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Executive Summary

Scope and Expert Opinion

Based on my review of primary regulatory documents, leaked Pfizer’s Chemistry-Manufacturing-Control (CMC) files, relevant legislation in the U.S. and EU, and other publicly available documentation, it is my expert opinion that the Covid-19 mRNA injections were deployed under military ‘medical-countermeasure’ rules that bypassed standard pharmaceutical safeguards, rendering them legally and functionally indistinguishable from a potential bio-chemical weapon.

1. The Dual-Use Nature of mRNA/DNA Platforms

Established “dual-use” designation – Since at least 1997, U.S. defense advisors (JASON group) and later the U.S. National Academies have listed gene-therapy platforms, including lipid-nanoparticle (LNP) mRNA systems utilized as vaccines, as technologies that can be weaponized (e.g., by delivering toxins, oncogenes, or immune-suppressive micro-RNAs).

Ease of weaponization – The same attributes that make mRNA attractive for therapy (cell entry, high expression) make it attractive for hostile use; even fragmented RNA (shRNA, miRNA) can dysregulate host gene expression without coding for proteins.

2. “Bait and Switch”: Consumers Worldwide Were Misled About the Legal Status of Covid-19 Products as Countermeasures – Medicines Used for Non-Medicinal Purposes, i.e. as Weapons.

Safeguard normally in force	How it was removed for Covid-19 mRNA products
Investigational New Drug Regulations/ IRB oversight	Products formerly developed as gene therapies were reclassified as “vaccines/countermeasures” based solely on declared intended use; safety-pharmacology, carcinogenicity, and mutagenicity packages were waived; emergency declarations and non-investigational status of countermeasures removed enforceability of all pharmaceutical regulations.
Current Good Manufacturing Practice (cGMP) inspections	PREP Act (U.S.) and EU Emergency Support Regulation 2016/369 (as amended 2020) allow the Secretary/Commission to waive cGMP entirely during a declared CBRN emergency.
Import-export regulations and manufacturer liability	Waived via EU supply agreements with pharmaceutical companies. Thorough indemnification of pharmas for any injury or death resulting from unsafe product, except in case of narrowly defined “willful misconduct” – parallels the US PREP Act in EU contract.
Independent batch testing in the EU	FDA-EMA Mutual Recognition Agreement (fully operational July 2019) lets EU Qualified Persons accept U.S. batch data sight-unseen.
Facility inspections every two years (21 CFR 600.21)	April 2019 FDA rule deleted inspection frequency and penalties; Covid travel bans then halted inspections outright.

Documentary Evidence of Non-Compliance with Good Manufacturing Practices and Product Adulteration (Potential Weaponization)

EMA leaks (Nov 2020) – ~1,000 pages show major objections: (i) non-existent cGMP packages; (ii) ≤50 % intact mRNA (specification quietly lowered from ≥70 %); (iii) missing analytical-method validation; (iv) unreviewed manufacturing changes.

Rentschler 2022 FDA Form 483 – Post-deployment inspection of Pfizer’s EU contractor documented cGMP violations, confirming earlier warnings. No enforcement actions taken.

Legal shield – 21USC§360bbb-3a(c) explicitly states that even if a product would be “adulterated or misbranded,” it cannot be treated as such once designated an EUA countermeasure. Same regulation- and liability-free conditions were implemented in EU via predatory purchasing contracts.

3. Evidence that Covid Response Was Not a Public Health Response, but a Classified Military Operation Utilizing Medicines as Weapons

All Covid-19 countermeasures, including bio-chemical substances marketed as “safe and effective vaccines”, were ordered by the DoD as a “large scale manufacturing demonstration” via Other Transactions Authority contracts. According to Operation Warp Speed/HHS Assistant Secretary for Preparedness and Response (ASPR) reports, the US Department of Defense (DoD) ordered and oversaw the development, manufacture, and distribution of all countermeasures.

The Covid Dossier (**Exhibit 1**) is a compilation of the evidence from many countries and regions of the world demonstrating that:

Covid was not a public health event, although it was presented as such to the world’s population. It was a global operation, coordinated through public-private intelligence and military alliances and invoking laws designed for CBRN (chemical, biological, radiological, nuclear) weapons attacks.

The Dossier contains information regarding the military/intelligence coordination of the Covid biodefense response in the U.S., U.K., Australia, Canada, the Netherlands, Germany, Italy, and many more locations. For as many countries as possible, the Dossier lists the military/intelligence agencies in charge of their country’s Covid response; dates on which emergency declarations were made in each country; military/intelligence-related agencies and bodies in charge of censorship/propaganda; and top people with military/intelligence jobs who were known or reported to hold leadership positions in the response. The Dossier also lists connections to global governing bodies, including the EU and UN/WHO, through which the response was coordinated, and provides a listing of the

military/intelligence/biodefense alliances that provided multinational frameworks for responding to a bioterror/bioweapons attack.

4. Covid-19 mRNA Injections are Indistinguishable from Bio-Chemical Weapons.

- **Covid-19 mRNA injections meet the statutory definition of “biological product” used as a countermeasure** for non-medicinal unapproved purposes, simultaneously exempt from drug-safety law and manufacturers' liability.
- **Potential qualification as a “biological weapon”** under 18 U.S.C. § 175 et seq. (possession or delivery of any agent “not reasonably justified by a prophylactic or protective purpose”) given the evidence of systematic adulteration and misbranding.
- **Foreseeability of harm** – Regulatory guidance for gene therapies and extensive scientific literature lists insertional mutagenesis, autoimmunity, and persistent expression as known risks; these were neither tested nor disclosed. Lack of cGMP compliance, evidence of adulteration and contamination, and large gaps in manufacturing process characterization at the time of the global launch demonstrate depraved indifference of the state and health authorities, intentionally putting millions of people at risk of death and severe injury.
- **Vicarious liability** – Defendants knew or should have known that no lawful pharmaceutical authorization existed for Covid-19 mRNA injections, that millions of people were exposed to foreseeable harm. Yet, they proceeded to lie to the public and implement coercive measures to increase the uptake of these shots.

Conclusions

- **Scientific** – The intrinsic dual-use danger of LNP-mRNA platforms demands the highest manufacturing and regulatory scrutiny; the opposite has occurred.
- **Regulatory** – Through a concerted global strategy (PREP Act, countermeasures, EU emergency regulations, MRAs), customary drug-safety law was suspended, enabling unchecked adulteration.
- **Forensic** – Leaked EMA files and later FDA inspection findings document objective manufacturing failures consistent with weaponization pathways described in U.S. biodefence literature.

Expert Witness Statement: Alexandra Latypova, MBA, POB 2981, Stateline, NV, USA

- **Legal** – Under U.S. and international law, a product delivered under the color of medicine but meeting the functional test of a bio-chemical weapon triggers potential criminal liability for all actors in the supply chain.

Prepared for counsel as foundational narrative; detailed citations, exhibits, and curriculum vitae available on request.

1. The Dual Use Nature of mRNA/DNA Platforms

Biological and bio-chemical weapons are both naturally derived and man-made materials designed to induce disease through the introduction of toxins and microorganisms. The method through which a bio-chemical weapon is deployed depends on the agent itself, its preparation, its durability, and the route of administration. Attackers may disperse these agents through aerosols or food and water supplies¹. In addition to externally dispersing such agents, introduction of bio-chemical agents via other means is described in literature dealing with bio-chemical weapons and terrorism. Specifically, use in consumer products, medicines, or even pet food and other products has been described as possible vectors of attack.²

In politics, diplomacy, and export control "dual use" refers to technology that can be used for both peaceful and military aims. mRNA/DNA technology, including embodiments as injectable drugs or vaccine products, has long been identified as a dual-use, potentially weaponizable technology^{3, 4, 5}. The "dual use dilemma" was first noted with the discovery of the process for synthesizing and mass-producing ammonia, which revolutionized agriculture with modern fertilizers but also led to the creation of chemical weapons during World War I. The dilemma has long been recognized in chemistry and physics, leading to international conventions and treaties, including the Chemical Weapons Convention and the Treaty on the Non-Proliferation of Nuclear Weapons.

In 1997 the JASON group⁶, an advisory committee to the US President on scientific matters pertaining to war technologies identified potential for genetically engineered pathogens in the following six groups:

- Binary biological weapons
- Designer genes
- **Gene therapy as a weapon**

¹ https://en.m.wikipedia.org/wiki/List_of_U.S._biological_weapons_topics

² <https://www.ncbi.nlm.nih.gov/books/NBK535870/>

³ <https://sites.dartmouth.edu/dujs/2013/03/10/genetically-engineered-bioweapons-a-new-breed-of-weapons-for-modern-warfare/>

⁴ <https://www.ncbi.nlm.nih.gov/books/NBK535887/>

⁵ <https://irp.fas.org/threat/cbw/nextgen.pdf>

⁶ <https://isgp-studies.com/jason-group-national-security-science>

- Stealth viruses
- Host swapping diseases
- Designer diseases

To date, both awareness and control systems for detecting and preventing potential subversion and misuse remain woefully inadequate. Despite the obvious threat introduced by advanced synthetic biology products, if misused as weapons, little to no control measures exist today beyond a handful of guidance documents for scientists and research institutions. These self-reporting requirements are largely ignored, and as evidenced by the NIH grants to Wuhan Institute of Virology, research that is likely to raise objections is offshored.

1.1. Methods for weaponization of mRNA/DNA technologies and products:

In principle, any drug or injectable medical product can be weaponized, i.e., used as a poison instead of medicine. This is because the consumer or healthcare provider cannot directly assess the product and its ingredients and must rely on regulators enforcing pharmaceutical law/regulations to ensure compliance and safety as the product travels through the manufacturing supply chain and distribution. Pharmaceutical substances contain potentially dangerous chemicals, and typically, the difference between a drug and a poison/lethal weapon is the precise dosage, which the pharmaceutical regulations are designed to keep tightly controlled. As an example, consider opioids for legitimate use - pain management vs. their potential for lethal overdose. A mislabeled opioid product with an incorrect specification for dosage would be an example of a weaponized medicine.

According to the literature on bioweapons, weaponization of gene therapy/mRNA technology or another DNA/RNA platform technology can be accomplished in numerous ways. Synthetic mRNA is a large molecule (~3000+ base pairs). It is unstable and fragile, breaking into smaller segments during manufacture, storage, and transportation. It has been demonstrated that segments of RNA, such as short hairpin RNAs (shRNAs) or micro RNAs (miRNAs), can be exploited as weapons, and do not need to be precisely made, nor do they need to “code” for anything specific.

The following paragraph is found in Chapter 6 of the 2018 edition of the textbook **“Biodefense in the Age of Synthetic Biology”**⁷:

⁷ <https://www.ncbi.nlm.nih.gov/books/NBK535870/>

“Small RNAs are an example of functional genetic information that could be horizontally transferred. Small RNAs, although not a genome modification per se, are important because they may prove capable of modifying gene expression and bringing about phenotypic change. The large number of small interfering RNA (siRNA), short hairpin RNA (shRNA), micro RNA (miRNA) (Zhang et al., 2007; Huang et al., 2008), and other small-RNA library studies in a variety of species and cells from different species, including human, provides a potential roadmap of what sequences may lead to what disease states or to modulation of defenses against disease. {...}

One reason that RNA delivery is potentially a viable biological threat is that even a small initial skew in gene expression (such as the changes in gene expression normally caused by miRNAs) could greatly alter the probability of an initial cellular alteration. Even small amounts of a targeted RNA would not modify the genome per se, but might allow or encourage cells to begin the process of self-transformation to tumors, as evidenced by the fact that a large number of pro-oncogenic miRNAs have already been discovered (O'Bryan et al., 2017). In addition to RNAs produced by viruses, bacteria produce numerous small regulatory RNAs; introduction of these into the endogenous microbiome could lead to dysbiosis. Larger mRNAs can also be delivered via liposomes and nanoparticles or by RNA replication strategies being developed for vaccine production (see Chapter 8, Rapid Development of Self-Amplifying mRNA Vaccines); these methods could potentially be used to express deleterious cargo such as toxins or oncogenes, similar to threats related to DNA vectors.”

Clearly, both small and larger RNA sequences can be introduced into the human body for nefarious purposes, including the promotion of cancer, dysbiosis, immune system suppression, and organ damage. This can be accomplished with and without incorporation of the weaponized RNA code into the host genome and by RNA sequences that do not need to encode any protein.

Furthermore, the same textbook states that vaccine platforms are recognized a potential vehicle for weaponization:

“Larger mRNAs can also be delivered via liposomes and nanoparticles or by RNA replication strategies being developed for vaccine production [referring to self-amplifying mRNA vaccine platform] ...these methods could potentially be used to express deleterious cargo such as toxins or oncogenes.”

Therefore, the mRNA/DNA products marketed as “vaccines” are, in principle, open to adulteration, whether intentional or due to a lack of proper manufacturing process controls and purity characterization. Technical capabilities that are required to reliably characterize and control these substances at the point of manufacture, in distribution, and administration, are nascent today and had not been routinely established by the manufacturers nor by the regulators in 2020-2021 when these substances were mass deployed worldwide.

2. “Bait and Switch”: Consumers Worldwide Were Misled About the Legal Status of Covid-19 Products as Countermeasures – Medicines Used for Non-Medicinal Purposes, i.e. as Weapons.

2.1. Summary of legal requirements under US and EU law for marketing pharmaceuticals as “safe and effective”.

In both the United States and the European Union, pharmaceutical regulations are designed to ensure that medicines are safe, effective, and of high quality before they reach the public. While there are many similarities between the U.S. and EU systems—especially in their reliance on scientific evidence—each has its own regulatory bodies and procedures for evaluating drugs and approving claims about safety and efficacy.

In the United States, the Food and Drug Administration (FDA), through its Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), is the primary authority responsible for approving pharmaceutical products. Before a new drug can be marketed, the sponsor must submit a New Drug Application (NDA) or Biologics License Application (BLA) that includes robust data from preclinical studies and clinical trials demonstrating the product's safety and efficacy for its intended use. The clinical trial process requires investigational status of the product under Investigational Drug Exemption and follows a structured progression through Phases I–III, with formal oversight by an independent Investigational Review Board (IRB) ensuring protection of human subjects and execution of valid informed consent procedures. Only after this thorough process—culminating in a favorable risk-benefit assessment—can safety and efficacy claims be made. The FDA also reviews the manufacturer’s compliance with current Good Manufacturing and Clinical Practices (cGxP), assuring the product’s fidelity to

the precise quantities of ingredients and labeling to ensure that all claims are substantiated and not misleading.

In the European Union, the regulatory landscape is governed by the European Medicines Agency (EMA) for centralized approvals, while national competent authorities (such as Germany's BfArM, France's ANSM or CBG/MEB in the Netherlands) handle decentralized or mutual recognition procedures. For most innovative drugs, especially those involving biotechnology or affecting multiple EU member states, the centralized procedure is mandatory. This involves submitting a Marketing Authorization Application (MAA), which must contain comprehensive data similar to what the FDA requires, including clinical and non-clinical findings. Safety and efficacy claims are scrutinized by the EMA's Committee for Medicinal Products for Human Use (CHMP) before an opinion is issued and authorization is granted by the European Commission.

In both jurisdictions, post-marketing surveillance is essential. Companies are required to conduct pharmacovigilance activities and may be asked to perform additional studies (Phase IV trials) to monitor long-term safety and effectiveness. Any promotional material or advertising must strictly reflect the approved labeling and claims; unsubstantiated or misleading claims can lead to regulatory action. Additionally, there are stringent requirements for transparency, including public disclosure of clinical trial data.

While the U.S. and EU systems have distinct regulatory structures and processes, there is significant harmonization through international initiatives, such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Mutual Recognition Agreements (discussed further in this testimony).

The pharmaceutical regulator in the Netherlands is the Medicines Evaluation Board (CBG/MEB). The CBG is responsible for assessing and monitoring the safety, efficacy, and quality of human and veterinary medicines in the Netherlands. It evaluates marketing authorization applications (MAAs) for new drugs and ensures that product information and claims are accurate, evidence-based, and compliant with regulatory requirements. The agency also participates in the European regulatory network, working closely with the European Medicines Agency (EMA) and other national authorities in the EU.

CBG's responsibilities include:

- Granting national marketing authorizations for medicines in the Netherlands.
- Participating in decentralized and mutual recognition procedures for drug approvals within the EU.
- Contributing to centralized EMA procedures, including involvement in scientific assessments through experts on committees like the CHMP.

- Monitoring pharmacovigilance and ensuring that medicines remain safe and effective post-approval.

The CBG operates under the Dutch Ministry of Health, Welfare and Sport and collaborates with the Health and Youth Care Inspectorate (IGJ), which enforces compliance with pharmaceutical laws and inspects manufacturers and healthcare providers.

2.2. Mutual Recognition Agreements between US FDA and EU EMA:

The actions of the US FDA are directly related to those of the EMA due to the Mutual Recognition Agreements that national food and drug regulators signed in the years leading up to 2020. These agreements are contracts that allow one regulator to accept, without further review, what another regulator in a different country or region has presumably examined and approved. This legal framework was created to promote harmonization and efficiency. However, during the orchestrated global COVID event, this structure was exploited by the perpetrators for malicious purposes, enabling a false facade of regulation by the FDA and allowing other regulatory agencies to simply accept FDA's statements without conducting mandatory independent reviews of the data.

Here is one MRA as an example, between the FDA and EMA.⁸ This US-EU MRA was entered into force on 1 November 2017 for human medicines and 30 May 2023 for veterinary products. It became fully operational for human medicines as of 11 July 2019:

*“qualified persons in the EU Member States **do not need to batch test** human medicines covered by the MRA, provided that they have verified that these controls have been carried out in the United States for products manufactured in and imported from the United States.”*

Most, if not all, other national food and drug regulatory systems now rely on the FDA regulations and their compliance/cGMP monitoring, without conducting any of their own reviews, regulation, batch testing, or other cGMP procedures.

⁸ <https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/compliance-research-and-development/good-manufacturing-practice/mutual-recognition-agreements-mra>

2.3. Covid-19 mRNA injections were deployed as Medical Countermeasures, while being falsely promoted to the public as normally regulated pharmaceutical products.

While the Covid-19 mRNA injections were broadly marketed as “safe and effective vaccines,” all Covid products and protocols entered the global markets without following the usual pharmaceutical manufacturing and distribution compliance standards for regulated drugs, due to their legal status as “countermeasures under a public health emergency.” In other words, they are considered non-medicinal. This status is managed by a completely different, militarized governance framework and a separate set of laws, originally designed to respond to time- and location-specific attacks involving Chemical, Biological, Radiological, and Nuclear (CBRN) weapons. The defendants were aware of this. The public has not been informed of the true legal status of these injections or their permitted use.

US FDA provides the following definition of medical countermeasures:

“Medical countermeasures (MCMs) are FDA-regulated products such as biologics, drugs, and devices that may be used in public health emergencies to diagnose, prevent, or treat diseases or conditions caused by CBRN threats or emerging infectious diseases.”⁹

While the statement on the FDA website claims that MCMs are “FDA-regulated”, this statement is misleading because it omits the fact that MCMs are not regulated like typical pharmaceutical products, as expected by consumers and healthcare providers.

Under U.S. federal law and EU law, for medicinal uses of medicinal products, FDA/EMA must formally approve any new investigational drug before a manufacturer can introduce it into interstate commerce.

This process requires the manufacturer to submit an Investigational New Drug application and obtain approval from the FDA/EMA for its use in regulated clinical research (trials). This regulated process is therefore called an “investigational” regulatory pathway. It mandates that a manufacturer conduct regulated clinical research trials, obtain Institutional Review Board’s (IRB) approval for clinical trial protocols, ensure independent safety monitoring, and secure informed consent from clinical trial volunteers. Additionally, the manufacture of drugs and biologics under investigational status must strictly comply with current Good Manufacturing Practices (cGMP) and broader cGxP regulations.

⁹ <https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/medical-countermeasures>

CMs can include both previously FDA/EMA approved medical products (e.g. opioids, ventilators, antibiotics, masks, swabs, etc), and new unapproved products (e.g. mRNA/DNA injections). However, the key distinction between MCMs and normally regulated medicines is the **statutory non-investigational categorization of MCMs**. Specifically, in US law, use of Emergency Use Authorized (EUA) covered countermeasures under a declared Public Health Emergency **cannot constitute a clinical investigation** (21 USC 360bbb-3(k)), therefore countermeasures cannot be tested for safety or efficacy in accordance with US law (21 CFR 312 and 21 CFR 601), nor can compliance with current Good Manufacturing Practices (cGMP) or Good Distribution Practices (GxP in general) be enforced by the FDA.

This re-categorization of previously approved and unapproved medical products deploys MCMs for “unapproved uses”. Together with the non-investigational status, this re-categorization precludes the use of MCMs as medicines, and, by removing consumer safeguards, leaves MCMs entirely open to weaponization.

The laws that enable the removal of all consumer safeguards and manufacturers’ liability include the PREP Act (2005)¹⁰, Sec 564 of the Food, Drug and Cosmetics Act (FDCA)¹¹ in the US and a set of EU provisions for “pandemic preparedness” and “medical countermeasures” (discussed in Section 2.5). The PREP Act and corresponding EU provisions for countermeasures waive enforcement of pharmaceutical law for products declared countermeasures under an existing emergency declaration and provide liability immunity to covered persons (except narrowly defined willful misconduct). The PREP Act law is subject to legal controversy, and a proposal for its repeal is currently pending in the US Congress¹².

Due to the declared non-investigational status of MCMs, while the manufacturers may choose and the FDA/EMA may ask to undertake some of the activities typically expected from an investigational clinical trial and manufacturing validation process, none of the typical pharmaceutical regulatory standards are applicable in an enforceable way. In general, any activities claimed as regulated investigational tests and processes for medical countermeasures should be deemed deceptive practices designed to manufacture a veneer of consumer protection where none exists, nor intended to exist.

FDA has the discretion to issue an EUA if, in the sole opinion of the HHS secretary, the product “may be effective” in treating the relevant disease or condition¹³. No other criteria

¹⁰ <https://aspr.hhs.gov/legal/PREPACT/pages/default.aspx>

¹¹ <https://www.fda.gov/regulatory-information/federal-food-drug-and-cosmetic-act-fdc-act/fdc-act-chapter-v-drugs-and-devices>

¹² <https://massie.house.gov/news/documentsingle.aspx?DocumentID=395737>

13 21 U.S.C. § 360bbb-3(c)(2)(A)

for approval apply in an enforceable way. There is no strict legal requirement to conduct clinical trials prior to authorization and no lawful human subject-protected clinical trials are possible due to statutory “non-investigational” status of countermeasures.

FDA will approve EUA countermeasures on incomplete/non-existent information based on an opinion of the HHS Secretary that “known and potential benefit of the product” may “outweigh the known and potential risks”¹⁴ and considers it unlikely that “comprehensive effectiveness data” will be available before an EUA grant. In contrast, for an investigational drug (under normal regulatory approval process) the FDA “shall” deny approval if the applicant “do[es] not show that such drug is safe.”¹⁵

There is no strict requirement for an Investigational New Drug exemption (IND), nor institutional review board (IRB) approval of a clinical trial protocol and informed consent forms. Therefore, the EUA status of a medical countermeasure precludes collection of the regulated clinical trial data and thus precludes reliable, valid scientific knowledge of risks and benefits associated with the EUA Countermeasure while it remains non-investigational.

Furthermore, there are no required standards for quality-control in manufacturing; no inspections of manufacturing procedures; no lot-release testing and no prohibition on wide variability among lots; no prohibition on adulteration; and no required compliance with Current Good Manufacturing Practices. EUA products, even though unregulated and non-standardized, “shall not be deemed adulterated or misbranded.”¹⁶

The EUA pathway for medical countermeasures is used only when the United States Secretary of Health and Human Services or Minister of Health in EU Member State(s) declares an emergency¹⁷. In the United States, the PREP Act emergency declarations for covid have been extended 12 times to last until end of 2029¹⁸, preventing enforceable regulations and extending the liability shield for deaths and injuries caused by the countermeasures.

In the Netherlands, the government formally classified COVID-19 as a Category A infectious disease under its national Public Health Act (Wet publieke gezondheid) on January 27, 2020. This classification — announced by Health Minister Bruno Bruins — activated a range of emergency measures. This step is effectively the national declaration

¹⁴ 21 U.S.C. § 360bbb3(c)(2)(B)

¹⁵ 21 U.S.C. § 355(d)(2); See also 42 U.S.C. § 262(a)(2)(RB) (biologic approved only if it actually “is . . . safe”).

¹⁶ 21 USC 360bbb-3a(c).

¹⁷ 21 U.S.C. § 360bbb-3(a)(1), (b).

¹⁸ <https://public-inspection.federalregister.gov/2024-29108.pdf>

of a public health emergency, empowering authorities under the Public Health Act. These powers enabled nationwide responses—such as lockdowns—without declaring a formal emergency status. The Netherlands never invoked a formal national “public health emergency” declaration; therefore, there’s no emergency status to formally end.

In summary, in both US and EU, legal status of a product, service, procedure or action designated as “countermeasure” is equivalent to that of a potential weapon. Medicinal products or potential medicinal products (unapproved drugs), when designated as “countermeasures” under real or fabricated emergency, are legally permitted to be used for non-medicinal purposes. The non-medicinal purposes include use as a weapon or an illegal human experiment. Misrepresentations of safety, efficacy, or contents of EUA products are allowed by the applicable law. The defendants knew or should have known this, yet they concealed this from the public and propagated monstrous lies and coercion to achieve the maximum scope of deployment of these pretend medicines, which are in fact bio-chemical weapons.

2.4. Legal Provisions for Countermeasures in EU.

While the relevant laws between US and EU are not identical, there are several EU provisions corresponding with the provisions in US in relation to “medical countermeasures”.

