UNITED STATES DEPARTMENT OF EDUCATION
400 MARYLAND AVENUE, SW
WASHINGTON, DC 20202

In the Matter of:	)	
	)	
Financial Value Transparency and	)	
Gainful Employment, Financial	)	Docket ED-2023-OPE-0089
Responsibility, Administrative	)	
Capability, Certification Procedures	)	
Ability to Benefit	)	
_____/		

PETITION FOR ADMINISTRATIVE HEARING

NOW, COMES, Steve Kirsch, Peter A. McCullough, MD, MPH, William Sumner Scott, JD, to Petition the United States Department of Education ("DoEd") to conduct a public hearing on the question of Certification Procedures for accreditation, in general, and the Council on Education for Public Health ("CEPH") accreditation, in particular, and, in support thereof, states as follows:

1. On May 3, 2023, the Accreditation Group, Office of Post Secondary Education, ("OPS") DoEd posted notice in the Federal Register (document number 2023-09362, Page 27876-27877) that written comments regarding the renewal application of CEPH to accredit institutions of Public Health and Public Health programs would be accepted until June 5, 2023.
2. On May 15, 2023, a copy of the CEPH renewal application was requested from OPS.
3. On May 17, 2023, OPS sent the request for a copy of the CEPH renewal application to the DoEd Freedom of Information Act ("FOIA") office.

4. On May 17, 2023, OPS was requested to extend the Time to comment on the CEPH renewal application until 30 days after a copy of the CEPH renewal application had been supplied for review. On the same day, OPS advised that there would be no extension of the comment period.
5. On May 19, 2023, Dr. McCullough filed his comments to the CEPH renewal application with OPS as instructed by the Federal Register Notice of May 3, 2023, identified above. Dr. McCullough's comments are attached as Exhibit 1 and are made a part hereof.
6. On May 22, 2023, Scott filed his comments to the CEPH renewal application with OPS as instructed by the Federal Register Notice of May 3, 2023, identified above. Scott's comments are attached as Exhibit 2 and made a part hereof.
7. On June 1, 2023, Kirsch filed his comments to the CEPH renewal application with OPS as instructed by the Federal Register Notice of May 3, 2023, identified above. Kirsch's comments are attached as Exhibit 3 and made a part hereof.
8. At Docket ID ED-2020-OGC-0150, the DoEd published interim regulations for issuance of rulemaking and guidance documents. Among the guidelines was the recognized need for transparency and public participation. The need for transparency was specifically recognized by release issued on February 8, 2022, which concluded:

> "This release affirms the Biden administration's commitment to greater transparency and serves to honor that commitment and ensure confidence in the Department's review process. We believe this approach – requested by

members of the public, advocates, and members of NACIQI - will allow for greater public participation and discussion and lead to a more robust and informed discussion at NACIQI public meetings.

We encourage members of the public to provide comments on any of the agencies under review or NACIQI's work at the forthcoming NACIQI meeting and hope the information provided today helps members of the public to do so."

9. OPS has advised it has no intention of permitting either transparency or public participation in the review of the renewal application of CEPH to accredit public health schools and programs. See OPS response:

Bounds, Herman May 17, 2023, 12:18 PM

No, the comment period will not be extended. Regarding notification of the receipt of written comments, my advice is that when comments are sent via the ThirdPartyComments@ed.gov please request a delivery receipt and a read receipt. No case number will be generated. Also, you used the term "hearing". That term is not applicable to the Third Party Written Comment process. This process is simply for the collection of Third Party written comments. A later Federal Register notice will be published with instructions regarding how to make oral comments during the National Advisory Committee on Institutional Quality and Integrity (NACIQI) meeting. Please see this explained under the Supplementary Information section of the Federal Register notice.

Sincerely,

Herman Bounds Jr., MS., Ed.S.
Director, Accreditation Group
Office of Post Secondary Education
US Department of Education
400 Maryland Ave
Washington DC 20202
Herman.Bounds@ed.gov<mailto:Herman.Bounds@ed.gov>
202-453-6128, Cell 202-407-6200

10. Procedures Requested:

A. Assignment of a docket number to this petition and all comments received by OPS to date in regard to the CEPH renewal application be published at the docket number with the ability of the public to view and download any and all entries made now and in the future to the docket.

B. The renewal application of CEPH put on hold to allow time for OPS to publish the CEPH renewal application on the assigned docket number to this Petition and on its website and give no less than 90 days for all interested parties to comment after said CEPH renewal application is published.

C. A complete list of the Institutions accredited by CEPH identified by those that mandated a vaccine for its faculty and staff to continue employment and students to attend class and those who did not be developed. Each of those institutions be required to respond to the notice for comment on the CEPH renewal application to explain the role or no action by CEPH in the vaccine mandate review process. In addition, they must be required to collect and publish the data related to their faculty, staff, and students' vaccine and general health experiences.

D. A mediator or hearing officer be appointed by the DoEd Secretary to collect evidence and submit a recommendation to the DoEd Secretary to identify those responsible for crimes against humanity, if any, and who was found to have committed those crimes.

E. The DoEd Secretary is to then to send his recommendations to the US Congress oversight committee responsible for Higher Education for Public Health for review and determination of how to best proceed.

F. All of these steps must be open to public review as they take place.

CONCLUSION

The USG imposition of mandates, participation in censorship, retaliation against those with opposing views has sufficiently corrupted all USG agencies, including sections of the DoEd.

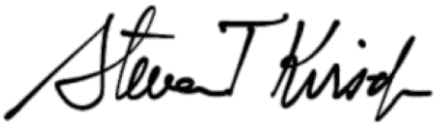
Great care must be taken if justice against those who harmed the public by the improper USG attempts to control and treat the pandemic is to be achieved.

The undersigned requested a copy of the CEPH renewal of accreditation application which the DoEd referred to its FOIA office. FOIA assigned number 23-01804-F and reported a copy of the application would be sent in the near future. A copy has not been received. PAM, WSS, and STK reserve the right to amend and/or supplement this Petition upon review of the CEPH application for renewal.

Respectfully submitted,

William Sumner Scott, JD
1078 Summit Avenue #565
Jersey City, NJ 07307
(908) 294-5363
04wmscott@comcast.net

Peter McCullough
The Kirsch Foundation
4546 El Camino Real, B10 #182
Los Altos, CA 94022
248.444.6905
peteramccullough@gmail.com



Steve Kirsch
Vaccine Safety Research Found, a project of The Kirsch Foundation
4546 El Camino Real, B10 #182
Los Altos, CA 94022
650.283.4347
stk@alum.mit.edu

cc: lking@ceph.org

EXHIBIT 1

WILLIAM SUMNER SCOTT
Attorney at Law
1078 Summit Avenue, # 565
Jersey City, NJ 07307

(908) 294-5363
04wmscott@comcast.net

May 19, 2023

Dr. Miguel Cardona
Secretary of Education
U. S. Department of Education
400 Maryland Avenue, SW
Washington, D.C. 20202

via email only
thirdpartycomments@ed.gov

Dear Dr. Cardona,

Following are comments, of Peter A. McCullough, MD, MPH™, ("PAM"), by the undersigned, together with his demand for hearing and subsequent denial of the authority of the Council on Education for Public Health ("CEPH") to accredit any institution of higher learning for any purpose.[1] This submission is made to you pursuant to 496(n)(1)(A) of the Higher Education Act (HEA) of 1965, as amended, to be the subject of a hearing that allows PAM discovery and other due process protections and, thereafter, considered by the National Advisory Committee on Institutional Quality and Integrity (NACIQI) during its summer 2024 meeting and, thereafter, acted upon by you to deny accreditation authority to CEPH.

I. REASON FOR DENIAL

1. CEPH is one of the agencies used by the United States Government ("USG") to force ignorance on the American people. From January 2019 to the date of this submission, various agencies of the USG issued opinions that a pandemic commonly called Covid-19 was in progress and that various treatments and vaccines had been developed to combat that pandemic. Numerous experts in the field of public

[1] The facts in these comments and request for hearing speak for themselves. The opinions are the views of PAM and are not represented to be the views of any other person or entity mentioned or not mentioned in these comments.

health and members of the public had views on how to deal with the pandemic that were contrary to the USG, CEPH, and the institutions they accredit. See the work of:

Steve Kirsch
Vaccine Safety Research Foundation
https://substack.com/@stevekirsch
https://www.vacsafety.org/

Childrens Health Defense
852 Franklin Ave. Suite 511
Franklin Lakes, NJ 07417
https://childrenshealthdefense.org/

No College Mandates
P. O. Box 553
Kentfield, CA 84814
https://nocollegemandates.com/

