; and to promote the public health of the community consistent with federal, State and local efforts to stem the pandemic.

172. The full safety and full efficacy of emergency-use authorized COVID-19 vaccines remains unknown.

173. All COVID-19 vaccines are currently undergoing clinical trials and therefore remain experimental vaccines.

174. The Due Process Clause prohibits Defendants from coercing any individual to accept an experimental medical product.

175. The Rule coerces the individual Plaintiffs to accept experimental vaccines and thus violates the Due Process Clause.

176. Since the Rule was not adopted as a result of any legislative action, elected officials accountable to the People have made no assessment of safety, efficacy, necessity, reasonableness, proportionality or discrimination from a COVID-19 mandate, in violation of the Due Process Clause of the Fourteenth Amendment.

177. Furthermore, when balancing the fundamental rights of the Plaintiffs with the objectives of the State, it is clear that the Rule is not necessary, reasonable, proportional or nondiscriminatory enough to achieve its stated interests, thus violating the Due Process Clause of the Fourteenth Amendment.

178. The Rule coerces healthcare workers in Maine, including the Individual Plaintiffs, to take vaccines that have not been shown to a reasonable degree of medical certainty to be safe or effective and have not been shown to be safe or effective long-term at all.

179. The Rule coerces administration of experimental vaccines that are still under investigation and are the subject of ongoing clinical trials.

180. The Rule coerces administration of vaccines for which data are insufficient to assess effectiveness in preventing infection or transmission at this time.

181. The Rule requires administration of vaccines that have not been proven safe and effective and for which there is no long-term safety or effectiveness data. Indeed, there is absolutely no information or data concerning the long-term safety or long-term efficacy of COVID-19 vaccines because of the fact that they have been tested on humans for such a short period of time.

182. Currently, it is not possible to know with any reasonable degree of medical certainty whether the risks from COVID-19 vaccines outweigh their purported benefits for the age group implicated by the Rule.

183. The Rule requires administration of vaccines that have injured and killed tens of thousands of people according to VAERS.

184. The Rule requires administration of vaccines that have proven ineffective against COVID-19 variants.

185. The Rule requires administration of vaccines that are being shown in the most recent medical literature to be ineffective in preventing the spread of COVID-19.

186. The Rule requires administration of vaccines to individuals who have recovered from COVID-19, for whom it is not medically necessary, and who are at elevated risk of harm from vaccination because of their natural-acquired immunity.

187. As a matter of law, any drug, device, or biologic, such as vaccines, approved for use under emergency-use authorization that is still under investigation cannot meet the requirements of the Due Process Clause for mandatory administration.

188. The Rule is not narrowly tailored to carry out a compelling state purpose.

189. Defendants' actions and omissions, under color of law, violate Plaintiffs' right to bodily integrity and medical freedom under the Due Process Clause of the Fourteenth Amendment.

190. The substantive due process rights of the United States and Maine Constitutions are coextensive. *Doe v. Williams*, 2013 ME 24, ¶ 65, 61 A.3d 718, 737.

191. Article 1, Section 1 of the Maine Constitution ("Natural Rights"), provides that all people have certain natural, inherent and unalienable rights, including enjoying life and liberty.

192. Article 1, Section 6-A of the Maine Constitution ("Discrimination against persons prohibited") provides in part that no person shall be deprived of life, liberty or property without due process of law.

193. The Law Court has recognized that individuals have a fundamental liberty interest in bodily integrity generally. *Doe*, 2013 ME 24, ¶ 65, 61 A.3d 718, 737 (quoting *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997)). Moreover, the Law Court has also recognized the fundamental liberty interest in refusing medical treatment specifically. *Green v. Commissioner of the Dept. of Mental Health, Mental Retardation & Substance Abuse Services*, 2001 ME 86, ¶ 15, 776 A.2d 612.

194. The Law Court has also stated that "liberty" is "freedom from all restraints except such as are justly imposed by law to secure the common welfare." *State v. Old Tavern Farm*, Inc., 133 ME 468, 472, 180 A. 473, 475 (1935). A law that directly proposes to destroy or modify personal rights when there is no public necessity therefor, is unconstitutional and void. *Id.* at 475, 180 A. at 477.

195. A substantive due process analysis turns on whether the challenged state action implicates a fundamental right. The Law Court has observed that:

> *[T]he Due Process Clause specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed. Second, we have required in substantive-due-process cases a careful description of the asserted fundamental liberty interest. Our Nation's history, legal traditions, and*

practices thus provide the crucial guideposts for responsible decisionmaking that direct and restrain our exposition of the Due Process Clause.

Doe, 2013 ME 24, ¶ 66, 61 A.3d 718. (quoting *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997)).

196. When a state action infringes on a fundamental right or fundamental liberty interest, the infringement must be narrowly tailored to serve a compelling state interest. *Doe*, 2013 ME 24, ¶ 66, 61 A.3d 718.

197. The Rule is not within the scope of the State's legitimate police power because Defendant has not shown that the Rule is narrowly tailored to serve the purpose of protecting the public health.