In the European Union (EU), medical countermeasures (MCMs) are regulated primarily through a framework of EU pharmaceutical, medical device, and public health laws, especially as they relate to preparedness for serious cross-border health threats. While the EU doesn’t use the term “medical countermeasure” as explicitly as the U.S. FDA does, the legal infrastructure supports the development, authorization, stockpiling, and deployment of such products in public health emergencies.

Key EU Laws and Regulations Governing Medical Countermeasures:

1. Regulation (EU) 2022/2371 “On serious cross-border threats to health”
 - Adopted: 2022
 - Establishes:
 - A Health Crisis and Pandemic Preparedness Plan
 - EU-level coordination of medical countermeasures

- The Health Emergency Preparedness and Response Authority (HERA)
- 2. Regulation (EU) 2022/123 “On a reinforced role for the European Medicines Agency (EMA)”
 - Adopted: January 2022
 - Purpose: Expands EMA’s role in monitoring, coordinating, and facilitating the development and availability of medicines and medical devices during public health emergencies.
 - Creates the Medicines Shortages Steering Group (MSSG) and Emergency Task Force (ETF).
 - Legal basis for emergency use authorizations of MCMs in the EU.
 - Legal reference:
Regulation (EU) 2022/123

3. Joint Procurement Agreement (JPA) under Article 5 of Decision 1082/2013/EU

- Enables EU Member States to jointly procure **vaccines, antivirals, PPE**, and other MCMs.
- Still operational as a **coordinated procurement tool** post-COVID under HERA.

4. In 2016 the EU enacted a Regulation (EU) 2016/369, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0369&from=EN> , which provides for emergency support within the European Union. Emergency support “*may be awarded through specific measures appropriate to the economic situation in the event of an ongoing or potential natural or man-made disaster.*” (Art. 1 (1)) Based on a decision of the Council according to Art. 2 of Regulation 2016/369/EU “*to activate the emergency support*” under this Regulation, after proposal submitted by the EU Commission, the stage has been set for financing “*specific measures*” against threat emerging from “*human made or natural disasters*”.

On 14 April 2020 this Regulation was amended by Regulation (EU) 2020/521¹⁹ with [retroactive effect as of 1 February 2020](#), in order to extend the application of this Regulation to emergency support during Covid-19 crisis.

In its Art. 1 the “**emergency support under Council Regulation (EU) 2016/369**” is activated.

This Regulation provides for an Annex of Regulation 2016/369/EU in which it enumerates the eligible measures which may be funded in case of emergency situations. It says that the **enumeration is not exhaustive**, and it reads:

*“The following actions may **be financed in case of pandemics with large-scale effect**:*

(a) temporary reinforcement of the medical workforce, exchange of medical professionals, hosting foreign patients or other type of mutual support;

(b) deployment of temporary healthcare facilities and temporary extension of existing healthcare facilities to relieve pressure on existing structures and increase overall healthcare capacity;

(c) activities to support the administration of large -scale application of medical tests and prepare the necessary scientific testing strategies and protocols;

*(d) setting up temporary **quarantine facilities** and other appropriate measures **at the Union borders**;*

*(e) **development, production or purchase and distribution of medical products**;*

*(f) **increases and conversions of production capacities for medical products as referred to in point (e) to address supply shortages**;*

(g) maintenance of the stock of medical products as referred to in point (e) and their disposal;

*(h) **actions to support the necessary steps to obtain approval for the use of the medical products as referred to in point***

***(e) if required**;*

(i) actions to develop appropriate methods to track the development of the pandemic and the results of measures implemented to address it;

¹⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0521&from=EN>

(j) organisation of ad-hoc clinical trials of potential therapies or diagnostics according to trial standards agreed at Union level;

(k) scientific validation of medical products, including potential new testing methods.

The above list is not exhaustive.'

Thus, (h) enables any actions asserted necessary to achieve the approval for the use of medical products. It enables avoiding any provisions applicable to medicinal products /drugs and medical devices.

Lit (j) shows that for “ad-hoc” clinical trials GCP (Good Clinical/ Good Manufacturing Practice laws) can be waived and replaced with rather vaguely defined “trial standards agreed at Union level”, meaning the rules agreed upon by unelected bureaucrats, rather the pharmaceutical regulations spelled out in the law that governs consumer safety in medical products.

2.5. Conditional Marketing Authorization (CMA) Pathway in EU Was Utilized to Deliver Countermeasures Under Color of Medicines

Extensive evidence of public deception by pharmaceutical companies acting in concert with the regulators became available in late November 2020, when approximately 1000 pages of Chemistry Manufacturing Controls (CMC) documentation and a set of internal email exchanges were leaked from EMA²⁰. The full set of leaked pages and emails is included in the Attachment to this affidavit. These documents demonstrated that public health officials in the European Union committed fraud on all citizens, giving the impression that they evaluated and approved the covid injections according to existing standards for medicinal products, at least based on conditional marketing authorizations (CMA). The documents revealed that behind the scenes regulators were concerned solely with the timing of the launch, even before any data was reviewed, and waiving or making up greatly reduced quality standards to help Pfizer “meet” those standards, based on Pfizer’s say-so and no scientific basis whatsoever. This deceptive “bait and switch” scheme was coordinated globally among the regulatory agencies – the FDA, EMA, MHRA, TGA, Health Canada and many others.

In the EU, the same net effect – absence of any enforceable compliance with pharmaceutical cGxP regulations and other relevant pharmaceutical law - has been

²⁰ <https://www.bmj.com/content/372/bmj.n627>

accomplished by forcing all Member States to sign EU-orchestrated predatory purchasing contracts with pharmaceutical manufacturers that waived all relevant pharmaceutical regulations and obligated national governments to indemnify the manufacturers in case of successful liability suits against pharma companies in the Member States. This indemnification included waiver of sovereign immunity (see p.32 of Pfizer Advanced Purchase Agreement with EU²¹). These contracts effectively prevented the Member States from exercising sovereign legislative powers with respect to pharmaceutical liability for these products in their countries. These contracts have been allegedly negotiated by Ursula von den Leyen by text messages. There is an ongoing investigation by the European Public Prosecutor's Office (EPPO) into the acquisition of COVID-19 vaccines in the European Union²². The defendants who acted as corresponding health authorities in the Netherlands knew or should have known that these contract clauses were predatory, violate the respective state's Constitution, and thus are unacceptable for a sovereign government, and would result in mass injuries among the citizens these public health officials had sworn the oath to protect.

One of the critical mechanisms of deception was tying all 27 EU Member States into one (blind) deal by promising that the vaccines in Europe will go through the Conditional Marketing Approval (CMA) regulatory pathway as opposed to the Emergency Authorization, i.e. the issue of Art 5(2) vs CMA. This is discussed in several emails included in the EMA documentation leak. For example:

²¹ https://dn721909.ca.archive.org/0/items/contract_03/Contract%203_text.pdf

²² <https://www.eppo.europa.eu/en/media/news/ongoing-eppo-investigation-acquisition-covid-19-vaccines-eu>

From: Boone Hilde <Hilde.Boone@ema.europa.eu>
Sent: Thursday, November 12, 2020 3:57 PM
To: SOLOMON Olga (SANTE) <Olga.Solomon@ec.europa.eu>; SCHMIDT Florian (SANTE) <Florian.SCHMIDT@ec.europa.eu>
Cc: GIRARD Thomas (EMA) <Thomas.Girard@ema.europa.eu>; CAVALERI Marco (EMA) <Marco.Cavaleri@ema.europa.eu>; WATHION Noel (EMA) <Noel.Wathion@ema.europa.eu>
Subject: Art 5(2) vs CMA

Dear Olga & Florian

Just a heads-up: we just finished the TC between the Commissioner and ECDC/EMA in which the Commissioner asked questions about the expected approval of the Pfizer vaccine, and timing of FDA vs EU approval. So, automatically the issue of national Art 5(2) vs CMA came up, which Noel explained in detail and also how we plan to further discuss it with the NCAs next week and in HMA. Guido also suggested to consider raising it with the Health Ministers at EPSCO.

Sandra and Giorgios said that they would further discuss also within SANTE, so, hence my email to you.

(Andrzej was also present)

Also of note:

The Commissioner said that, since EC made a commitment to the MSs and EP that the vaccines will be available to all MSs at the same time – and that therefore it will be important that MSs will not be ‘forced’ to use that national route due to “delays” in the formal approval procedure. She also said that she will be prepared to call relevant health ministers personally to avoid the use of Art 5(2).

Best regards,

Hilde

The Art 5(2) is an Emergency Authorization mechanism available individually to the Member States. This authorization is issued for one year only, it is issued by each state and each state can revoke it independently. The CMA is a pan-EU mechanism in which the individual states have no say. The CMA in EU, however, is a **non-emergency investigational** pathway which, prior to 2020, had only been used for oncology drugs as a "right to try" or "compassionate use" for terminally ill patients. It is similar to the Expanded Access Use²³ (EAU, not to be confused with the EUA) in the US. Both CMA and EAU pathways however are investigational, meaning legally designated as medicinal use and purpose of the product. However, as discussed above, the “countermeasures” are non-investigational substances designated for non-medicinal purposes, thus coloring them as CMA or “BLA” is fraud and deception associated with their use as weapons.

²³ <https://www.fda.gov/news-events/public-health-focus/expanded-access>

As it is spelled out in law, the CMA sounds like a much stronger regulation and compliance mechanism vs Art5(2):

Emergency Use vs Conditional Marketing Authorization (CMA) in Europe

...CMA follows a controlled and robust framework providing safeguards that emergency use authorisations might not. In reality, an emergency use authorisation is not an authorisation of the vaccine but an authorisation of the temporary use of the unauthorised vaccine. The CMA ensures that all pharmacovigilance, manufacturing controls including batch controls for vaccines and other post-approval obligations apply in a legally binding manner [...]. Notably:

- It ensures a rigorous monitoring, through the EU pharmacovigilance system, of the safety of the medicine across the EU. [...]
- It ensures post-authorisation safety monitoring and allows the collection of additional data in a structured manner. [...]
- Rigorous manufacturing including batch release for vaccines and distribution, are subject to the same ongoing controls as for all authorised medicines. The monitoring of the manufacturing processes ensures that the medicine is manufactured and controlled according to high pharmaceutical standards in the context of large scale commercialisation.

https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/questions-and-answers-covid-19-vaccination-eu_en#authorisation

The important difference between Art 5(2) and CMA is that it puts liability onto the manufacturer, and that's what was promised to be enforced via the use of the pan-EU CMA authorization:

Difference in liability for EU Emergency Use vs Conditional Marketing Authorization (CMA)

Under an EU Conditional Marketing Authorisation (CMA), liability is with the holder of the marketing authorisation. The marketing authorisation holder will be responsible for the product and its safe use. The CMA is valid for a one-year period, on a renewable basis and contains the same rights and liability for its holder as per that of a standard marketing authorisation. In addition, the holder of a CMA has specific obligations such as to complete or conduct new studies within a defined time period in order to confirm that the benefit/risk balance remains positive.

In the case of an Emergency Use Authorisation to temporarily authorise the distribution as an unauthorised product (Art. 5(2) of Directive 2001/83), EU legislation requires Member States to remove administrative and civil liability from the manufacturer and marketing authorisation holder, when this emergency use is recommended or required by the Member State.

Note: Previously, CMA approach in EU was used only for oncology drugs

https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/questions-and-answers-covid-19-vaccination-eu_en#authorisation

However, in a classic bait-and-switch fraudulent inducement scheme the public health authorities in the EU and the Netherlands never meant to hold the pharmas to any of those promised CMA standards. The EU supply contracts with pharmaceutical companies waived all the relevant consumer safety enforcement regulations and laws in their countries. In effect, this removed any meaning from the CMA standards for consumer safety and manufacturer liability, because no enforcement = no law!

For example, see the EU supply agreement with Pfizer²⁴ wrt Indemnification:

In summary, the net effect of the PREP Act (i.e. removal of all relevant pharmaceutical regulations and manufacturers' liability) was accomplished in EU via centralizing supply agreements under the pan-EU fraudulent scheme designed to pass military countermeasures onto the consumers under the color of CMA-authorized and later "fully approved" vaccines.

²⁴ https://dn721909.ca.archive.org/0/items/contract_03/Contract%203_text.pdf

2.6. Direct evidence of noncompliance of the covid mRNA/DNA injections with normal pharmaceutical regulations, expected by the consumers and healthcare providers.

Approximately 1000 pages of Pfizer's manufacturing documentation were leaked from the European Medicines Agency (EMA) at the end of 2020 showing absence of the Good Manufacturing Practice (cGMP) compliance less than 2 weeks before the product was deployed onto billions of consumers worldwide. The leak of the documents was [authenticated by the British Medical Journal](#). The EMA did not deny the authenticity of the documents. In addition to the manufacturing documentation, the EMA files also contain 14 screenshots of emails dating from mid to late November 2020. The email exchanges are between the EMA staff and senior executives at the agency and their correspondence with the FDA and MHRA (the UK regulator). These emails demonstrate that the EMA reviewers were under massive political pressure to invent new ways of approving the inherently non-approvable dangerous products. It is evident from the emails, comments and objections raised by the EMA review staff that they were not aware of the legal status of the Covid-19 injections as countermeasures, nor that the regulatory review of the data was not material to their deployment.

It is also evident that the EMA leadership were concerned primarily with coordinating the launch dates, and the "authorization" of these shots for all EU Member States was a forgone conclusion. The pressure to overlook all regulatory deficiencies was emanating from the very top of the US, UK and EU governments.

There were severe and unresolvable - given the purposefully unrealistic timeline - issues with the quality of the product the EMA staff were pressured to ok. The manufacturing process was woefully out of compliance. The EMA reviewers raised more than 100 objections to approval, including several Major Objections. Specifically, Major Objections included

- 1) lack of cGMP compliance;
- 2) lack of mRNA integrity and large amounts of mRNA fragments (**some of which can be characterized as miRNA, siRNA and shRNA - all potential weaponization components as described above**);
- 3) many significant gaps in manufacturing documentation making it impossible to determine if the product could be made as described.

Emails leaked from EMA also demonstrate that the EU regulators were only concerned with the dates of product launch and were not going to review the necessary data prior to

launch. The process was highly political and not scientific. The EMA regulators took verbal assurances from the FDA officials instead of reviewing the data. As stated above, the EMA staff reviewers objected to the data, but the high-ranking officials ignored and over-ruled their concerns.

Lack of cGMP compliance means that no assurances can be made that the products contain specific ingredients in specific amounts in the units dispensed to the patients. Therefore, in addition to the product being dangerous, no informed consent is possible.

One of the key elements guaranteeing the quality of the drug substance is a product specification based on the current state of product development as well as science and technology. For this, the framework is set by International Conference on Harmonization (ICH) guideline Q6A “Test procedures and acceptance criteria for new drug substances and new drug products: chemical substances”²⁵. The specification defines a list of tests along with references to analytical procedures and appropriate acceptance criteria for the quality assessment of the respective product regarding identity, assay/quantity, purity/impurities, and potency/ biological activity.

All analytical procedures must be fully validated, which means that either standard, previously validated methods are used, or if proprietary/novel – then the manufacturer must invent and fully validate the assays that are used for novel techniques. This requires, among other things, definitive tests with positive and negative controls as well as full and traceable documentation “audit trail” for every test. Commercial secrecy is not an excuse for failure to comply with these requirements. Even if the manufacturer does not wish to publicly disclose their analytical procedures, they still must submit full transparent documentation to the FDA who holds it on file (and this fact is formally communicated to purchasers of the product for their own GxP compliance).

In Pfizer’s CMC documentation leaked at the end of 2020, the reviewers from EMA noted that there was no description of the “non-compendial”, i.e. Pfizer’s own developed proprietary methods for analytical procedures. This made it impossible to evaluate the scientific accuracy of the proprietary methods used by Pfizer to control the quality of produced injections.

Numerous product and process control parameters were proprietary, not well defined, some were not yet invented, and none were scientifically validated. For example, the test used for the **mRNA identity** testing was chosen RT-PCR (real-time PCR). However, the mRNA is a highly unstable and fragile substance, which, while manipulated and chemically

²⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q6a-specifications-test-procedures-and-acceptance-criteria-new-drug-substances-and-new-drug-products>

“optimized” for stability, still has shown a great degree of fragility. As a result, the integrity of the mRNA has been problematic, especially with the scale up of manufacturing.

One of the Major Objections (MO) from the EMA reviewers stated in the leaked Pfizer CMC documentation was lack of mRNA integrity, i.e. low % of RNA in the vial conforming to the specification and a very high % of broken RNA pieces:

From: Jekerle Veronika <Veronika.Jekerle@ema.europa.eu>
Sent: 24 November 2020 12:02
To: Korakianiti Evdokia <Evdokia.Korakianiti@ema.europa.eu>
Cc: Facchini Claudio <claudio.facchini@ema.europa.eu>; Moseley Jane <Jane.Moseley@ema.europa.eu>; van der Stappen Ton <ton.vanderstappen@ema.europa.eu>; Dooley Brian <Brian.Dooley@ema.europa.eu>; Rager Irene <Irene.Rager@ema.europa.eu>; Seguin Vanessa <Vanessa.Seguin@ema.europa.eu>
Subject: update from BWP meeting on BioNTech

Dear Evdokia,

The BWP has just discussed the BioNTech BWP and below you will find the main conclusions:

The Dossier is generally of good quality considering the speed in development and compilation.

- 3 major objections are agreed:

- **MO1:** GMP distant assessments for US manufacturing sites (Note: Distance assessment on the Wyeth, Andover site (DS, QC DS, QC DP) and on the Pfizer, Chesterfield site (QC DS, QC DP) are ongoing → interim reports expected 11 Dec 2020, MO reworded to allow statement of GMP)
- **MO2:** Differences in the level of mRNA integrity; comparability between clinical and commercial material, DS and DP is questioned (Note: root cause analysis ongoing on 2 additional PPQ batches manufactured with a slightly adjusted process – waiting for results, if RNA integrity is improved back to initial levels this could be accepted / characterisation data requested to understand protein variability from mRNA fragments → potential impact on safety).
- **MO3:** Pending PPQ-batches for DP: comparability, process validation and stability (Note: as above: 2 PPQ batches manufactured and currently undergoing testing).
- Note that full information on two novel excipients (lipid in the nanoparticles) is not yet provided. This data is expected in the next CMC wave.

Conclusions: a number of major concerns remain that impact the benefit/risk of the vaccine (efficacy/safety) most notably the comparability issue around % mRNA integrity. These concerns are shared by most member states. **An approval by the end of the year could potentially be possible, if these concerns + GMP will be resolved.** Any remaining Quality issues will need to be considered in the context of overall B/R (& could potentially be addressed via specific obligations/Annex II conditions/recommendations).

The BWP report reflecting these conclusions is undergoing written adoption today.

With thanks to Ton, Brian and Claudio,

Kind regards,

Veronika

Veronika Jekerle, PhD

Head of Pharmaceutical Quality Office

Quality and Safety of Medicines

Office: 09-N-02

Extension: 8438

The large amount of non-conforming RNA was deemed impurity by the EMA reviewers. It is, indeed, a major problem - the entire claimed efficacy of the product allegedly depended on the “correct code” to produce the “Wuhan spike protein” using the cellular machinery of the injected individuals. Here we have evidence of the regulators objecting to approval due to the fact that many other things besides the “Wuhan spike protein” can happen in the cells bombarded with broke RNA pieces, **which is a known weaponization method for mRNA vaccines as discussed above.**

Instead of stopping the approval and demanding that the mRNA integrity is resolved, the regulators simply arbitrarily moved the acceptance criterium for the %mRNA integrity from the previous standard of 70%+ to just greater than 50%.

That means that a large portion of drug substance is allowed to contain “junk” RNA material, fragments, and uncharacterized pieces, some of them large enough to code for unknown and possibly aberrant proteins, and most of them falling into the category of micro RNAs (miRNAs). These short sequences, while non-coding, are known to interfere with cellular processes and are implicated in cancer pathways²⁶.

Ultimately, the regulatory review itself and the objections raised by the EMA reviewers did not matter - the product was going to be pushed on the market regardless of the regulatory objections due to the military CBRN response that was invoked globally, in secret from the public.

2.7. Removal of requirements for biologics manufacturing facility inspections:

Neither the FDA nor EMA conducted the manufacturing facilities inspections for Pfizer and its suppliers in 2020, citing covid emergency. When the manufacturing facility inspections resumed in 2022, Pfizer’s major European contractor, Rentschler, was found in violation of cGMP (form 483 issued). This means the supply chain for Pfizer in Europe was not in compliance between 2020 and 2022. No enforcement action was taken by the regulators, as per EUA law there is no enforcement possible.

It is also worth noting that in 2019, evidently in preparation for the Covid-19 operation, then US FDA Commissioner Scott Gottlieb changed the federal regulations governing inspection of licensed facilities manufacturing **all biological products including ‘vaccines’**, from at least every two years to unspecified times; eliminated enforcement provisions if a licensed

²⁶ <https://www.nature.com/articles/sigtrans20154>

facility failed an inspection; and eliminated all inspection duties for FDA inspectors. Prior to the rule change, 21 CFR 600.21, Time of inspection, read:

“The inspection of an establishment for which a biologics license application is pending need not be made until the establishment is in operation and is manufacturing the complete product for which a biologics license is desired.

In case the license is denied following inspection for the original license, no reinspection need be made until assurance has been received that the faulty conditions which were the basis of the denial have been corrected. An inspection of each licensed establishment and its additional location(s) shall be made at least once every 2 years. Inspections may be made with or without notice, and shall be made during regular business hours unless otherwise directed.”

Effective May 2, 2019, the last three sentences of 21 CFR 600.21 were removed.

There is currently no legal requirement for an initial FDA inspection; no minimum interval for subsequent FDA inspections, and there are no legal consequences for compliance failures, such as establishment or product license denial or revocation.

The legal mechanisms through which FDA regulation of biological product manufacturing disappeared, included a Direct Final Rule and a Proposed Rule, simultaneously issued by Federal Register notice on Feb. 26, 2018, and an April 2, 2019 Final Rule, issued by then-FDA Commissioner Scott Gottlieb.

2.8. Arbitrary reclassification of mRNA/DNA gene therapies as “Covid-19 vaccines”:

Regarding the technology platform itself (mRNA in lipid nanoparticle [LNP], or DNA in adenoviral vector) - both are known as "transfection" technologies. The purpose of the product design is to deliver various bio-chemical cargo inside the cellular membranes, and often into the cell's nucleus where DNA resides. Transfection methods using a wide variety of RNA and DNA technologies are a well-established scientific reality. For example, as published in this literature review paper²⁷:

²⁷ <https://pmc.ncbi.nlm.nih.gov/articles/PMC8067914/>

*“A systematic literature search based on PRISMA guidelines ([Moher et al., 2009](#)) was established to identify relevant published studies or protocols that fit into this review’s scope ([Fig. 1](#)). Databases that were employed for the literature search included Scopus, Google Scholar, and PubMed. The keywords being used during the search included “transfection”, “co-transfection”, “chemicals”, “reagents”, **“DNA”**, **“siRNA”**, **“shRNA”**, **“miRNA”**, **“plasmid”**, **“oligonucleotides”**, “efficiency”, “safety”, “cytotoxicity”, “controls” and other related key terms. An initial search returned about 5,000 articles, published protocols, or handbooks from various databases that reported the descriptions or comparisons between different transfection methods, types of transfected nucleic acids, transfection control, transfection efficiency assessment methods and transfection reagents.”*

The design of the genetic therapy products is identical to that of the covid “vaccines”: the LNPs will deliver the cargo attached to them into the cells, i.e. **transfect the cells**. The LNP platform or adenovirus platform are just 2 different types of "cargo trucks", the LNP being particularly effective in hacking the cells. The fact that it is a transfection technology is documented very widely in science literature and in regulatory documents. Both Moderna and BioNTech characterized their mRNA technologies as experimental, a “therapy” and in early development stages in SEC filings immediately preceding the pandemic. Moderna's 2019 Form 10-K specifically noted: "mRNA medicines are a novel and unproven approach... No mRNA immunotherapy has been approved, and none may ever be approved."

No mRNA pharmaceutical products were approved by any regulatory authorities in the world before 2020. This was due to numerous failures to meet pharmaceutical safety and compliance standards. All products in development repeatedly ran into safety issues and could not advance even into the first phase of the human testing^{28, 29}.

3. Covid-19 mRNA injections were financed, developed and deployed worldwide via a military campaign coordinated through military and security alliances.

²⁸ <https://www.statnews.com/2017/01/10/moderna-trouble-mrna/>

²⁹ <https://thewashingtonstandard.com/moderna-a-company-in-need-of-a-hail-mary/>

3.1. Covid-19 was not a public health event, but a global military operation:

Covid operation was not a public health event, although it was presented as such to the world's population. It was a global operation, coordinated through public-private intelligence and military alliances and invoking laws designed for CBRN (chemical, biological, radiological, nuclear) weapons attacks.

