

IMPACT FEES

QUESTIONS:

Chriss Street's 4 questions for Supervisors & City Councils:

- 1) Are you considering terminating impact fees after the US Supreme Court decision calling them an unconstitutional tax?
- 2) How much in impact fees have you charged over the last 10 years?
- 3) If you are not going to terminate impact fees, how do you plan to justify them as fees rather than taxes?
- 4) Have you set up a process to handle refunds to residents that were inappropriately assessed impact fees in the past?

NewCaliforniaState.com

(877) 828-2753

COUNT 10

16 STH

AMENDMENT SLAVERY

It is evident over the last 3 years since the most corrupt Presidential Election in American history of 2020 that the coordinated design for the destruction of the United States has come from Joe Biden and Gavin Newsom who have both spearheaded the effort to trample on and destroy the United States Constitution.

Nothing is more glaring to the American Citizens that both Joe Biden and Gavin Newsom have complete contempt for the rule of Constitutional Law than to witness the duality with which they are both openly violating Article IV, Section 4 and its three guarantees of a republican form of government, keeping all Americans free from invasion and that of domestic violence. It is clear both are committing treason.

The three most assured aspects of our Constitution is the guarantee that all three elements of Article IV, Section 4 will be adhered to by all *Compact* members of the Union of States. Like a three legged stool, to remove one leg, the stool itself becomes destablalized and ultimately useless. Likewise if one state fails to provide anyone of the three guarantees then the Union of States becomes less stable. If anyone state fails to provide all three elements of Article IV, Section 4 it is in default of its responsibilities to its Citizens to Constitutionally govern.

The Federal government under Biden and the State government of California under Newsom both have removed the legs out from under Article IV, Section 4 and thus destabilized the Union of States we call the United States of America.

Our "republican form" of government vanishes when corrupt election systems destroy our God given rights to self govern. So it is with "invasion" when the citizens have no authority to control who enters the county invaders take over our land. Then "domestic violence" follows and becomes the new law of the land.

Only once in our American history have we witnessed the collapse of all three elements of Article IV, Section 4 and that was the Civil War of 1861-1862. Now on the eve of our Nation's second Civil War comes mankinds most evil institution the same evil institution that brought us the first civil war **Slavery**.

Due to the lack of Constitutional Governance slavery has found a home in California. Encouraged and supported by Gavin Newsom and Joe Biden slavery in all its variants flourishes. The most evil of slave evil is child sex trafficking where babies to teen children are bought and sold for sexual pleasure or organ transplant in China. The later are slaughtered and their organs "harvested". Gavin Newsom and Joe Biden's evil is ours now.

The governments of the United States and California, the current socialist president of the United States governor/dictator and mono-party system, along with local officials, are following a coordinated design with the intent to actively engage in "<u>Acts of Insurrection</u>" against the United States Constitution. This is Treason.

republican form of government

Biden and Newsom both were placed into their respective positions by numerous fraudulent elections.

Biden and Newsom both preside as dictators of all three branches of their respective governments. The government branches long succumbed to the fraudulent elections and the treasonous bureaucratic state that now both rule what are known as a democracies.

keeping all Americans free from invasion and that of domestic violence

Biden and Newsom both openly endorse and use the machinery of government to support the invasion of the United States and California destruction of lawful behavior by promoting domestic violence. In a recent letter to Joe Biden from Texas Governor Greg Abbott who wrote, "President Biden and his Administration have left Americans and our country completely vulnerable to unprecedented illegal immigration pouring across the Southern border. Instead of upholding the rule of law and securing the border, the Biden Administration has attacked and sued Texas for stepping up to protect American citizens from historic levels of illegal immigrants, deadly drugs like fentanyl, and terrorists entering our country."

The Governor Pro Tempore from New California State Robert Paul Preston in a letter of support for Governor Abbott joined with 25 other state governors by stating:

"New California State stands in solidarity with Governor, Greg Abbott, and the Citizens of Texas in utilizing every tool and strategy, including razor wire fences, to secure the border."

