JFK VACCINATION ASSISTANCE ACT OF 1962

NATIONAL CHILDHOOD VACCINE INJURY ACT

PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT

FDA EMERGENCY PANDEMIC USE AUTHORIZATION

COUNTERMEASURE INJURY 'NO' COMPENSATION PROGRAM

HHS - DOD OPERATION WARPED SPEED. . .

THESE DIKTATS SUBORNED GENOCIDE IN AMERIKA AND GLOBALLY

MOST ALL FUNDED BY AMERIKAN TAXPAYERS'

GENOCIDAL DIKTATS MUST BE IMMEDIATELY !!!

REPEALED, REVOKED, RESCINDED AND CANCELLED. . .

DO NOT RESUSCITATE!

!!! IMMEDIATELY WAS 62 YEARS AGO

NUREMBERG 2.0

NΩW

22 OCT 2020

VRBPAC COVID-19 'VACCINES'

SAFETY DEFECTS

PROXIMATE CAUSE - CAUSE IN FACT

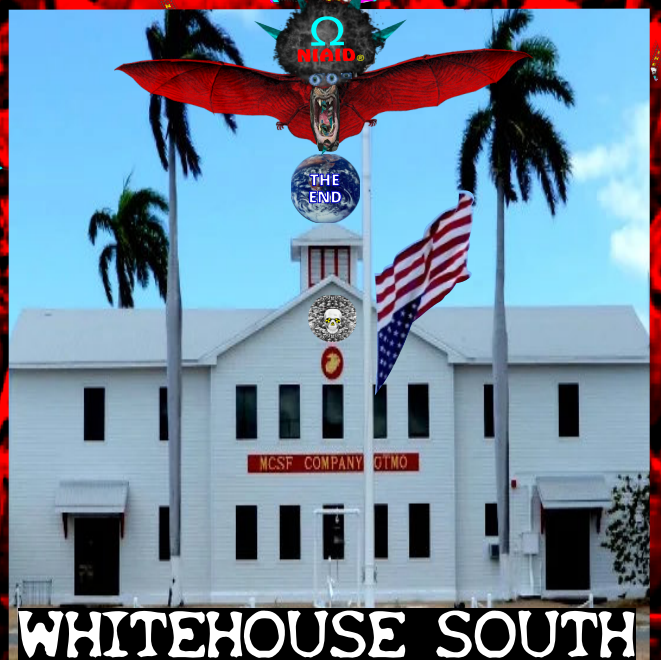
ACCELERATED UGLY DEATH
GUILLAIN-BARRÉ SYNDROME
ACUTE DISSEMINATED ENCEPHALOMYELITIS
TRANSVERSE MYELITIS
ENCEPHALITIS/MYELITIS/ENCEPHALOMYELITIS/
MENINGOENCEPHALITIS/MENINGITIS/ ENCEPHOLAPATHY
OTHER ACUTE DEMYELINATING DISEASES
CONVULSIONS/SEIZURES
STROKE
NARCOLEPSY AND CATAPLEXY
ANAPHYLAXIS SHOCK
NON-ANAPHYLACTIC ALLERGIC REACTIONS
ACUTE MYOCARDIAL INFARCTION - HEART ATTACK
MYOCARDITIS/PERICARDITIS - PERMANENT DAMAGE
80 UNIQUE AUTOIMMUNE DISEASES
FEMALE-MALE FERTILITY SUPRESSION
PREGNANCY AND BIRTH BAD OUTCOMES
DESTROYS NATURAL IMMUNITY - NHEJ-HR DNA REPAIR
THROMBOCYTOPENIA - LOW PLATELET BLEEDOUT
DISSEMINATED INTRAVASCULAR COAGULATION - BLOOD CLOTS EVERYWHERE
VENOUS THROMBOEMBOLISM
ARTHRITIS AND ARTHRALGIA/EXCRUTIATING FOREVER JOINT PAIN
KAWASAKI DISEASE
BELL'S PALSY
MULTIPLE SCLEROSIS
MULTISYSTEM INFLAMMATORY SYNDROME - ALL SYSTEM MELTDOWN
VACCINE ENHANCED DISEASE - ANTIBODY DEPENDENT ENHANCEMENT