198. Defendants' actions and omissions, under color of law, violate Plaintiffs' right to bodily integrity and medical freedom under Article I of the Maine Constitution.

199. Plaintiffs seek a Declaratory Judgment that the Rule is unlawful and invalid under the 14th Amendment of the U.S. Constitution and Article I of the Maine Constitution.

COUNT 6

The Rule is Preempted by Federal Law

200. Plaintiffs reallege and reincorporate by reference all prior paragraphs of this Complaint as though fully set forth herein.

201. The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2.

202. Where state and federal law directly conflict, state law must give way.

203. State law is naturally preempted to the extent of any conflict with a federal statute.

204. State and federal law conflict where it is impossible for a private party to comply with both state and federal requirements.

205. The Supremacy Clause requires that federal requirements for informed consent supersede state laws and regulations that conflict with EUA provisions.

206. The new mandate imposed by the Rule is preempted by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., specifically, 21 U.S.C. § 360bbb-3 ("Authorization for medical products for use in emergencies") because it conflicts with the requirements of that statute.

207. Congress enacted, and from time to time has amended, the Food, Drug and Cosmetic Act, in part, to occupy the field concerning the approval, licensure, and administration of vaccines, especially vaccines authorized for emergency use.

208. Pursuant to federal law, only the U.S. Secretary of Health and Human Services (the "Secretary") is authorized to introduce into interstate commerce, during a declaration of emergency, a biological product, which includes vaccines, that is intended for use in an actual or potential emergency under the specific requirements set forth in 21 U.S.C. §360bbb-3.

209. Only the Secretary is authorized by federal law to establish the conditions and requirements for the administration of emergency-use authorized biologics.

210. 21 U.S.C. § 360bbb-3 sets forth the "required conditions" for unapproved vaccines that are authorized for emergency use. These "required conditions" apply to "a person who carries out any activity for which the authorization is issued."

211. As a condition of emergency use authorization, the Secretary is required to establish "appropriate conditions designed to ensure that individuals to whom the product is administered are informed" of, inter alia, "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." 21 U.S.C. § 360bbb-3.

212. The Secretary has established such appropriate conditions concerning the currently available COVID-19 vaccines, consistent with federal law, by not mandating COVID-19 vaccines and requiring the use of EUA Fact Sheets that must be given to caregivers and recipients of COVID-19 vaccines, informing them of their right to accept or refuse administration of the vaccine.

213. Moreover, federal law specifically deprives the Secretary of the power to mandate emergency use authorized treatments, devices, or biologics of any kind, including vaccines, since the law specifically requires the Secretary to establish conditions to ensure that individuals to whom the product is administered are informed of the option to accept or refuse vaccination. 21 U.S.C. § 360bbb-3.

214. Congress passed the Food, Drug and Cosmetic Act generally, and § 360bbb-3 in particular, to occupy the field of emergency-use authorized vaccine approval and vaccine administration procedures, to set forth all required conditions for such use, and to preempt the States from approving vaccines affecting interstate commerce for emergency use on their own, and from deviating or contradicting its regulations and guidance concerning vaccines. Additionally, preemption is implied where there is actual conflict between federal and state law concerning vaccines.

215. The Rule conflicts with or fails to comply with the appropriate conditions established by the Secretary and the FDA for the administration of COVID-19 emergency-use authorized vaccines.

216. The Rule does not give healthcare workers "the option to accept or refuse administration" of COVID-19 vaccines without subjecting them to severe sanctions, notably the

loss of the employees' jobs and livelihoods, with associated emotional distress and insecurity. The Rule thus punishes healthcare workers for exercising their right under 21 U.S.C. § 360bbb-3 to informed consent, including the right to refuse to be vaccinated with a COVID-19 vaccine.

217. Defendants are not authorized to alter, amend, deviate or conflict with any of the conditions established by the Secretary for the use and administration of emergency use authorized biologics. The Rule conflicts with the Secretary's orders and directives for the use and administration of emergency use authorized biologics by coercing healthcare workers in Maine to waive their rights to informed consent codified by 21 U.S.C. § 360bbb-3.

218. Plaintiffs seek a Declaratory Judgment that the Rule is preempted by federal law.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment:

A. Declaring that the new mandate imposed by the Rule was not promulgated in accordance with the provisions of the Maine Administrative Procedure Act and is therefore unlawful;

B. Declaring that the new mandate imposed by the Rule is an unconstitutional burden on the fundamental rights to (i) personal autonomy and bodily integrity, (ii) voluntary, informed consent, and (iii) the right to refuse medical treatment;

C. Declaring that the new mandate imposed by the Rule conflicts with, and is preempted by, the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., and is therefore unlawful.

D. Declaring that the Defendants and their respective employees, officers, agents, and successors, and all persons acting in concert with each or any of them, are permanently enjoined from taking any steps whatsoever to enforce the new mandate imposed by the Rule;

E. Directing Defendant JEANNE M. LAMBREW to take steps as soon as possible to repeal the new mandate imposed by the Rule; and

F. Granting such other and further relief as the Court deems just and proper.

Dated this 2nd day of September, 2021.

Respectfully submitted,

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