ACTS OF INSURRECTION

"The United States government, the Biden Executive Administration and mono-party system, along with state and local officials, are following a coordinated design with the intent to actively engage in "Acts of Insurrection" against the United States Constitution and its Citizens.

ACTS OF SECESSION

The United States government, in conjunction with the Biden Executive Administration, has usurped power, has actively engaged in "Acts of Secession" and has created a reign of terror on United States Citizens living in the United States of America, with the intent to secede from the United States of America to thus destroy the very Union of States which secures our Liberty and Freedom."

Today California is in a state of free fall at all levels. This free fall has been orchestrated over the last 170 years by socialist and communist and we're now nearing the end of their socialist/communist plan that clearly demonstrates a design to reduce United States Citizens living in California under absolute Despotism. All their plans have been in direct violation of both Article IV, Section 4 and Article VI of the United States Constitution.

Let it be know to all the world New California State and the State of California are not the properties, not the administrative state, not the province of any theocratic ruler, nor any monarch, nor foreign entity or government but are *States* in the United States of America.

We, the citizens of the State of New California, and the sovereign Counties that lie within, united by our United States Constitution declare that this newly formed and sovereign State and "this nation, under God, shall have a new birth of freedom—and that government of the people, by the people, for the people, shall not perish from the earth."

Let it be known New California State will be brought into the Union of States as the 51st State with a *republican* form of government.

Gavin Newsom has enabled fraudulent election systems and has once again demonstrated why there is *no viable government in California* under his watch.

The Newsom Democracy has Devolved into a Dictatorship and thus Seceded from the People of California.

An unconstitutional *administrative state* now exists in California, in direct violation of the September 9, 1850, *Compact* with the United States of America. The state of California no longer functions as a *republican* form of government, no longer provides freedom from invasion and domestic violence.

ACTS OF INSURRECTION

The government of California, the current socialist governor/dictator and mono-party system, along with local officials, are following a coordinated design with the intent to actively engage in "<u>Acts of Insurrection</u>" against the United States Constitution.

ACTS OF SECESSION

The government of California, in conjunction with the socialist state executive, instituted wherever the current socialist governor/dictator has usurped power, has actively engaged in "<u>Acts of Secession</u>" and has created a reign of terror on United States Citizens living in California, with the intent to secede from the United States of America to thus destroy the very Union of States which secures our Liberty and Freedom.

ABDICATION OF AUTHORITY

Betrayal by the sitting **pusillanimous**, socialist governor/dictator of California, the mono-party legislature and local elected officials is evidence of "<u>Abdication of their Responsibilities of Authority and Sovereignty</u>" over the Citizens of the United States living in California State.

ACTIONS

A reorganized, restorative government of California, consistent with the *Compact* of 1850, with the Congress of the United States, has been established, which is republican in form of government with an executive branch, judicial branch and a bi-cameral legislative branch.

This concludes these proceedings.

newcaliforniastate.com or ncs51.com (877) 828 2753



New California State is a new state in development forming from the State of California. New California State is exercising its God-given Rights as declared in the 1776 United States Declaration of Independence and as ratified in the 1789 United States Constitution under Article IV Sections 3 & 4. New California is the making of a new state, just like 50 other states have been formed to make Union of States.

- PUBLIC COMMENT -

County Board of Supervisors Meeting

Good Morning Board:

We are coming to you this morning in peace as "WE THE PEOPLE" to give you Notice and Instruction so that you and your agents may provide due care.

This NATIONAL LOCKDOWN NOTICE has already been given to 50 state governors, to the President of the United States, to the Supreme Court, to the United States Senate and the United States Congress. We are now giving you a copy.

In JANUARY we learned that the federal government, in alignment with the World Health Organization, has announced an amendment to a credible threat of a public health emergency. Their expanding countermeasures now include both Ebola and Marburg viruses, and extension of liability immunity to "manufacturers" "distributors" "program planners" "qualified persons and their officials", "agents", and "employees" (we have included this report in our Notice envelope just given to you.)