HUMAN EXTINCTION VECTORS

825.2 Million Patients With
High Quality Data Were Used
To Find These Safety Defects

GENOCIDE SCIENCE

>>>



WHITEHOUSE SOUTH

FDA Vaccine Surveillance: Pre-licensure Pharmacovigilance Planning

“Safety throughout the lifecycle” approach for vaccines (pre- and post-licensure):

- Manufacturer submits pharmacovigilance plans (PVP) of proposed post-licensure surveillance activities
  - Submitted for BLA and for EUA
  - Post-licensure commitment (PMC) – studies, registries for general safety concern
  - Post-licensure requirement (PMR) – clinical study, epidemiological study, registries, etc. to verify a specific safety signal
  - Routine pharmacovigilance – Passive surveillance (VAERS), review of safety literature, available studies, etc.

U.S. FOOD & DRUG ADMINISTRATION

CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness

Steve Anderson, PhD, MPP
Director, Office of Biostatistics & Epidemiology, CBER

VRBPAC Meeting
October 22, 2020

FDA Vaccine Surveillance Programs: Post-Licensure

1. **Passive Surveillance of Vaccines**
   - Vaccine Adverse Event Reporting System (VAERS)
     - Management shared by CDC and FDA

2. **Active Surveillance Monitoring Program**
   - FDA BEST
   - FDA-CMS partnership

FDA Vaccine Surveillance Programs: Post-Licensure

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VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

CDC + FDA

http://vaers.hhs.gov

VAERS – FDA CBER Efforts

- CDC presentation covered VAERS so will provide summary of FDA efforts
- **FDA and CDC have weekly and bi-weekly coordination meetings** on VAERS and Pharmacovigilance activities between CBER OBE and OBE Division of Epidemiology (DE) and CDC Immunization Safety Office
- **CBER DE Physicians will be reviewing the serious adverse event reports** from VAERS for COVID-19 vaccines – review of individual reports, death reports, conduct aggregate analyses, case-series, etc.
- **FDA will utilize statistical data-mining methods** to detect disproportional reporting of specific vaccine-adverse event combinations to identify AEs that are more frequently reported

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FDA Vaccine– Legislative Authorization Active Surveillance

Legislation, mandates and Current Surveillance

FDA Amendments Act of 2007:

- Directed FDA to develop an active risk identification and analysis system – such as Sentinel, and later BEST, and others and covers ≥100 million persons

Prescription Drug User Fee Act VI (2017)

- Discussion between FDA and Industry on Priority Areas - Renewed every 5 yrs
- Provides resources/funding for Sentinel, BEST, real-world evidence, etc

COVID-19 Vaccine Monitoring Data Considerations

- **Rapid data access** for near real time surveillance
- **Large databases of tens of millions of patients** for evaluating vaccine rare serious adverse events
- **Data representing integrated care spectrum** – outpatient, physician, inpatient, etc.
- **High quality data** to assess and confirm potential adverse events or safety concerns for COVID-19 vaccines
- **Data with significant clinical detail** or medical chart access

1. FDA Biologics Effectiveness and Safety (BEST) System

- Several partners – Acumen, IBM Watson, IQVIA, OHDSI, HealthCore, Humana, Optum, Healthagen, Academic organizations
- Represents variety of healthcare settings – inpatient, emergency department, outpatient, etc.

BEST Initiative Expansion

CLAIMS Data Sources

Data Sources	Type	Patients (millions)
MarketScan	Claims	254
Blue Health Intelligence	Claims	33.6
Optum	Claims	70
HealthCore	Claims	56
Healthagen	Claims	26
OneFlorida Clinical Research Consortium (Medicaid)	Claims	6.7