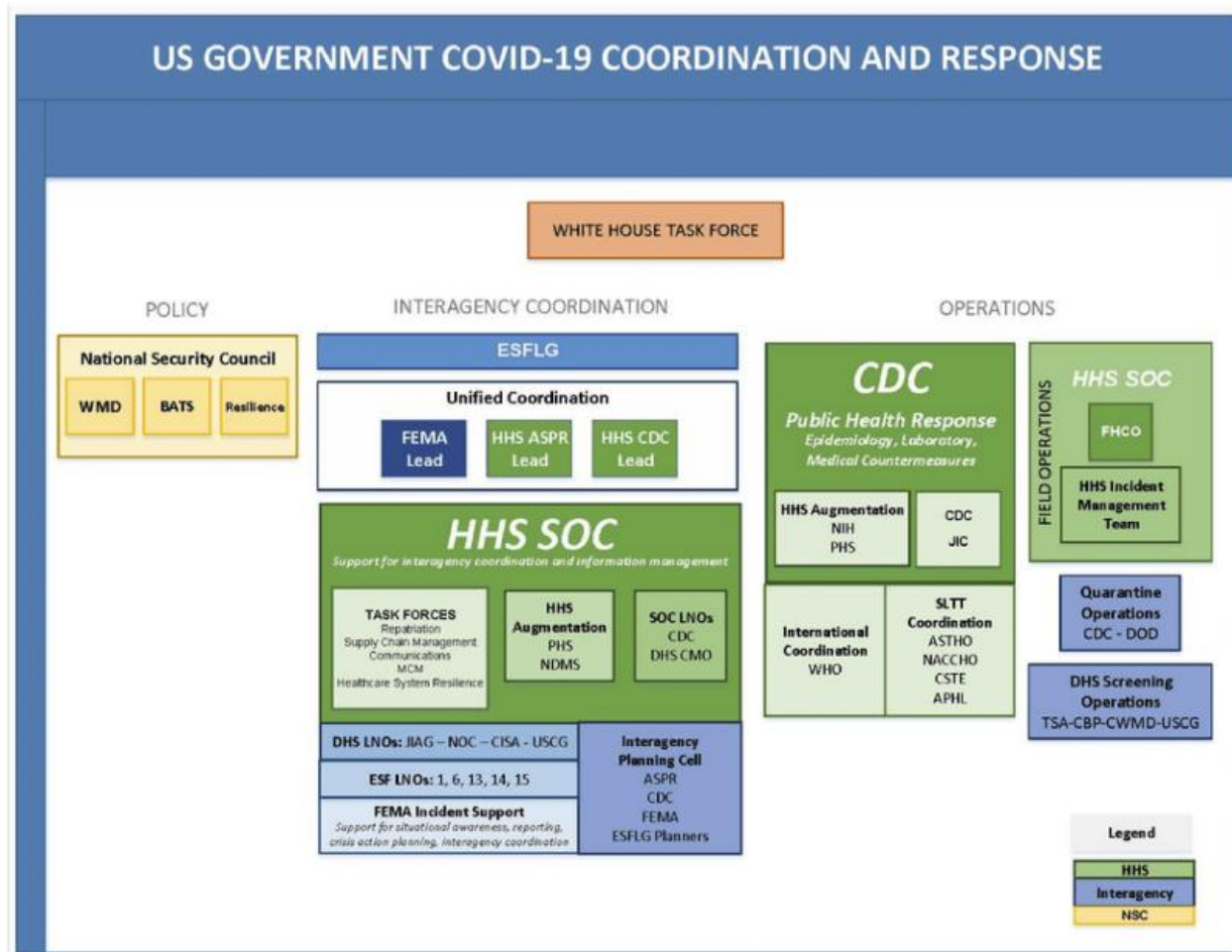
In the US, the National Security Council (and not Department of Health and Human Services) is in charge of Covid policy in the US. In other countries of the world, covid campaign was coordinated via identical mechanisms, with military and intelligence apparatus leading the response policy (as in a war), and public health agencies presenting a false front of a public health emergency to the public. **See Exhibit 1 for detailed evidence of the global military campaign, including the evidence for the Netherlands and other EU countries.**

In the US, March 13, 2020: "PanCAP Adapted U.S. Government COVID-19 Response Plan" (PanCAP-A) states that United States policy in response to SARS-CoV-2 is set not by the public health agencies designated in pandemic preparedness protocols (Pandemic and All Hazards Preparedness Act,³⁰ PPD-44,³¹ BIA), but rather by the National Security Council, or NSC. NSC does not have regular attendees from public health agencies and its focus is national security and foreign policy matters."

Below is the organization chart from the PanCAP-A document, p.9:

³⁰ <https://www.govinfo.gov/content/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf>

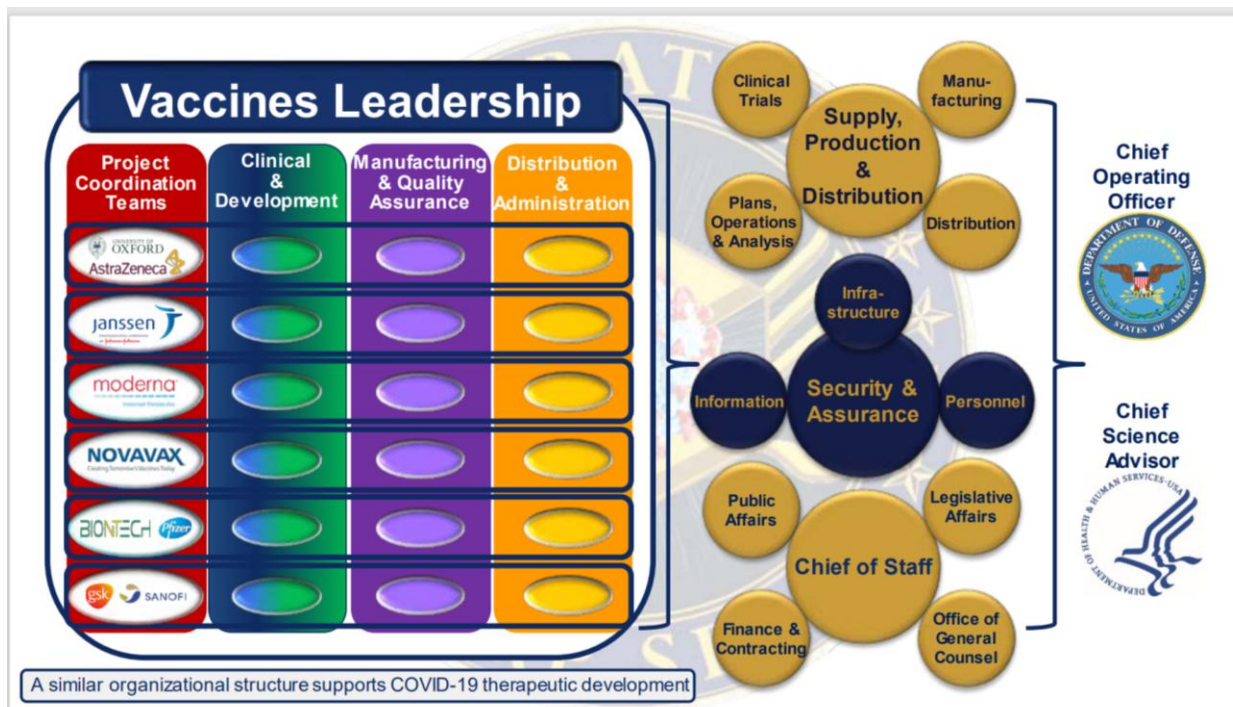
³¹ <https://www.in.gov/dhs/files/FEMA-Fact-Sheet-COVID-Response-3.4.20.pdf>



3.2. Operation Warp Speed Organization Structure

According to the Operation Warp Speed/ASPR reports, Operation Warp Speed was declared as a “collaborative” effort of the DOD and HHS to produce “safe and effective” Covid-19 vaccines and therapeutics. However, according to the organizational chart, the DOD was formally the Chief Operating Officer, while HHS had the Chief Science Advisor position.³²

³² See “VRBPAC-10.22.20-Meeting-Presentation-COVID19-Vaccine-Development-Portfolio.pdf” in Attachment



VRBPAC-10.22.20-Meeting-Presentation-COVID19-Vaccine-Development-Portfolio.pdf

Notably, the next seniormost layer of the organization is controlled by the US Government and includes all supervisory roles for manufacturing, clinical trial design and implementation, planning operations and analysis, distribution, public affairs, contracting, legal and other functions. The pharmaceutical companies are the third level down in this organization.

A report by STAT News in 2020 pointed out that roughly 60 military officials, including four generals, were involved in the leadership of Operation Warp Speed, many of them without any previous healthcare experience. Out of roughly 90 leadership positions on the organizational chart, only 29 were not employed by the DoD.³³

The unclassified October 2020 documents from Operation Warp Speed presentations at the FDA's Vaccines and Related Biological Products Advisory Committee reveal control of the US Government over nearly all product design and implementation aspects of the development for Covid countermeasures³⁴.

³³ <https://www.statnews.com/pharmalot/2020/09/28/pharmalittle-operation-warp-speed-is-more-army-than-science-jjs-covid-19-vaccine-moves-forward/>

³⁴ See "VRBPAC-10.22.20-Meeting-Presentation-COVID19-Vaccine-Development-Portfolio.pdf" in Attachment

3.3. Review of DoD/BARDA Contracts for Covid Countermeasures

Hundreds of Covid countermeasures contracts became available via "freedom of information" (FOIA) requests in partially redacted form.³⁵ Review of these contracts indicates a high degree of control by the US Government (DoD/BARDA) and specifies the scope of deliverables as "demonstrations" and "prototypes" only. Demonstration is a fake, performative activity. Medicinal products administered to people cannot be characterized as "demonstrations and prototypes" however, weapons can be ordered as prototypes. The contracts also include the removal of all liability for the manufacturers and any contractors along the supply and distribution chain under the 2005 PREP Act and related federal legislation.

While the DoD/BARDA countermeasure contracts refer to safety and efficacy requirements for vaccines and mention current Good Manufacturing Practices (cGMP) compliance, these items are explicitly carved out as not being paid (or ordered) by the US Government.

The contracts were structured under Other Transactions Authority (OTA) - a method of contracting that was utilized by the DoD and BARDA for all Covid-related countermeasures ordered from the private industry. The OTA method of contracting allows federal agencies to order otherwise-regulated products bypassing any such regulations, as well as financial accountability mechanisms that cover standard government contracting, and other laws that regulate disclosure and Intellectual Property (IP) derived from publicly funded research.³⁶

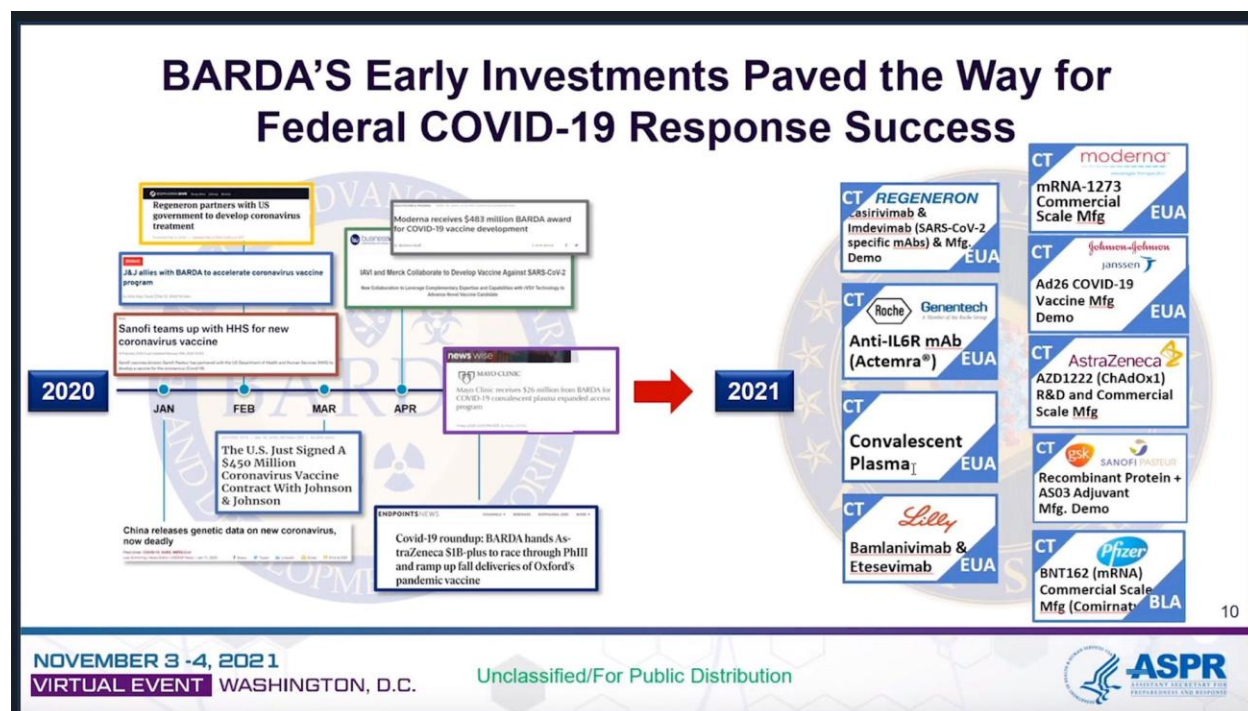
"Other" is a catchall category that is not a contract, not a research grant, not a procurement, etc.: not any normally regulated/accountable government contracting.

DoD used OTA to order vaguely defined "prototypes" and "demonstrations" that are not subject to regulatory scrutiny.

BARDA's own report, lists Covid-19 products as "demonstrations" or at best "large scale manufacturing":

³⁵ <https://www.keionline.org/covid-contracts>

³⁶ <https://www.keionline.org/bn-2020-3>



3.4. DoD/BARDA countermeasures produced by established network of defense contractors

The DoD/BARDA contracts for “countermeasures” are managed by Advanced Technology International (ATI).³⁷ ATI mostly manages R&D consortia for the Department of Defense for things like weapons manufacturing, metal casting and forging, ship production and technology aimed at “countering Weapons of Mass Destruction (WMDs).” Two of these consortia related to biomedical projects.

The Medical Technology Enterprise Consortium (MTEC), operating on behalf of the U.S. Army Medical Research and Development Command, includes technology for gene-editing, nanotechnology, “telehealth solutions,” artificial limbs and brain implants. MTEC is currently developing a wearable device to diagnose Covid-19 before symptoms appear.

The Medical CBRN Defense Consortium (MCDC)³⁸ currently includes ~300+ large and small businesses and academic entities that “support the Department of Defense’s (DoD) medical pharmaceutical and diagnostic requirements to counter Chemical, Biological, Radiological and Nuclear (CBRN) threat agents” and enable “prototype technologies for

³⁷ <https://www.ati.org/>

³⁸ <https://www.medcbrn.org/current-members/>

therapeutic medical countermeasures targeting viral, bacterial and biological toxin targets of interest to the DoD,” including the development of vaccines.

Through the mechanism of Other Transactions Authority, MCDC contracted with hundreds of companies to deliver Covid-related “countermeasures.” Pfizer doses were ordered on July 20, 2020, through Base Agreement between Advanced Technologies Inc (ATI, a DOD vendor management company) and Pfizer, Inc., identified as MCDC Base Agreement No. 2020-532:

- July 21, 2020, MCDC Technical Direction Letter or Statement of Work (SOW) for "COVID-19 Pandemic - Large Scale Vaccine Manufacturing Demonstration" between Pfizer and DOD/Advanced Technologies Inc.³⁹

The contracts specified that the product will be shipped to the DoD as sole purchaser. The delivered product is not serialized – i.e., unit doses are not barcoded and thus not traceable under normal pharmaceutical distribution rules which exist to flag any safety or quality issue in the supply chain. The product thus is open to both falsification/mislabeling and adulteration. The product was shipped to DoD and handled through a “black box” DoD distribution system, ostensibly due to the cold chain storage requirements, which were later removed, but the distribution practice via military contractors and military contracts did not change.

The product was specified as “US Government property”⁴⁰ until it is injected into a person. All persons performing any tasks along manufacturing, supply chain, distribution and administration of the shots are “covered persons” under PREP Act liability shields, as long as they follow US Government orders. Regardless of place of employment, they are deemed to be US Government employees for purposes of this work.

Importantly, the DOD contracts describe Covid countermeasures as intended for “civil and military application.”

³⁹ <https://www.keionline.org/misc-docs/DOD-ATI-Pfizer-Technical-Direction-Letter-OTA-W15QKN-16-9-1002-21July2020.pdf>

⁴⁰ <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html#6-23-22>

4. Conclusions and Expert Opinion:

Based on my review of primary regulatory documents, leaked Pfizer's Chemistry-Manufacturing-Control (CMC) files, relevant legislation in the U.S. and EU, and other publicly available documentation, it is my expert opinion that the Covid-19 mRNA injections were deployed under military 'medical-countermeasure' rules that bypassed standard pharmaceutical safeguards, rendering them legally and functionally indistinguishable from potential bio-chemical weapons.

Covid-19 injections were deceptively presented to the public under color of medicines, falsely advertised as "safe and effective vaccines".

Individuals who prescribed, purchased and/or administered the Covid-19 (mRNA) injections participated in war crimes and/or genocide (democide).

EXHIBIT 1: The Covid Dossier – A record of military and intelligence agencies leadership and coordination of the global Covid operation.

The dossier includes information for US, UK, Canada, Australia, Germany, the Netherlands, Italy, other EU countries, Switzerland, Turkey, Latin America and Asia.

EXECUTIVE SUMMARY

The Covid Dossier is a compilation of the evidence we have amassed over the last three years supporting the following claim:

Covid was not a public health event, although it was presented as such to the world's population. It was a global operation, coordinated through public-private intelligence and military alliances and invoking laws designed for CBRN (chemical, biological, radiological, nuclear) weapons attacks.

The Dossier contains information regarding the military/intelligence coordination of the Covid biodefense response in the U.S., U.K., Australia, Canada, the Netherlands, Germany, Italy, and many more locations. For some countries we have extensively documented information. For others, we have some documentation of military/intelligence involvement, but not all the details. For as many countries as possible, we list the military/intelligence agencies in charge of their country's Covid response; dates on which emergency declarations were made in each country; military/intelligence-related agencies and bodies in charge of censorship/propaganda; and top people with military/intelligence jobs who were known or reported to hold leadership positions in the response. We also list connections to global governing bodies, including the EU and UN/WHO, through which the response was coordinated. In the final section, we include a list of military/intelligence/biodefense alliances that provide multinational frameworks for responding to a bioterror/bioweapons attack.

On February 4th, 2020, two things happened that almost nobody knows about, but that played an important role in the course of recent world history:

1) Two declarations for CBRN (weapons of mass destruction) emergencies – EUA and PREP Act – made by the U.S. Secretary of Health and Human Services, were registered on this date. [ref][ref]

EUA stands for Emergency Use Authorization. Legally, EUA powers are intended for situations of grave, immediate emergencies involving weapons of mass destruction. They allow for the use of countermeasures against CBRN (chemical, biological, nuclear or radiological) agents without the regulatory oversight intended to ensure safety and efficacy, because the immediate threat of a CBRN attack is deemed so much greater than any potential risks caused by the countermeasures.[ref] The PREP Act is the legal indemnity granted to anyone involved in using an EUA countermeasure, because if a weapon of mass destruction is involved, the risk of the CBRN attack is so great that no one should face legal consequences for potential collateral damage caused by using unregulated countermeasures.

In order to activate EUA, the law requires “A determination by the Secretary of HHS that there is a public health emergency... that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent(s). [ref] So when the EUA was officially activated on February 4, 2020, it was in essence a declaration of a state of emergency involving weapon(s) of mass destruction.

[This PREP Act Public Health Emergency declaration has been repeatedly renewed and is currently in effect through December 31, 2029.](#)

2) A pharmaceutical executive was caught on tape saying that the U.S. Department of Defense called to inform him “that the newly discovered Sars-2 virus posed a national security threat.” [ref] Also see the AstraZeneca audio file in Attachments.

It is important to note that on February 4, 2020, there were fewer than a dozen confirmed cases of the novel coronavirus disease (later called Covid-19) in the US, and zero deaths. Worldwide, the death count was fewer than 500. There was nothing about the virus, at least as it was presented publicly, that would make anyone believe it posed a threat to national security.

These two events are remarkable for several reasons:

- They indicate that the beginnings of Covid were rooted in national security machinations, not public health considerations.
- They also strongly suggest that the deployment of the EUA “medical countermeasures” under Public Health Emergency declaration was officially launched at a time when an emergency, much less a national or a global one, could

not possibly be determined. No public health parameters justifying that a novel virus posed a “threat to national security” existed at the time of the EUA and PREP Act declarations.

Thus, on this day five years ago, **a military CBRN countermeasure deployment campaign was officially launched** against a poorly defined illness that was alleged to have killed a few hundred people worldwide.

Within six weeks of this date, in order to ensure a market for the countermeasures (among other aims), the lockdown-until-vaccine response – which is a military/counterterrorism plan and has nothing to do with public health [[ref](#)] – went into effect all over the world.

It is crucially important to understand that Covid was a globally coordinated response, based on legal frameworks intended for biodefense/biowarfare situations. The attack that initiated the global Covid response could have been real, perceived or invented – regardless of the trigger, the lockdown-until-vaccine paradigm originated in the military/intelligence biodefense playbook, not in any scientifically based or epidemiologically established public health plan.[[ref](#)]

This means that nothing about the response – masking, distancing, lockdowns, vaccines – was part of a public health plan to respond to a disease outbreak. Rather, every aspect of the response was intended to induce public panic in order to gain compliance with biodefense operations, culminating with the injection of unregulated mRNA products, which were legally treated as biodefense military countermeasures (MCMs), into billions of human beings.

Covid Dossier: the Netherlands⁴¹

Military/intelligence agencies and alliances involved in response:

- **National Coordinator for Security and Counterterrorism (NCTV)** [[ref](#)]
- **NATO** [[ref](#)]
- **European Union** [[ref](#)]

Dates, types and names of unprecedented emergency declarations:

- **March 15, 2020:** “new additional measures to combat the COVID-19 outbreak” (closure of schools, restaurants, sports/fitness facilities)[[ref](#)]

⁴¹ The Dutch government disclosed a secret obligation to comply with NATO Resilience goals (news article): <https://deanderekrant.nl/kabinet-erkent-navo-is-de-baas/>

- **March 23, 2020:** “intelligent lockdown” announcement [[ref](#)]

Military/IC-affiliated groups involved in messaging/propaganda/censorship:

- **Ministry of Defense Land Information Manoeuvre Centre (LIMC)** [[ref](#)][[ref](#)][[ref](#)][[ref](#)]
- **National Coordinator for Security and Counterterrorism (NCTV)**[[ref](#)]
- **National Core Team Crisis Communication (NKC)** (led by the NCTV)[[ref](#)]
- **Interdepartmental Working Group on Disinformation** (includes Defense, Foreign Affairs and Justice Departments, among others) [[ref](#)]

Key figures in Covid response linked to military, IC, NATO, EU:

- Marion Koopmans [[ref](#)]
- Pieter-Jaap Aalbersberg [[ref](#)]

Evidence presented in the documents released by the government of the Netherlands under freedom of information lawsuits ([WOB documents](#)) contains the following:

- NCTV, and not the public health agencies, was in charge of policy, organization and communication control from the start of the “Covid-19 pandemic”;
- NCTV and not the health agencies decided on most of the “covid measures”;
- NCTV worked with LIMC, the military surveillance unit that secretly observed the Dutch civilians without a legal basis;
- NCTV worked with the NCSC, which developed activities without a legal basis;
- NCTV was deliberately and knowingly breaking the law;
- There are international connections with security services that used similar frameworks and military doctrine such as the NCTV in the Netherlands.

Analysis of the hundreds of thousands of pages released by the Dutch government in response to FOIA requests demonstrates a remarkable picture about the crisis organization surrounding Covid-19 and the special role that the **National Coordinator for Security and Counterterrorism** (NCTV⁴²) played in it. The NCTV, and not the public health agencies, was in charge of all policy decisions and carried out various operational activities for which there was no legal basis in the Dutch law.

⁴² *Nationaal Coördinator Terrorismedbestrijding en Veiligheid*

The NCTV is currently led by Pieter-Jaap Aalbersberg and was [founded in 2011](#) as a continuation of the 2004 National Counterterrorism Coordinator (NCTb). The NCTb was established at the time to coordinate all anti-terrorism activities between the various services such as the Police and AIVD. Since 2011, the NCTV has been an independent entity operating under the Ministry of Justice and Security. [The National Cyber Security Center \(NCSC\)](#) was established for the Cyber Security focus area, which fell under the NCTV. Since 1 January 2019, the NCSC has become a separate executive agency (uitvoeringsorganisatie) within the Ministry of Justice and Security. However, the NCTV remains its commissioning authority ("opdrachtgever"), setting strategic priorities and policy direction while the NCSC carries out operational cybersecurity work.

Prior to 2020, the [NCTV had already been in the news](#) due to improper practices under the name "counterterrorism". [Infiltration techniques were used](#) on the Internet to observe and influence citizens' online behavior using avatars or [troll accounts on social media](#). In the real world, infiltration also [took place in mosques](#).

In 2020, with the announcement of a global "pandemic", crisis response organizations were set up by all countries to act in "lockstep". Similar structure was established in the Netherlands. In 2022 various "freedom of information" [\(WOB\) requests were granted after judicial intervention](#). These releases demonstrate the central role that the NCTV has played in the policy, oversight and all other aspects of the so-called "covid response". The NCTV played the pivotal role in policy and decision making. This was the case for the Covid-19 Directors Consultation (DOC), the Catshuis Consultation, the Departmental Crisis Center Consultation (DCC), the Ministerial Covid Committee¹⁹ (MCC) and the Civil Service Covid-19 Commission (ACC).

4. Terugkoppeling overleg

a. Catshuis
 Er wordt een terugkoppeling gegeven van het Catshuis door de NCTV, waarbij de sporen die momenteel worden uitgewerkt nader worden toegelicht.

Het eerste spoor betreft het maatregelenpakket van maart, waarbij scholen en contactberoepen niet gesloten worden en detailhandel open blijft. Het tweede spoor betreft het maart pakket waarbij scholen en niet-essentiële detailhandel gesloten wordt. Het derde spoor betreft een avondklok. Spoor twee en drie worden overwogen voor enkel de zwaarst getroffen regio's.

VR bepleit om slechts twee variabelen te introduceren en geen drie. Het voorstel zou dan zijn om spoor twee en drie te laten gelden voor dezelfde regio's.

OCW bepleit het open houden van onderwijs. Daarvoor wordt aandacht gevraagd voor bibliotheek en categorie doorstroomlocatie vallen.