We have also learned that the government was never granted any authority to lock down the people, even in times of emergency. The main object of government is the protection and preservation of personal rights, private property, and public liberties. The government just serves for our benefit as public officers, trustees and servants of the people.

We are also attaching a list of unalienable rights, which <u>includes the right to accept or refuse ANY medical treatment FOR ANY REASON.</u>

Since this BOARD has a history of putting the city under health emergency orders for extended periods of time, we are very concerned that another round of involuntary lockdowns and health orders could occur in our fair county.

Please take Notice that <u>all states in our REPUBLICAN form of government</u> have sworn to protect individual liberty <u>as a condition to be hired as trustees</u>. The people of America are all guaranteed to have the same rights in all states.

As an elected official, do you believe it is your duty to always protect the natural rights of the people so they are guaranteed enjoyment of all their natural rights?

Or ... do you believe that in some time of panic or emergency that you can remove the people's rights to freely exercise liberty: movement, worship, commerce, or any other purpose that is lawful?

If so, please show constitutional authority where you get that power, posting this granted authority conspicuously within the next 15 days notifying the public and all agents.

If you cannot show where you got the authority and you take any action blocking the people's rights to enjoy freedom, then any lockdown, mandate, or forced use of any medical device will be construed as being done with malice, intent, full knowledge and understanding against your trust indenture, your contract with the people, the Constitution.

This Notice is given in PEACE and with the love of CHRIST that you and your agents may provide due care to those who have all political power, THE PEOPLE.

Thank you.

National Lock Down Notice

I, Sandra Margoez, one of the People as seen in the California Constitution Article 2 Section 1, Sul Juris, do provide you with this notice that you and your agents may provide due care:

Please take notice that the People have assembled to consult for our common good, and now realize that the government was never granted any authority to lockdown the People, in any state, as the Government just serves as public officer, trustees and servants of the People and for our benefit (please see evidence below):

California Constitution Preamble: The People Established The Constitution To Secure Our Freedom "We, the People of the State of California, grateful to Almighty God for our freedom, in order to secure and perpetuate its blessings, do establish this Constitution."

Maxim of Law: 77f. No freeman shall be deprived of life, liberty or property but by the lawful judgment of his peers, or by the law of the land —that is by the common law. C.L.M.

Maxim of Law: 51p. The main object of government is the protection and preservation of personal rights, private property, and public liberties, and upholding the law of God. American Maxim. [Underline added for emphasis]

Virginia Constitution Bill of Rights Text of Section 2: People the Source of Power - "That all power is vested in, and consequently derived from, the people, that magistrates are their trustees and servants, and at all times amenable to them." [Underline added for emphasis]

New Hampshire Constitution Text of Article 8: Accountability of Magistrates and Officers; Public's Right to Know - "All power residing originally in, and being derived from, the people, all the magistrates and officers of government are their substitutes and agents, and at all times accountable to them..." [Underline added for emphasis]

Massachusetts Constitution Text of Preamble [To help you understand your purpose as government and the people's power to correct]: - "The end of the institution, maintenance, and administration of government, is to secure the existence of the body politic, to protect it, and to furnish the individuals who compose it with the power of enjoying in safety and tranquility their natural rights, and the blessings of life: and whenever these great objects are not obtained, the people have a right to alter the government, and to take measures necessary for their safety, prosperity and happiness. [Underline added for emphasis]"

Please take notice that all states in our republican form of government have sworn to protect individual liberty as a condition to be hired as Trustees, and the People of America are all guaranteed to have the same rights in all States. If it is your duty to protect the right for the people to enjoy their natural rights, yet you believe that in some time of panic or emergency that you can remove the People's right to freely exercise liberty, movement, worship, commerce, or any other purpose that is lawful, please show constitutional authority granting you that power within 15 days, sworn under penalty of perjury, by affidavit and post conspicuously notifying the public, or you agree that any action you carry out against any of the People, or of blocking the People's rights to enjoy freedom, any lockdown, mandate, or forced use of any medical device is done with malice, intent, and purposeful transgression against your trust indenture/constitution. You further agree that should you not notify all agents that there is no power or granted right to limit the People's rights guaranteed in the constitutions, that you shall pay \$10,000,000 personally, for any encroachment against the rights of the People and this notice shall stand as evidence against you that any transgression was with full knowledge and understanding of this issue.