Data lag: 1-12 months depending on data source

BEST Initiative Expansion
EHR Data Sources

Data Sources	Type	Patients (millions)
MedStar Health	EHR	6
IBM Explorys	EHR	90
Regenstrief Institute	Claims and EHR	20.2
Columbia University	EHR	6.6
University of Colorado	EHR	17
University of California San Francisco	EHR	3.2
PEDSnet Clinical Research Consortium	EHR	6.2
Optum EHR	EHR	105
OneFlorida Clinical Research Consortium	EHR	5.6
OneFlorida Clinical Research Consortium	Linked EHR-Claims	1.5
MarketScan Explorys Claims-EHR (CED)	Linked EHR-Claims	5.5
Optum	Linked EHR-Claims	50

Data lag: 1-2 weeks to 4 months depending on data source

2. CMS (Center for Medicare & Medicaid Services)

- **Federal Partners**
  - Ongoing FDA-CMS partnership on vaccine safety since 2002
  - Data cover very large population of approximately 55 million elderly US beneficiaries ≥65yrs of age
  - >92% of US elderly use Medicare so database represents the elderly population and not a sample
  - Represents variety of healthcare settings – inpatient, outpatient, etc.
  - Consists of claims data with access to medical charts

Limitations of Data Systems

- Not all claims and EHR data systems can be used to address a vaccine safety or effectiveness regulatory question

- Each data system has its limitations
  - Populations, healthcare settings, clinical detail, necessary parameters, data lag, exposures and outcomes that are captured

FDA COVID-19 vaccine safety surveillance planning

“Near real-time surveillance” or rapid-cycle analyses (RCA)

- FDA plans on monitoring 10 -20 safety outcomes of interest to be determined based on:
  - Pre-market review of sponsor safety data submitted to FDA
  - In coordination with federal partners, international regulatory partners and organizations, academic experts, others
  - Literature and regulatory experience with similar vaccines, novel vaccine platforms, and using other relevant data
  - FDA plans on using CMS data for COVID-19 vaccine RCA – near real time with efforts

FDA Safety Surveillance of COVID-19 Vaccines : DRAFT Working list of possible adverse event outcomes ***Subject to change***

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

FDA Experience with Near Real Time Surveillance / RCA

FDA and CMS - RCA

- Conduct “near real-time” surveillance for annual influenza vaccine and Guillain-Barre Syndrome(GBS) since 2007
- Support confirmation of CDC rapid-cycle analyses of safety for seasonal influenza vaccine, Shingrix, and others

FDA Sentinel – Rapid Surveillance

- Near real-time, rapid surveillance in 2017-2018 seasonal influenza vaccine – evaluation of 6 health outcomes of interest

FDA COVID-19 vaccine safety surveillance Plans

- **Epidemiological analyses**
  - Need capability to resolve potential safety signals identified from near real-time surveillance, TreeScan and other sources
  - Rapid queries and small epidemiological studies
  - Larger self-controlled, cohort, comprehensive protocol-based studies

COVID-19 Vaccine Effectiveness Surveillance Plans

- COVID-19 vaccine(s) – there may be limited information available at licensure on level and duration of effectiveness
- Manufacturers may conduct certain COVID-19 vaccine effectiveness post-licensure studies
- FDA may conduct COVID-19 vaccine effectiveness studies
  - General effectiveness studies – including subpopulations of interest
  - Duration of protection studies
  - Others
- FDA coordinating COVID-19 Vaccine Effectiveness efforts with the CDC NCIRD through monthly, bi-monthly meetings

FDA-CMS-CDC Vaccine Effectiveness Experience

- Extensive experience with the data and methods needed to conduct vaccine effectiveness studies
- Produced several vaccine effectiveness and relative vaccine effectiveness studies for influenza and zoster vaccines
- Conducted duration of effectiveness analysis of Zostavax vaccine

FDA-CMS Vaccine Effectiveness Experience

- Actively studying risk factors for COVID-19 and preparing to study safety and effectiveness of vaccines and biologics therapies
- More than 30 publications since 2012
- Results included in Congressional testimony

CBER COVID-19 Vaccine Monitoring Transparency Considerations

- Master Protocols for Safety and Effectiveness outcomes
- Posting of draft protocols for public comment
- Posting of final protocols and final study reports on the BESTinitiative.org website

US Government-wide Efforts COVID-19 Vaccine Monitoring

Large US Government Effort

FDA Coordinating its COVID-19 vaccine safety and effectiveness monitoring efforts with other government agencies:

- Centers for Disease Control (CDC)
- Centers for Medicare& Medicaid Services (CMS)
- Veterans Administration (VA)
- National Institutes of Health
- Department of Defense
- Indian Health Services

US Government-wide Efforts
COVID-19 Vaccine Monitoring (2)

Large US Government Effort

- Weekly meetings between FDA and CDC, regular meetings with VA and CMS
- Planned sharing of protocols, discussion safety and effectiveness outcomes of interest
- Coordinated planning and conduct of surveillance activities such as near real time surveillance/ RCA between FDA, CDC, CMS, VA, and DOD

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- CBER OBE Colleagues
- CDC Colleagues
- CMS Colleagues
- VA Colleagues
- FDA Partners: Acumen, IBM Watson – and new partners in FY2021

Explaining Operation Warp Speed

What's the goal?

OPERATION WARP SPEED (OWS) AIMS TO BEGIN DELIVERY OF 300 MILLION DOSES OF A SAFE, EFFECTIVE VACCINE FOR COVID-19 BY JANUARY 2021, AS PART OF A BROADER STRATEGY TO ACCELERATE THE DEVELOPMENT, MANUFACTURING, AND DISTRIBUTION OF COVID-19 VACCINES, THERAPEUTICS, AND DIAGNOSTICS (COLLECTIVELY KNOWN AS COUNTERMEASURES).

How will the goal be accomplished?

BY INVESTING IN AND COORDINATING COUNTERMEASURE DEVELOPMENT, OWS WILL ALLOW COUNTERMEASURES SUCH AS A VACCINE TO BE DELIVERED TO PATIENTS MORE RAPIDLY WHILE ADHERING TO STANDARDS FOR SAFETY AND EFFICACY.

Who's working on Operation Warp Speed?

OWS IS A PARTNERSHIP AMONG COMPONENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), INCLUDING THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), THE FOOD AND DRUG ADMINISTRATION (FDA), THE NATIONAL INSTITUTES OF HEALTH (NIH), AND THE BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA), AND THE DEPARTMENT OF DEFENSE (DOD). OWS ENGAGES WITH PRIVATE FIRMS AND OTHER FEDERAL AGENCIES, INCLUDING THE DEPARTMENT OF AGRICULTURE, THE DEPARTMENT OF ENERGY, AND THE DEPARTMENT OF VETERANS AFFAIRS. IT WILL COORDINATE EXISTING HHS-WIDE EFFORTS, INCLUDING THE NIH'S ACCELERATING COVID-19 THERAPEUTIC INTERVENTIONS AND VACCINES (ACTIV) PARTNERSHIP, NIH'S RAPID ACCELERATION OF DIAGNOSTICS (RADX) INITIATIVE, AND WORK BY BARDA.

What's the plan and what's happened so far?

DEVELOPMENT: TO ACCELERATE DEVELOPMENT WHILE MAINTAINING STANDARDS FOR SAFETY AND EFFICACY, OWS HAS BEEN SELECTING THE MOST PROMISING COUNTERMEASURE CANDIDATES AND PROVIDING COORDINATED GOVERNMENT SUPPORT.

PROTOCOLS FOR THE DEMONSTRATION OF SAFETY AND EFFICACY ARE BEING ALIGNED, WHICH WILL ALLOW THESE HARMONIZED CLINICAL TRIALS TO PROCEED MORE QUICKLY, AND THE PROTOCOLS FOR THE TRIALS WILL BE OVERSEEN BY THE FEDERAL GOVERNMENT (NIH), AS OPPOSED TO TRADITIONAL PUBLIC-PRIVATE PARTNERSHIPS, IN WHICH PHARMACEUTICAL COMPANIES DECIDE ON THEIR OWN PROTOCOLS. RATHER THAN ELIMINATING STEPS FROM TRADITIONAL DEVELOPMENT TIMELINES, STEPS WILL PROCEED SIMULTANEOUSLY, SUCH AS STARTING MANUFACTURING OF VACCINES AND THERAPEUTICS AT INDUSTRIAL SCALE WELL BEFORE THE DEMONSTRATION OF EFFICACY AND SAFETY AS HAPPENS NORMALLY. THIS INCREASES THE FINANCIAL RISK, BUT NOT THE PRODUCT RISK.