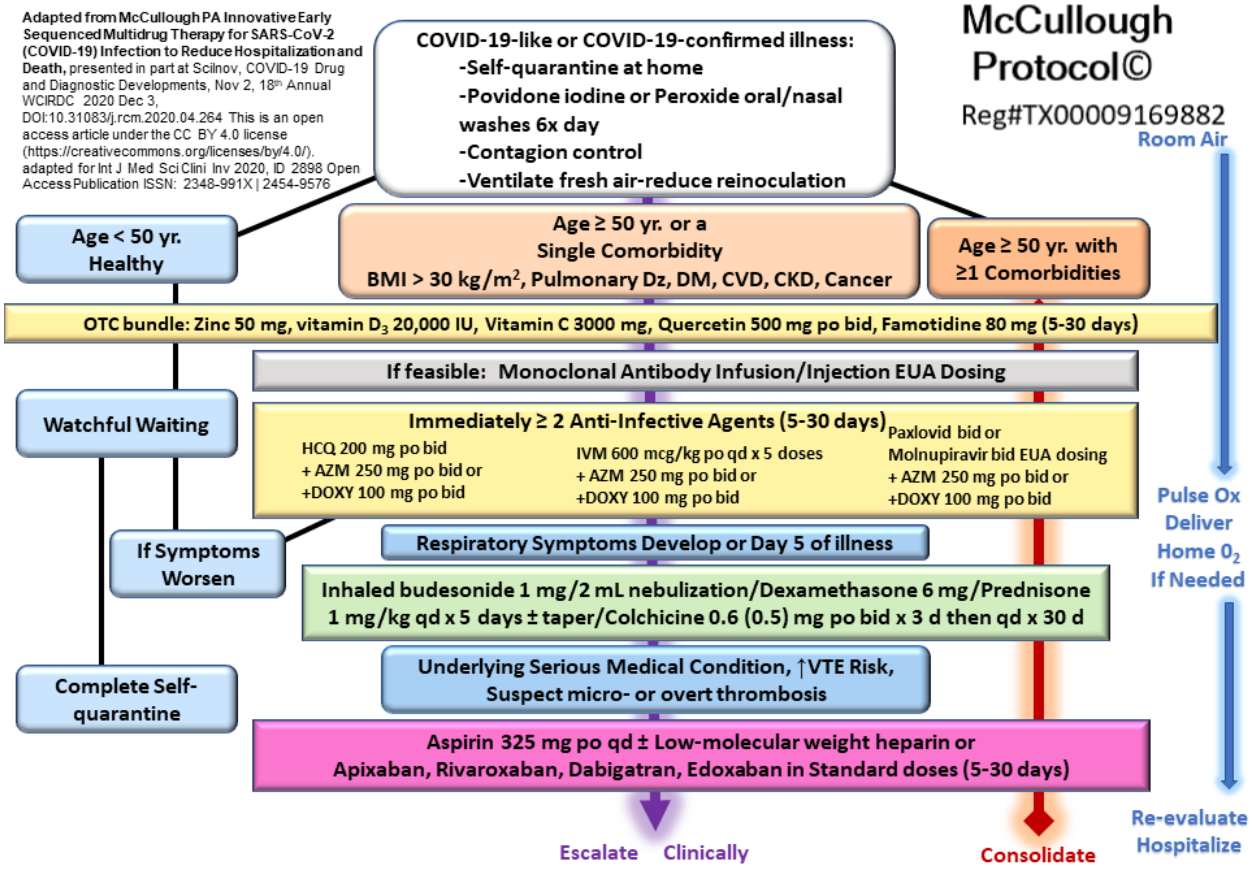
Dr. Simone Gold
America's Frontline Doctors
P. O. Box 131808
Houston, TX 77219-1808 https://www.americasfrontlinedoctors.org/about-us

2. Rather than a scientific method of analysis of opposing views, CEPH and the institutions it accredits stifled the free speech of those who opposed the USG protocols and also mandated, unsafe, and ineffective vaccines. Many of the institutions CEPH accredits and members of the public health professions accepted money from the USG and drug manufacturers or their designees as bribes or rewards or grants or promises of future employment for prescribing USG recommended and mandated treatments and vaccines. CEPH took no steps to eliminate conflicts of interest and otherwise preserve and protect the quality and integrity of the institutions it accredits. CEPH is not worthy of renewal to continue the malicious introduction of unproven methods of treatment and withholding of vaccine results from the public.

3. PAM and those health professionals listed above, and many others, questioned the need, effectiveness, and potential harm, including death from the use of the USG recommended inadequate or inappropriate treatment, lockdowns, masks, social distancing, and mandated unsafe, and ineffective vaccines. All of these actions deviated from the community standard of care. Specifically:

A. The unsafe, and ineffective vaccines were experimental and evidence of harm to lab animals existed. CEPH made no effort to require tests be conducted to determine the effectiveness of the use of ventilators, low-dose dexamethasone, veklury (remdesivir), and other NIH recommended treatments for Covid-19 although evidence of harm by use of those methods existed.

B. Community standard of care treatments such as combinations of viricidal nasal sprays/gargles, Ivermectin, Hydroxychloroquine, prednisone, doxycycline, azithromycine, budesonice nebulization, colchicine, aspirin, enoxaparin were more reliable and produced better results to stop the pandemic than did the USG recommendations listed above, particularly the mandated unsafe, and ineffective vaccines.



C. CEPH never put any rules or regulations in place to teach that the health industry was obligated to investigate all avenues of treatment and control of the virus. Results of the use of the USG recommended treatments and vaccines as compared with the alternative treatments were withheld from the public. CEPH and its member institutions made no objection.

D. The USG and or its designees paid and continue to pay health professionals' bonuses for Covid-19 diagnosis and for the use of specific treatments, medicines, and unsafe, and ineffective vaccines. The acceptance of these payments was never objected to by CEPH. No investigation of the potential conflicts of interest was conducted by CEPH or any of its member institutions.

E. Those who opposed the USG recommended actions were subjected to USG orchestrated censorship and professional reprisal with attacks upon their clinical authority to practice their designated medical and related field. CEPH made no objection to those attacks.

F. CEPH made no objection to the lockdowns, separation of the vaccinated from the unvaccinated or use of masks to control the spread of the virus in spite of the fact that no trials were conducted to prove these efforts were necessary or effective.

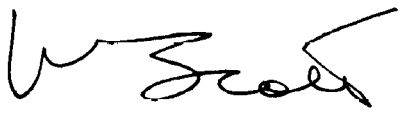
II. CEPH inaction to preserve intellectual honesty, quality, and integrity in the field of public health administration requires the denial of its renewal and decertification as the agency to accredit institutions that teach public health practices and standards.

III CONCLUSION

If the American people are to have a quality health system, the effort must begin with an educational system that teaches the value of free speech, truth, and ethics to our students of higher learning. One of the steps to achieve that goal is the removal of CEPH from the power to control how Public Health treatments and protocols are taught.

PAM reserves the right to amend and/or supplement these comments upon review of the CEPH application for renewal which is expected to be supplied by the Department of Education for public view at some time in the near future.

Respectfully submitted,
Peter A. McCullough, MD, MPH™



By: William Sumner Scott, J. D.
Legal Counsel to Dr. McCullough

WSS;lf

cc: lking@ceph.org
distribution list

A read receipt has been requested. Please acknowledge acceptance of these comments and assign a case number for the hearing to be conducted.

EXHIBIT 2

WILLIAM SUMNER SCOTT
1078 Summit Avenue, #565
Jersey City, NJ 07307

(908) 294-5363
04wmscott@comcast.net

May 22, 2023
Rev May 25, 2023

Dr. Miguel Cardona
Secretary of Education
U. S. Department of Education
400 Maryland Avenue, SW
Washington, D.C. 20202

via email only
thirdpartycomments@ed.gov

Dear Dr. Cardona,

Following are William Sumner Scott, individually, (first person or "WSS"), comments, demand for hearing and request to deny the authority of the Council on Education for Public Health ("CEPH") to accredit any institution of higher learning for any purpose.[2] This submission is in response to Federal Register document number 2023-09362, page 27876-27877 and pursuant to 496(n)(1)(A) of the Higher Education Act (HEA) of 1965, as amended, in word format, to be assigned a docket number and subject to a hearing pursuant to rule making and guidance under the Administrative Procedures Act applicable to the Department of Education, 34 CFR Part 9.

A copy of the comments of Peter A. McCullough, MD, MPH™, ("PAM") to the CEPH application for renewal filed May 19, 2023, is attached, and incorporated into these comments - Exhibit A.

[2] The facts in these comments and request for hearing speak for themselves. The opinions are my views and are not represented to be the views of any other person or entity mentioned or not mentioned in these comments.

I. Lack of quality of the Public Health Programs at Institutions of Higher Education Accredited by CEPH.

A. After World War II, the United States Government ("USG") prosecuted German doctors who were found to have conducted medical experiments on subjects without their consent in the case of US v Brandt, et al.

B. In the Brant verdict rendered on August 27, 1947, is a section entitled "Permissible Medical Experiments" which listed the ten points commonly called the Nuremberg Code ("Code"). The ten points incorporated in these comments and are attached as Exhibit B.

C. As detailed in the PAM comments and adopted in these comments, the mandate of experimental vaccines against the American Public by various agencies of the USG sufficiently violated the Code to be deemed crimes against humanity. Particularly:

i The USG treatments and vaccines were imposed by USG sponsored censorship of the existence of effective alternative treatments such as the combinations of viricidal nasal sprays/gargles, Ivermectin, Hydroxychloroquine, prednisone, doxycycline, azithromycine, budesonice nebulization, colchicine, aspirin, and enoxaparin. See PAM comments attached as Exhibit A.

ii The PAM recommended case by case diagnosis and treatments were more reliable and produced better results to stop the pandemic than did the USG recommendations of ventilators, low-dose dexamethasone, veklury (remdesivir), and other NIH recommended treatments for Covid-19, including the mandated unsafe, and ineffective vaccines.

iii Community standard of care required the evaluation of each individual patient with a prescribed treatment which in the best judgment of the medical professional will cure or reduce the adverse effects of the symptom. This standard of care is commonly called a "Protocol". The PAM protocol for diagnosis of Covid-19 and other viral symptoms is identified in paragraph I., 3., B of Exhibit A.

iv CEPH never provided guidance to the institutions on Public Health it accredits to prevent the imposition of crimes against all of humanity in general and their respective faculty, staff, and students, in particular.