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Date

1/23/2024

Date

Email Address

National Lock Down Notice

I, David Capizano, one of the People as seen in the California Constitution Article 2 Section 1, Sui Juris, do provide you with this notice that you and your agents may provide due care:

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YOUR UNALIENABLE RIGHTS

If You Do Not Know Your Rights, You Effectively Have None!

UNALIENABLE RIGHTS are the Inherent, Sovereign, Natural Rights that existed before the creation of government, and which, being antecedent to and above the constitutions of the states and federal government, CAN NEVER BE TAKEN AWAY, diminished, aftered, or liened upon by the state, subject only to the due process of the COMMON LAW. Nor can any Unalienable Right be fundamentally removed, whether mistakenly by contract through coercion or non-disclasure, which is froud and unenforceable in law, or knowingly by renunciation, which is contrary to Natural Law or God's Law. UBERTY is the intersection of FREEDOM and MORALITY.

THE ORIGINAL, PERMANENT, UNALIENABLE RIGHTS OF EVERY MAN OR WOMAN,

INCLUDE, but are not limited to:

- THE RIGHT TO Self Defense When Threatened With Harm, Loss, Or Deceit
- THE RIGHT TO Security From Abuse, Persecution, Tyranny, And War
- THE RIGHT TO Expose Truth And Knowledge Necessary To One's Rights And Freedoms
- THE RIGHT TO Accept Or Refuse Any Medical Treatment For Any Reason
- ♦ THE RIGHT TO Life, THE RIGHT TO Breathe Freely, THE RIGHT TO Health Choices
- THE RIGHT TO Peaceful Association, Assembly, Expression, And Protest
- THE RIGHT TO Consensual Marriage, and to exist as a Family, retaining all Parental Rights for their children
- THE RIGHT TO Travel and Move in The Ordinary Course Of One's Life And Business
- THE RIGHT TO Refuse To Kill Under Command, By Reason Of Conscience
- THE RIGHT TO Live in Peace And Be Left Alone When Abiding in God's Law.
- THE RIGHT TO produce and obtain Food and Beverages for Their Own Body
- ♣ THE RIGHT TO Practice Religion, The Right to Worship in Dress And Custom
- THE RIGHT TO Freedom of Speech, Freedom of Thought, Freedom of Belief, Freedom of Emotion, Freedom of Attitude, Freedom of Choice, Freedom of Opinion, Freedom of Discernment
- THE RIGHT TO Contract, Or Not To Contract, Which is Unlimited
- THE RIGHT TO Earn A Living in A Fair Exchange For One's Work, with Wages or Any Trade Goods
- THE RIGHT TO Privacy And Confidentiality, Free From Unwarranted Invasion
- THE RIGHT TO Control And Hold One's Property Lawfully Without Trespass
- THE RIGHT TO Due Process Of Law, With Notice And Opportunity To Defend
- THE RIGHT TO Be Presumed Innocent, Suffering No Detention Or Arrest, No Search Or Seizure.
 Without Reasonable Cause
- THE RIGHT TO Remain Silent When Accused, THE RIGHT TO Avoid Self-Incrimination
- THE RIGHT TO Equality in The Eyes Of The Law, And To Equal Representation
- THE RIGHT TO Trial By Jury, Seing An Impartial Panel Of One's Peers
- THE RIGHT TO Appeal in Law Against Conviction Or Sentence, Or Both
- THE RIGHT TO The Pursuit Of Happiness

Surely The Most Critical Failure of THE PEOPLE has been their Failure To Ensure The Teaching And Common Knowledge of our Unalienable Rights. By the Path Of Ignorance, whether by Apathy or Deception, THE PEOPLE arrive in a state Of Exploitation, Oppression, And Tyranny.

SHARE & TEACH OTHERS!