De VNG wijst op het waterbedeefte bij Daarnaast wordt aandacht gevraagd voor afwijkingen van de routekaart. Verder wordt ingangsdata.

5. Verantwoordelijkheidsverdeling onder Twm
 BZK licht toe dat de notitie met J&V en VWS is opgesteld, aangezien op de agenda BZK als penvoerder is genoemd. De winstwaarschuwing wordt afgegeven dat de verantwoordelijkheidsverdeling weer kan wijzigen met wijzigingen van de wet.

De NCTV geeft aan dat vanaf beide kanten wordt gelobbyd voor meer of minder bevoegdheden. Voor het debat worden de voor- en nadelen van beide scenario's uitgewerkt.

In reactie geeft VWS aan te twijfelen aan de noodzaak van het dieper uitwerken van verschillende scenario's. Hier wordt door VWS op terug gekomen (actiepunt).

6. Parlementair (mondelinge toelichting NCTV)
 Buiten reikwijdte

3. Maatregelenpakket (mondelinge toelichting NCTV)
 Buiten reikwijdte

4. Terugkoppeling ACC-19 en MCC-19
 NCTV geeft een terugkoppeling van de MCC-19.

NP vraagt naar de tijdlijn omtrent de avondklok en de communicatie hieromtrent. NCTV geeft aan dat in de MCC-19 hier geen conclusies over zijn getrokken.

Buiten reikwijdte

The WOB documents show that almost all decisions were made in the so-called “Tower”, or the office of the Prime Minister of the Netherlands. Very frequent consultations took place here between then Prime Minister Mark Rutte, the Health minister Hugo de Jonge, the Minister of Justice and Security Ferdinand Bernhard Joseph Grapperhaus and a delegation or input from the NCTV. Decisions on measures down to the lowest level of detail were taken in “the Tower”, such as the number of people allowed to meet indoors, the face mask mandates that was contrary to the Outbreak Management Team’s (OMT)⁴³ advice, the values chosen on the corona dashboard and whether or not to allow the schools to stay open. In the various consultations, the new or upcoming measures were explained by the NCTV. The agency also prepared environmental analyses that demonstrated extensive citizen surveillance.

The NCTV operational tasks included monitoring resistance to the government narratives and censorship of what the government deemed ‘disinformation’. ‘Disinformation’ must be interpreted here as information that conflicts with information provided by the government. The definitions of objectively testable truth do not apply here. Therefore, the information

⁴³ The OMT is coordinated by the National Institute for Public Health and the Environment (RIVM).

censored by NCTV was not censored because it was false or inaccurate. It was censored solely because it conflicted with the government-prescribed narratives.

The NCTV also commissioned the Land Information Manoeuvre Center (LIMC), a military unit founded in 2019 that specializes in surveilling citizens' online behavior on the Internet. The military had been trained in the Behavioral Dynamics Methodology (BDM) in Latvia since 2016. This methodology is also called PSYOPS2; a method of online psychological warfare that weakens an enemy without the use of deadly weapons. The training was provided at the time by the [SCL-Group](#), the parent company of the controversial company [Cambridge Analytica](#).

Voorbereidingen Oprichting 109OSINT (LIMC)

2017				
	3	BDM opleiding 1		
	a		BDI Methodology Overview SCL GROUP	openbaar

21-6-2018		feedback 1CMI Command Course
5-7-2018		PVA onderzoek BDM behoud in context
11-12-2018		presentatie leiderschap Generaal de Rijke

15-2-2019		ATB BDM opleiding 2019
14-2-2019		Offer 1CMICO 6 week Course
1-5-2019		presentatie BDM opleiding
1-5-2019		Betaling Emic

	Casestudy Litouwen	
		Project Asterix; perception of the Lithuanian public EFP

	EMIC cursus materiaal	The Behavioural Dynamics Methodology for strategic communication practitioners
--	-----------------------	--

BDM trainingen in 2017 gestart
BDM Plan van Aanpak
BDM training 2019

2. Minister Bijleveld heeft de Tweede Kamer laten weten dat dit ten behoeve van de coronacrisis was

Citaat uit haar brief van 7 mei 2021: "Voordat ik daar nader op reageer, ga ik eerst kort in op het belang om verantwoord te experimenteren met informatiegestuurd optreden en op de achtergrond waartegen de experimenteersomgeving LIMC werd opgericht, namelijk de COVID-19 crisis."

onafhankelijke, interne toezichthouder van Defensie op het gebied van gegevensbescherming.⁸ Ik onderschrijf de conclusies uit het rapport en neem de aanbevelingen over. Voordat ik daar nader op reageer, ga ik eerst kort in op het belang om verantwoord te experimenteren met informatiegestuurd optreden en op de achtergrond waartegen de experimenteersomgeving LIMC werd opgericht: **namelijk de COVID-19 crisis**.

Bron: https://www.tweedekamer.nl/kamerstukken/brieven_regering/detail?id=2021Z07581&did=2021D16726 (p. 2)

Created: 17-11-2022 | Bron: <https://wobcovid19.rijksoverheid.nl/> | Twitter: @ceescees72

During the “pandemic” period there was close cooperation between the LIMC and the NCTV. This was evident, among other things, from the mutual secondment of LIMC soldiers to the NCTV. The LIMC sub-unit 109-OSINT, which stands for Open Source Intelligence, prepared weekly reports called “Disinformation Weekly”.

Like NCTV, the Land Information Manoeuvre Centre of the Royal Netherlands Army monitored citizens and organizations without any legal basis. The independent Brouwer committee ruled in 2023 that the armed forces had deployed themselves on domestic soil. What is less well known is that the NCTV acted as the commissioning party for that LIMC and sat at the table for months during discussions about the deployment of military

intelligence capacity. A formal request for this was never ultimately submitted—but the discussions certainly took place.

NCTV opdrachtgever LIMC

31

31 maart 2020	DIZ v23-11-20	Bespreking bij NCTV met LIMC, NCTV, NP, CHU en DIZ
31 maart 2020	CLAS v23-11-20	Uitnodiging bij NCTV om te komen praten over invulling behoefted desinformatie. Hierbij was DGB en DIZ aanwezig

From: BS/AL/HDB/Belmdwrs* @mindef.nl
Date: Tuesday, 17 March 2020 at 14:16:06
To: BS/AL/DJZ/Clust. INT* @mindef.nl
Subject: Advies - verzoek onderzoek JISTARC desinformatie

Beste ,

Ik hoop dat alles goed met je gaat in deze bijzondere tijden.

Ik heb gisteren het verplichtte thuiswerken onderbroken voor een interdepartementale werkgroep desinformatie. Aanleiding waren de signalen van desinformatie rondom corona.

Tijdens het overleg bleek dat de signalering en duiding van desinformatie nog niet op orde is. En marge van de vergadering vroeg de NCTV of Defensie hier een rol in zou kunnen spelen men dacht bijvoorbeeld aan de nieuwe campagne van JISTARC aangezien zij OSINT-capaciteit hebben.

(De NCTV weet dit gezien hun dossierhouder desinformatie vanuit Defensie gedetacheerd is, nml.)

Ikzelf sta niet onwillend tegenover dit verzoek, zeker omdat er nog veel te winnen is op signalering/duiding van desinfo bij deze casus, en daar interdepartementaal nu weinig capaciteit voor is.

Via via heb ik begrepen dat van JISTARC in het kader van oefenen en gereedstelling zo'n verzoek wel ziet zitten.

Voor we echter beslissen of we tot zo'n verzoek overgaan, wil ik echter weten of dit mag.

Het verzoek en de werkzaamheden die er uit voort zouden komen, moeten rechtmatig zijn. Gezien de gevoeligheden rondom het mandaat van JISTARC, wil ik voorkomen dat zij door een verzoek als dit hun juridisch boekje te buiten gaan (om het zo te stellen).

Kortom, kan jij mij hier in adviseren?

Het zou gaan om een verzoek om open source onderzoek (monitoring en duiding) naar Nederlandse berichtgeving, in het bijzonder desinformatie, rondom Corona in een afgebakende periode. Het gaat daarbij alleen om OSINT-onderzoek, en geen heimelijke activiteiten.

Doel is een beter beeld te krijgen van de kwantiteit en effecten van desinformatie en dit interdepartementaal te kunnen delen.

We kunnen hier ook altijd even over bellen als dat makkelijker is, ik ben bereikbaar op:

Hartelijke groet,

Van: BS/AL/DJZ/Clust. INT* @mindef.nl
Datum: woensdag 18 maart 2020 om 10:32:00
Aan: BS/AL/HDB/Belmdwrs* < @mindef.nl>, BS/AL/DJZ/CI.
NTRH* @mindef.nl
Cc: BS/AL/DJZ/Clust. INT* @mindef.nl
Onderwerp: RE: Advies - verzoek onderzoek JISTARC desinformatie

Beste ,

Dit klinkt een beetje als een u-bocht: de NCTV heeft belangstelling maar laat jou het verzoek doen om vervolgens wel van jou de opbrengst te krijgen. Wellicht chargeer ik het een beetje, maar helaas zien we wel vaker varianten hierop. Ik begrijp dat het alleen om de berichten gaat en niet om de

[Pagina nummer]

"daders", maar (a) er ontbreekt nog steeds een grondslag – dit is geen taak van Defensie, maar van de NCTV; (b) het duiden van informatie als zijnde desinformatie vereist nog steeds meer dan alleen rondkijken op internet en daarvoor zijn de Diensten echt aan zet; (c) rondkijken op social media en het verzamelen van berichten daaruit zonder tot personen herleidbare gegevens is best een uitdaging en ik heb grote twijfels of dat op de juiste wijze zal worden uitgevoerd zonder verdere toezichtmechanismen – en die ontbreken voor JISTARC.

Kortom, ik vraag me in gemoede af waarom dit een rol of taak voor Defensie zou zijn en ik zie geen (wettelijke) grondslag om dit op eigen initiatief (al dan niet daartoe aangezet door de NCTV) te gaan uitvoeren.

Met vriendelijke groet,

The WOB documents also show that through an operation order, the LIMC had to prepare some X300 drones equipped with infrared cameras jointly with Geographic Information System (GIS) specialists. That would, in their own words, enable this unit to better enforce lockdown and curfews through drone images.

11

OOCL
Commandant OOCL

AANVULLINGEN COVID-19



CLAS2020004625 / 1-4-2020

HQ OOCL
APELDOORN
301812B MRT20
Referentienummer:
2020004625

FRAGO 007 B11 OPERATIEBEVEL NUMMER 2020-025 (AANVULLINGEN COVID-19) VAN COMMANDANT OPERATIONEEL ONDERSTEUNINGSCOMMANDO LAND (OOCL)

Refertes:
FRAGO NO. 006 bij OPERATIEBEVEL NO. 2020-710 (COVID-19), referentie CLAS2020004530

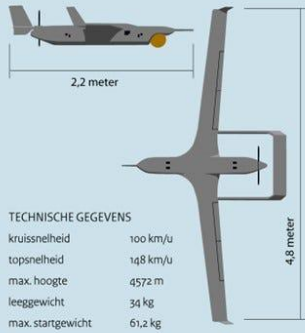
(5) JISTARC

- (a) Stel gereed een detachement Integrator X-300 (personeel en materieel) tbv *aerial surveillance* / militaire bijstand taken;
- (b) Stel het detachement NLT 061600B APR20 op een *notice to action* van 48 uur;
- (c) **Draag zorg voor mogelijkheid tot beeldontsluiting naar civiel gezag;**
- (d) **Hrm mogelijke inzet in zowel het NLD als CARIB-gedeelte van het Koninkrijk;**
- (e) **Meldt aan HQ OOCL welke ondersteuning/escalaties er eventueel nodig zijn om de operationalisatie van de X-300 te versnellen;**
- (f) **Detailspraken met het KPMU tbv kleedpakketten tbv (mogelijke) inzet in de CARIB volgen na OPG DOPS/CLAS en indien van toepassing;**
- (g) DIRLAUTH met het Marine Hoofdkwartier CARIB (MHKC) na toestemming OPCEN HQ OOCL, indien er een opdracht komt tbv inzet in de CARIB.

(6) LIMC

Neem 1x analist van het KCT onder bevel tot 1 juni 2020 of langer indien noodzakelijk.

INTEGRATOR



TECHNISCHE GEGEVENS

kruissnelheid	100 km/u
topsnelheid	148 km/u
max. hoogte	4572 m
leeggewicht	34 kg
max. startgewicht	61,2 kg



Launcher
op trailer gemonteerd,
pneumatisch geactiveerd



ICOMC2
command &
control



Skyhook
geen netten, startbaan
onafhankelijk recovery systeem

De X-300 Integrator is een onbemand verkenningssysteem (unmanned aerial system, UAS). Het bijbehorende vliegtuigje is herkenbaar aan zijn dubbele staart (twinboom).

NCTV integrated activities with the Public Prosecution Service, the National Police, and Defense. The LIMC reported directly to the Police when a, for example a public protest or a demonstration was expected and made an estimate of its size. Organizations such as Virus Truth and Farmers Defense Force were surveilled in a targeted manner. Police and Public Prosecution Service officials visited the LIMC every week, combining the LIMC's observation activities with the investigative powers of the Public Prosecution Service and the police. Data went from NCTV to LIMC, which indicates targeted surveillance. People who spoke out on social media expressing their free opinions that contradicted the government narrative got police sent to their doors.

Politie komt iedere donderdag naar LIMC.

25

Van: [redacted] CLAS/OOCL/JISTARC/DIV/IGP D

Verzonden: donderdag 17 september 2020 14:08

Aan: [redacted] CLAS/OOCL/VUSTCO/41AFD/C-GEVBT/E-PEL;
[redacted] CLAS/OOCL/JISTARC/STSTESK/ST/SIE S3/BUR OPN;
MA, CLAS/OOCL/JISTARC/106INLNCIE/A-ASIC;
[redacted] CLAS/OOCL/JISTARC/106INLNCIE/A-ASIC;
[redacted] CLAS/OOCL/JISTARC/106INLNCIE/A-ASIC;
[redacted] CLAS/OOCL/JISTARC/109OSINT/REGIOGP

CC: [redacted] CLAS/OOCL/HQ/LIMC;
[redacted] CLAS/OOCL/JISTARC/STSTESK/ST/KCEN;
[redacted] CLAS/OOCL/JISTARC/DIV/BUR ACK

Onderwerp: afspraken/highlights politie ind actiepunten

FYI en actie:

Vandaag politiemedewerkers [redacted] en [redacted] gsm)
ontvangen in verband met aanvang werkzaamheden LIMC.

Afspraken/highlights

- [redacted] bekijkt de samenwerking beleidsmatig (juridisch, onder welke voorwaarden informatiedeling mogelijk etc.) en zal geregeld op het LIMC aanwezig zijn om de samenwerking te verkennen;
- [redacted] is een OSINT-analist van de politie; hij heeft de bevoegdheid om beroepsmatig op sociale media actief te zijn; hij zal voortaan iedere donderdag aanwezig zijn op het LIMC en bij 109 OSINT om inhoudelijk de samenwerking op OSINT-gebied in beweging te krijgen;
- Afgesproken is dat [redacted] deze week binnen het Virus narratief (pseudogestanschaanlijke discussie; weerstand tegen COVID-19 maatregelen) de situatie op sociale media monitort; daarbij kijkt hij vooral naar oproepen in de virtuele dimensie op activiteiten uit te gaan voeren in de fysieke dimensie (lees demonstraties, blokkades, petities) etc. Zijn bevindingen presenteert hij volgende week donderdag 24 september tijdens de sync meeting desinfo hier op het LIMC; deze resultaten zijn dan aanleiding voor het afspreken van verdere activiteiten;
- Desinfo team vast nadenken over vervolgacties voor [redacted];
- Vanuit 109 zal [redacted] functioneren als POC naar [redacted] en [redacted] graag de inhoudelijke POC's vanuit het desinfo team naar [redacted]; ik zal zelf de lijntjes met [redacted] kort houden en terugkoppeling verzorgen naar C- en CS-LIMC;
- Aan de (wnd) LIMC [redacted] en [redacted] het verzoek om toegang tot kazern en LIMC te faciliteren voor aanstaande donderdag 24 september;
- Vooralsnog dus op de donderdagen presentie van de politie in het LIMC; het is mogelijk/waarschijnlijk dat dit op termijn wordt uitgebreid naar twee dagen inclusief een extra OSINT-midw.

Tot zover.

LIMC produceert Weekly desinformatie.

Politie met opsporingsbevoegdheid komt naar LIMC.

Wordt hier gericht naar personen gezocht?

OSINT:

- Defensie ondervindt dezelfde problemen met het juridisch kader omtrent persoonsgegevens als de politie, maar politie heeft meer ruimte voor openbare orde en strafvordering;
- De vraag bestaat of het mogelijk is om gegevens van politie uit te wisselen met defensie om zo alsnog analyses te kunnen doen;
- Het is onduidelijk wat de grens is tussen openbare orde en strafvordering;
- In het geval de politie haar producten mag delen met defensie, hoe kan dit worden bewerkstelligd?
- Tot op heden nog geen aanbod / verzoek vanuit politie voor bijstand o.g.v. politiewet.

Immediately after the establishment of the LIMC, questions were raised about the legal basis for its activities surveilling personal data of citizens. As revealed by the WOB documents, a political struggle took place for more than six months, while the unlawful surveillance activities continued. The dilemma that the ministers faced was that Minister of Defense Anna Theodora Bernardina Bijleveld-Schouten (Bijleveld) acted contrary to the law and that Minister Grapperhaus did not want to sign off on MSOB (Military Support in Public Interest). MSOB is a legal framework that allows the Dutch Armed Forces to assist civilian authorities when doing so serves the public interest and civilian capabilities are insufficient or unavailable. The legal basis for MSOB is found primarily in the Armed Forces Support Act and the Police Act 2012, together with implementing regulations issued by the Ministry of Defense. These laws authorize the armed forces to support civilian authorities under specified conditions while maintaining civilian command over the mission. Therefore, the NCTV acted outside the law, as there was no MSOB authorization issued for the involvement of the Dutch military forces in Covid-19 activities.

Niemand durft verantwoordelijkheid te dragen voor onwettige activiteiten

12

Het LIMC

- Het LIMC is een mooi initiatief, dat innovatie, gereedstelling (van analisten) en inzet (het levert producten op waar bij civiele partners behoefte aan is) combineert.
- Er zijn drie sporen bekeken voor een juridisch grondslag voor werk en producten van LIMC: WIV / politiewet / NCTV. Er is uiteindelijk gekozen voor het laatste spoor, o.a. omdat zo informatie het makkelijkst gedeeld zou kunnen worden.
- Wat nodig is vanuit het NCTV zijn twee dingen: een MSOB & een verwerkersovereenkomst (DEF geen eigen mandaat, maar treedt dan op namens NCTV). Deze zijn beide in gang gezet, (bijna) afgerond, maar nooit ingediend. Daarmee is de juridische basis, volgens DJZ, niet geregeld.
- Waar zit het nu op vast?
 - o DGB: er is niet voldaan aan de juridische voorwaarden die DJZ stelt (MSOB & verwerkersovereenkomst).
 - o CLAS/LIMC: Er is terughoudendheid aan de zijde van de DGB, daarom wordt MSOB niet ingediend. MIN J&V gaat MINDEF niet om steun vragen als hij niet weet dat het antwoord "ja" gaat zijn. (CLAS-er bij NCTV bevestigd dit)
- Dus, het lijkt er op dat de juridische basis niet ingevuld wordt, omdat de DGB geen voorstander is van LIMC.
- Om het nog wat ingewikkelder te maken: CLAS (inclusief CLAS-juristen) is er van overtuigd dat MSOB / verwerkersovereenkomst niet nodig zijn voor de huidige situatie, maar pas als LIMC verder de diepte in wil.

After [two articles](#) about the LIMC appeared in press, a parliamentary debate followed, with the result that the LIMC's activities were stopped in November 2020. Minister Bijleveld invoked the fact that she was not aware of the activities until November 2020. However, the WOB documents show that Van Bijleveld was already aware of this situation in March 2020.

24/8/2020: Persoonlijke brief van Bijleveld waarin ze door de Luitenant-Generaal Wijnen op de hoogte wordt gesteld van LIMC activiteiten

Koninklijke Landmacht

Minister d.v.z. CDS

I.a.b.
DGB
DIZ

nota

Doorontwikkeling Commando Landstrijdkrachten in het Informatie Domein

Excellente, *best be!*

Ik heb u eerder mondeling geïnformeerd over de ontwikkelingen qua informatie-gestuurd optreden (IGO) binnen het Commando Landstrijdkrachten en toezegde u hieromtrent nadere schriftelijk te informeren. Die toezegging doe ik bij dezen gestand.

Kern

Het is duidelijk dat belang van de informatieomgeving alomte zoneremt. Versterkingen op het gebied van informatie-gestuurde optreden (IGO) dragen bij aan een Koninklijke Landmacht die toekomstbestendig is en blijft, zodat we ook in komende internationale crises en conflicten op de taak berekend en succesvol zijn. De informatieomgeving is groot. Is niet voorbehouden aan een domein of organisatie, en bestaat conceptueel uit drie dimensies: de fysieke, virtuele en cognitieve dimensie. Optreden in het landschap betekent het coördineren binnen deze drie dimensies om de generatie effecten te bereiken binnen een politiek-strategische doelstelling. Om het concreet te maken: effecten in het fysieke domein gaan bijvoorbeeld over afschieten of intensiveren met wapensystemen, in het virtuele domein bijvoorbeeld over Cyber and Electromagnetic Activities (CEMA) en in het cognitieve domein het beïnvloeden van de drijveren van groepen. Omdat het landstreken zijn per definitie tussen menselijke actoren en groepen afwezig, is effectiviteit in de cognitieve dimensie cruciaal. Op zich is dit niets nieuws. Manoeuvre-oorlogvoering (Manoeuvre Approach) is bij de landmacht doctrineel ingebed. Kern is het ontwerpen van de wil te weten bij het opspelen van onze wil aan tegenstanders. Overigens volgt we hiermee de NAVO-doctrine voor het landmijn.

Koninklijke Landmacht

Ministerie van Defensie
Commando Landstrijdkrachten

Medische Kwaliteit
Informatie

Externe Relaties
Nieuwste 1
MPC USA
Postbus 10004
3000 AA Utrecht
www.landm.nl

Contactgegevens
Telefoon
E-mail

Datum
4 augustus 2020

De referentie
CLAS26704210000

Bij beschrijving, afmeten, naar referentie en uitvoering
verwijzen.

wikkelen. Deels gaat om het vastleggen van succesvolle experimenten. Ik stel vast dat kortdurend moderniseren en innoveren zich inmiddels bewezen hebben; op dat pad zullen we onverminderd doorgaan. Ik ga er hieruit vanuit dat de randvoorwaardelijke programma's GfT en Future/77th succesvol worden uitgevoerd.

De belangrijke activiteiten die ik binnen de Landmacht ben gestart of op korte termijn wil uitvoeren, zijn:

- De oprichting van een Wapen van Informatie Manoeuvre met daarin de korpsen Inlichtingen & Veiligheid en Communicatie & Engagement.
- De ontwikkeling van een Land Information Manoeuvre Centre (LIMC) waarin data science, gedragswetenschap en analyse capaciteit worden gebundeld om tot een betere situational awareness and situational understanding (SASU) te komen. Verbetering van de digitale weerbaarheid binnen de landmacht (mede in verband met Federated Mission Network (FMN) issues), alsmede de oprichting van een tactische cyber nucleus, primair voor defensieve cyber taken ter ondersteuning van gevechtsoptredes op tactisch niveau. Dit sluit aan bij de Defensie Cyber Strategie en reduceert kwetsbaarheid, maar is eerder ben gewezen.
- Het formen van een volwaardige Robotics en Autonomie Systemen (RAS) eenheid die met data science en artificiële intelligentie (AI) een force multiplier moet worden. Hiermee geef ik invulling aan de vorming van arbeidsintensieve capaciteiten.

Deze operationele capaciteiten vloeien niet alleen logischgewoont uit hetgeen we met de Defensie 2018 in gang hebben gezet, daarvoor spreek ik ook regelmatig met CDS en DGB. Hoewel is dat beleidsmatig, juridische en moreel-ethische kaders leidend zijn in de verdere ontwikkeling en die horen hierin strikt gevoeld. Daartoe heb ik DGB en DIZ gevraagd te ondersteunen.

Nadat ik de achtergrond verder heb beschreven, licht ik bevestigende activiteiten toe.

Achtergrond

Hoewel de essentie van oorlogvoering niet is veranderd, is de omgeving waarbinnen de krijgsmacht optreedt de afgelopen jaren complexer geworden. Er is niet altijd een scherpere scheiding tussen een virtuele, internet en cyber wereld en statelijk en niet-staatelijk actoren (hybrid warfare). We doen ons werk onder het oog van de hele wereld waarbij door de informatiebeschikbaarheid en -aanbod het geheimhouding niet langer is gegarandeerd. Door de nieuwe heen is er sprake van convergerende belangen tussen actoren, statelijk en niet statelijk. Deze realiteit uit zich op verschillende manieren en hevigheid. Machtinstrumenten worden ingezet om belangen te verdedigen of te kozen van anderen tegen belangen te steunen. In een dergelijke staat van (permanente) competitie wordt de rol van informatie steeds belangrijker. Informatie is niet alleen essentieel voor versterking en effectieve besluitvorming, maar wordt ook een middel waarbij de kracht en geloofwaardigheid van het narratief dijnlijk de doorslag geeft.