SELECT ACTIONS TO SUPPORT OWS VACCINE AND THERAPEUTIC DEVELOPMENT SO FAR INCLUDE:

- **March 30:** HHS ANNOUNCED $456 MILLION IN FUNDS FOR JOHNSON & JOHNSON'S (JANSSEN) CANDIDATE VACCINE. PHASE 1 CLINICAL TRIALS BEGAN IN BELGIUM ON JULY 24TH AND IN THE U.S ON JULY 27TH.
- **April 16:** HHS MADE UP TO $483 MILLION IN SUPPORT AVAILABLE FOR MODERNA'S CANDIDATE VACCINE, WHICH BEGAN PHASE 1 TRIALS ON MARCH 16 AND RECEIVED A FAST-TRACK DESIGNATION FROM FDA. THIS AGREEMENT WAS EXPANDED ON JULY 26 TO INCLUDE AN ADDITIONAL $472 MILLION TO SUPPORT LATE-STAGE CLINICAL DEVELOPMENT, INCLUDING THE EXPANDED PHASE 3 STUDY OF THE COMPANY'S MRNA VACCINE, WHICH BEGAN ON JULY 27TH.
- **May 21:** HHS ANNOUNCED UP TO $1.2 BILLION IN SUPPORT FOR ASTRAZENECA'S CANDIDATE VACCINE, DEVELOPED IN CONJUNCTION WITH THE UNIVERSITY OF OXFORD. THE AGREEMENT IS TO MAKE AVAILABLE AT LEAST 300 MILLION DOSES OF THE VACCINE FOR THE UNITED STATES, WITH THE FIRST DOSES DELIVERED AS EARLY AS OCTOBER 2020 AND PHASE 3 CLINICAL STUDIES BEGINNING THIS SUMMER WITH APPROXIMATELY 30,000 VOLUNTEERS IN THE UNITED STATES.
- **July 7:** HHS ANNOUNCED $450 MILLION IN FUNDS TO SUPPORT THE LARGE-SCALE MANUFACTURING OF REGENERON'S COVID-19 INVESTIGATIONAL ANTI-VIRAL ANTIBODY TREATMENT, REGN-COV2. THIS AGREEMENT IS THE FIRST OF A NUMBER OF OWS AWARDS TO SUPPORT POTENTIAL THERAPEUTICS ALL THE WAY THROUGH TO MANUFACTURING. AS PART OF THE MANUFACTURING DEMONSTRATION PROJECT, DOSES OF THE MEDICINE WILL BE PACKAGED AND READY TO SHIP IMMEDIATELY IF CLINICAL TRIALS ARE SUCCESSFUL AND FDA GRANTS EUA OR LICENSURE.
- **July 7:** HHS ANNOUNCED $1.6 BILLION IN FUNDS TO SUPPORT THE LARGE-SCALE MANUFACTURING OF NOVAVAX'S VACCINE CANDIDATE. BY FUNDING NOVAVAX'S MANUFACTURING EFFORT, THE FEDERAL GOVERNMENT WILL OWN THE 100 MILLION DOSES EXPECTED TO RESULT FROM THE DEMONSTRATION PROJECT.
- **July 22:** HHS ANNOUNCED UP TO $1.95 BILLION IN FUNDS TO PFIZER FOR THE LARGE-SCALE MANUFACTURING AND NATIONWIDE DISTRIBUTION OF 100 MILLION DOSES OF THEIR VACCINE CANDIDATE. THE FEDERAL GOVERNMENT WILL OWN THE 100 MILLION DOSES OF VACCINE INITIALLY PRODUCED AS A RESULT OF THIS AGREEMENT, AND PFIZER WILL DELIVER THE DOSES IN THE UNITED STATES IF THE PRODUCT SUCCESSFULLY RECEIVES FDA EUA OR LICENSURE, AS OUTLINED IN FDA GUIDANCE, AFTER COMPLETING DEMONSTRATION OF SAFETY AND EFFICACY IN A LARGE PHASE 3 CLINICAL TRIAL, WHICH BEGAN JULY 27TH.
- **July 31**: HHS ANNOUNCED APPROXIMATELY $2 BILLION IN FUNDS TO SUPPORT THE ADVANCED DEVELOPMENT, INCLUDING CLINICAL TRIALS AND LARGE SCALE MANUFACTURING, OF SANOFI AND GLAXOSMITHKLINE'S (GSK) INVESTIGATIONAL ADJUVANTED VACCINE. BY FUNDING THE MANUFACTURING EFFORT, THE FEDERAL GOVERNMENT WILL OWN THE APPROXIMATELY 100 MILLION DOSES EXPECTED TO RESULT FROM THE DEMONSTRATION PROJECT. THE ADJUVANTED VACCINE DOSES COULD BE USED IN CLINICAL TRIALS OR, IF THE FDA AUTHORIZES USE, AS OUTLINED IN AGENCY GUIDANCE, THE DOSES WOULD BE DISTRIBUTED AS PART OF A COVID-19 VACCINATION CAMPAIGN.
- **August 5:** HHS ANNOUNCED APPROXIMATELY $1 BILLION IN FUNDS TO SUPPORT THE LARGE-SCALE MANUFACTURING AND DELIVERY OF JOHNSON & JOHNSON'S (JANSSEN) INVESTIGATIONAL VACCINE CANDIDATE. UNDER THE TERMS OF THE AGREEMENT, THE U.S. GOVERNMENT WILL OWN THE RESULTING
100 MILLION DOSES OF VACCINE, AND WILL HAVE THE OPTION TO ACQUIRE MORE. THE