II. Remedy Required

A. The United States legal system normally looks to USG agencies, including its Public Health agencies, to supply expert analysis of specific fields of endeavor upon which to base its factual determinations. In the instance of the pandemic analysis, all USG agencies with authority to regulate public health failed to conduct studies to justify the mandate of vaccines or the recommendation of any treatment. These failures render the USG Public Health agencies unreliable and conflicted to conduct a review of the wrongs committed.

B. The sections of the US Department of Education (the "DoE") that awards grants, student financing, and scholarships are also conflicted.

C. The US Department of Justice has done nothing to protect the public from the harm caused by the USG mandated vaccines and recommended treatments. It has turned its back on the bribes, bonuses, grants, and awards paid to the medical professions and hospitals, therefore, it is not the proper agency to investigate the quality of Public Health in the United States.

D. Subject to the opportunity for discovery and all concerned persons to present evidence, the DoE, accreditation section, is the best available agency to conduct a hearing on the questions of were crimes against humanity committed and who should be held accountable.

III. IMPROPER EMERGENCY USE AUTHORIZATION

A. On February 15, 2023, Joseph A. Ladapo, MD, Ph.D., Florida Surgeon General, wrote a letter to the FDA-CDC to question the quality of data collection regarding Emergency Use Authorized vaccines to treat Covid-19. See Ladapo letter incorporated herein by reference - Exhibit C.

B. On March 10, 2023, U. S. Food and Drug Administration Commissioner Robert M. Calif, MD and Center for Disease Control and Prevention Director, Rochelle P. Walensky, MD, MPH sent a joint letter to respond to Dr. Ladapo to assert the death and injury statistics collected by the Vaccine Adverse Event Reporting System ("VAERS") and other sources are reliable and prove the vaccines are safe and effective. See FDA-CDC response incorporated herein by reference Exhibit D.

C. On May 9, 2023, Department of Health and Human Services Secretary Xavier Becerra signed the Eleventh Amendment to the Declaration under section 319F–3 the Public Readiness and Emergency Preparedness Act ("PREP") to adopt changes and republish all prior Amendments. A copy is attached and incorporated by reference - Exhibit E.

D. None of the correspondence identified as Exhibits C, D, and E, made the assertion that EUA was not warranted to distribute, much less mandate, the experimental Covid-19 vaccines because effective alternative treatments detailed by PAM in his Protocol cited in Section I, paragraph C, 1 &2 above and Exhibit A attached were available.

E. On May 9, 2023, HHS Secretary Beccerra signed the 11th Amendment to the declaration under the PREP ACT for COVID 19 Medical Countermeasures without reference to or consideration of the alternative measures identified by PAM in Exhibit A. See Exhibit F.

F. The USG Covid-19 vaccine positions are maintained by censorship and intimidation against those who make public contrary opinions.

IV. DATA COLLECTION

A. Various institutions of higher learning mandated the experimental vaccines as a condition precedent to continue employment and attend class. A representative sample of those institutions is incorporated herein by reference - Exhibit G attached.

B. A copy of these comments has been sent to each of them with the demand they immediately rescind their mandatory vaccine policy and

install a method to collect and publish the health history of their students without disclosure of their identities.

C. The Secretary of Education is requested, as part of his review of the accreditation procedures of CEPH, to require the institutions of Public Health that CEPH accredits to collect and publish the results of the vaccines upon their faculty, staff and students.

V. PROPER PROCEDURES

A. The renewal application of CEPH must be put on hold to allow time for the DoE to publish the CEPH renewal application on its website and give no less than 90 days for all interested parties to comment.

B. A complete list of the Institutions accredited by CEPH that mandated a vaccine for its faculty and staff to continue employment and students to attend class must be developed. Each of them must be required to respond to the notice for comment on the CEPH renewal application to explain the role or no action by CEPH in the vaccine mandate process. In addition, they must be required to collect and publish the data related to their faculty, staff, and students' vaccine experiences.

C. A mediator must be appointed by the DoE Secretary to collect evidence and submit a recommendation to the DoE Secretary to identify those responsible for crimes against humanity, if any, and who was found to have committed those crimes.

D. The DoE Secretary is to then to send his recommendations to the US Congress oversight committee responsible for Higher Education for Public Health for review and determination of how to best proceed.

E. All of these steps must be open to public review as they take place.

VI. CONCLUSION

The USG imposition of mandates, participation in censorship, retaliation against those with opposing views has sufficiently corrupted all USG agencies, including sections of the DoE.

Great care must be taken if justice against those who harmed the public by the improper USG attempts to control and treat the pandemic is to be achieved.

The undersigned requested a copy of the CEPH renewal of accreditation application which the DoE referred to its FOIA office. FOIA assigned number 23-01804-F and reported a copy of the application would be sent to me in the near future.

WSS reserves the right to amend and/or supplement these comments upon review of the CEPH application for renewal.

A read receipt for these comments has been requested. Please acknowledge acceptance of these comments and assign a case number for the hearing to be conducted.

Respectfully submitted,

William Sumner Scott, J. D.
1078 Summit Avenue #565
Jersey City, NJ 07307

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WSS;lf

cc: lking@ceph.org
Peter A. McCullough, MD, MPH™
World Peace Through Education Foundation, Inc.
distribution list

EXHIBIT A

WILLIAM SUMNER SCOTT
Attorney at Law
1078 Summit Avenue, # 565
Jersey City, NJ 07307

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04wmscott@comcast.net

May 19, 2023

Dr. Miguel Cardona
Secretary of Education
U. S. Department of Education
400 Maryland Avenue, SW
Washington, D.C. 20202

via email only
thirdpartycomments@ed.gov

Dear Dr. Cardona,

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Steve Kirsch
Vaccine Safety Research Foundation
https://substack.com/@stevekirsch
https://www.vacsafety.org/

Childrens Health Defense
852 Franklin Ave. Suite 511
Franklin Lakes, NJ 07417
https://childrenshealthdefense.org/

No College Mandates
P. O. Box 553
Kentfield, CA 84814
https://nocollegemandates.com/

Dr. Simone Gold
America's Frontline Doctors
P. O. Box 131808
Houston, TX 77219-1808
https://www.americasfrontlinedoctors.org/about-us

4. Rather than a scientific method of analysis of opposing views, CEPH and the institutions it accredits stifled the free speech of those who opposed the USG protocols and also mandated, unsafe, and ineffective vaccines. Many of the institutions CEPH accredits and members of the public health professions accepted money from the USG and drug manufacturers or their designees as bribes or rewards or grants or promises of future employment for prescribing USG recommended and mandated treatments and vaccines. CEPH took no steps to eliminate conflicts of interest and otherwise preserve and protect the quality and integrity of the institutions it accredits. CEPH is not worthy of renewal to continue the malicious introduction of unproven methods of treatment and withholding of vaccine results from the public.

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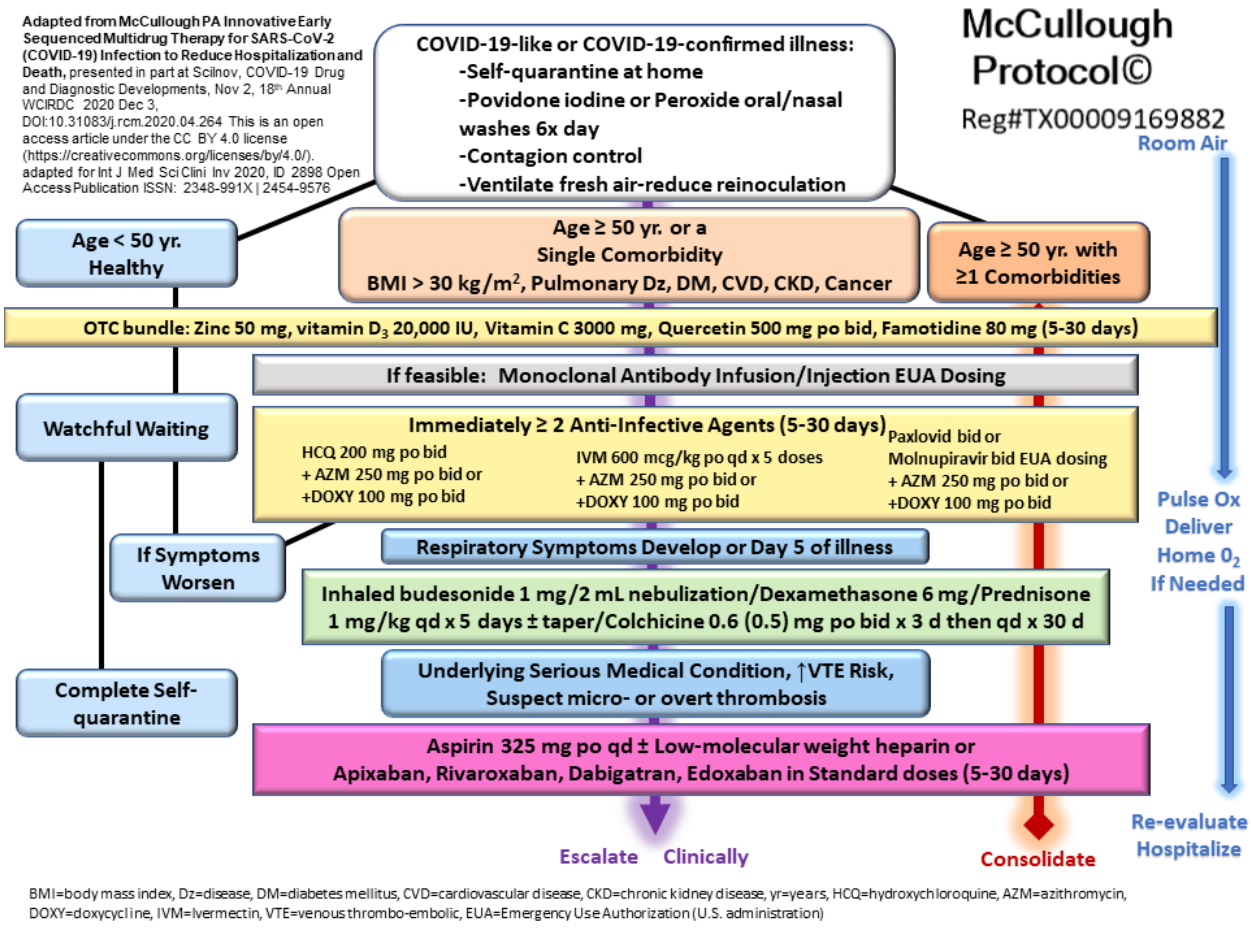

C. CEPH never put any rules or regulations in place to teach that the health industry was obligated to investigate all avenues of treatment and control of the virus. Results of the use of the USG recommended treatments and vaccines as compared with the alternative treatments were withheld from the public. CEPH and its member institutions made no objection.