Koninklijke Landmacht

Ministerie van Defensie
Commando Landstrijdkrachten

Datum
4 augustus 2020

De referentie
CLAS26704210000

Tot slot

De ontwikkelingen binnen de informatieomgeving gaan snel en bieden vele mogelijkheden. Helaas bestaat er ook een keerzijde. Een keerzijde die kwaadwillenden kunnen uitbuiten en een bedreiging vormt voor Nederland en onze democratische rechtsorde. Een relevante krijgsmacht moet zich hierop voorbereiden en doorontwikkelen. Voor de landmacht zal ik met de oprichting van het Wapen van de Informatie Manoeuvre, met de vorming van een Land Information Manoeuvre Center, met verhoging van de digitale weerbaarheid en de oprichting van een RAS-eenheid concrete stappen in de fysieke, virtuele en cognitieve dimensie van de informatieomgeving. Ik zie dit als een eerste tranche van versterking van het IGO in het landschap, mede voortvloeiend uit de Defensie 2018.

Ondersteun met de volop door met andere IGO-experimenten en innovaties in lijn met het gedachtegoed van de Defensie 2018. Zodra die experimenten succesvol zijn, zal ik in overleg met CDS en DGB en uitdarm met naachtrijking van de financiële kaders - met voorstellen komen de landmacht ter zake versterken

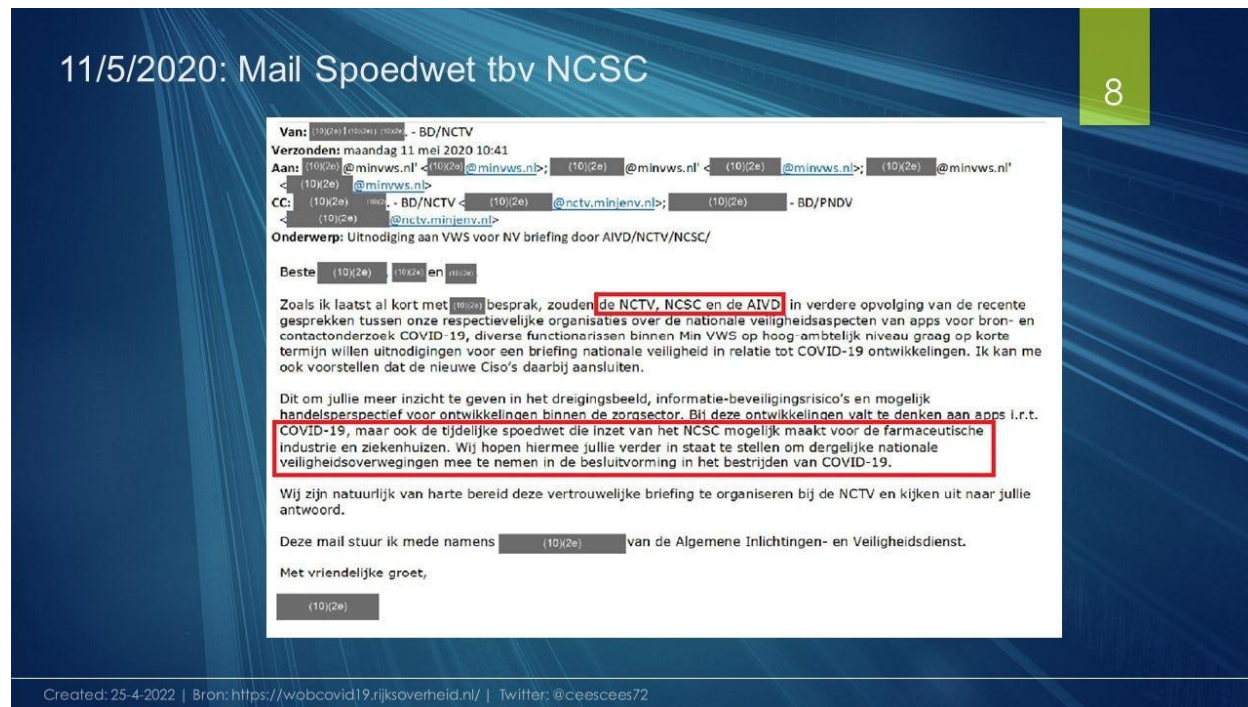
Wijnen *je hieue voldonde ginfarmen te hebben.*

DE COMMANDANT LANDSTRIJKKRACHTEN

M.H. Wijnen
Luitenant-generaal

Page 2 van 5

Another unit that falls under the NCTV is the National Cyber Security Center ([NCSC](#)). NCTV and NCSC demanded all public and private healthcare institutions to join the NCSC's National Detection Network (NDN), by placing a network sensor within the healthcare institution's own computer network. This network sensor sends out data from inside the corporate network, also processing user and personal data. There was no legal basis for this processing.



Initially, this requirement was issued for the hospital networks that already had their own cyber security solutions, it would later also concern all laboratories and pharmaceutical companies. In a draft version of the legislative amendment, it was formulated in such a broad manner that parking garages, container terminals and even political parties also had to join the NDN.

NCSC kan ook de netwerken monitoren van Politieke Partijen 14

2.1.1 Aanleiding en probleembeschrijving

Artikel 3, eerste lid, Wbni regelt, zoals vermeld in de inleiding, als primaire taak van het NCSC het verlenen van bijstand aan vitale aanbieders en aanbieders die onderdeel zijn van de rijksoverheid bij het treffen van maatregelen om de continuïteit van hun diensten te waarborgen of te herstellen, en het daartoe verrichten van analyses en technisch onderzoek. Het NCSC kan bij die analyses en dat technisch onderzoek ook dreigings- en incidentinformatie (waaronder persoonsgegevens) met betrekking tot netwerk- en informatiesystemen van andere aanbieders, die geen vitale aanbieder zijn en evenmin deel uitmaken van de rijksoverheid, verkrijgen. Dit kan bijvoorbeeld een veiligheidsregio, politieke partij of beheerder van parkeervoorzieningen betreffen. Andere voorbeelden hiervan zijn een distributeur van voedselwaren, containeroverslagbedrijf en ICT-leverancier, zoals in de inleiding benoemd. In dit kader wordt doorgaans gesproken van "restdata" of "bijvangst". Artikel 3, tweede lid, Wbni regelt dat het NCSC deze informatie, met inbegrip van persoonsgegevens, kan verstrekken aan verschillende zogeheten schakelorganisaties. Hieronder vallen onder meer bij ministeriële regeling aangewezen computercrisisteams en OKTT's, die de hiervoor bedoelde andere aanbieders als doelgroep hebben en hen over de voor hen relevante dreigingen of incidenten kunnen informeren en adviseren. Een voorbeeld van een computercrisisteam is de stichting Z-CERT, het *computer emergency response team* voor aanbieders in de zorgsector. Een voorbeeld van een OKTT is Cyberweerbaarheidscentrum Brainport, waarover meer in paragraaf 2.2.1.

Als "bijvangst" kan data van politieke partijen, containerbedrijven, ICT-leveranciers en parkeervoorzieningen aan "schakelorganisaties" worden doorgegeven.

Created: 25-4-2022 | Bron: <https://wobcovid19.rijksoverheid.nl/> | Twitter: @ceesces72

When several pharmaceutical companies declined this intrusive government surveillance, an official suggested that installing the NCSC network sensor be part of the vaccine negotiations. The idea was probably that this form of financial enticement would convince these companies to have a surveillance device placed within their corporate networks.

12/8/2020: Farmaceuten bedanken voor de eer om een NCSC sensor binnen hun bedrijfsnetwerk te laten plaatsen. Onderdeel maken van de onderhandelingen?

Van: (10)(2e) (10)(2e) (10)(2e) (10)(2e) @minvws.nl
Verzonden: woensdag 12 augustus 2020 15:45
Aan: (10)(2e) (10)(2e) @minvws.nl
CC: (10)(2e) (10)(2e) @minvws.nl (10)(2e) (10)(2e) @minvws.nl
Onderwerp: Hulp NCSC onderdeel onderhandelingen

Beste (10)(2e)

Met wie kan DI bespreken hoe we hulp van NCSC onderdeel maken van de lopende onderhandelingen met farmaceuten?

Het idee is dat met deze insteek dit aanbod van het NCSC makkelijker verteerbaar wordt voor farmaceuten die deze hulp tot nog toe afwijzen.

In het kader van de spoedwet Wbni heeft NCSC haar diensten aangeboden aan (o.m.) 3 farmaceuten. 2 van deze farmaceuten hebben vriendelijk bedankt voor de eer wat vreemd lijkt, daar de andere (vergelijkbare) farmaceut de geboden hulp zeer waardeert.

De zorg van de overige collega's (10)(2e) die betrokken zijn bij de uitvoer van de spoedwet Wbni, waarmee op korte termijn geregeld kan worden dat bij COVID-19-bestrijding betrokken bedrijven en overheden digitaal weerbaarder worden, is dat de digitale weerbaarheid beter kan en dat wij (de overheid) niet het maximale hebben gedaan om dit te bewerkstelligen.

Graag je reactie.

Met vriendelijke groet,

(10)(2e)
Directie Informatiebeleid | CIO
Ministerie van Volksgezondheid, Welzijn en Sport

3

Bron:
<https://wobcovid19.rijksoverheid.nl/publicaties/cda30094ed3df3a4754ba54ffe4a9815/documenten-fv-venm-aug-2020-deelii.pdf>

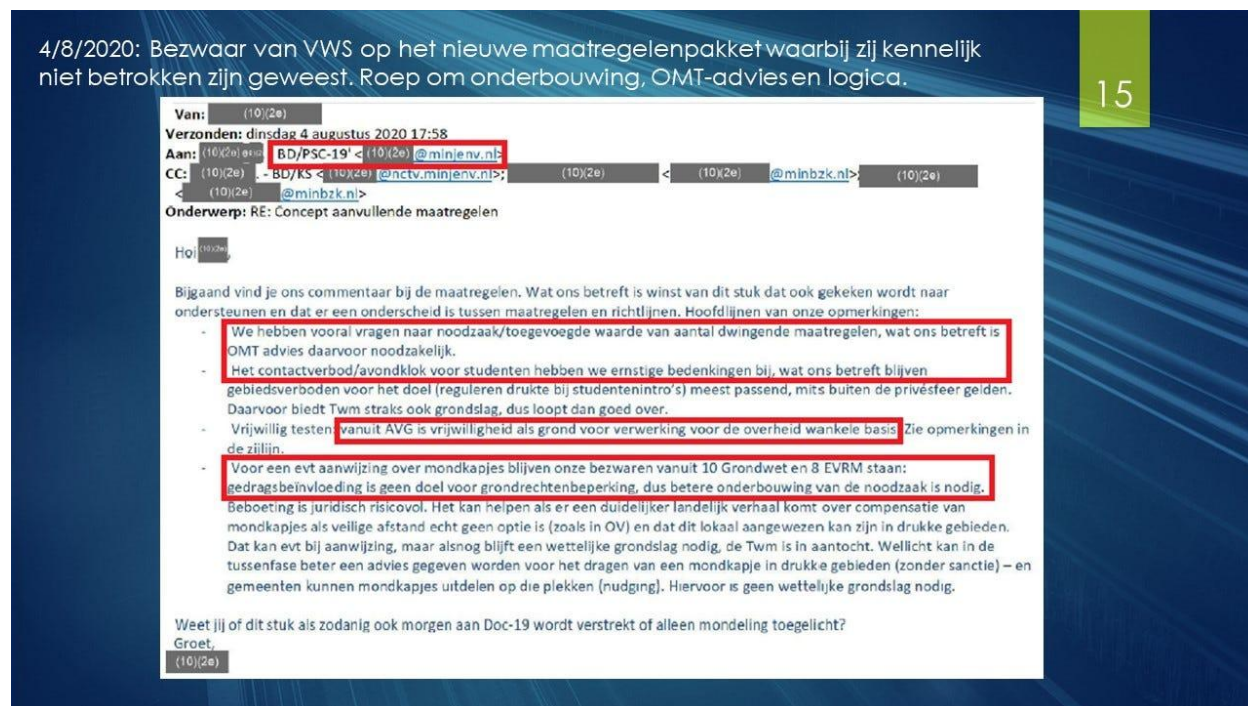
Pagina: 2070

Created: 25-4-2022 | Bron: <https://wobcovid19.rijksoverheid.nl/> | Twitter: @ceesces72

Internal government correspondence shows that all covid measures had been discussed at a much earlier stage than they were publicized. The enforcement issue always played a leading role in this. It turned out that in March 2020 there were already frequent consultations about the legal basis for measures such as face masks and the curfew.

[illegible]

The staff of the Ministry of Health (VWS) objected to the above email. They were not involved in the development of the package of covid measures and there was a need for substantiation and logic. The outrage of VWS is evident from the response below to the previous email. This is the evidence that “covid” was not a public health emergency, as advertised to the public. The officials of the Health Ministry were kept in the dark and sidelined from the decision making about the alleged “health” measures.



The secretive crisis organization surrounding the pandemic was not only authoritarian, but also totalitarian. An email dated August 11 shows that both the Public Prosecution Service and the Judiciary were involved in the handling of the impending “covid” measures.

20

11/8/2020: OM en Rechtspraak betrokken bij voorgenomen verplichte maatregelen.

Van: [redacted] - BD/PSC-19
Verzonden: dinsdag 11 augustus 2020 12:18
Aan: [redacted] <[redacted]>, @minvws.nl <[redacted]>, @minvws.nl <[redacted]>
[redacted] <[redacted]>, @minvws.nl <[redacted]>, - BD/DRC <[redacted]>, @minienw.nl <[redacted]>
[redacted] <[redacted]>, @minienw.nl <[redacted]>, - BD/DWJZ/JZW
[redacted] <[redacted]>, @minienw.nl <[redacted]>, - BD/DRB <[redacted]>, @minienw.nl <[redacted]>, - BD/AL
[redacted] <[redacted]>, @minienw.nl <[redacted]>, - BD/DJOAVBOZ <[redacted]>, @minienw.nl <[redacted]>
[redacted] <[redacted]>, @om.nl <[redacted]>, @om.nl <[redacted]>, @brandweer.nl <[redacted]>
[redacted] <[redacted]>, - BD/DWJZ/SBR <[redacted]>, @minienw.nl <[redacted]>, @minienw.nl <[redacted]>
[redacted] <[redacted]>, @minienw.nl <[redacted]>, - BD/PSC-19
CC: [redacted] <[redacted]>, @minienw.nl <[redacted]>, - BD/PSC-19 <[redacted]>, @minienw.nl <[redacted]>

Onderwerp: SPOED - acties operationaliseren verplichtende maatregelen Covid-19, l.b.v. CALL 16.00u
Urgentie: Hoog

Beste allen,

In vervolg op de call van vanochtend met minister Grapperhaus en diverse telefoongesprekken en overleggen over het operationaliseren van de mogelijkheid voor (voorslag selectieve) inzet van meer verplichtende maatregelen, bijgaand:

Een intern conceptmemo waarin de mogelijkheden kort zijn beschreven:

Een lijst met een 10-tal issues die door het OM (in concept) zijn geïdentificeerd voor het uitvoeringsproces van quarantainemaatregelen en die wij hier met instemming van het OM delen.

Ten overvloede het dringende verzoek vertrouwelijk met deze gegevens om te gaan.

Proces

Om 16 uur is er een call met de minister van JenV met dezelfde deelnemers als vanmorgen (+OM) waarin voor alle issues helder moet zijn hoe deze 10 punten worden aangepakt of zullen worden aangepakt om start uitvoering mogelijk te maken met ingang van maandag 17 augustus. Zoals vanmorgen besproken bereidt iedereen dat voor zijn/haar organisatie/deeldeel en in onderlinge afstemming voor.

Graag ontvangen we zo snel mogelijk, en liefst voor 14:30 uur een eerste terugkoppeling van hoe een en ander kan worden ingeregeld en hoe de punten die geïdentificeerd zijn zullen worden geadresseerd, waar mogelijk in korte bullets die input kunnen vormen voor het gesprek met de minister en de tekst van de brief van VWS; als er belangrijke blokkades zijn kunnen die nog tijdig worden geadresseerd voor de call van 16 uur met de minister.

VWS stuurt zo snel mogelijk een eerste concepttekst rond voor de Kamerbrief die vandaag nog uit zal gaan.

The email exchanges show the dissatisfaction of the other departments with the situation. New public measures of the strictest kind were prepared without the involvement of the health ministry.

16/8/2020: De nieuwe organisatie en werkwijze tonen dat (streng) maatregelen eerst binnen de J&V organisatie worden gedeeld voordat ze naar VWS gaan.

Van: (10)(2e) <(10)(2e)> @minjenv.nl
Verzonden: zondag 16 augustus 2020 10:26
Aan: (10)(2e) <(10)(2e)> @minbzk.nl
CC: (10)(2e) <(10)(2e)> @minvws.nl; (10)(2e) <(10)(2e)> @minjenv.nl; (10)(2e) <(10)(2e)> @minjenv.nl; (10)(2e) <(10)(2e)> @minjenv.nl
Onderwerp: FW: Input maatregelen brief

Ha (10)(2e)

Ter kennisneming: ik ontvang via (10)(2e) de onderstaande reactie van PSC-19 op het radicale maatregelendocument van VR-AA dat (10)(2e) afgelopen vrijdag aan ons voorlegde. (Ierzijde: ik vind het een beetje iasig dat (10)(2e) alleen informatie lijkt te delen als hij iets van ons nodig heeft. Ik zoek nog naar een constructieve manier om dat aan te kaarten...)

Het goede nieuws is dat het punt over de Twm duidelijk is gemaakt. ☺

Groet,

Van: (10)(2e) <(10)(2e)> @minjenv.nl
Verzonden: zondag 16 augustus 2020 14:57
Aan: (10)(2e) <(10)(2e)> @minvws.nl; (10)(2e) <(10)(2e)> @minbzk.nl
CC: (10)(2e) <(10)(2e)> @minvws.nl; (10)(2e) <(10)(2e)> @minjenv.nl; (10)(2e) <(10)(2e)> @minjenv.nl
Onderwerp: RE: Input maatregelen brief

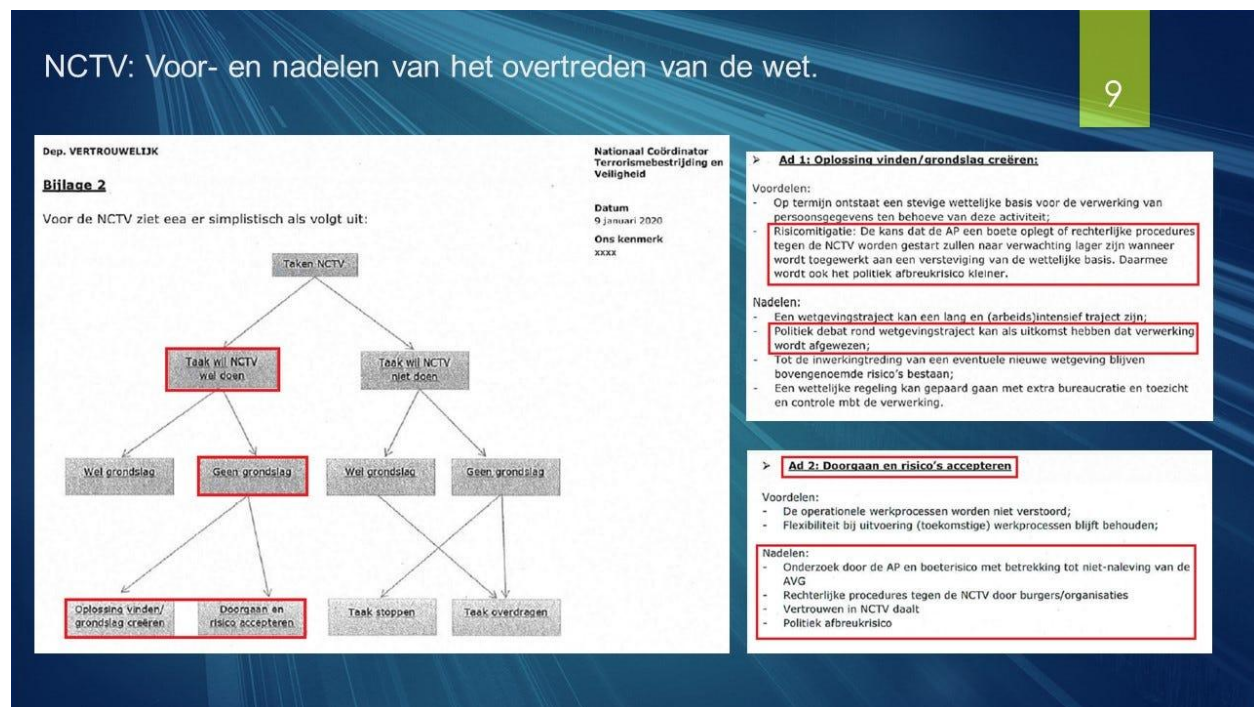
Beste (10)(2e) en (10)(2e)

Ik reageerde vrijdag jl. intern JenV kort op dit stuk. Voelde me toen niet vrij het met jullie te delen want het werd me vertrouwelijk toegezonden en er werd verzocht het niet te verspreiden en het stuk was nog prematuur begreep ik. Maar nu jullie het ook kennen mail ik bijgaand mijn korte reactie met daaronder een mailsliert.

Groet,

On 28 January 2020, the National Coordinator for Security and Counterterrorism (NCTV) chaired the first interdepartmental coordination meeting on COVID-19. On that very same day, a memo was submitted to the management team stating that part of its own tasks had no legal basis. The agency was therefore simultaneously taking the lead on a national crisis and aware that its own legal footing was shaky.

Three weeks before that first crisis meeting, on 9 January 2020, the NCTV presented itself with four options for dealing with the legal basis problem: create a legal basis, stop the task in question, transfer that task, or simply continue operating without legal basis and accept the risks. For that last option, the benefits were listed in business-like terms: undisturbed work processes, continuity. The downsides? Investigations by the Dutch Data Protection Authority, lawsuits from citizens, and political damage. NCTV drew up a decision tree for its own operations which outlined how to deal with the non-existent legal bases for their own actions. This is evidence of NCTV knowingly operating outside the law under Ministry of Justice within a democratic constitutional state.



While the initial lockdown had its legal basis in emergency regulations, the Netherlands has legal restrictions on the declaration of a state of emergency. The state of emergency declaration requires an inevitable danger, and measurable indicators must be linked to the state of emergency, which is time-limited.

There was an expiration date on the application of emergency regulations to restrict citizens' fundamental rights. For this reason, the process was started at the end of March 2020 to create a legal basis for restricting fundamental rights in the longer term, so that emergency regulations no longer had to be used. The idea of the Temporary Covid-19 Measures Act (TWM), also called “Spoedwet”, was born with this.

Contrary to what many people think, namely that the TWM was an initiative of Hugo de Jonge, the idea and the first draft version of the TWM comes entirely from the NCTV within the Ministry of Justice and Security. It was already known on March 25, 2020 that an emergency law was being drawn up within Justice & Security.

25/3/2020: Overleg met minister VWS. JenV is bezig (een) speedwet mogelijk te maken.

4

VERSLAG mBT Cb 25 maart

PROCES

Crisis	Coronavirus
Datum, tijdstip en locatie	25 maart 2020, 11:30
Volgend overleg	26 maart 2020, 11:30

Aanwezigen:

- Hugo de Jonge
- Paul Blokhuis
- Martin van Rijn
- (10)(2e) (DGV)
- (10)(2e) (10)(2e) (CN)
- (10)(2e) (10)(2e) (LZ)
- (10)(2e) (DCC)
- (10)(2e) (10)(2e) (DCC)
- (10)(2e) (DCC)
- (10)(2e) (PG)
- (10)(2e) (10)(2e) (CZ)
- (10)(2e) (10)(2e) (LZ)
- (10)(2e) (10)(2e) (Dco)
- Korrie Louwes (IGJ)
- (10)(2e) (GMT)
- (10)(2e) (NCTV)
- (10)(2e) (RIVM)

IGJ

- JenV is bezig om een speedwet mogelijk te maken om rechterlijke machtigheden af te geven ihkv de Wvgr en Wzd.

Bron:
<https://wobcovid19.rijksoverheid.nl/publicaties/c4b89b0939b38dd79efd496ba963dfc4/bijlagen-bij-wob-deelbesluit-gaangaande-overleggen-vws-in-de-periode-van-maart-2020.pdf>

Pagina: 13

Created: 25-4-2022 | Bron: <https://wobcovid19.rijksoverheid.nl/> | Twitter: @ceescees72

This first version was distributed by an NCTV official on Wednesday, April 1, 2020, according to the WOB documents.

1/4/2020: NCTV verspreidt eerste concepten speedwet Covid19.

5

Van: NCC - NCTV <nctv@nctv.minjenv.nl>
Verzonden: woensdag 1 april 2020 19:25
Onderwerp: Agenda en stukken IAO 2 april 2020, 10.00 u

Geachte dame/heer,

Zie de bijlagen.

Opmerking: of de Speedwet COVID-19 JenV tijdens het IAO behandeld gaat wordt, verneemt u morgen.

Met vriendelijke groet,

Nationaal CrisisCentrum (NCC)

E: nctv@nctv.minjenv.nl
T: (10)(2e) (algemeen nummer)
T: (10)(2e) (incident nummer)
F: +31 (0)70 756 9500

Bron:
<https://wobccovid19.rijksoverheid.nl/publicaties/619308c6b71260e357854781c817f942/bijlagen-bij-wob-deebesluit-overnieg-wvs-april-2020.pdf>

Pagina: 1143

To: (10)(2e) (10)(2e) @minvws.nl; (10)(2e) @minvws.nl
From: (10)(2e)
Sent: Wed 4/1/2020 5:28:20 PM
Subject: FW: Agenda en stukken IAO 2 april 2020, 10.00 u
Received: Wed 4/1/2020 5:28:20 PM
20200402 Agenda IAO Covid-19 10.00u-132302343299616914.docx
Actielist IAO dd 02042020-132302343495118161.xlsx
02 Ambtelijk memo voor afweging vliegverboden i.v.m. uitbraakcoronavirus COVID-19-132302343645926780.DOCX
Ontmoedingsaanpak buitenlandse toerisme IAO ICCh 2 april 2020-132302343751983181.pdf
Speedwet COVID-19 JenV - wetsvoorstel 01042020 versieMR-132302352851443913.docx
Speedwet COVID-19 JenV - MvT 01042020 versieMR-132302352970821175.docx

Hi,
De stukken.
Grt: (10)(2e)

Created: 25-4-2022 | Bron: <https://wobccovid19.rijksoverheid.nl/> | Twitter: @ceescees72

Within VWS it was assumed that the legal basis would be regulated in the Public Health Act. However, when the first corona wave came to an end and people could enjoy the summer holidays, feverish work continued on the TWM in an established interdepartmental working group, with a leading role for the NCTV.