- **August 11:** HHS ANNOUNCED UP TO $1.5 BILLION IN FUNDS TO SUPPORT THE LARGE-SCALE MANUFACTURING AND DELIVERY OF MODERNA'S INVESTIGATIONAL VACCINE CANDIDATE. UNDER THE TERMS OF THE AGREEMENT, THE U.S. GOVERNMENT WILL OWN THE RESULTING 100 MILLION DOSES OF VACCINE, AND WILL HAVE THE OPTION TO ACQUIRE MORE. THE VACCINE, CALLED MRNA-1273, HAS BEEN CO-DEVELOPED BY MODERNA AND SCIENTISTS FROM THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID), PART OF THE NATIONAL INSTITUTES OF HEALTH. NIAID HAS CONTINUED TO SUPPORT THE VACCINE'S DEVELOPMENT INCLUDING NONCLINICAL STUDIES AND CLINICAL TRIALS. ADDITIONALLY, BARDA HAS SUPPORTED PHASE 2/3 CLINICAL TRIALS, VACCINE MANUFACTURING SCALE UP AND OTHER DEVELOPMENT ACTIVITIES FOR THIS VACCINE. THE PHASE 3 CLINICAL TRIAL, WHICH BEGAN JULY 27, IS THE FIRST GOVERNMENT-FUNDED PHASE 3 CLINICAL TRIAL FOR A COVID-19 VACCINE IN THE UNITED STATES.

AS ANNOUNCED ON MAY 15, THE VACCINE DEVELOPMENT PLAN IS AS FOLLOWS, SUBJECT TO CHANGE AS WORK PROCEEDS:

- **Fourteen** PROMISING CANDIDATES HAVE BEEN CHOSEN FROM THE 100+ VACCINE CANDIDATES CURRENTLY IN DEVELOPMENT—SOME OF THEM ALREADY IN CLINICAL TRIALS WITH U.S. GOVERNMENT SUPPORT.
- **The 14** VACCINE CANDIDATES ARE BEING NARROWED DOWN TO ABOUT SEVEN CANDIDATES, REPRESENTING THE MOST PROMISING CANDIDATES FROM A RANGE OF TECHNOLOGY OPTIONS (NUCLEIC ACID, VIRAL VECTOR, PROTEIN SUBUNIT), WHICH WILL GO THROUGH FURTHER TESTING IN EARLY-STAGE CLINICAL TRIALS.
- **Large-scale** RANDOMIZED TRIALS FOR THE DEMONSTRATION OF SAFETY AND EFFICACY WILL PROCEED FOR THE MOST PROMISING CANDIDATES.