D. The USG and or its designees paid and continue to pay health professionals' bonuses for Covid-19 diagnosis and for the use of specific treatments, medicines, and unsafe, and ineffective vaccines. The acceptance of these payments was never objected to by CEPH. No investigation of the potential conflicts of interest was conducted by CEPH or any of its member institutions.

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F. CEPH made no objection to the lockdowns, separation of the vaccinated from the unvaccinated or use of masks to control the spread of the virus in spite of the fact that no trials were conducted to prove these efforts were necessary or effective.

III. CEPH inaction to preserve intellectual honesty, quality, and integrity in the field of public health administration requires the denial of its renewal and decertification as the agency to accredit institutions that teach public health practices and standards.

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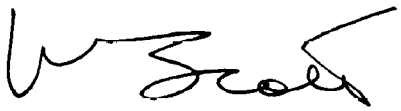
If the American people are to have a quality health system, the effort must begin with an educational system that teaches the value of free speech, truth, and ethics to our students of higher learning. One of the steps to achieve that goal is the removal of CEPH from the power to control how Public Health treatments and protocols are taught.

PAM reserves the right to amend and/or supplement these comments upon review of the CEPH application for renewal which is expected to be supplied by the Department of Education for public view at some time in the near future.

Respectfully submitted,
Peter A. McCullough, MD, MPH™



By: William Sumner Scott, J. D.
Legal Counsel to Dr. McCullough

WSS;lf

cc: lking@ceph.org
distribution list

A read receipt has been requested. Please acknowledge acceptance of these comments and assign a case number for the hearing to be conducted.

EXHIBIT B

The ten points of the Nuremberg Code were given in the section of the U. S. v Brandt, et al, verdict titled "Permissible Medical Experiments" August 20, 1947:

1. The voluntary consent of the human subject is absolutely essential. 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, overreaching, 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. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.[13]
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

EXHIBIT C

FLORIDA
HEALTH

Vision: To be the Healthiest State in the Nation

February 15, 2023

Robert M. Calif7 MD, MACC
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Springs, MD 20993

Rochelle P. Walensky, MD, MPH
Director Centers for Disease Control and Prevention
2877 Brandywine Rd, Room 2402
Atlanta, GA 30341

Drs. Calif and Walensky,

The COVID-19 pandemic brought many challenges that the health and medical field have never encountered. Although the initial response was led by a sense of urgency and crisis management, I believe it is critical that as public health professionals, responses are adapted to the present to chart a future guided by data and common sense.

As Florida's Surgeon General, it was in the public's best interest to issue guidance for using mRNA COVlD-19 vaccines in children and in young men based on the absence of a health benefit in clinical trials. This guidance followed preliminary data analyses by the Florida Department of Health. We continue to refine and expand these findings, including addressing methodological issues inherent to evaluating vaccine safety and efficacy.

In addition to Florida's analysis of mRNA COVID-19 vaccines, academic researchers throughout our country and around the globe have seen troubling safety signals of adverse events surrounding this vaccine. Their concerns are corroborated by the substantial increase in VAERS reports from Florida, including life-threatening conditions. We have never seen this type of response following previous mass vaccination efforts pushed by the federal government. Even the HI NI vaccine did not trigger this sort of response. In Florida alone, we saw a 1,700% increase in reports after the release of the COVID-I9 vaccine, compared to an increase of 400% in vaccine administration for the same period. The reporting of life threatening conditions increased 4,400%.

This increase in adverse events, compared to the percent increase in vaccine use, further explains the significant uptick we are seeing in VAERS reports. These findings are unlikely to be related to changes in reporting given their magnitude, and more likely reflect a pattern of increased risk from mRNA COVlD-19 vaccines. We need unbiased research, as many in the academic community have performed, to better understand these vaccines' short- and long term effects.

According to a recent study, mRNA COVID-1 9 vaccines were associated with an excess risk of serious adverse events, including coagulation disorders, acute cardiac injuries, Bell's palsy, and encephalitis, to name a few. This risk was I in 550, much higher than other vaccines. To claim these vaccines are "safe and effective" while minimizing and disregarding the adverse events is unconscionable.

Communication between physicians and patients is a standard ethical practice that is fundamental to public health. Health care professionals should have the ability to accurately communicate the risks and benefits of a medical intervention to their patients without fear of retaliation by the federal government. The State of Florida remains dedicated to responding to COVID-I9 and other public health concerns through data-driven decisions. We will continue to shed light on the safety and efficacy of medications, including mRNA COVID-I9 vaccines, that could be an imminent threat to those with preexisting conditions. We will also promote the importance of prevention by supporting good nutrition, exercise, and other healthy habits. As a father, physician, and Surgeon General for the State of Florida, I request that your agencies promote transparency in health care professionals to accurately communicate the risks these vaccines pose. I request that you work to protect the rights and liberties that we are endowed with, not restrict, and diminish them.

I look forward to your responses and appreciate your support of our collective efforts to serve the health and safety of Florida and our nation.

Sincerely,

s/Joseph A. Ladapo
Joseph A. Ladapo, MD, Ph D
State Surgeon General

EXHIBIT D

FDA U. S. Food & Drug Administration

CDC Center for Disease Control and Prevention

March 10, 2023

Joseph A. Ladapo, M.D., Ph.D.
State Surgeon General
Florida Department of Health
4052 Bald Cypress Way, Bin A-00
Tallahassee, FL 32399-1701

Sent Via Electronic Mail Only

Dear Dr. Ladapo,

Thank you for your letter regarding COVID-19 vaccine safety. We appreciate this opportunity to address your questions and we would like to correct the associated misinterpretations and misinformation about the data from the Vaccine Adverse Event Reporting System (VAERS), in the spirit of transparency and supporting and serving the health of our nation.

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) continue to diligently monitor a variety of data sources to identify any potential risks of the vaccines and to ensure that information is available to the public. That said, focusing on adverse events in the absence of causal association and without the perspective of countervailing benefits is a great disservice to both individuals and public health. Like every other medical intervention, there are adverse effects from vaccination. Serious adverse events from COVID-19 vaccines are rare and are far outweighed by the benefits of these vaccines for every age group.

The claim that the increase of VAERS reports of life-threatening conditions reported from Florida and elsewhere represents an increase of risk caused by the COVID-19 vaccines is incorrect, misleading and could be harmful to the American public. The FDA-approved and FDA-authorized COVID-19 vaccines have met FDA's rigorous scientific and regulatory standards for safety and effectiveness and these vaccines continue to be recommended for use by CDC for all people six months of age and older. Both FDA and CDC have continued to collect outcome data from multiple sources that demonstrate the clear benefit of COVID-19 vaccines in preventing death, serious illness, and hospitalization from SARS-CoV-2 infection, along with indicating a modest benefit in the prevention of infection and transmission that wanes over time, even as new variants have emerged. Additional benefits include a reduced risk of known complications from SARS-CoV-2 infection, including post-COVID conditions, COVID-19- associated stroke and heart disease, and COVID-19-induced venous thromboembolism.

Reports of adverse events to VAERS following vaccination do not mean that a vaccine caused the event. Since December 2020, almost 270 million people have received more than 670 million doses of COVID-19 vaccines in the U.S., with over 50 million people having received the updated bivalent vaccine. **The Emergency Use Authorizations (EUAs) for the COVID-19 Vaccines require sponsors and vaccine providers to report certain adverse events through VAERS, so more reports should be expected.** Recent concerns about increased reports of cardiovascular events provide an instructive example of the need to do further analysis when increased reporting of an event occurs. Despite increased reports of these events, when the concern was examined in detail by cardiovascular experts, the risk of stroke and heart attack was actually lower in people who had been vaccinated, not higher.

FDA and CDC physicians continuously screen and analyze VAERS data for possible safety concerns related to the COVID-19 vaccines. For signals identified in VAERS, physicians from FDA and CDC screen individual reports, inclusive of comprehensive medical record review. Most reports do not represent adverse events caused by the vaccine and instead represent a pre-existing condition that preceded vaccination or an underlying medical condition that precipitated the event.