Covid Dossier – Other Countries

U.S.

Military/intelligence agencies in charge of pandemic response:

- **National Security Council (NSC)** [[ref](#)]
- **FEMA/Department of Homeland Security (DHS)** [[ref](#)]
- **Department of Defense (DOD)** [[ref](#)]

Dates when those agencies were known to be in charge:

- **Mid-January 2020:** NSC classified Covid meetings “starting mid-January” [[ref](#)]

- **March 13, 2020:** NSC officially in charge of pandemic policy in *Pandemic Crisis Action Plan-Adapted* – the U.S. government’s Covid response plan [\[ref\]](#)
- **March 18, 2020:** FEMA/DHS takes over as Lead Federal Agency, replacing HHS [\[ref\]](#)

Dates, types and names of unprecedented emergency declarations:

- **February 4, 2020** EUA declaration [\[ref\]](#)
- **February 4, 2020** [retroactive from March 17, 2020] **PREP Act declaration** [\[ref\]](#)
- **March 13, 2020** **Stafford Act in all states simultaneously** (1st time in history) [\[ref\]](#)

Military/intelligence agencies involved in public communications/propaganda/censorship:

- **Government Task Force, coordinated by NSC**, controls all pandemic messaging starting February 27, 2020 [\[ref\]](#)[\[ref\]](#)
- **Department of Homeland Security (DHS)** [\[ref\]](#)
- **Cybersecurity & Infrastructure Security Agency (CISA)** [\[ref\]](#)
- **Cyber Threat Intelligence League (CTIL)** (crossover US/UK) [\[ref\]](#)

Key figures in Covid response linked to military, IC, UN/WHO:

- Deborah Bix [\[ref\]](#)[\[ref\]](#)[\[ref\]](#)[\[ref\]](#)
- Michael Callahan[\[ref\]](#) [See also *PsyWar* by Robert Malone MD MS, Kindle version p. 237]
- Richard Danzig [\[ref\]](#)[\[ref\]](#)
- Richard Hatchett [\[ref\]](#)[\[ref\]](#)[\[ref\]](#)[\[ref\]](#)
- Matt Hepburn [\[ref\]](#)[\[ref\]](#)[\[ref\]](#)[\[ref\]](#)
- Robert Kadlec [\[ref\]](#)[\[ref\]](#)[\[ref\]](#)
- Carter Mecher [\[ref\]](#)
- Matt Pottinger [\[ref\]](#)
- Mike Ryan [\[ref\]](#)[\[ref\]](#)
- Luciana Borio [\[ref\]](#)
- Terry Adirim [\[ref\]](#)

U.K.

Military/intelligence agencies in charge of pandemic response:

- **Ministry of Defense (MOD)** “Operation Rescript” [\[ref\]](#)
- **Covid Support Force** (MOD Report - [ref](#))
- **Joint Biosecurity Centre (JBC)** [\[ref\]](#)[\[ref\]](#)[\[ref\]](#)[\[ref\]](#)

Dates those agencies were publicly known to be in charge:

- **March 18, 2020:** Covid Support Force (20,000 military personnel) [\[ref\]](#)
- **May 2020:** (at the latest) JBC [\[ref\]](#) [\[Wikipedia: “it’s existence was announced”\]](#)

Dates, types and names of unprecedented emergency declarations:

- **March 13, 2020** UK Advisory Committee on Dangerous Pathogens reached a unanimous decision that Covid-19 was not a high consequence infectious disease [\[ref\]](#)

March 18, 2020 Public Health England announced that Covid-19 was not a high consequence infectious disease [\[ref\]](#)

- **March 23, 2020 national lockdown** [\[ref\]](#)
- **March 25, 2020 Coronavirus Act 2020** [\[ref\]](#)

Military/IC-affiliated groups involved in messaging/propaganda/censorship:

- **Ministry of Defense team** [\[ref\]](#)
- **iSAGE** [\[ref\]](#)
- **77th Brigade** [\[ref\]](#)
- **Nudge Unit** [\[ref from March 11 2020\]](#) / **Behavioral Insights Team** – now “fully owned by Nesta” (National Endowment for Science, Technology and the Arts) [\[ref\]](#)
- **RAF analysts** [\[ref\]](#)
- **Cyber Threat Intelligence League (CTIL)** (crossover US/UK)[\[ref\]](#)

Key figures in Covid response linked to military, IC, UN/WHO

- Roy Anderson [\[ref\]](#)
- Dominic Cummings [\[ref\]](#)[\[ref\]](#)

- Jeremy Farrar [\[ref\]](#) [\[ref\]](#)[\[ref\]](#)
- Clare Gardiner [\[ref\]](#)
- Richard Hatchett (crossover US/UK) [\[ref\]](#)[\[ref\]](#)[\[ref\]](#)[\[ref\]](#)
- Tom Hurd [\[ref\]](#) [\[ref\]](#)
- Thomas Waite [\[ref\]](#)
- Simon Manley (UK Director-General Covid-19) [\[ref\]](#)

Australia

Military/intelligence agencies and special committees involved in response:

- **National Cabinet** “exempt from freedom of information laws”[\[ref\]](#)
- **National Security Committee of Cabinet** [\[ref\]](#)
- **Australian Defense Force COVID-19 Task Force** [\[ref\]](#)
- **National COVID-19 Commission Advisory Board (NCC)** [\[ref\]](#)

Dates those agencies/committees were publicly known to be in charge:

- **March 9, 2020:** Australian Defense Force COVID-19 Task Force [\[ref\]](#)
- **March 13, 2020:** National Cabinet established [\[ref\]](#)
- **March 25:** NCC [\[ref\]](#)

Dates, types and names of unprecedented emergency declarations:

- **March 5, 2020 National Coordination Mechanism activated** [\[ref\]](#)
- **March 13, 2020 National Partnership on COVID-19 Response** [\[ref\]](#)
- **March 18, 2020 Human Biosecurity Emergency Declaration** (first in history) [\[ref\]](#)

Key figures in Covid response linked to military, IC, UN/WHO:

- Lt Gen John Frewen [\[ref\]](#)[\[ref\]](#)
- Jane Halton [\[ref\]](#)[\[ref\]](#)[\[ref\]](#)
- Edward Holmes [\[ref\]](#)
- Major General Paul Kenny [\[ref\]](#)

Canada

Military/intelligence agencies and special committees involved in response:

- **Canadian Armed Forces (CAF) Operation LASER** 24,000-person response force [\[ref\]](#)
- **CAF Operation VECTOR** (vaccine planning and distribution)[\[ref\]](#)
- **Cabinet Committee on COVID-19** [\[ref\]](#)

Dates those agencies/committees were publicly known to be in charge:

- **January 23, 2020:** first Operation LASER planning meeting [\[ref\]](#)
- **March 2, 2020:** Operation LASER officially launched
- **March 4, 2020:** Cabinet Committee officially announced [\[ref\]](#)

Dates, types and names of unprecedented emergency declarations:

In Canada, the emergency declarations were made by the provinces, as follows [\[ref\]](#):

- **March 13, 2020 Quebec provincial public health emergency**
- **March 16, 2020 Prince Edward Island public health emergency**
- **March 17, 2020 British Columbia (BC) public health emergency**
- **March 17, 2020 Alberta provincial public health emergency**
- **March 17, 2020 Ontario provincial state of emergency**
- **March 18, 2020 BC state of emergency under Emergency Program Act**
- **March 18, 2020 Saskatchewan provincial state of emergency**
- **March 18, 2020 Yukon public health emergency**
- **March 19, 2020 Northwest Territories public health emergency**
- **March 19, 2020 Nunavut public health emergency**
- **March 20, 2020 Manitoba provincial state of emergency**
- **March 22, 2020 Nova Scotia provincial state of emergency**

Military/IC-affiliated groups involved in messaging/propaganda/censorship:

- **CAF** began to gather intelligence on pandemic disinformation in January 2020 [[ref](#)]
- **CAF** deployed psyop program on civilians [[ref](#)]
- **Canadian Joint Operations Command (CJOC)** [[ref](#)]
- **Canadian military intelligence unit - Precision Information Team (PiT)** [[ref](#)][[ref](#)]

Key figures in Covid response linked to military, IC, UN/WHO:

- Bill Blair [[ref](#)]
- Crystia Freeland [[ref](#)][[ref](#)]
- Brian Santarpia [[ref](#)]
- Teresa Tam [[ref](#)]
- Dr. Gary Kobinger [[ref](#)]

Germany

Military/intelligence agencies, committees, and groups involved in response & dates they were announced

- **February 27/28: Corona Crisis Team (Corona-Krisenstab)** [[ref](#)] led by Ministry of Health and Ministry of the Interior (equivalent of DHS + DOJ) [[ref](#)]
- **November 2021: new Crisis Team** for vaccines (led by military)[[ref](#)]
- **NATO** [[ref](#)][[ref](#)]
- **All vaccine shipments** were delivered/distributed in Germany via a single location – a NATO military base [[ref](#)]

Key figures in Covid Response linked to NATO, UN/WHO, military, IC:

- **Major General Carsten Breuer** [[ref](#)][[ref](#)]
- **General Hans-Ulrich Holtermann** [[ref](#)][[ref](#)]
- **Christian Drosten** [[ref](#)][[ref](#)]
- **Bernhard Schwartländer** [[ref](#)]

Italy

Military/intelligence agencies, committees, and groups involved in response & dates they were announced

- **CTS (Comitato Tecnico Scientifico, or Technical Scientific Committee)** established February 5, 2020 [\[ref\]](#)
- **NATO Rapid Deployable Corps Italy** – “a battle-ready NATO formation that can effectively operate in support of all NATO core tasks, including collective defence, crisis management, and cooperative security through partnerships.” [\[ref\]](#)
- The Italian **CTS (Comitato Tecnico Scientifico, or Technical Scientific Committee)** was established on February 5, 2020 “with consultancy and support competence for coordination activities to overcome the epidemiological emergency due to the spread of Coronavirus.” [\[ref\]](#)

Military/IC-affiliated groups involved in messaging/propaganda/censorship

- **Department of Information for Security (DIS):** The DIS intensified its monitoring and analysis activities related to pandemic-related threats, such as disinformation and potential espionage activities, starting in March 2020. [REF NEEDED]

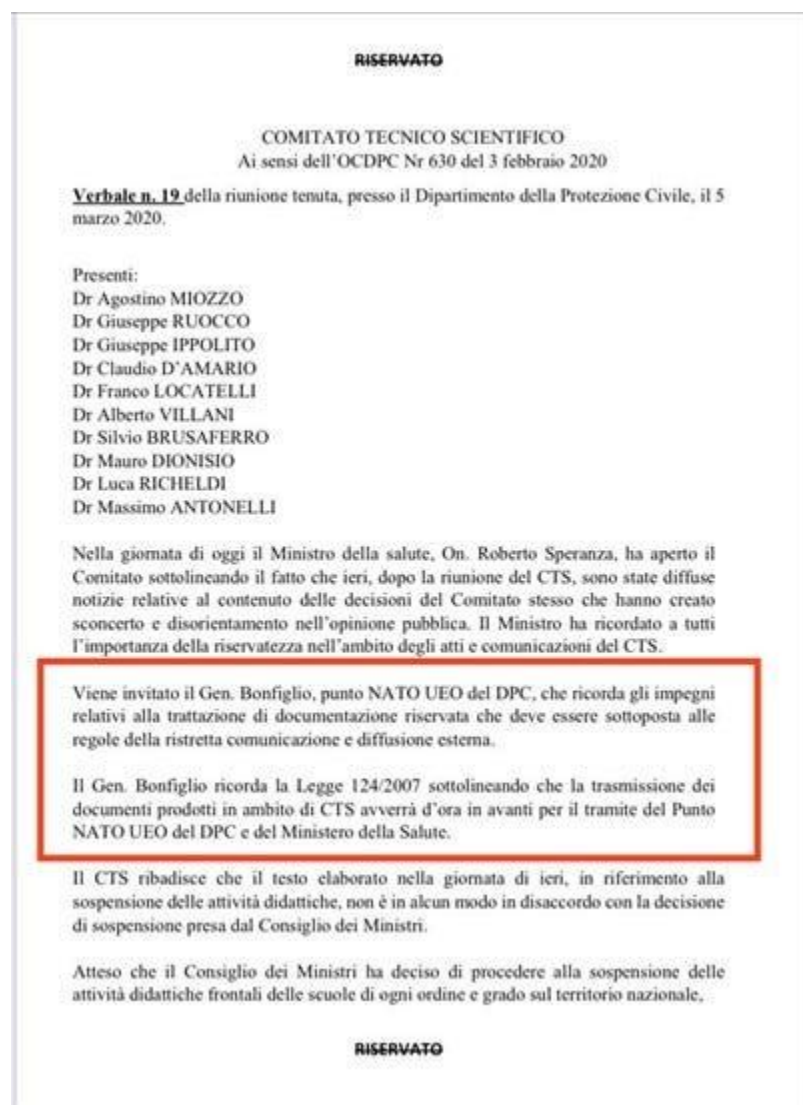
Dates, types and names of unprecedented emergency declarations

- **January 31, 2020:** Resolution of the Council of Ministers -- Declaration of a state of emergency due to the health risk associated with the emergence of diseases caused by transmissible viral agents. Duration: six months. Published in the Official Gazette No. 26 on February 1, 2020. [\[ref\]](#)
- **March 9, 2020:** National Lockdown [\[ref\]](#)

Key figures in Covid Response linked to NATO, UN/WHO, military, IC

- **General Francesco Paolo Figliuolo** [\[ref\]](#)
- **General Francesco Bonfiglio** [\[ref\]](#)
- Minutes of a CTS meeting held on March 5, 2020, obtained through FOIA [\[ref\]](#), include statements by General Bonfiglio, identified as belonging to the “NATO UEO point of the DPC.” [\[ref\]](#)

Below is a screenshot of the minutes in Italian, followed by English translation:



Gen. Bonfiglio, NATO WEU Point of the Department of Civil Defense, is invited and reminds of the commitments regarding the handling of confidential documentation that must be subject to the rules of restricted external communication and dissemination.

Gen. Bonfiglio recalls Law 124/2007 emphasizing that the transmission of documents produced in CTS (Scientific Technical Committee) will henceforth be done through the NATO WEU Point of the Department of Civil Defense and the Ministry of Health.

France

Military/intelligence agencies, committees, and groups involved in response & dates they were announced

- **Conseil de Defense (Defense Council), February 29, 2020** [\[ref\]](#)[\[ref\]](#) This is the equivalent of the U.S. National Security Council. After 2/29/20, it met once a week, at least 40 times. Meetings were classified top secret. Cell phones were prohibited. And all notes taken were stamped top secret. Some were kept in safes. The others were burned. [\[ref\]](#)

Covid Dossier: Norway

Key figures in Covid Response linked to NATO, UN/WHO, military, IC

- **Espen Rostrup Nakstad:** “In the four weeks that have passed since the strictest restrictions since World War II were introduced in Norway, Espen Rostrup Nakstad has become an important and clear spokesperson for Norwegian health authorities.” [\[ref\]](#)
- A CBRNE (chemical, biological, radiological, nuclear and explosive) expert, Nakstad served as the Norwegian Armed Forces' Senior Consultant in CBRNE Medicine and has represented Norway in the NATO Joint Health Agriculture and Food Group (JHAFG) [\[ref\]](#)

Spain, Austria, Portugal, Ireland, Slovakia, Hungary, Turkey & Switzerland

For these countries, we have some information regarding military and intelligence roles in each country's pandemic response:

- **The Spanish army** was deployed in **March and April of 2020**, and again in **September**, when the army started enforcing coronavirus lockdown restrictions in Madrid. [\[ref\]](#) By **October 2020**, the military was tasked with track-and-trace of "cases" [\[ref\]](#)
- **In Austria, Major General Rudolf Striedinger was co-leader of the national Covid crisis coordination (GECKO)** [\[ref\]](#)
- **In Portugal, a COVID-19 Vaccination Plan Task Force** was set up by the Portuguese government on November 23, 2020, by joint order (despacho) of the **Minister of National Defense, João Gomes Cravinho**, the Minister of Internal Administration, Eduardo Cabrita, and the Minister of Health, Marta Temido. [\[ref\]](#) It

was initially led by Francisco Ramos, former Secretary of State for Health, but he was replaced in February 2021 by **vice-admiral Henrique de Gouveia e Melo**, a naval officer who was already part of the task force. [\[ref\]](#)

- **In Ireland, a Joint Task Force (JTF)** was established under **Operation FORTITUDE** in March 2020 to coordinate the contribution of the Defense Forces to the whole-of-Government COVID-19 response, [\[ref\]](#) commanded by Brigadier General Kevin Campion. [\[ref\]](#)
- **In Slovakia, in October/November 2020, The Armed Forces of the Slovak Republic** was entrusted with the task of coordinating and managing operation “Joint Responsibility,” the main goal of which was to conduct nationwide testing of 5.5 million people. [\[ref\]](#)
- **In Hungary**, as reported in July 2020, Prime Minister Viktor Orban had put **Hungary’s security forces front and centre of the fight against the novel coronavirus**, with police officials chairing daily press conferences, military commanders assigned to head major hospitals and military advisers deployed in key strategic companies to ensure their smooth running. [\[ref\]](#)
- **In Turkey**, as reported in 2024, the Ministry of Health worked closely with the Ministry of Interior, which oversees the **paramilitary Gendarmerie General Command**, to coordinate the implementation of measures to battle the pandemic. Externally, the Ministry of Foreign Affairs spearheaded the use of the **Turkish military**, because of its organizational capacity, to help produce, transport, and distribute aid to foreign nations. **This deployment of hard power through the quasi-military gendarmerie and the regular army allowed President Recep Tayyip Erdoğan to demonstrate his willingness to participate in alliances...** [\[ref\]](#)
- **In Switzerland:** Switzerland is not a NATO country, but nevertheless, its military participated and coordinated the covid and mRNA vaccine-related campaign, just like we observed in most other countries of the world. The Swiss army chief, Thomas Süssli [\[ref\]](#), signed some of the purchasing agreements with the "vaccine" manufacturers. But in all actuality, those were signed by Divisionär (equivalent to Major General) **Andreas Stettbacher**, Former **Chief Medical Officer of the Swiss Armed Forces** and **Federal Delegate for the Coordination of the Medical Service**. During the COVID-19 crisis, **Andreas Stettbacher** played a key role in the **national pandemic response**, including **the procurement of COVID-19 vaccines**. He was part of the federal coordination team and worked closely with various authorities on:

- Medical logistics
- Vaccine procurement contracts
- Coordination with pharmaceutical companies (e.g., Pfizer, Moderna)
- Strategic health planning during the declared "health emergency"

He was also involved in the **Swiss COVID Taskforce** and contributed to decisions on vaccine rollout and stockpiling.

The "start date" in Switzerland was March 16, 2020

On March 16, 2020, the Federal Council declared the “extraordinary situation” according to the Epidemics Act from midnight to April 19, 2020. All shops (except groceries), markets, restaurants, bars and entertainment and leisure facilities had to remain closed and a ban was in effect for private and public events. [\[ref\]](#)

Brigadier Raynald Droz at a media conference in Berne (capital) on March 24, 2020 (only in German) [\[ref\]](#)

Chronology of the pandemic from the General Swiss Military Magazine [\[ref\]](#)

Swiss militia soldiers get historic call up to fight coronavirus [\[ref\]](#)

Swiss Army Pharmacy Implements GDP-Compliant Temperature Monitoring for COVID-19 Vaccines [\[ref\]](#)

The brigadier Raynald Droz who played an important role and the fact that the logistics of vaccine distribution in Switzerland were also handled by the army (or the army pharmacy) could be mentioned.

Note that Divisionär (2 star general) Andreas Stettbacher, former Chief Medical Officer of the Swiss Armed Forces was removed from his position following internal controversy and public scrutiny during the COVID-19 response. However, he challenged the dismissal legally and, as a result of that process, was reinstated.

 [vtg.admin.ch – Andreas Stettbacher](https://vtg.admin.ch/Andreas-Stettbacher)

This explains the conflicting information across various media sources and platforms — some reported his removal, while others still list him officially in position due to the reinstatement.

Latin America

- **In Brazil**, as reported in July, 2020: **General Eduardo Pazuello, “a military general with no experience, remains health minister.”** Furthermore, since Pazuello took over the Ministry of Health, **“at least 25 members of the military have been appointed, most with no public health experience.** Many criticize the government for pushing technical knowledge aside by appointing military personnel.” [\[ref\]](#)
- **In Chile, on March 18, 2020, a public state of exception [emergency] was declared.** as reported by the International Commission of Jurists (ICJ) in October 2020, “military forces have had a key and outsized role in Chile’s response to the COVID-19 pandemic. The state of exception allowed the President to appoint **16 “Chiefs of National Defence”** (Jefes de la Defensa Nacional), one in each region of the country. These Chiefs, who are high-ranking military officials, had extensive powers in their designated regions, including powers more appropriately held by public health experts in the context of public health emergency such as the one brought about by COVID-19.” [\[ref\]](#)
- **In Peru**, on April 1, 2020, with a reported total of 30 deaths and 1,065 infections attributed to the novel coronavirus, the military called up its reservists for the first time in the country’s history. As reported by AP “Peru had never called up reservists, not even during the internal armed conflict with the Shining Path terrorist group between 1980 and 2000 or during the cholera outbreak in 1991.” [\[ref\]](#)

Asia

- **Sri Lanka**, as reported in April 2023, **extensively used its military and intelligence agencies for pandemic control during the COVID-19 crisis.** [\[ref\]](#)
- **In the Philippines**, as reported in July 2021, **starting in March 2020 “the government adopted a militarized approach** in its fight against the COVID-19 pandemic whose **council is predominantly a group of former military officers.”** [\[ref\]](#)
- **In Indonesia**, according to one report, the government “involved the military institution in responding to the emerging outbreak.... This therefore involved the creation of **COVID-19 task force consisting mostly of military personnel.**” [\[ref\]](#)

Military/intelligence/biodefense plans & alliances

The following plans and alliances provide frameworks for responding to a bioterror/bioweapons attack. The information provided in this Dossier suggests they may have been invoked in the global Covid response.

- **U.S. Chemical, Biological, Radiological, and Nuclear Response (9/9/2016)** This publication provides joint doctrine for military domestic or international response to minimize the effects of a chemical, biological, radiological, or nuclear incident. [\[ref\]](#)
- **Medical Countermeasures Consortium** - a four-nation partnership involving the Defence and Health Departments of Australia, Canada, the United Kingdom and the United States. [\[ref\]](#)
- **Quadripartite Medical Intelligence Committee (QMIC)** the health equivalent of the Five Eyes intelligence-sharing alliance [\[ref\]](#)
- **NATO - Joint Chemical, Biological, Radiological and Nuclear Defence Centre of Excellence** [\[ref\]](#)
- **EU - Common Security and Defence Policy (CSDP)** [\[ref\]](#)
- **NATO's doctrine for Chemical, Biological, Radiological, and Nuclear (CBRN) defense is outlined in documents such as AJP-3.8(A), [Allied Joint Doctrine for Chemical, Biological, Radiological, and Nuclear Defence](#)**, which was published on March 30, 2012. This doctrine provides NATO strategic and operational commanders with fundamental principles for planning, executing, and supporting NATO operations where the threat and/or risk of intentional or accidental use of CBRN substances are assessed or exist.
- **NATO also has a [Combined Joint CBRN Defence Task Force \(CJ-CBRND-TF\)](#)** that is specifically trained and equipped to deal with CBRN incidents and/or attacks against NATO populations, territory, or forces. This task force includes the CBRN Defence Battalion and the CBRN Joint Assessment Team, both of which are multinational and multifunctional teams capable of rapid deployment to participate in the full spectrum of NATO operations.
- [NATO CBRN Defense Policy](#)
- [ABCANZ \(American, British, Canadian, Australian, New Zealand\) Force cooperation and nudge units](#)

EXHIBIT 2: PETITION FOR ADMINISTRATIVE ACTION REGARDING COVID-19 VACCINE LICENSURE, ASKING FDA TO DEEM COVID-19 VACCINES MISBRANDED AND ADULTERATED.



852 Franklin Ave., Suite 511
Franklin Lakes, NJ 07417

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
Commissioner Martin A. Makary M.D., M.P.H.
5630 Fishers Lane, Room 1061
Rockville, MD 20852

December 8, 2025

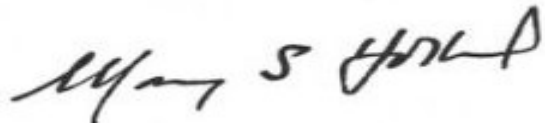
Dear Commissioner Martin A. Makary M.D., M.P.H.:

Enclosed is a Citizen Petition filed on behalf of Children's Health Defense by Mary S. Holland, Esq., Chief Executive Officer, Brian S. Hooker, Ph.D., Chief Scientific Officer, Kim Mack Rosenberg, General Counsel, and Ray L. Flores II, Senior Outside Counsel requesting that FDA revoke all licensure for COVID-19 mRNA vaccines as improperly granted.