MANUFACTURING: THE FEDERAL GOVERNMENT IS MAKING INVESTMENTS IN THE NECESSARY MANUFACTURING CAPACITY AT ITS OWN RISK, GIVING FIRMS THE CONFIDENCE TO INVEST AGGRESSIVELY IN DEVELOPMENT WHICH WILL ALLOW FASTER DISTRIBUTION OF AN EVENTUAL VACCINE. MANUFACTURING CAPACITY FOR SELECTED CANDIDATES WILL BE ADVANCED WHILE THEY ARE STILL IN DEVELOPMENT, RATHER THAN SCALED UP AFTER APPROVAL OR AUTHORIZATION. MANUFACTURING CAPACITY DEVELOPED WILL BE USED FOR WHATEVER VACCINE IS EVENTUALLY SUCCESSFUL, IF POSSIBLE GIVEN THE NATURE OF THE SUCCESSFUL PRODUCT, REGARDLESS OF WHICH FIRMS HAVE DEVELOPED THE CAPACITY.

SELECT ACTIONS TO SUPPORT OWS MANUFACTURING EFFORTS SO FAR INCLUDE:

- **The May 21, April 16, and March 30** HHS AGREEMENTS WITH ASTRAZENECA, MODERNA, AND JOHNSON & JOHNSON RESPECTIVELY INCLUDE INVESTMENTS IN MANUFACTURING CAPABILITIES.
- **June 1:** HHS ANNOUNCED A TASK ORDER WITH EMERGENT BIOSOLUTIONS TO ADVANCE DOMESTIC MANUFACTURING CAPABILITIES AND CAPACITY FOR A POTENTIAL COVID-19 VACCINE AS WELL AS THERAPEUTICS, WORTH APPROXIMATELY $628 MILLION, USING EMERGENT'S BARDA-SUPPORTED CENTER FOR INNOVATION IN ADVANCED DEPARTMENT AND MANUFACTURING.
- **July 27:** HHS ANNOUNCED A TASK ORDER WITH TEXAS A&M UNIVERSITY AND FUJIFILM TO ADVANCE DOMESTIC MANUFACTURING CAPABILITIES AND CAPACITY FOR A POTENTIAL COVID-19 VACCINE, WORTH APPROXIMATELY $265 MILLION, USING ANOTHER BARDA-SUPPORTED CENTER

- **August 4**: GRAND RIVER ASEPTIC MANUFACTURING INC., (GRAM) GRAND RAPIDS, MICHIGAN, WAS AWARDED A $160 MILLION FIRM-FIXED-PRICE CONTRACT FOR DOMESTIC

DISTRIBUTION: BEFORE THE COUNTERMEASURES ARE APPROVED OR AUTHORIZED, THE PROGRAM WILL BUILD THE NECESSARY PLANS AND INFRASTRUCTURE FOR DISTRIBUTION.

HHS PLANS FOR A TIERED APPROACH TO VACCINE AND THERAPEUTIC DISTRIBUTION, WHICH WILL BUILD ON ALLOCATION METHODOLOGY DEVELOPED AS PART OF PANDEMIC FLU PLANNING AND BE ADJUSTED BASED ON EXPERIENCE FROM THE COVID-19 RESPONSE SO FAR, DATA ON THE VIRUS AND ITS IMPACT ON POPULATIONS AND THE PERFORMANCE OF A GIVEN COUNTERMEASURE, AND THE NEEDS OF THE ESSENTIAL WORKFORCE. OWS WILL EXPAND DOMESTIC MANUFACTURING AND SUPPLIES OF SPECIALIZED MATERIALS AND RESOURCES, SUCH AS GLASS VIALS, THAT CAN BE NECESSARY FOR DISTRIBUTION. DOD'S INVOLVEMENT WILL ENABLE FASTER DISTRIBUTION AND ADMINISTRATION THAN WOULD HAVE OTHERWISE BEEN POSSIBLE.