Adverse events must be compared to background rates in the population. This VAERS review methodology allows for successful identification of rare adverse reactions related to specific COVID-19 vaccines (e.g., Guillain-Barré Syndrome, thrombosis with thrombocytopenia syndrome, and immune thrombocytopenia following use of the Janssen COVID-19 Vaccine or myocarditis, pericarditis and anaphylaxis following use of the Pfizer-BioNTech and Moderna COVID-19 vaccines). Information about these adverse reactions is included in the fact sheets for healthcare providers administering vaccine and vaccine recipients and caregivers. FDA and CDC also continue to post summaries of the key safety monitoring findings and present the data publicly at regularly scheduled advisory committee meetings.

In addition to VAERS, FDA and CDC utilize complementary active surveillance systems to monitor the safety of COVID-19 vaccines. Active surveillance involves proactively obtaining and rapidly analyzing information occurring in millions of individuals recorded in large healthcare data systems to verify safety signals identified through passive surveillance or to detect additional safety signals that may not have been reported as adverse events to passive surveillance systems. FDA is conducting active surveillance using the Sentinel BEST (Biologics Effectiveness and Safety) System and collaborating with the Center for Medicare and Medicaid Services (CMS) and Department of Veterans Affairs (VA). These efforts complement those of CDC's Vaccine Safety Datalink (VSD) and the v-safe text-based monitoring system for conducting surveillance of adverse events, as well as the Clinical Immunization Safety Assessment (CISA) Project. FDA and CDC are also collaborating with other non-federal partners, including state and local health departments.

Based on available information for the COVID-19 vaccines that are authorized or approved in the United States, the known and potential benefits of these vaccines clearly outweigh their known and potential risks. Additionally, not only is there no evidence of increased risk of death following mRNA vaccines, but available data have shown quite the

opposite: that being up to date on vaccinations saves lives compared to individuals who did not get vaccinated. Multiple well conducted, peer-reviewed, published studies here and here demonstrate that the risk of death, serious illness and hospitalization is higher for unvaccinated individuals for every age group. Because we are not the only country in the world using COVID-19 vaccines, we also benefit from the experience of other countries. More than 13 billion doses of COVID-19 vaccines have been given around the world, including hundreds of millions of doses of mRNA vaccines and hundreds of millions of doses to children. Consistent with our data, these multiple international partners have robust monitoring for both safety and effectiveness. They find little evidence of widespread adverse events, also detect rare events as we do, and conclude that the benefits of the vaccines generally far outstrip their risks.

While many studies could be cited, a retrospective cohort study using the CDC's Vaccine Safety Datalink found no increased risk of death for the mRNA and Janssen vaccines across age, sex, and race/ethnicity groups. They found that crude non-COVID-19 mortality rates among COVID-19 vaccine recipients were lower than those among unvaccinated comparators. Another study using mathematical modeling estimated that the vaccines saved an estimated 14 million lives from COVID-19 in 185 countries and territories between December 8, 2020, and December 8, 2021. Vaccination is also associated with a reduction of post-acute sequelae of COVID-19. The data supporting the benefits of the COVID-19 vaccines have been critically reviewed and accepted by the medical and public health community, including state and local public health agencies and academic and professional organizations.

The most recent estimate is that those who are up to date on their vaccination status have a 9.8 fold lower risk of dying from COVID-19 than those who are unvaccinated and 2.4 fold lower risk of dying from Covid-19 than those who were vaccinated but had not received the updated, bivalent vaccine. Roughly 90% of deaths from COVID-19, as carefully classified by the CDC, in recent months have occurred among those who were not up to date on their vaccines. Furthermore, as stated above, emerging reports indicate a possible reduction in the risk of post-COVID conditions in vaccinated people who survive an infection.

As the leading public health official in state, you are likely aware that seniors in Florida are under-vaccinated, with just 29% of seniors having received an updated bivalent vaccine, compared to the national average of 41% coverage in seniors. **It is the job of public health officials around the country to protect the lives of the populations they serve, particularly the vulnerable. Fueling vaccine hesitancy undermines this effort.**

We agree that communication between patients and their health care providers is critical, and fully support clear, accurate communication about the benefits and risks of medical products. It is inaccurate to suggest that the federal government will "retaliate" against any health care provider for communicating with their patients about the benefits and risks of a particular medical product.

Over the course of the pandemic, FDA and CDC have held numerous public meetings to discuss the safety and effectiveness of the COVID-19 vaccines where detailed safety data are shared with outside experts and public comment is encouraged. Further, FDA publishes the full

regulatory action package containing hundreds of pages summarizing clinical studies and review for each COVID-19 approval on FDA's website (see "COVID-19 Vaccines Authorized for Emergency Use or FDA Approved") and CDC publishes an extensive amount of information on their clinical use in Interim Clinical Considerations. Complete information about both benefits and risks helps health care providers better care for their patients.

Unfortunately, the misinformation about COVID-19 vaccine safety has caused some Americans to avoid getting the vaccines they need to be up to date. This has led to unnecessary death, severe illness and hospitalization. These tragic outcomes not only have a devastating effect on individuals and their families, but they also create a tremendous strain on our healthcare systems and clinicians, potentially compromising care for other patients.

We stand firmly behind the safety and effectiveness of the mRNA COVID-19 vaccines, which are fully supported by the available scientific data. Staying up to date on vaccination is the best way to reduce the risks of death and serious illness or hospitalization from COVID-19. Misleading people by overstating the risks, or emphasizing the risks without acknowledging the overwhelming benefits, unnecessarily causes vaccine hesitation and puts people at risk of death or serious illness that could have been prevented by timely vaccination.

Sincerely,

s/Robert M. Califf

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration

s/Rochelle P. Walensky

Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention

EXHIBIT E

Eleventh Amendment to the Declaration under the PREP Act for COVID-19 Medical Countermeasures

On May 9, 2023, Secretary Becerra signed the 11th amendment to the declaration under the PREP Act for COVID-19 Medical Countermeasures. The Secretary issues this amendment to clarify that COVID-19 continues to pose a credible risk of a future public health emergency, add two new limitations on distribution, extend the time period of coverage for certain Covered Countermeasures and Covered Persons, clarify the time period of coverage for Covered Persons authorized under the Declaration, and extend the duration of the Declaration to December 31, 2024.

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a PREP Act declaration. The declaration provides immunity from liability (except for willful misconduct) for claims:

- of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions
- determined by the Secretary to constitute a present, or credible risk of a future public health emergency
- to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures

A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

COVID-19 PREP Act Declarations

The end of the COVID-19 Public Health Emergency Declaration does not automatically terminate PREP Act coverage. To learn more, view our COVID-19 PREP Act FAQs.

Declaration and Amendments

- Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (March 17, 2020)
- First Amendment to Declaration under the PREP Act for Medical Countermeasures against COVID-19 (April 15, 2020)
- Second Amendment to Declaration under the PREP Act for Medical Countermeasures against COVID-19 (June 8, 2020)
- Third Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (August 24, 2020)
- Fourth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (December 3, 2020)
- Fifth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (February 2, 2021)
- Sixth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (February 16, 2021)
- Technical Correction to Fifth and Sixth Amendments to the Declaration under the PREP Act for Medical Countermeasures Against COVID-19 (February 22, 2021)
- Seventh Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (March 11, 2021)
- Eighth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID–19 (August 4, 2021)
- Ninth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID–19 (Fact Sheet | PDF Presentation)
- Technical Correction to Ninth Amendment to the Declaration under the PREP Act for Medical Countermeasures Against COVID-19 (October 4, 2021)
- Tenth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 (January 7, 2022)
- Eleventh Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 (May 12, 2023)

ACTION:

Notice of amendment.

SUMMARY:

The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to update the determination of a public health emergency and clarify the disease threat, add two new limitations on distribution, extend the time period of coverage for certain Covered Countermeasures and Covered Persons, clarify the time period of coverage for Covered Persons authorized under the Declaration, extend the duration of the Declaration to December 31, 2024, and to republish the Declaration in full.

DATES:

This amendment is effective as of May 11, 2023.

FOR FURTHER INFORMATION CONTACT:

L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202–260–0365, *paige.ezernack@hhs.gov*.

SUPPLEMENTARY INFORMATION:

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct" as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, § 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the former Secretary, Alex M. Azar II, declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the declaration was renewed effective April 26, 2020, July 25, 2020, October 23, 2020, January 21, 2021, April 21, 2021, July 20, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 11, 2023. The public health emergency declared under section 319 of the PHS Act is anticipated to no longer be in effect as of the

end of the day on May 11, 2023. Nonetheless, as stated in section I of this amended PREP Act Declaration, I have determined there is a credible risk that COVID–19 may in the future constitute such an emergency and am thus amending this Declaration to prepare for and mitigate that risk.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, 2020, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, 2020, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause. (85 FR 35100, June 8, 2020). On August 19, 2020, the former Secretary amended the Declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 52136, Aug. 24, 2020).

On December 3, 2020, the former Secretary amended the Declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary's Declaration and authorizations issued by the Department's Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond, added an additional category of qualified persons under Section V of the Declaration *i.e.*, healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's liability protections; made explicit that there are substantive federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the Declaration in full. (85 FR 79190, Dec. 9, 2020).

On February 2, 2021, the Acting Secretary Norris Cochran amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 7872, Feb. 2, 2021). On February 16, 2021, the Acting Secretary amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 9516, Feb. 16, 2021) and on February 22, 2021, the Department filed a notice of correction to the February 2 and February 16 notices correcting effective dates stated in the Declaration, and correcting the description of qualified persons added by the February 16, 2021 amendment. (86 FR 10588, Feb. 22, 2021). On March 11, 2021, the Acting Secretary amended the Declaration to add additional Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under the Declaration. (86 FR 14462, Mar. 16, 2021).