This Citizen Petition incorporates results, findings, and conclusions gained by Alexandra (Sasha) Latypova, M.B.A., an independent writer and researcher on topics related to pandemic preparedness, EUA Countermeasures, and the PREP Act. Ms. Latypova is a pharmaceutical and medical device industry veteran with 25 years of experience across cardiovascular, oncology, immunology, CNS, infectious disease/HIV, musculoskeletal, and ophthalmic diseases. She co-led industry's largest validation study of AI-enabled analysis of electrocardiographic data collected in clinical trials. This effort resulted in the FDA revising its E14 Guidance for Industry, improving the precision and accuracy of cardiovascular safety studies, and introducing the first artificial intelligence-driven methods that maintain rigorous safety standards while reducing costs and risks to clinical trial subjects.

Mary S. Holland, Esq., and Brian S. Hooker, Ph.D., are available to answer questions and to provide any additional relevant information. We look forward to your timely review of this petition.

Sincerely,

A handwritten signature in black ink that reads "Mary S. Holland". The signature is written in a cursive, flowing style.

**Mary S. Holland, Esq.,
Chief Executive Officer**

A handwritten signature in black ink that reads "Brian S. Hooker". The signature is written in a cursive, flowing style.

**Brian S. Hooker, Ph.D.,
Chief Science Officer**

A handwritten signature in black ink that reads "Kim Mack Rosenberg". The signature is written in a cursive, flowing style.

**Kim Mack Rosenberg,
CHD General Counsel**

A handwritten signature in blue ink that reads "Alexandra Latypova". The signature is written in a cursive, flowing style.

**Ray L. Flores II,
Senior Outside Counsel**

cc:
Sasha Latypova

VIA ELECTRONIC FILING

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND THE FOOD AND DRUG ADMINISTRATION**

**PETITION FOR ADMINISTRATIVE
ACTION REGARDING COVID-19
VACCINE LICENSURE**

Docket No. _____

CITIZEN PETITION

On behalf of Children’s Health Defense, the undersigned submit this petition under 21 C.F.R. § 10.20, § 10.30, § 50.23, § 600 – 680, § 601.2, 21 U.S.C. § 352, and § 553(e) of the Administrative Procedure Act.

We ask the Commissioner of the Food and Drug Administration (FDA) to deem Moderna’s SPIKEVAX and all its currently marketed Biologics License Application (“BLA”) versions (including MNEXSPIKE) and Pfizer/BioNTech’s Comirnaty, and all its BLA versions, misbranded; and, that he initiates corrective actions at the agency’s disposal, including revoking

the BLA for these vaccines due to a lack of compliance with FDA regulations for the reasons set forth herein.

Under U.S. law, particularly the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act (PHSA) (for biologics), a “misbranded” drug or biologic is one that is labeled, promoted, or packaged in a false, misleading, or noncompliant way, meaning it fails to meet FDA labeling or disclosure requirements. That is the case here.

Misbranding is a legal designation, not just a descriptive one, that constitutes a violation of federal law ([21 U.S.C. § 352](#)) that can trigger seizure, injunction, criminal penalties, and/or license revocation.

Vaccines can reach the arms of Americans under investigational or non-investigational pathways that are separate and distinct: (a) the non-investigational Emergency Use Authorization (EUA) pathway (meaning a product that is not part of a clinical investigation under an Investigational New Drug (IND) application and exemption); or, (b) the investigational Biologics License Application (BLA) pathway, or its sub-category; an investigational Expanded Access Use (EAU) pathway that is part of the clinical investigation pathway.

The key distinction between the investigational and non-investigational pathway is the differing legal requirements that are associated with the approval and labeling of the biologic product. Among its many requirements, clinical investigations (aka “clinical trials”), for purposes of the BLA, require oversight of an Institutional Review Board (IRB)⁴⁴ and strict adherence to all other clinical trial requirements, as well as strict and enforceable compliance with the current Good Manufacturing and Good Laboratory Practices (cGxP).

Importantly, a product that had previously obtained full BLA licensure can be labeled EUA during a declared public health emergency for more rapid access or unapproved indications and thus can exist in two versions – BLA-labeled and EUA-labeled. However, a product that never received BLA licensure and only reached the market through the non-investigational EUA pathway cannot be granted BLA without first demonstrating full compliance with the investigational BLA standards. COVID-19 mRNA vaccines have not demonstrated full compliance.

During the tumultuous time of Operation Warp Speed, the FDA granted COVID-19 mRNA vaccines EUA status in December 2020, by correctly (under EUA standards) waiving the legal

⁴⁴Public Law 93-348 [The National Research Act](#) issued [45 CFR § 46](#): Protection of Human Subjects. The National Research Act is overseen by the Office of Human Research Protections. The Act also formalized a regulated IRB process through local institutional review boards, also overseen by the Office of Human Research Protections.

requirements of IRB oversight, clinical trials,⁴⁵ and current Good Manufacturing and Laboratory Practices (cGxP) compliance that are strictly required for the IND and BLA pathways.

However, the FDA allowed Pfizer to follow the non-investigational EUA pathway even when it unlawfully granted Pfizer's Comirnaty COVID-19 vaccine BLA licensure on August 23, 2021, while leaving its "interchangeable" EUA Pfizer-BioNTech version on the market. Then, on January 31, 2022, the agency granted full BLA approval to Moderna's SPIKEVAX COVID-19 vaccine even though it continuously followed a non-investigational EUA pathway.

Now that there are no EUA COVID-19 vaccines⁴⁶ in the United States, all currently available vaccines are BLA-labeled, albeit improperly. According to the FDA, the Pfizer-BioNTech vaccine that initially reached the market as an EUA countermeasure "is marketed" under the Comirnaty label.⁴⁷ According to Moderna, its COVID-19 vaccine that initially reached the market as an EUA countermeasure was then and is marketed as SPIKEVAX (COVID-19 Vaccine, mRNA).⁴⁸

EUA vaccines cannot be merely marketed under a BLA label, however. There are licensing standards that need to be met but are not. There is no evidence that the current mRNA COVID-19 vaccine licensures comply with the legal standards of BLA labeling. In fact, it is quite the contrary.

The most egregious of the FDA's violations is that the only human clinical studies for COVID-19 vaccines were conducted under an EUA pathway that lacked IRB oversight and were not legally compliant clinical investigations. In addition, ample evidence points to the FDA's continual waiver of most (if not all) normally applicable BLA standards, such as cGMP/cGLP compliance in R&D and manufacture of these products.

⁴⁵ In addition, neither the expanded use access (EAU), nor emergency use authorization (EUA) pathways constitute a *clinical trial/clinical investigation* under [21 CFR § 312.3\(b\)](#) and [21 U.S.C. § 360bbb-3\(k\)](#), respectively.

⁴⁶ Federal Register, *Revocation of Emergency Use of Three Biological Products; Availability* (October 2, 2025) <https://www.federalregister.gov/documents/2025/10/02/2025-19272/revocation-of-emergency-use-of-three-biological-products-availability>

⁴⁷ FDA, *FDA Approves First COVID-19 Vaccine* (August 23, 2021) <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>

⁴⁸ FDA, *FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS) EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)* (p. 17 *14)(June 17, 2022) <https://www.fda.gov/media/157232/download>

COVID-19 vaccines that the FDA authorized for market under an EUA pathway in December 2020 *jumped tracks* without satisfying requisite standards to become BLA-labeled (Pfizer, August 23, 2021, and Moderna, January 31, 2022). By law, manufacturing practices and the data collected while under an EUA status can never satisfy regulatory and statutory BLA standards, as legal investigational pathway standards are explicitly made inapplicable to the non-investigational uses of products (under EUA). In a court declaration,⁴⁹ Peter Marks, then head of the FDA's Center for Biologics Evaluation and Research (CBER), correctly stated that, "products approved under BLAs are required to have the labeling that was approved as part of BLA." These COVID-19 vaccines were manufactured under EUA standards, without clinical trials, and without continuous compliance with BLA labeling standards. They cannot remain in interstate commerce because they are, in fact, misbranded products. By law, their licenses must be revoked.

In 2025, both Comirnaty and SPIKEVAX labels have been substantially revised with indication and usage restrictions,⁵⁰ and additional warnings for myocarditis/pericarditis.⁵¹ These actions were warranted; however, they do not rectify the underlying mislabeling violations described herein. This Petition is not arguing about the safety or efficacy of marketed COVID-19 mRNA vaccines, but rather violations of BLA labeling standards under the law.

The burden is on the FDA to prove that all BLA standards were satisfied when it fully licensed Pfizer's and Moderna's vaccines, which it cannot do.

⁴⁹ Declaration of Peter Marks, N.D. Fla. Case Number 3:21-cv-0121 p. 6 ¶11 (October 21, 2021) <https://www.docdroid.net/xQZCCkd/declaration-of-marks-pdf>

⁵⁰ FDA, *FDA Approves and Authorizes Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants* (August 22, 2024) <https://www.fda.gov/news-events/press-announcements/fda-approves-and-authorizes-updated-mrna-covid-19-vaccines-better-protect-against-currently>

⁵¹ FDA, *FDA Approves Required Updated Warning in Labeling of mRNA COVID-19 Vaccines Regarding Myocarditis and Pericarditis Following Vaccination* (June 25, 2025) <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-approves-required-updated-warning-labeling-mrna-covid-19-vaccines-regarding-myocarditis-and>

Therefore, based on the foregoing, the undersigned ask the FDA to revoke all mRNA COVID-19 vaccine licensure based on the FDA's continuing lack of adherence to proper BLA standards.

I. ACTIONS REQUESTED

1. Petitioners ask the FDA to revoke all BLA's for every mRNA COVID-19 vaccine for all demographic groups because manufacturers do not and have never met BLA standards. Further, in granting licensure, FDA failed to enforce these standards.
2. Petitioners ask the FDA to find Comirnaty (all versions) and SPIKEVAX (including MNEXSPIKE) mislabeled/misbranded.
3. Petitioners ask the FDA to find Comirnaty (all versions) and SPIKEVAX (including MNEXSPIKE) adulterated or potentially adulterated.
4. Petitioners ask the FDA to properly designate every mRNA COVID-19 vaccine as an Emergency Use Authorization biologic as long as the HHS Secretary's Declaration of Emergency is in effect. [21 U.S. Code § 360bbb-3\(c\)](#)).

II. STATEMENT OF GROUNDS

A. All available COVID-19 mRNA vaccines fail to meet BLA licensure standards

New biological products that have never been approved for market before (such as mRNA vaccines prior to 2020) must follow these mutually exclusive regulatory pathways to reach the U.S. market:

Feature	IND/BLA Pathway	EUA Pathway
Legal Authority	21 U.S.C. § 355 / 42 U.S.C. § 262	21 U.S.C. § 360bbb-3
Status	Investigational medicine	Non-investigational use

Purpose	Research & full licensure	Emergency distribution
IRB Oversight	Required (21 CFR 56)	Not required
Informed Consent	Required (21 CFR 50)	Not required
cGxP compliance	Required	Not required

Each regulatory pathway is briefly discussed below.

1. Emergency Use Authorization (EUA)

According to the FDA, under section 564 of the [\(FD&C Act\)](#), when the HHS Secretary declares that 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 Chemical, Biological, Radiological and Nuclear (“CBRN”) threat agents when certain criteria are met, such as instances when there are no adequate, approved, and available alternatives.

During an emergency, [21 USC 360bbb-3a\(c\)](#) authorizes the HHS Secretary to deviate “from current good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation.” Further, a countermeasure, “shall not be deemed adulterated or misbranded under this chapter because ... the Secretary has authorized deviations from current good manufacturing practices.”

Unlike standard research under 21 CFR Parts 50 and 56, EUA use is not a “clinical investigation” and therefore does not require IRB approval or informed consent under those parts. There are alternative disclosure obligations:

[21 U.S.C. § 360bbb-3\(e\)\(1\)\(A\)\(ii\)\(III\)](#) requires that recipients be informed of:

1. The option to accept or refuse administration of the product,
2. The consequences, if any, of refusing, and
3. The alternatives to the product that are available and of their benefits and risks.

What is sometimes referred to as the EUA Fact Sheet requirement replaces traditional “informed consent” under human-subjects research rules.⁵²

Additionally, EUA products are deployed on the market based on only a “may be effective”⁵³ opinion of the HHS Secretary and are not subject to formal product recall procedures, applicable to regular pharmaceutical products.

Therefore, licensure requirements of 21 C.F.R. Part 610 (General Biological Products Standards) are, in effect, waived by 21 USC 360bbb–3(a)(2)(A), and when products are brought to the market under EUA regulations, with its lax FDA enforcement, manufacturers are on an honor system to self-monitor.

2. Biologics License Application (BLA)

According to the FDA, the Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce ([21 CFR 601.2](#)). The BLA is regulated under [21 CFR 600 – 680](#). A BLA is submitted by any legal person or entity who is engaged in manufacturing or an applicant for a license who takes responsibility for compliance with product and establishment standards. [Form 356h](#) specifies the requirements for a BLA, which the FDA must formally review before granting the licensure, and to which the manufacturer is bound to comply continuously, including:

- Applicant information
- Product/Manufacturing information
- Pre-clinical studies
- Clinical studies
- Labeling

Thus, the FDA can only license biologics that meet (purity, potency, safety, efficacy, manufacturing compliance, labeling disclosure/marketing compliance, and other applicable legal standards) requirements.

⁵² FDA, *GUIDANCE DOCUMENT Emergency Use Authorization of Medical Products and Related Authorities* (p. 15) (January 2017)

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#:~:text=b.%20Information%20for,preparation%20>

⁵³ [21 U.S. Code § 360bbb-3\(c\)](#) - *Authorization for medical products for use in emergencies, criteria for issuance of authorization.*

Importantly, BLA licensure is not a one-time event; it requires ongoing, strictly enforceable compliance with applicable statutes while the product remains in interstate commerce.

For purposes of this Petition, the manufacturing compliance (cGMP), preclinical studies compliance (cGLP), and clinical investigation compliance are briefly outlined below. Compliance with these requirements ensures accurate and truthful disclosure in the labeling of BLA biological products. Absent adherence to such procedures, biologics are mislabeled and misbranded and are therefore subject to recall and BLA licensure revocation.

a. Manufacturing compliance requirements for BLA (cGMP):

cGMP requirements for biologics, purity/potency/safety are described in [21 CFR 600–610](#), which establish the general FDA standards for biological products, including vaccines licensed under the Public Health Service Act ([42 U.S.C. § 262](#)). 21 CFR Part 610 describes General Biological Product Standards, i.e., core technical standards for vaccines and similar biologics.

In principle, to initially receive and continue to maintain a biologics license, a manufacturer must continuously demonstrate, for the specific product, its end-to-end production and supply chain:

1. **Safety** – product causes no undue harm when used as intended. (§610.11 Safety). This part requires testing in animals or other validated models.
2. **Purity** – free from contamination or unintended substances. (§610.12 Purity). Product must be free from extraneous materials (cell debris, endotoxins, residual DNA, etc.).
3. **Sterility** (§610.10): Each lot must be free of contaminating microorganisms.
4. **Potency** – proven biological activity consistent with intended therapeutic or immunologic effect. (§610.17–§610.18 Potency & Stability). Potency must be demonstrated using validated biological or immunological assays.
5. **Identity and Constituents** (§610.13–§610.15). Validated tests must confirm correct identity and permissible additives.
6. **Expiration Dating**: Manufacturers must establish expiration dating based on real-time stability data.
7. **Consistency** – validated manufacturing process ensures reproducibility of quality.
8. **Compliance with cGMP** – per [21 CFR Parts 210 & 211](#), adapted for biologics.

To comply with the above-mentioned requirements for purposes of BLA licensure,⁵⁴ manufacturers must:

⁵⁴ Regulatory Bases: The requirements to show *controlled, reproducible production* come primarily from:

- establish, validate, and consistently apply controlled production methods that
- ensure each lot of a biologic product is safe, pure, potent, and stable, as verified through documented testing, records, and continuous FDA oversight.

Establishing a manufacturing process that is compliant with the legal requirements of the BLA is complex. It typically takes many years to license an entirely new product or technology platform, numerous compliance requirements are specified in the law, and several overarching principles must be continuously upheld:

1. A validated and BLA-compliant manufacturing process⁵⁵ must be fully representative of the final/current commercial lot production process. Due to uncertainties inherent in the design of new innovative biological products, the manufacturing for novel technologically advanced platforms typically requires many changes and iterations as the production is scaled from pilot/research scale to commercial scale. Thus, to obtain a BLA, the manufacturers are required to fully validate and demonstrate compliance with the law for the final commercial scale process.
2. The BLA manufacturing process must be fully representative of the product lots used in clinical trials and preclinical studies upon which the labeling – including claims of safety and efficacy – is established.
3. Throughout pivotal clinical trials and post BLA, each production lot must demonstrate lot-to-lot consistency⁵⁶ and pass identity, purity, safety, sterility, potency, and stability tests (§§ 610.10–610.13) in order to meet the labeling specifications preapproved in the

21 CFR Parts [600 & 610](#) — General biologics standards (licensing, testing, lot control).
21 CFR Parts [210 & 211](#) — Current Good Manufacturing Practice (cGMP).

11.1 FDA, *Guidance for Industry Process Validation: General Principles and Practices* (January 2011). <https://www.fda.gov/media/71021/download>

11.2 FDA, *Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)* (January 2023), <https://www.fda.gov/media/113760/download>

11.3 FDA, *Development and Licensure of Vaccines to Prevent COVID-19 Guidance for Industry* (October 2023), <https://www.fda.gov/media/139638/download>

⁵⁵ FDA, *Guidance for Industry, Process Validation: General Principles and Practices* (January 2011). <https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf>

⁵⁶ 21 CFR [610.1 & 610.12–610.20](#)

Biologics License Application (BLA). If variability arises, the manufacturer must investigate and demonstrate that it does not compromise quality.

Manufacturing process validation is a vast area of law and regulation, which generally includes:

- Design qualification (DQ) – define process and critical quality attributes.
- Installation/operational qualification (IQ/OQ) – verify equipment and system performance.
- Performance qualification (PQ) – produce several consecutive lots that meet all release criteria under routine conditions. These lots are often called Process Performance Qualification (PPQ) lots.⁵⁷

For continued BLA licensure, the above-mentioned requirements are fully enforceable by the FDA. The FDA must withdraw licensure for any of the listed category violations. While manufacturers may volunteer to adhere to these standards under EUA, none of the above-mentioned categories are strictly required or enforced by the FDA under EUA.

b. Pre-clinical compliance requirements for BLA (Good Laboratory Practices, cGLP):

Regulatory Basis for cGLP Requirements is the [21 CFR Part 58](#) – Good Laboratory Practice for Nonclinical Laboratory Studies and associated FDA Guidance for Industry documents.⁵⁸ To meet BLA licensure standards, the manufacturers must demonstrate that the data used to support human clinical trials are representative of the final biological product as dispensed to the consumer, and are reliable, traceable, and scientifically valid. FDA explicitly states that GLP applies when nonclinical safety studies are intended to support research or marketing applications for biologics, drugs, or medical devices (§58.1(a)).

In the context of vaccines, this includes:

- **Toxicology studies** (single and repeat-dose toxicity, and reproductive toxicity)
- **Local tolerance studies** (e.g., intramuscular or subcutaneous injection sites)
- **Biodistribution studies** (required for novel platforms like mRNA or viral vectors)
- **Immunopathology or adjuvant safety** studies

⁵⁷ Ibid. Footnote 12

⁵⁸ **15.1** FDA, *Guidance for Industry Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers in Preventive Vaccine Clinical Trials* (2007) <https://www.fda.gov/media/73679/download>;

15.2 FDA, *Guidance for Industry Preclinical Assessment of Investigational Cellular and Gene Therapy Products* (November 2013) <https://www.fda.gov/media/87564/download>

- **Safety pharmacology** if system effects are relevant (required for novel platforms and when biodistribution shows systemic exposure)

Exploratory or proof-of-concept immunogenicity studies, or early mechanism-of-action studies, are not required to be GLP and can be conducted under research-quality conditions. However, any pivotal safety studies cited in a BLA must comply with GLP. In its Guidance for Industry documents, the FDA requires that, if a study cannot fully comply with GLP (e.g., species model constraints), deviations must be scientifically justified, documented, and disclosed to FDA.⁵⁹

c. BLA-compliance requirements for human subjects in investigational clinical trials

When a sponsor submits a biologics license application under Public Health Service Act § 351(a) (42 U.S.C. § 262), part of the “safe, pure, and potent” demonstration relies on legally defined clinical investigations in humans.

FDA regulations make clear that:

- Humans may not be enrolled in research unless informed consent has been obtained ([21 CFR 50.20](#)).
- An IRB must review and approve human-subject research ([21 CFR 56.109\(a\)](#)).
- Documentation of consent and IRB decisions must be maintained (§ 50.27 and § 56.109(c)).

Thus, IRB oversight and informed consent are strict prerequisites for data from human clinical trials to be acceptable to FDA for biologics licensing (BLA).

Clinical trials, defined per [21 CFR Part 312](#) as “clinical investigation” studies, must follow a set of laws and regulations,⁶⁰ which are intended to protect the rights, safety, and welfare of human subjects participating in human trials, ensure the quality, validity, and integrity of the clinical trial

⁵⁹ **16.1** FDA, *Guidance for Industry S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals* (July 1997) (page 3, section III.A (“General Principles”)); <https://www.fda.gov/media/72028/download>; and

16.2 FDA, *Guidance for Industry Preclinical Assessment of*

Investigational Cellular and Gene Therapy Products

(November 2013) <https://www.fda.gov/media/87564/download>

⁶⁰ FDA, *Regulations: Good Clinical Practice and Clinical Trials* (January 21, 2021)

<https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials>

data, and promote the availability of new medical products to the public. These laws and regulations define the roles and responsibilities of entities, such as sponsors, clinical investigators, and institutional review boards. In addition, various guidance documents⁶¹ and standard operating procedures⁶² are available to clarify policies and procedures for the IND process.

d. BLA Requirements for Representative Commercial Process/Product

Crucially, the initial and ongoing compliance with BLA requires that data used to support licensure come from processes representative of the final commercial manufacturing process. This is because in biologics manufacture, the process is the product. Discussing the cGMP on its website,⁶³ the FDA states that:

A consumer usually cannot detect (through smell, touch, or sight) that a drug product is safe or if it will work. While CGMP requires testing, testing alone is not adequate to ensure quality. In most instances testing is done on a small sample of a batch (for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets), so that most of the batch can be used for patients rather than destroyed by testing.

Clearly, “testing alone” is not sufficient to ensure ongoing BLA compliance. Testing of one or many doses of one or many batches of a product that does not accurately represent the actual product injected into a consumer cannot and will not meet the BLA standards established by the FDA.

The FDA explicitly requires that manufacturing and testing used to support licensure (including preclinical and clinical material) be representative of the final commercial process:

- Same or scaled-equivalent facilities, equipment, and controls.
- Same cell substrate or vector system, purification steps, and formulation.
- Same process control strategy and release specifications.

⁶¹ Ibid.

⁶² FDA, *Biologics Procedures (SOPPs)* (October 31, 2025)

<https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-procedures-sopps>

⁶³ FDA, *Facts About the Current Good Manufacturing Practice (CGMP)* (November 21, 2025)

<https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp>

In the context of cGMP, preclinical studies must reflect the intended clinical/commercial material, meaning that the test article(s) used in preclinical studies should be representative of the material intended for clinical use, manufactured using comparable processes and controls to those planned for clinical and commercial production, while significant manufacturing changes after preclinical testing may necessitate additional bridging studies to demonstrate comparability.⁶⁴

The FDA cites specific regulations for process validation and reporting (e.g., 21 CFR 211.22, 211.100, 211.110(a), and 211.165) when explaining why manufacturing changes late in development can require additional qualification or bridging studies.⁶⁵

In the context of cGMP, Clinical and PPQ Manufacturing must reflect the final commercial process. This means that the process must be defined, controlled, and validated to yield consistent product quality, which inherently requires it to represent what will be commercially manufactured.

FD&C Act § 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), and 21 CFR 210/211 and 21 CFR 601.20 collectively require that the actual facilities and equipment used to manufacture the licensed biologic operate in a state of cGMP control and validated performance.

In addition, FDA Guidance “Process Validation: General Principles and Practices”⁶⁶ defines manufacturing Process Qualification as:

During the process qualification (PQ) stage of process validation, the process design is evaluated to determine if it is capable of reproducible commercial manufacture.

PPQ (Process Performance Qualification) lots, i.e. the manufacturing validation lots submitted for the BLA, must be made using the same process, materials, and controls as final commercial production. If these criteria are not met, the process is not considered validated for licensure.

FDA Guidance “CMC Information for Human Gene Therapy INDs” (2023)⁶⁷ specifies that the manufacturing process and analytical methods used for clinical production should be

⁶⁴ “FDA, *Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products Draft Guidance for Industry* (July 2023) <https://www.fda.gov/media/170198/download>

⁶⁵ Ibid.

⁶⁶ FDA, *Guidance for Industry Process Validation: General Principles and Practices* (January 2011), (p. 13 of 22) <https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf>

⁶⁷ FDA, *Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs) Guidance for Industry* (January 2020) <https://www.fda.gov/media/113760/download>

representative of those intended for commercial manufacturing; that significant changes during development should be assessed for impact on product comparability, and that demonstration of process control and reproducibility should be based on production-scale runs that reflect the final process design.