TABLE 1-ESTIMATED ANNUAL REPORTING BURDEN 1

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 58.35(b)(7); Quality assurance unit § 58.185; Reporting of nonclinical laboratory study results	300 300	60.25 60.25	18,075 18,075	1 27.65	18,075 499,774
Total	**************************************	***************************************	**************	**************************************	517,849

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 58.29(b); Personnel	300	20	6,000	.21 (13 minutes)	1,260
§ 58.35(b)(1)-(6), and (c); Quality assurance unit	300	270.76	81,228	3.36	272,926
§ 58.63(b) and (c); Maintenance and calibration of equipment.	300	60	18,000	.09 (5 minutes)	1,620
§ 58.81(a)—(c); SOPs	300	301.80	90,540	.14 (6 minutes)	12,676
§ 58.90(c) and (g); Animal care	300	62.70	18,810	.13 (8 minutes)	2,445
§ 58.105(a) and (b); Test and control article characterization.	300	5	1,500	11.8	17,700
§ 58.107(d); Test and control article handling	300	1	300	4.25	1.275
§ 58.113(a); Mixtures of articles with carriers	300	15.33	4.599	6.8	
§ 58.120; Protocol	300	15.38	4.614		31,273
§ 58.195; Retention of records	300	251.50	,-	32.7	150,878
U	300	201.00	75,450	3.9	294,255
Total	***********	P-42-44-42-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4	***************************************	4.144.104.174.1021.071.174.174.174.174	786,308

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on an evaluation of the information collection, we are retaining the currently approved estimates. Our assumptions made regarding the time needed for the respective activities is based on our experience with the information collection and informal communications with respondents.

Dated: November 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy. [FR Doc. 2023–26044 Filed 11–24–23; 8:45 am] BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Declaration Under the Public Readiness and Emergency Preparedness Act for Countermeasures Against Ebolavirus and/or Ebola Disease and Marburgvirus and/or Marburg Disease

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to amend the Declaration for Countermeasures against Marburgvirus and/or Marburg Disease to cover both Ebolaviruses and Marburgviruses and republishes the declaration, as amended. The amended republished Declaration clarifies that the disease threat includes Ebolaviruses and Marburgviruses, updates the title of the Declaration, expands the Covered Countermeasures, and extends the effective time period.

DATES: The amendment is effective as of January 1, 2024.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, U.S. Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202–260–0365, PREPAct@hhs.gov.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the U.S. Department of Health and Human Services (the HHS 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.

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.

The PREP Act Declaration for Countermeasures Against Marburgvirus and/or Marburg Disease was first issued effective November 25, 2020. (85 FR 79198 (December 9, 2020)). The PREP Act Declaration for Ebola Virus Disease Vaccines was first issued December 3, 2014 (79 FR 73315 (Dec.10, 2014)), and amended December 3, 2015 (80 FR 76541 (Dec. 9, 2015)), December 3, 2016 (81 FR 89471 (Dec. 12, 2016)), and December 1, 2018 (84 FR 764 (Jan. 31, 2019)). The Declaration for Ebola Virus

Disease Therapeutics was issued effective February 27, 2015 (80 FR 22534 (April 22, 2015)), and amended February 27, 2015 (80 FR 76536 (December 9, 2015)), and December 1, 2018 (84 FR 757 (January 31, 2019)).

2018 (84 FR 757 (January 31, 2019)). I am extending PREP Act Coverage for both Ebolaviruses and Marburgviruses due to the continued national security threat posed by these viruses. Ebolaviruses and Marburgviruses have the potential to cause significant morbidity and mortality during outbreaks. The risk of domestic cases is high due to ongoing outbreaks in other countries over the past decade.
Development of and stockpiling vaccines, therapeutics, devices, and diagnostics for all species of both Ebolaviruses and Marburgviruses is needed for continued U.S. preparedness against the credible threat of a public health emergency due to outbreaks of these viruses