On August 4, 2021, I amended the Declaration to clarify categories of Qualified Persons and to expand the scope of authority for certain Qualified Persons to administer seasonal influenza vaccines to adults. (86 FR 41977, Aug. 4, 2021). On September 14, 2021, I amended the Declaration to expand the scope of authority for certain Qualified Persons to administer COVID–19 therapeutics subcutaneously, intramuscularly, or orally (86 FR 51160, Sept. 14, 2021) and on September 30, 2021, the Department filed a notice of correction to the September 14 notice clarifying the terms "ACIP recommendations" and "ACIP's standard immunization schedules." (86 FR 54696, Oct. 4, 2021). On January 7, 2022, I amended the Declaration to expand the scope of authority for licensed pharmacists to order and administer and qualified pharmacy interns to administer seasonal influenza vaccines. (87 FR 982, January 7, 2022).

I am now amending section I of the Declaration to update the determination of a public health emergency to state that COVID–19 presents a credible risk of a future public health emergency. While the Public Health Emergency declared pursuant to section 319 of the PHS Act is anticipated to no longer be in effect as of the end of the day on May 11, 2023, COVID–19 continues to present a credible risk of a future public health emergency. Continued coverage under the PREP Act, as provided in this Declaration, is intended to prepare for and mitigate that credible risk.

I am amending section VII of the Declaration to add a new limitation on distribution to provide coverage under this PREP Act Declaration through December 31, 2024 for manufacturing, distribution, administration and use of Covered Countermeasures while they are authorized for emergency use (EUA) by the Food and Drug Administration (FDA) pursuant to section 564 of the Federal Food, Drug & Cosmetic (FD&C) Act, regardless of any federal agreement related to manufacturing, distribution, administration or use of the countermeasures, and regardless of any federal, regional, state, or local emergency Declaration. This extended PREP Act coverage extends to manufacturers, distributors, program planners, qualified persons authorized under state law to administer the Covered Countermeasures, and qualified persons who are licensed pharmacists, pharmacy interns, and pharmacy **technicians authorized under this Declaration to order and/or administer the Covered Countermeasures, when consistent with the terms of the EUA and is intended to allay any concerns about liability risks arising from continued manufacturing, distribution, administration or use of Covered Countermeasures while they are authorized under an EUA.**

I am also amending section VII of the Declaration to add a new limitation on distribution to provide coverage under this PREP Act Declaration through December 31, 2024 for manufacturing, distribution, administration and use of Covered Countermeasures that are COVID–19 vaccines licensed by FDA, and any FDA approved or cleared in vitro diagnostic product or other device used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom regardless of any federal agreement related to manufacturing, distribution, administration or use of the vaccines or devices, and regardless of any federal, regional, state, or local emergency Declaration. This extended PREP Act coverage is intended to ensure that COVID–19 vaccines and devices remain eligible for

coverage under the Countermeasures Injury Compensation Program and to ensure consistency in coverage for approved/cleared and authorized devices.

I am amending section VIII of the Declaration to clarify that the category of disease, health condition or health threat includes the burden on healthcare providers caused by coterminous seasonal influenza infections and COVID–19 infections.

I am also amending section XII of the Declaration to extend the time period of PREP Act coverage through December 31, 2024 to Qualified Persons who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, Covered Countermeasures that are COVID–19 vaccines, seasonal influenza vaccines, and COVID–19 tests regardless of any federal agreement related to manufacturing, distribution, administration or use of these Covered Countermeasures and regardless of any federal, regional, state or local emergency Declaration or other limitations on distribution stated in section VII of the Declaration. Extending the time period for PREP Act coverage for licensed pharmacists, pharmacy interns, and qualified technicians allows for continued access by the recipient Population to Covered Countermeasures that are COVID–19 vaccines, seasonal influenza vaccines and COVID–19 tests.

As stated in prior amendments to this Declaration,[1] licensed pharmacists, pharmacy interns and qualified pharmacy technicians are well positioned to provide continued access to Covered Countermeasures, particularly in certain areas or for certain populations that have too few primary-care providers or that are otherwise medically underserved. As of 2022, nearly 90 percent of Americans lived within five miles of a community pharmacy.[2] During the COVID–19 pandemic, the majority of Americans have received their COVID–19 vaccines and tests from a pharmacy. In addition, continued access by the Population to seasonal influenza vaccines mitigates risks that seasonal influenza infections, in conjunction with COVID–19 infections, could overwhelm healthcare providers.

As qualified persons, these licensed pharmacists, pharmacy interns, and qualified pharmacy technicians will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration. To the extent that any State law would otherwise prohibit these healthcare professionals who are a "qualified person" from prescribing, dispensing, or administering Covered Countermeasures that are COVID–19 vaccines, seasonal influenza vaccines or COVID–19 tests, such law is preempted.[3]

Finally, I am amending section XII of this Declaration to clarify the time period of coverage for other qualified persons authorized under section V of the Declaration, and to extend the duration of the Declaration to December 2024 to coincide with the duration of other COVID–19 response programs.[4]

Other conforming changes and technical corrections are made throughout the Declaration for consistency and clarity.

To the extent any term previously in the Declaration, including its amendments, is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling. This Declaration must be construed in accordance with the Advisory Opinions of the Office of the General Counsel (Advisory Opinions).[5] I incorporate those Advisory Opinions as part of this Declaration. This Declaration is a "requirement" under the PREP Act.

I. Determination of Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that the spread of SARS–CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a credible risk of a future public health emergency. I further determine that use of any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency that former Secretary Azar declared on January 31, 2020 under section 319 of the PHS Act for the entire United States to aid in the response of the nation's healthcare community to the COVID–19 outbreak.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.

IV. Liability Protections

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability protections as prescribed in the PREP Act and conditions stated in this Declaration are in effect for the Recommended Activities described in Section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are "manufacturers," "distributors," "program planners," "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

"Order" as used herein and in guidance issued by the Office of the Assistant Secretary for Health [6] means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required.

"Qualified person" includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) "a person within a category of persons so identified in a Declaration by the Secretary" under subsection (b) of the PREP Act. 42 U.S.C. 247d–6d(i)(8)

In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration; [7]

(b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act.

(c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy),[8] (1) vaccines that the Centers for Disease Control and Prevention (CDC)/Advisory Committee on Immunization Practices (ACIP) recommend [9] to persons ages three through 18 according to CDC's/ACIP's standard immunization schedule or (2) seasonal influenza vaccine administered by qualified pharmacy technicians and interns that the CDC/ACIP recommends to persons aged 19 and older according to CDC's/ACIP's standard immunization schedule; or (3) FDA authorized or FDA licensed COVID–19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns or technicians under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA.

ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to CDC's/ACIP's COVID–19 vaccine recommendation(s).

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to CDC's/ACIP's standard immunization schedule.

iv. In the case of seasonal influenza vaccine administered by qualified pharmacy technicians and interns, the vaccination must be ordered and administered according to CDC's/ACIP's standard immunization schedule.

v. In the case of pharmacy technicians, the supervising pharmacist must be readily and immediately available to the immunizing qualified pharmacy technician.

vi. The licensed pharmacist must have completed the immunization training that the licensing State requires for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the ACPE to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

vii. The licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

viii. The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation; [10]

ix. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.

x. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;

xi. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and

xii. The licensed pharmacist, the licensed or registered pharmacy intern and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.[11] Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or a pharmacist or pharmacy intern as authorized under the section V(d) of this Declaration, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID–19 vaccination effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to Documentation of completion of the Centers for Disease Control and Prevention COVID–19 (CDC) Vaccine Training Modules [12] and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, who confirms competency of the healthcare provider in preparation and administration of the COVID–19 vaccine(s) to be administered.

(g) Any member of a uniformed service (including members of the National Guard in a Title 32 duty status) (hereafter in this paragraph “service member”) or Federal government, employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government service members, employees, contractors, or volunteers are qualified persons if the following requirement is met: The executive department or agency by or for which the Federal service member, employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that service member, employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that service member, employee, contractor, or volunteer, even if those authorized duties or

responsibilities ordinarily would not extend to members of the public or otherwise would be more limited in scope than the activities such service member, employees, contractors, or volunteers are authorized to carry out under this Declaration.

(h) The following healthcare professionals and students in a healthcare profession training program subject to the requirements of this paragraph:

1. Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered;

2. Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;

3. Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental, podiatry, optometry or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a currently practicing healthcare professional experienced in administering intramuscular injections who administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered;

Subject to the following requirements:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. Vaccination must be ordered and administered according to CDC's/ACIP's COVID–19 vaccine recommendation(s);

iii. The healthcare professionals and students must have documentation of completion of the Centers for Disease Control and Prevention COVID–19 Vaccine Training Modules and, if applicable, such additional

training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID–19 vaccines;

iv. The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering vaccinations is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID–19 vaccine(s) to be administered and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID–19 vaccines;

v. The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation; [13]

vi. The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and

vii. The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

(i) A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy) [14] FDA authorized, approved, or licensed COVID–19 therapeutics. Such State licensed pharmacists and the State licensed or registered interns or technicians under their supervision are qualified persons only if the following requirements are met:

i. The COVID–19 therapeutic must be authorized, approved, or licensed by the FDA;

ii. In the case of a licensed pharmacist ordering a COVID–19 therapeutic, the therapeutic must be ordered for subcutaneous, intramuscular, or oral administration and in accordance with the FDA approval, authorization, or licensing;

iii. In the case of licensed pharmacists, qualified pharmacy technicians, and licensed or registered pharmacy interns administering the COVID–19 therapeutic, the therapeutic must be administered subcutaneously, intramuscularly, or orally in accordance with the FDA approval, authorization, or licensing;

iv. In the case of qualified pharmacy technicians, the supervising pharmacist must be readily and immediately available to the qualified pharmacy technician;

v. In the case of COVID–19 therapeutics administered through intramuscular or subcutaneous injections, the licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of COVID–19 therapeutics, the recognition and treatment of emergency reactions to COVID–19 therapeutics, and any additional training required in the FDA approval, authorization, or licensing;

vi. The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation; [15]

vii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID–19 therapeutics; including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events; and

viii. The licensed pharmacist, the licensed or registered pharmacy intern and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) that apply to the administration of COVID–19 therapeutics.