SELECT ACTIONS TO SUPPORT OWS DISTRIBUTION EFFORTS INCLUDE:

- **May 12**: DOD AND HHS ANNOUNCED A $138 MILLION CONTRACT WITH APIJECT FOR MORE THAN 100 MILLION PREFILLED SYRINGES FOR DISTRIBUTION ACROSS THE UNITED STATES BY YEAR-END 2020, AS WELL AS THE DEVELOPMENT OF MANUFACTURING CAPACITY FOR THE ULTIMATE PRODUCTION GOAL OF OVER 500 MILLION PREFILLED SYRINGES IN 2021.
- **June 9:** HHS AND DOD ANNOUNCED A JOINT EFFORT TO INCREASE DOMESTIC MANUFACTURING CAPACITY FOR VIALS THAT MAY BE NEEDED FOR VACCINES AND TREATMENTS::
- **June 11**: HHS ANNOUNCED $204 MILLION IN FUNDS TO CORNING TO EXPAND THE DOMESTIC MANUFACTURING CAPACITY TO PRODUCE APPROXIMATELY 164 MILLION VALOR GLASS VIALS PER YEAR IF NEEDED. VALOR GLASS PROVIDES CHEMICAL DURABILITY TO MINIMIZE PARTICULATE CONTAMINATION. THE SPECIALIZED GLASS ALLOWS FOR RAPID FILLING AND CAPPING METHODS THAT CAN INCREASE MANUFACTURING THROUGHPUT BY AS MUCH AS 50 PERCENT COMPARED WITH CONVENTIONAL FILLING LINES, WHICH IN TURN CAN REDUCE THE OVERALL MANUFACTURING TIME FOR VACCINES AND THERAPIES.
- **June 11**: HHS ANNOUNCED $143 MILLION TO SIO2 MATERIALS SCIENCE TO RAMP UP CAPACITY TO PRODUCE THE COMPANY'S GLASS-COATED PLASTIC CONTAINER, WHICH CAN BE USED FOR DRUGS AND VACCINES. THE NEW LINES PROVIDE THE CAPACITY TO PRODUCE AN ADDITIONAL 120 MILLION VIALS PER YEAR IF NEEDED.

Who's leading Operation Warp Speed?

HHS SECRETARY ALEX AZAR AND DEFENSE SECRETARY MARK ESPER OVERSEE OWS, WITH DR. MONCEF SLAOUI DESIGNATED AS CHIEF ADVISOR AND GENERAL GUSTAVE F. PERNA CONFIRMED AS THE CHIEF OPERATING OFFICER. TO ALLOW THESE OWS LEADERS TO FOCUS ON OPERATIONAL WORK, IN THE NEAR FUTURE THE PROGRAM WILL BE ANNOUNCING SEPARATE POINTS OF CONTACT, WITH DEEP EXPERTISE AND INVOLVEMENT IN THE PROGRAM, FOR COMMUNICATION WITH CONGRESS AND THE PUBLIC.

What are you doing to make these products affordable for Americans?

THE ADMINISTRATION IS COMMITTED TO PROVIDING FREE OR LOW-COST COVID-19 COUNTERMEASURES TO THE AMERICAN PEOPLE AS FAST AS POSSIBLE. ANY VACCINE OR THERAPEUTIC DOSES PURCHASED WITH US TAXPAYER DOLLARS WILL BE GIVEN TO THE

How is Operation Warp Speed being funded?

CONGRESS HAS DIRECTED ALMOST $10 BILLION TO THIS EFFORT THROUGH SUPPLEMENTAL FUNDING, INCLUDING THE CARES ACT. CONGRESS HAS ALSO APPROPRIATED OTHER FLEXIBLE FUNDING. THE ALMOST $10 BILLION SPECIFICALLY DIRECTED INCLUDES MORE THAN $6.5 BILLION DESIGNATED FOR COUNTERMEASURE DEVELOPMENT THROUGH BARDA AND $3 BILLION FOR NIH RESEARCH.