I am amending the PREP Act Declaration for Countermeasures Against Marburgvirus and/or Marburg Disease to cover countermeasures previously covered under the Declaration for Ebola Virus Disease Vaccines and the Declaration for Ebola Virus Disease Therapeutics due to the similarities of the viruses and the need to expand Covered Countermeasures against Ebola Disease to include all vaccines, diagnostics, and devices in addition to previously covered vaccines and therapeutics, and to cover these countermeasures when administered or used by an Authority Having Jurisdiction to respond to a declared emergency, in addition to previously covered activities directly supported by the United States. All previously Covered Countermeasures for Ebolavirus and distribution activities continue to be covered. This action has the effect of combining the three previous Declarations into one amended Declaration and makes PREP Act coverage for Ebolavirus countermeasures consistent with PREP Act coverage provided for other health threats, including Marburg, Smallpox, Pandemic Influenza, Anthrax, and Acute Radiation Syndrome and emerging infectious diseases such as COVID-19.1 This amended Declaration for Countermeasures Against Ebolavirus and/or Ebola Disease and Marburgvirus and/or Marburg Disease supersedes the PREP Act Declaration for Ebola Virus Disease Vaccines and the PREP Act Declaration for Ebola Virus Disease Therapeutics. The Declarations for Ebola Virus Disease Vaccines and Ebola

Virus Disease Therapeutics will expire under their own terms on December 31, 2023 and this amended Declaration becomes effective January 1, 2024, effectively replacing the three prior Declarations.

To be consistent with the most current World Health Organization
International Classification of Diseases, the term Ebola disease or "EBOD" is used in this Declaration to refer to the disease, health condition, or threat to health that constitutes or may constitute a public health emergency. The term Marburg Disease or "MARD" is used in this Declaration to refer to the disease, health condition, or threat to health that constitutes or may constitute a public health emergency.

Specifically, I am now amending the PREP Act Declaration Against Marburgvirus and/or Marburg Disease Countermeasures to: amend the title of the declaration to reflect that it covers Ebolaviruses and Marburgviruses; update Section I to identify the public health threat as arising from Ebolaviruses and Marburgviruses; update Section VI to amend the definition of Covered Countermeasures and to extend coverage to all vaccines, diagnostics, and devices for Ebolavirus in addition to vaccines and therapeutics; extend Section VII of the Declaration to provide coverage for Ebolavirus Countermeasures when administered or used by an Authority Having Jurisdiction to respond to a declared emergency; update Section VIII to amend the category of disease to be inclusive of Ebolaviruses and Marburgviruses; extend in Section XII the effective time period of the declaration through December 31, 2028; and republish the declaration in its entirety, as amended.

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Description of This Amendment by Section

I am now amending the title of the Declaration to "Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Countermeasures against Ebolaviruses and/or Ebola Disease and Marburgvirus and/or Marburg Disease."

Section I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

I am amending Section I of the Declaration to update the determination of a public health emergency to state that the spread of Ebolaviruses and Marburgviruses, and any resulting diseases or conditions including EBOD and MARD, and any virus or disease subcategories of these, presents 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.

Section VI. Covered Countermeasures

I am amending Section VI of the Declaration to include any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to diagnose, mitigate, prevent, treat, cure, or limit EBOD, MARD, or the transmission of Ebolaviruses, Marburgviruses, or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

Section VIII. Category of Disease, Health Condition, or Threat

I am amending Section VIII of the Declaration to update the category of disease to include any diseases or conditions including EBOD and MARD caused by Ebolaviruses and Marburgviruses, or any virus or disease subcategories of these or virus mutating therefrom.

Section XII. Effective Time Period

I am extending the effective time period for the Declaration through December 31, 2028.

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

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Countermeasures Against Ebolavirus and/or Ebola Disease and Marburgvirus and/or Marburg Disease

To the extent any term previously included in the Declaration for Countermeasures Against Marburgvirus and/or Marburg Disease, the Declaration for Vaccines Against Ebola Virus Disease, or the Declaration for Therapeutics Against Ebola Virus Disease, including amendments, are inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

I. Determination of Public Health Emergency

42 U.S.C. 247d-6d(b)(1)

I have determined that there is a credible risk that the spread of Ebolaviruses and Marburgviruses, and

See https://aspr.hhs.gov/legal/PREPact/Pages/
default.aspx.