(j) Any pharmacist who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State or who is authorized under Section V(d) of this Declaration who prescribes, dispenses, or administers seasonal influenza vaccines, or a pharmacy intern as authorized under the section V(d) of this Declaration who administers seasonal influenza vaccines, in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, so long as the license or certification of the pharmacist or pharmacy intern has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are:

(a) Any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured:

i. To diagnose, mitigate, prevent, treat, or cure COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

ii. to limit the harm that COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, might otherwise cause;

(b) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in paragraph (a) above;

(c) a product or technology intended to enhance the use or effect of a product described in paragraph (a) or (b) above; or

(d) any device used in the administration of any such product, and all components and constituent materials of any such product.

To be a Covered Countermeasure under the Declaration, a product must also meet 42 U.S.C. 247d–6d(i)(1)'s definition of "Covered Countermeasure."

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability protections are afforded to Covered Persons only for Recommended Activities involving:

(a) Covered Countermeasures that are related to present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements;

(b) Covered Countermeasures that are related to activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of Emergency;

(c) Covered Countermeasures other than those described in subsection (e) that are:

i. Licensed, approved or cleared by the FDA (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or PHS Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

ii. a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom.

To qualify for this third distribution channel, a Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA licensure, approval, or clearance (or pursuant to an Investigational New Drug Application or Investigational Device Exemption), or the NIOSH approval;

(d) Covered Countermeasures that are authorized by the FDA under section 564 of the FD&C Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom. To qualify for this fourth distribution channel, a Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA authorization; or

(e) Covered Countermeasures that are COVID–19 vaccines licensed by the FDA to prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom and any approved or cleared in vitro diagnostic product or other device used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom. To qualify for this fifth distribution channel, a Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA license, clearance, or approval.

As used in this Declaration, the terms "Authority Having Jurisdiction" and "Declaration of Emergency" have the following meanings:

(i) The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, city, county, tribal, state, or federal boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere of authority.

(ii) A Declaration of Emergency means any declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal declaration in support of an Emergency Use Authorization under Section 564 of the FD&C Act unless such declaration specifies otherwise.

I have also determined that, for governmental program planners only, liability protections are afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (a) donation; (b) commercial sale; (c) deployment of Covered Countermeasures from federal stockpiles; or (d) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is not only COVID–19 caused by SARS–CoV–2, or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID–19, SARS–CoV–2, or a virus mutating therefrom, including the threat of increased burden on the healthcare system due to seasonal influenza infections occurring at the same time as COVID–19 infections, which will lead to an increase in the rate of infectious diseases.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures. Where there are limited Covered Countermeasures, *not* administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute "relating to . . . the administration to . . . an individual" under 42 U.S.C. 247d–6d. For example, consider a situation where there is only one dose [16] of a COVID–19 vaccine, and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID–19. In that circumstance, the failure to administer the COVID–19 vaccine to the person in a less-vulnerable population "relat[es] to . . . the administration to" the person in a vulnerable population. The person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals to whom the liability protections of this Declaration extend include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability protections are afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability protections are afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability protections are afforded to manufacturers and distributors without regard to whether the Covered Countermeasure is used by or administered in any designated geographic area; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

COVID–19 is a global challenge that requires a whole-of-nation response. There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc.* v. *Darue Eng'g. & Mf'g.,* 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities. The world faced an unprecedented pandemic. To effectively respond, there needed to be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc.* v. *Darue Eng'g. & Mf'g.,* 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act. Under the PREP Act, the sole exception to the immunity from suit and liability of covered persons under the PREP Act is an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct by such covered person. In all other cases, an injured party's exclusive remedy is an administrative remedy under section 319F–4 of the PHS Act. Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to Covered Countermeasures through PREP Act Declarations.[17]

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

The effective time period for Covered Countermeasures and Covered Persons depends on the means of distribution identified in Section VII of this Declaration as applied to categories of Countermeasures and Qualified Persons:

(a) Liability protections for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through the means of distribution identified in Section VII(a) of this Declaration, begin on March 27, 2020 and extend through December 31, 2024.

(b) Liability protections for all other Covered Countermeasures identified in Section VI of this Declaration, through means of distribution identified in Section VII(a) of this Declaration, begin on February 4, 2020 and extend through December 31, 2024.

(c) Liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as identified in Section VII(b) of this Declaration, begin with a Declaration of Emergency as that term is defined in Section VII (except that, with respect to qualified persons who order or administer a routine childhood vaccination that CDC/ACIP recommends to persons ages three through 18 according to CDC's/ACIP's standard immunization schedule, liability protections began on August 24, 2020), and last through (a) the final day the Declaration of Emergency is in effect, or (b) December 31, 2024, whichever occurs first.

(d) Liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration that are licensed, approved or cleared by the FDA begin on December 9, 2020, and last through the final day the Declaration of Emergency is in effect or December 31, 2024 whichever occurs first. Liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration that are approved by NIOSH last for the time period stated in section (a) of this Section XII.

(e) Liability protections for all Covered Countermeasures identified in Section VII(d) of this Declaration begin on December 9, 2020, and last until December 31, 2024, regardless of any Declaration of Emergency that might otherwise terminate the time period of coverage under paragraphs (c) or (d) of this Section XII.

(f) Liability protections for all Covered Countermeasures identified in Section VII(e) of this Declaration begin on December 9, 2020, and last until December 31, 2024, regardless of any Declaration of Emergency that might otherwise terminate the time period of coverage under paragraphs (c) or (d) of this Section XII.

(g) Liability protections for Manufacturers, Distributors, and Program Planners, as defined at 42 U.S.C. 247d–6d(i), begin on February 4, 2020, and last through the time periods stated in paragraphs (a)–(f) of this Section XII.

(h) Liability protections for Qualified Persons who are a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed begin on February 4, 2020, and last through the time periods stated in paragraphs (a)–(f) of this Section XII.

(i) Liability protections for Additional Qualified Persons identified under section V of the Declaration and in Guidance implementing section V of the Declaration begin on the dates listed below, and last through the time periods stated in paragraphs (a)–(d) of this section XII of the Declaration, unless otherwise stated in this paragraph (i).

i. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and licensed or registered pharmacy interns and qualified pharmacy technicians to administer CDC/ACIP recommended vaccines for persons aged three through 18 (other than seasonal influenza vaccines and COVID–19 vaccines) begins on August 24, 2020.

ii. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and licensed or registered pharmacy interns and qualified pharmacy technicians to administer CDC/ACIP recommended seasonal influenza vaccines for persons aged three through 18 begins on August 24, 2020, and lasts through December 31, 2024 regardless of the time periods stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

iii. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, COVID–19 vaccines to individuals aged three and above begins on February 4, 2020 and lasts through December 31, 2024 regardless of the time periods stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

iv. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, seasonal influenza vaccines to individuals aged nineteen and above begins on August 4, 2021 and lasts through December 31, 2024, regardless of the time periods stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

v. Liability protections for Qualified Persons under section V(e) of the Declaration begin on February 4, 2020.

vi. Liability protections for Qualified Persons under section V(f) of the Declaration begin on February 2, 2021.

vii. Liability protections for Qualified Persons under section V(g) of the Declaration begin on February 16, 2021, and last through December 31, 2024.

xiii. Liability protections for Qualified Persons who are physicians, advanced practice registered nurses, registered nurses, or practical nurses under section V(h) of the Declaration begin on February 2, 2021 with additional conditions effective as of March 11, 2021 and liability protections for all other Qualified persons under section V(h) begin on March 11, 2021.

ix. Liability protections for Qualified Persons under section V(i) of the Declaration who are licensed pharmacists to order and administer and qualified pharmacy technicians and licensed or registered pharmacy interns to administer COVID–19 therapeutics identified in Section VII(d) of the Declaration begin on September 9, 2021 and last through December 31, 2024 regardless of time periods stated in paragraphs (c)–(d) of this section or limitations on distribution stated in section VII (a)–(b) of this Declaration.

x. Liability protections for Qualified Persons under section V(i) of the Declaration who are licensed pharmacists to order and administer and qualified pharmacy technicians and licensed or registered pharmacy interns to administer COVID–19 therapeutics identified in Section VII(c) of the Declaration begin on September 9, 2021.

xi. Liability protections for Qualified Persons under section V(j) of the Declaration begin on December 30, 2021.

xii. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference,[18] to administer COVID–19 tests who are licensed pharmacists begin April 8, 2020 and last until December 31, 2024 regardless of any limitations stated in paragraphs (c)–(d) of this Section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

xiii. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference,[19] to administer COVID–19 tests who are licensed or registered pharmacy interns or qualified pharmacy technicians begin October 20, 2020 and last until December 31, 2024 regardless of any limitations stated in paragraphs (c)–(d) of this Section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

xiv. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference,[20] who are pharmacies when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer COVID–19 vaccines to individuals aged three and above, seasonal influenza vaccines to individuals aged three through eighteen, seasonal influenza vaccines to individuals aged nineteen and above, COVID–19 tests, and COVID–19 therapeutics identified in Section VII(d) of the Declaration begin October 29, 2020 and last until December 31, 2024 regardless of any limitations stated in paragraphs (c)–(d) of this Section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

xv. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference,[21] who are pharmacies when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer CDC/ACIP recommended vaccines for persons aged three through 18 (other than seasonal influenza vaccines and COVID–19 vaccines) and countermeasures identified in Section VII(c) of the Declaration begin October 29, 2020.

xv. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference [22] to prescribe or administer point-of-care COVID–19 tests, using anterior nares specimen collection or self-collection, for screening in congregate facilities across the Nation who are licensed healthcare practitioners begin August 31, 2020 and last until December 31, 2024 regardless of any limitations stated in paragraphs (c)–(d) of this Section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at the toll-free number 1–855–266–2427 or *http://www.hrsa.gov/cicp/*.