² See https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC8637750/.

any resulting diseases or conditions including Ebola Disease (EBOD) and Marburg Disease (MARD), and any virus or disease subcategories of these may in the future constitute a public health emergency. For the purposes of this Declaration, MARD is the illness resulting from infection by any virus of the Orthomarburgvirus genus. EBOD is the illness resulting from infection of any of the following virus species of the Orthoebolavirus genus:

- Bundibugyo virus
- Ebola virus
- Sudan virus
- Taï Forest virus
- Ebolaviruses with undefined pathogenicity in humans

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 Immunity

42 U.S.C. 247d-6d(a), 247d-6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this Declaration is 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. 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; (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; and (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with section 564A of the FD&C Act.

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: (1) any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to diagnose, mitigate, prevent, treat, cure, or limit the harm EBOD, MARD, or the transmission of Ebolaviruses, Marburgviruses, or a virus mutating therefrom, any device used in the administration of any such product, and all components and constituent materials of any such product; (2) any product to diagnose, mitigate, prevent, treat, or cure a serious or lifethreatening disease or condition caused by a product described in clause (1); or (3) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (1) or (2). Covered Countermeasures must be

Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution 42 U.S.C. 247d}6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements, or activities directly conducted by the Federal Government; or

(b) 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 an emergency.

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 immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) 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 any diseases or conditions including EBOD and MARD caused by Ebolaviruses and Marburgviruses, or any virus or disease subcategories of these or virus mutating therefrom.

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 purpose of distributing and dispensing countermeasures.

X. Population

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

The populations of individuals include any individual who uses or is administered the Covered

Countermeasures in accordance with this Declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is 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 immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in any designated geographic area; liability immunity is 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.

XII. Effective Time Period 42 U.S.C. 247d-6d(b)(2)(B)

Liability immunity for Covered Countermeasures through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction and extends through December 31, 2028.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a Declaration and lasts through (1) the final day the emergency Declaration is in effect, or (2) December 31, 2028, whichever occurs first.

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 Strategic National Stockpile (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)

The December 3, 2014, Declaration under the PREP Act for Countermeasures Against Ebola Virus Disease Vaccines was first published on December 10, 2014, and amended and republished on December 9, 2015, December 12, 2016, and January 31, 2019. The republished amended Declaration for Countermeasures Against Ebolavirus and/or Ebola Disease and Marburgvirus and/or Marburg Disease supersedes the Declaration for Countermeasures Against Ebola Virus Disease Vaccines.

The February 27, 2015, Declaration under the PREP Act for Countermeasures Against Ebola Virus Disease Therapeutics was first published on April 22, 2015, and amended and republished on December 9, 2015, December 12, 2016, and January 31, 2019. The republished amended Declaration for Countermeasures Against Ebolavirus and/or Ebola Disease and Marburgvirus and/or Marburg Disease supersedes the Declaration for Countermeasures Against Ebola Virus Disease Therapeutics.

The November 25, 2020, Declaration under the PREP Act for Gountermeasures Against Marburgvirus and/or Marburg Disease was published on December 9, 2020. This is the first amendment to and republication of the Declaration.

Any further amendments to this Declaration will be published in the Federal Register, as warranted.

Authority: 42 U.S.C. 247d-6d.

Dated: November 21, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–26075 Filed 11–24–23; 8:45 am] BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amend Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Institute Special Emphasis Panel T32 Diversity Training Grants, December 1, 2023, 11:00 a.m. to 1:00 p.m., National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20892 which was published in the Federal Register on October 26, 2023, FR Document No. 2023–23751, 88 FRN 73863.

This notice is being amended to change the meeting title to "The National Heart, Lung, and Blood Institute Special Emphasis Panel T32 Member Conflicts SEP." The meeting is closed to the public.

Dated: November 20, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–26020 Filed 11–24–23; 8:45 am] BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Customs Broker Permit User Fee Payment for 2024 and Announcement of eCBP Portal Payment Option

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document provides notice to customs brokers that the annual user fee that is assessed for each