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Amendments to this Declaration will be published in the **Federal Register** , as warranted.

*Authority:*42 U.S.C. 247d–6d.

Dated: May 9, 2023.

Xavier Becerra,

Secretary, U.S. Department of Health and Human Services.

[1] Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, 85 FR 53126 (August 24, 2020); Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, 87 FR 982 (April 14, 2022).

[2] Gallagher, A. "Study: 88.9% of US Population Lives Within 5 Miles of a Community Pharmacy," Pharmacy Times (August 4, 2022) available at: *https://www.pharmacytimes.com/view/study-88-9-of-us-population-lives-within-5-miles-of-a-community-pharmacy* (last visited Apr. 21, 2023).

[3] Department of Health and Human Services General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act, May 19, 2020, available at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf.* (last visited April 14, 2023). *See also,* Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 12, 2021, available at: *https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf* (last visited April 14, 2023).

[4] Section 4113, Consolidated Appropriations Act, 2023, Public Law 117–328 (December 29, 2022).

[5] *See, e.g.,* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, Apr. 17, 2020, as Modified on May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf* (last visited Apr. 3, 2023); Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Apr. 3, 2023); Advisory Opinion 20–03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf* (last visited Apr. 3, 2023); Advisory Opinion 20–04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf* (last visited Apr. 3, 2023).

[6] Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Apr. 3, 2023); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Apr. 3, 2023).

[7] See, *e.g.,* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Apr. 3, 2023); Guidance for PREP Act Coverage for COVID–19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020,

available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf* (last visited Apr. 3, 2023); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Apr. 3, 2023); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Apr. 3, 2023); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Apr. 3, 2023) (collectively, OASH PREP Act Authorizations). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

[8] Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, "State-licensed or registered intern" (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. Similarly, states vary on licensure and registration requirements for pharmacy technicians. Some states require certain education, training, and/or certification for licensure or registration; others either have no prerequisites for licensure or registration or do not require licensure or registration at all. As used herein, to be a "qualified pharmacy technician," pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a CPhT certification from either the Pharmacy Technician Certification Board or National Healthcareer Association. *See* Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020 at 2, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Apr. 3, 2023).

[9] Where the term CDC/ACIP recommendations, standard immunization schedules, or similar language is used, this includes both direct CDC recommendations as well as recommendations adopted by the CDC Director after recommendation by ACIP, which are commonly referred to as ACIP recommendations or schedules.

[10] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act,

OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Apr. 3, 2023); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Apr. 3, 2023).

[11] See, *e.g.*, Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Apr. 3, 2023).

[12] See COVID–19 Vaccine Training Modules, available at *https://www.cdc.gov/vaccines/covid-19/training.html*.

[13] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Apr. 3, 2023); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Apr. 3, 2023).

[14] Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, "State-licensed or registered intern" (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. Similarly, states vary on licensure and registration requirements for pharmacy technicians. Some states require certain education, training, and/or certification for licensure or registration; others either have no prerequisites for licensure or registration or do not require licensure or registration at all. As used herein, to be a "qualified pharmacy technician," pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a CPhT certification from either the Pharmacy Technician Certification Board or National Healthcareer Association. *See* Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020 at 2, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Apr. 3, 2023).

[15] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Apr. 3, 2023); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Apr. 3, 2023).

[16] For simplicity, this example assumes a patient only requires one dose of the vaccine.

[17] 42 U.S.C. 247d–6d(b)(7) provides that "[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection."

[18] See, Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Apr. 3, 2023).

[19] Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Apr. 3, 2023).

[20] PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, OASH, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Apr. 14, 2023).

[21] PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, OASH, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Apr. 14, 2023).

[22] Guidance for PREP Act Coverage for COVID–19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, August 31, 2023, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf* (last visited April 14, 2023). [FR Doc. 2023–10216 Filed 5–11–23; 8:45 am]

EXHIBIT F

Emergency Use Authorization

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Content current as of 05/12/2023

About Emergency Use Authorizations (EUAs)

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), when the Secretary of HHS declares that an emergency use authorization is appropriate, FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-**threatening diseases or conditions caused by CBRN threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.** The HHS declaration to support such use must be based on one of four types of determinations of threats or potential threats by the Secretary of HHS, Homeland Security, or Defense.

Please note: a determination under section 319 of the Public Health Service Act that a public health emergency exists, such as the one issued on January 31, 2020, does not enable FDA to issue EUAs. On February 4, 2020, the HHS Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Subsequent HHS declarations supporting use of EUAs and based on this determination are described in the blue boxes below.

Information on terminated and revoked EUAs can be found in archived information.

Public Readiness and Emergency Preparedness Act (PREP Act)

Information on the PREP Act can be found here.

The PREP Act amended the Public Health Service Act (PHS Act) to add section 319F-3 (42 U.S.C. 247d-6d). The HHS Secretary has issued several Declarations pursuant to section 319F-3 of the PHS Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

PREP Act - COVID-19 Related Information

On May 9, 2023, HHS Secretary Becerra signed the 11th amendment to the declaration under the PREP Act for COVID-19 Medical Countermeasures. The Secretary issued this amendment to clarify that COVID-19 continues to pose a credible risk of a future public health emergency, add two new limitations on distribution, extend the time period of coverage for certain Covered Countermeasures and Covered Persons, clarify the time period of coverage for Covered Persons authorized under the Declaration, and extend the duration of the Declaration to December 31, 2024.

EXHIBIT G

EXHIBIT G – Revised 05-25-2023

Representative Sample of Institutions of Higher Learning that mandated experimental vaccines as a condition precedent to continued employment and students' class attendance.

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EXHIBIT 3

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650.283.4347
stk@alum.mit.edu

June 1, 2023

Dr. Miguel Cardona
Secretary of Education
U. S. Department of Education
400 Maryland Avenue, SW
Washington, D.C. 20202

via email only
thirdpartycomments@ed.gov

Dear Secretary Cardona,

Following are our comments for you to consider when you review the National Advisory Committee on Institutional Quality and Integrity ("NACIQI") recommendation regarding the renewal application of the Council on Education for Public Health ("CEPH") to accredit schools of public health and public health programs offered in settings other than schools of public health.

As our name denotes, we are engaged in the research and treatment of Covid-19 symptoms. CEPH conducted either too little, or no research of symptom treatments by the schools and programs it accredits. To the contrary, CEPH allowed the schools to mandate unproved vaccines and treatment procedures that were incentivized by United States Government ("USG") payments to health care professionals and hospitals. This created conflicts of interest between the public health administrators CEPH regulates and the students those administrators teach to the detriment of the public.

Specifically:

The Covid-19 vaccines were a new genetic technology, mRNA oriented, with no test studies to determine outcomes.

Early in 2021, a paper published by 57 authors, from 17 Countries, was sent to Government leaders who were in charge of vaccines all over the World. CEPH censored that paper and all other presentations that focused on treatment rather than the vaccines. CEPH made no opposition to the vaccine Emergency Use Authorization even though alternative treatment methods that were safer than the vaccines were available.

No control over the production of the spike protein was developed before CEPH allowed the institutions it accredits to mandate or recommend the Covid-19 vaccines.

The genome of cells has been changed by Pfizer vaccine. No tests on humans were conducted before CEPH allowed the vaccine to be mandated and delivered to the public.

The mRNA is 60 days in the lymph nodes. Should be out in a day or two. 245 days later, it is still in the blood.

US 17,568 deaths per CDC. Under reported 30 fold. Equals 500,000 vaccine deaths in the US.

Proven that the vaccine is causing heart damage. More likely to have heart damage than covid. Harm to children by the vaccine is acute. Leaves scar on the heart which can lead to heart failure.

Before 2020, athlete deaths per year in Europe = 29. Total 283 since 2020 introduction of the vaccines.

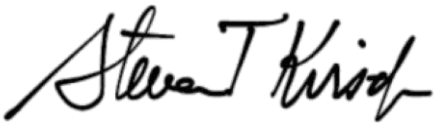
Blood clots in the eyes.

Leading cause of death is now from unknown causes and all we have to point to are the vaccines.

Accordingly, we demand a full hearing by the Department of Education pursuant to the Administrative Procedures Act to allow us to present evidence that CEPH should be removed as the accreditation agency for schools and programs of public health and, further, that the conflicts of interests created by the incentive payments be eliminated.

We reserve the right to amend and supplement these comments once we have had a chance to review the CEPH application for renewal and any response CEPH may make to our or any other comments.

Very truly yours,



Steve Kirsch
Founder

cc: lking@CEPH.org