Finally, BLA Review Standard ([21 CFR §601.2\(a\)](#)) states that:

To obtain a biologics license under section 351 of the Public Health Service Act for any biological product ... [the application shall include] sample(s) representative of the product for introduction or delivery for introduction into interstate commerce

This means that the FDA requires evidence that the *exact* process proposed for commercial use can reproducibly make a product meeting all standards – one cannot obtain a BLA license for a product on the basis of a research-grade or pilot-scale process.

e. When Manufacturing Process Is Not Representative

If preclinical or clinical material differs substantially from the final process:

- Bridging studies must be performed to compare the new and old lots (analytical comparability + potentially new animal or clinical data).
- FDA may reject PPQ data if the validation lots are not representative of commercial manufacturing.
- The BLA may be Refuse To File (RTF) until comparability or validation is demonstrated.

f. When a drug or biologic is considered misbranded

Examples of misbranding relevant to this Petition include:

1. False or Misleading Labeling ([21 U.S.C. § 352\(a\)\(1\)](#)) categorizes a product as misbranded; “If its labeling is false or misleading in any particular.” Specific examples include claims of safety or effectiveness which are not supported by data, or omission of material facts, such as risks and limitations of use.

2. Failure to Comply With cGMP

If a product’s labeling implies that it was manufactured under approved standards but cGMP (21 CFR Parts 210–211 for drugs; 600–680 for biologics) was not followed, the product may be considered adulterated and misbranded.

To rectify misbranding, the FDA has numerous enforcement mechanisms, including:

- FDA can issue a Warning Letter or request voluntary recall.

- Products may be detained or seized under [21 U.S.C. § 334](#).
- Manufacturers may lose licensure under [PHSA § 351\(d\)](#) for biologics.

B. The FDA failed to follow its own regulatory guidelines when it illegally granted BLAs to COVID-19 mRNA vaccines

The FDA granted the BLAs to Pfizer and Moderna without following the BLA requirements specified in the FDA's own regulations and the law. Substantial evidence points to several such glaring violations that are also contrary to historically established regulatory practice.

1. Evidence that Comirnaty and SPIKEVAX labels are non-compliant with legal standards for cGMP (noncompliant clinical data (Section 14 of BLA label))

In late November 2020, records for Pfizer's COVID-19 vaccine regulatory review were publicly released by a data leak from the European Medicines Agency.⁶⁸ The authenticity of the documents was confirmed by the British Medical Journal.⁶⁹ The EMA did not deny the authenticity of the documents. The documents also contain some of the FDA reviewers' correspondence with Pfizer. In addition to the manufacturing documentation, the EMA files also contain 14 screenshots of emails dating from mid to late November 2020.⁷⁰ The email exchanges are between the EMA staff and senior executives at the agency and their correspondence with the FDA and MHRA (the UK regulator). These emails demonstrate that the EMA reviewers were under massive political pressure to overlook all regulatory deficiencies. It is also evident that the EMA and FDA leadership at the time were concerned primarily with coordinating the launch dates, and the "authorization" of these shots was a foregone conclusion.

Emails leaked from EMA also demonstrate that the EU regulators were primarily concerned with the dates of product launch prior to reviewing the necessary regulatory data package. The process was highly political and not scientific. As stated above, the EMA staff reviewers objected to the data, but the high-ranking officials appeared to have ignored and overruled their concerns.

⁶⁸ European Medicines Agency leaked files

⁶⁹ British Medical Journal, *The EMA covid-19 data leak, and what it tells us about mRNA instability* (March 10, 2021)

<https://www.bmj.com/content/372/bmj.n627>

⁷⁰ European Medicines Agency leaked emails

The regulatory review and approval standards in the United States and the European Union are substantially the same due to the International Conference on Harmonization (ICH) and Mutual Recognition Agreements. The documents show that the first regulatory review of Pfizer's manufacturing process, a so-called "rolling review", began on or around November 26, 2020. During this review, the Biologics Working Party (BWP) at the European Medicines Agency identified three Quality Major Objections (MOs)⁷¹ during the assessment of Pfizer's CMC documentation. There were severe and unresolvable – given the unrealistic timeline – issues with the quality of the product the EMA staff were pressured to ok. The manufacturing process was woefully out of cGMP compliance. Specifically, major objections included:

MO1: lack of cGMP compliance and inability to establish it prior to launch;

MO2: lack of mRNA integrity and large amounts of mRNA fragments, and incomparability of the commercial process (PPQ batches) with the process that was used to make the doses for the pivotal clinical trial that had just wrapped up the data collection;

MO3: many significant gaps in manufacturing documentation making it impossible to determine if the product could be made as described. The manufacturing process compliance with cGMP (BLA or CMA standards) could not be verified at all.

Additionally, 100+ objections and observations were issued by the reviewers flagging a variety of serious concerns with the manufacturing process quality and data completeness.

The EMA regulatory review of Pfizer CMC documentation revealed that the Phase 3 data could not satisfy the BLA standards. The two main reasons for this failure were:

- The manufacturing process used to produce the Phase 3 clinical trial drug product (aka Process 1) was found non-representative of the commercial scale manufacturing process being presented to the regulatory review (Process 2); and
- The scaled Process 2 was found non-compliant with cGMP requirements due to numerous identified deficiencies and large gaps - missing or pending normally required information. This made it impossible for the regulators to evaluate Pfizer's process for cGMP compliance prior to commercial distribution of the product.

Each one of these reasons by itself precludes the possibility of Pfizer's Phase 3 clinical trial data, from late fall of 2020, being acceptable for BLA labeling in August of 2021.

⁷¹ Ibid.

The magnitude and severity of the cGMP non-compliance issues identified by the European regulators at that time preclude the possibility that the data from the Phase 3 COVID-19 vaccine clinical trials could satisfy the accurate BLA labeling at a later date.

The pivotal trials for COVID-19 vaccines had completed primary Phase 3 data collection in late fall of 2020. Specifically, for Pfizer, the data lock for the primary efficacy endpoints was on November 14, 2020,⁷² and for Moderna - on or before November 16, 2020.⁷³ Both dates are prior to the dates of the EMA/FDA CMC regulatory review for Pfizer, which happened around November 26, 2020. At that time, Moderna's CMC documentation was not available for review at all. While for both vaccines, final trial completion dates are listed in 2022-2023, both trials broke the blinding and removed the placebo control groups by injecting the participants with the COVID-19 vaccines starting around December 2020. This, too, is a serious violation of the BLA standards, but is acceptable for EUA. Some special-population post-market studies were performed in 2021-2022 (e.g., in children and some immunocompromised populations, updated product versions); however, none were BLA-compliant.

The FDA cannot claim that objections and observations of the European regulators are not relevant. Unlike the FDA, the EMA used an investigational regulatory pathway (Conditional Marketing Authorization, CMA⁷⁴) for initially deploying COVID-19 vaccines in the EU. The CMA standards are substantially similar to the BLA standards in the United States, as they apply to the products legally deemed investigational. In fact, until COVID-19 vaccines, the CMA pathway had never been utilized for approving any product for a very broad indication and mass deployment. CMA requires the same cGMP compliance as any commercially approved investigational drug or biologic, while allowing for some regulatory commitments post-market. Therefore, the major objections of the EMA reviewers are highly relevant as evidence of major

⁷² FDA, *Pfizer-BioNTech Covid-19 vaccine (BNT162, PF-07302048)*

Vaccines and Related Biological Products Advisory Committee Briefing Document: 10 December 2020, p.8; <https://www.fda.gov/media/144246/download>

⁷³ Businesswire, *Moderna Announces Primary Efficacy Analysis in Phase 3 COVE Study for Its COVID-19 Vaccine Candidate and Filing Today with U.S. FDA for Emergency Use Authorization* (November 30, 2020) <https://www.businesswire.com/news/home/20201130005506/en/Moderna-Announces-Primary-Efficacy-Analysis-in-Phase-3-COVE-Study-for-Its-COVID-19-Vaccine-Candidate-and-Filing-Today-with-U.S.-FDA-for-Emergency-Use-Authorization>

⁷⁴ NIH, National Library of Medicine Pub Med Central, *The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines* (January 13, 2021) <https://pmc.ncbi.nlm.nih.gov/articles/PMC7833511/>

deficiencies with respect to the BLA-readiness of Pfizer's manufacturing process at the time of the primary data completion of its pivotal Phase 3 trial.

The FDA cannot claim that these manufacturing compliance violations have been resolved between 2020 and 2025, for the following reasons:

Even if the FDA can demonstrate that Pfizer's Comirnaty manufacturing process is cGMP compliant today, the manufacturing process today is NOT the same process that was used to manufacture the Phase 3 trial material. Therefore, the data from the Phase 3 trial do not represent the product that is being shipped today, and the product should be deemed mislabeled.

Even if the FDA has discretion to use the so-called "real world" observational data as supporting evidence for various regulatory decisions, these "real-world" data alone, regardless of how voluminous, are not a valid substitute for legally prescribed evidentiary data package collected in cGMP compliant manner, as required for BLA labeling.

Effect: the data from Phase 3 trials, which are included in several sections of Comirnaty and SPIKEVAX BLA labels (Sections 6, 8, 14), cannot be deemed representative of the commercially shipped SPIKEVAX and Comirnaty vials. This means that vials being distributed in interstate commerce today are mislabeled for purposes of BLA.

2. Evidence that Preclinical and Toxicology sections of Comirnaty, SPIKEVAX, and MNEXSPIKE labels do not comply with BLA standards (cGLP)

In June 2020, the FDA published "Development and Licensure of Vaccines to Prevent COVID-19." This guidance document is final, was implemented without prior public participation, and is intended to remain in effect for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, and currently extended to December 31, 2029. Regarding the nonclinical assessments for COVID-19 vaccines (2020) the FDA guidance⁷⁵ states that:

For a COVID-19 vaccine candidate consisting of a novel product type and for which no prior nonclinical and clinical data are available, nonclinical safety studies will be required prior to proceeding to FIH [first-in-human] clinical trials 21 CFR 312.23(a)(8). (P.6)

When needed to support proceeding to FIH clinical trials, nonclinical safety assessments including toxicity and local tolerance studies must be conducted under conditions

⁷⁵ FDA, *Development and Licensure of Vaccines to Prevent COVID-19 Guidance for Industry* (October 2023) <https://www.fda.gov/media/139638/download>

consistent with regulations prescribing good laboratory practices for conducting nonclinical [*sic*] laboratory studies (GLP) (21 CFR Part 58). Such studies should be completed and analysed [*sic*] prior to initiation of FIH clinical trials. When toxicology studies do not adequately characterize risk, additional safety testing should be conducted as appropriate. (P.7)

The agency also states that where the guidance says “should,” those sentences describe nonbinding recommendations, while where it says “must” and cites the applicable law, it describes enforceable items.

There were no nonclinical or clinical data available for mRNA-1273 (later SPIKEVAX) or BNT162b2 (later Comirnaty) before 2020. Both products formulated in lipid nanoparticles constitute entirely novel biologic products and active substances, requiring strict adherence to BLA standards if the product is to be labeled as such.

Review of Moderna’s FOIA Productions of SPIKEVAX Nonclinical Summaries⁷⁶ and Comirnaty Nonclinical Summaries⁷⁷ revealed severe non-compliance with BLA standards and the FDA’s own Guidance for mRNA vaccines.

a. The BLA requirement for completion of nonclinical safety studies prior to the start of the first-in-human trials was not met by either Pfizer or Moderna products.

Specifically, Moderna initiated human clinical studies on March 16, 2020.⁷⁸ For the biodistribution component of the non-clinical assessment, Moderna submitted a non-GLP study for another unapproved product, mRNA-1647 (a construct of 6 different mRNAs which had been in development for an experimental cytomegalovirus vaccine), completed in male animals only, in 2017. Since this study was non-GLP and did not include SPIKEVAX formulation (mRNA 1273), the biodistribution for SPIKEVAX has not been studied under BLA standards at all. For other components of Moderna’s non-clinical package, studies that utilized mRNA-1273 or its

⁷⁶ Moderna Nonclinical Summaries Responsive records 4.pdf (February 28, 2022)

⁷⁷ HHS, *Re: FDA FOIA Request 2021-4379; Judicial Watch, Inc. v. U.S. Department of Health and Human Services*, 21-cv-2418 (April 13, 2022) <https://www.judicialwatch.org/wp-content/uploads/2022/08/JW-v-HHS-Biodistribution-Prod-4-02418.pdf>

⁷⁸ Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus (March 16, 2020) https://s29.q4cdn.com/435878511/files/doc_news/2020/03/16/moderna-announces-first-participant-dosed-nih-led-phase-1-study.pdf

components were all initiated after March 16, 2020, and key data were still indicated as pending or incomplete when the FOIA production was obtained in 2022.⁷⁹

Pfizer initiated human clinical studies in April 2020, and its pivotal Phase 3 trial on July 27, 2020. As evidenced in the Nonclinical Summaries FOIA production, Combined Fertility and Developmental Study (DART) for Comirnaty was completed on October 12, 2020, and the biodistribution study was completed on September 24, 2020. The 17-Day Intramuscular Toxicity Study of BNT162B2 (V9) in Wistar Han Rats (Study 20GR142) is noted in conflicting terms in the documentation. In one summary table, this study is listed as “Completed.” However, other sections state that this study was “Ongoing” at the time of the review, noting that the remaining endpoints (serology and microscopic pathology from the dosing phase, plus all recovery phase endpoints) were pending submission. No specific experimental completion date or final report date is provided for Study 20GR142 in the available document production.⁸⁰

b. The GLP requirements for BLA were not met.

The nonclinical summaries (Module 2.4 and associated sections) for the Pfizer/BioNTech vaccine candidate BNT162b2 detail a total of 17 individual studies or definitive reports across the domains of Pharmacology, Pharmacokinetics/ADME, and Toxicology. While some GLP-compliant studies were included in the package, the whole nonclinical package cannot be deemed GLP-compliant, as several key required studies were non-GLP. Specifically, the only two GLP studies that evaluated the final BLA product candidate were the intramuscular Repeat-Dose Toxicity Study 20GR142 and the Reproductive Toxicity study (DART 20256434, Sponsor Reference No. RN9391R58). Another Repeat-Dose Toxicity Study (Study 38166) is listed as GLP; however, it was conducted with the vaccine candidate that was not the final BLA licensed vaccine product, but another version. Single Dose Pharmacokinetics (PK) and Excretion Study (PF-07302048) evaluated the novel lipid excipients (ALC-0315 and ALC-0159) and is listed as non-GLP. Since these lipids have never been used in any approved biologic product, it is a violation of the BLA standards. Finally, the critical component of the toxicology assessment, the biodistribution study, “Tissue Distribution Study (Radiolabeled Lipid/mRNA), study number 185350, was not conducted under GLP conditions. The final report explicitly states that GLP

⁷⁹ Ibid. Footnote 34 p. 349, 353, 354, 355.

⁸⁰ **37.1** MDPI, *Toxicological Assessments of a Pandemic COVID-19 Vaccine—Demonstrating the Suitability of a Platform Approach for mRNA Vaccines* Giovanelli M. (February 11, 2023) <https://www.mdpi.com/2076-393X/11/2/417>

37.2 Pfizer Inc., 17-Day Intramuscular Toxicity Study of BNT162B2 (V9) 17-DAY INTRAMUSCULAR TOXICITY STUDY IN WISTAR HAN RATS WITH A 3-WEEK RECOVERY STUDYID: 20GR142 (January 19, 2021) https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/030123/125742_S1_M4_20gr142_nsdrp.pdf

regulations are not applicable to studies of this nature; therefore, no claim of GLP compliance is made. This is acceptable for the EUA regulatory pathway; however, it violates the regulatory standards for BLA products.⁸¹

The nonclinical summaries for Moderna's SPIKEVAX contain several versions of the same documentation package. They appear to contain information derived from 9 individual studies or types across the domains of Pharmacology, Pharmacokinetics, and Toxicology. In addition, several tests for individual components of the lipid nanoparticle technology are included. The only GLP-compliant study of mRNA-1273 (SPIKEVAX) in the entire package is the Developmental & Reproductive Toxicity (DART). This is the only study that satisfies both the BLA requirement for GLP and for representative product testing. All primary pharmacology studies for SPIKEVAX were non-GLP. All other studies in the submission do not meet the GLP requirements. In many instances, GLP studies of irrelevant products (not SPIKEVAX) are included. These may satisfy the EUA standards but do not meet the BLA standards because the tested materials are not representative of the commercial product.⁸²

The nonclinical studies for Moderna's MNEXSPIKE⁸³ contain only one GLP-compliant study with representative product "Combined Perinatal/Postnatal Developmental & Reproductive Toxicity Study." The study was conducted in females only, and no male reproductive toxicity was assessed. This violation of BLA standard is further discussed in section (f) below. The remainder of nonclinical studies for MNEXSPIKE were non-GLP compliant. The "Non-GLP Repeat Dose Toxicity and Immunogenicity Study," (see p. 9) in addition to being non-GLP, was conducted with non-representative products (mRNAs-1284 and -1285). However, MNEXSPIKE is mRNA-1283. The "Nonclinical Pharmacology Studies Supporting mRNA-1283"⁸⁴ were all non-GLP compliant.

⁸¹ Ibid. Footnote 33

⁸² Moderna mRNA-1273 (SPIKEVAX) Nonclinical Program

⁸³ FDA, *Summary Basis for Regulatory Action MNEXSPIKE* p. 15 (May 30, 2025)
<https://www.fda.gov/media/187164/download?attachment>

⁸⁴ Ibid. Table 6, p. 16-17

On or around November 28, 2025, an internal memo⁸⁵ from Vinayak Kashyap Prasad M.D., M.P.H., director of the FDA's CBER, leaked to the press, opened with:

I am writing to report that OBPV [Office of Biostatistics and Pharmacovigilance] career staff have found that at least 10 children have died after and because of receiving COVID-19 vaccination. These deaths are related to vaccination (likely/probable/possible attribution made by staff). That number is certainly an underestimate due to underreporting, and inherent bias in attribution.

This statistic is based on an initial analysis of 96 deaths in children who received COVID-19 vaccines. Director Prasad also wrote:

This is a profound revelation. For the first time, the US FDA will acknowledge that COVID-19 vaccines have killed American children.

c. Safety Pharmacology assessments were not performed for Pfizer and Moderna mRNA COVID-19 Vaccines

Safety pharmacology was omitted entirely for both products, with Pfizer citing WHO guidelines for vaccines from 2005 as justification.

Per **ICH S6(R1)** – *Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals*, dedicated “safety pharmacology studies” are not routinely required for vaccines, unless the vaccine contains a novel active substance, new excipient, or delivery system with potential systemic pharmacologic activity. Otherwise, repeat-dose toxicity and local tolerance studies (often in one relevant animal species) are considered sufficient. However, vaccine preclinical safety evaluation must still demonstrate absence of undue toxicity or adverse physiological effects — and this is part of the nonclinical section of the Biologics License Application (BLA) under 21 CFR 601.2 and 21 CFR 600.3(p).

In other words, if a vaccine's components (e.g., adjuvants, delivery platforms, genetic vectors) could interact with physiological systems (CNS, cardiovascular, respiratory, etc.), then focused safety pharmacology is warranted. Biodistribution studies are conducted in part to determine the

⁸⁵ Vinay Prasad MD MPH, *Subject: Deaths in children due to COVID-19 vaccines and CBER's path forward* (November 2025)

systemic exposure effects. For both Pfizer and Moderna's products, the biodistribution studies have demonstrated distribution and accumulation of the product in major organ systems, including the heart and cardiovascular system. This and the fact that the products were extremely novel active substances means that, for purposes of BLA licensing, they required at least some dedicated safety pharmacology assessments before initiating human trials.

Further evidence that this should have been done before granting the BLA license is the fact that four years afterwards, on April 17, 2025, the FDA found that children and young adults were put at undue risk for serious and often permanent heart damage by these vaccines and required Pfizer and Moderna to update the label with a warning for myocarditis.⁸⁶ In the meantime, these products were mandated for college students for whom they were advertised as "safe" via inaccurate BLA labeling.

d. Moderna's SPIKEVAX biodistribution was studied in male animals only, while SPIKEVAX and MNEXSPIKE are BLA-labeled for both sexes

Moderna's only biodistribution study is officially titled "A Single Dose Intramuscular Injection Tissue Distribution Study of mRNA-1647 in Male Sprague-Dawley Rats." Thus, it fails BLA licensing standards on three counts: it was not studying the representative product, it was non-GLP, and it was not studying it for the intended clinical population.⁸⁷

For a biologic (including vaccines) intended for use in both sexes, biodistribution studies limited to males are not considered sufficient to fully characterize risk – unless the sponsor provides a scientifically justified rationale that female testing is not relevant or feasible. FDA and ICH guidance explicitly expect that both sexes are evaluated when the product is intended for both. Per 21 CFR 312.23(a)(8), nonclinical studies must include "adequate information about pharmacological and toxicological studies of the drug in animals... sufficient to support a conclusion that it is reasonably safe to begin human trials." This means that the studies must reflect the intended clinical population (i.e. both sexes in this case).

While in some cases, the biodistribution in one of the sexes can be omitted, the sponsor must provide a robust scientific justification (e.g., "no target expression or receptor distribution differences between sexes in preclinical data"). This justification must be included in the BLA nonclinical summary.

⁸⁶ **43.1** FDA, *Safety Labeling Change Notification Letter - COVID-19 Vaccine, mRNA (COMIRNATY)* (April 17, 2025) <https://www.fda.gov/media/186581/download?attachment>
43.2 FDA, *Safety Labeling Change Notification Letter - COVID-19 Vaccine, mRNA (SPIKEVAX)* (April 17, 2025) <https://www.fda.gov/media/186580/download?attachment>

⁸⁷ Ibid. Footnote 34 p. 3-671

There was no justification provided by Moderna for excluding female animals from the biodistribution study, and none exists. Pfizer's study was conducted in both male and female rats and demonstrated distribution and accumulation of the LNPs in the ovaries, indicating potentially serious reproductive toxicity risk. The risk was later confirmed by scientific peer-reviewed studies.⁸⁸

e. Statistically significant increase in fetal abnormalities was found in Moderna's DART study

In a FOIA production,⁸⁹ the full report for the study was not included and indicated it is still pending as of 2022. Safety assessments in the study appear to be very limited, however, the following findings were described in the summary.

In the rat pups, the following skeletal malformations were observed:

In the F1 generation [rat pups], there were no mRNA-1273-related effects or changes in the following parameters: mortality, body weight, clinical observations, macroscopic observations, gross pathology, external or visceral malformations or variations, skeletal malformations, and mean number of ossification sites per fetus per litter. mRNA-1273-related variations in skeletal examination included statistically significant increases in the number of F1 rats with 1 or more wavy ribs and 1 or more rib nodules. Wavy ribs appeared in 6 fetuses and 4 litters with a fetal prevalence of 4.03% and a litter prevalence of 18.2%. Rib nodules appeared in 5 of those 6 fetuses.

Statistically significant increases of skeletal abnormalities constitute a serious signal of risk, requiring additional studies for exclusion/characterization of this risk. To date, the BLA label for SPIKEVAX, Section 8.1 states: "Available data from published observational studies following use of mRNA COVID-19 vaccines during pregnancy do not show a risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes." Observational studies are considered low-quality scientific evidence that do not meet BLA standards.

⁸⁸ MDPI, *Impact of mRNA and Inactivated COVID-19 Vaccines on Ovarian Reserve* (March 21, 2025)

<https://www.mdpi.com/2076-393X/13/4/345>

⁸⁹ Ibid. Footnote 34 p. 692

When issuing the BLA license, the FDA obligated Moderna to complete several post-market studies, including two studies focusing on use in pregnancy:

Study mRNA-1273-P902: As per the FDA Approval Letter⁹⁰ for SPIKEVAX (Jan 31 2022) – this study is described as: “*Moderna mRNA-1273 Observational Pregnancy Outcome Study.*”

The

milestone dates for this study were listed as Final Protocol Submission: July 31 2022; Study Completion Date: September 30 2023; Final Report Submission: June 30 2024.

Study mRNA-1273-P905: The FDA Approval Letter lists this as: “Monitoring safety of Spikevax in pregnancy: an observational study using routinely collected health data in five European countries.” The milestone dates: Final Protocol Submission: November 4 2021, (completed); Study Completion Date: March 31 2023; Final Report Submission: December 31 2023.

Extensive searches conducted by the authors of this Petition could *not* locate an FDA document or Moderna public disclosure stating that the final report has been submitted or accepted by the FDA.

Non-completed post-market commitments constitute a serious violation of the BLA standard.

It is possible that Moderna completed these studies and the FDA has received the final reports; however, they are not reflected in the BLA label for SPIKEVAX. This too violates the BLA licensing standards for this product.

f. Reproductive toxicity in males was not assessed for either Pfizer’s Comirnaty (all versions) or Moderna’s SPIKEVAX and MNEXSPIKE

For both Pfizer and Moderna, the biodistribution studies demonstrated distribution and accumulation of LNPs in testes, yet no assessments of male fertility were performed. The reproductive toxicity studies (DART) for Comirnaty, SPIKEVAX, and MNEXSPIKE⁹¹ did not vaccinate the male animals prior to mating. This constitutes a major data gap, as the BLA product labels advertise this product as intended for men and women of reproductive age.

⁹⁰ FDA, *BLA Approval SPIKEVAX* (January 31, 2022)
<https://www.fda.gov/media/155815/download>

⁹¹ Moderna, *MNEXSPIKE package insert*, “Animal Data” p. 20 of 34 (August 2025)
<https://www.fda.gov/media/186738/download>

For biologics, including vaccines, evaluation of male reproductive organ toxicity is a standard component of the nonclinical safety package supporting a BLA, especially when the product is intended for use in men and women of reproductive potential.

Both the FDA and ICH guidance specify that if the biologic shows tissue distribution to reproductive organs, then specific fertility studies in male animals may be required, assessing sperm count, motility, morphology, mating success and fertility index, testicular weight, and histology. These are typically separate studies or add-ons to repeat-dose toxicity studies.

ICH S6(R1), §5.2.3: “When reproductive organs are affected in toxicity studies, or there is a plausible mechanism for such an effect, further specific fertility studies should be considered.”

For gene- or mRNA-based biologics, the FDA Guidance (2020): Nonclinical Biodistribution for Gene Therapy Products states that “Sponsors should evaluate distribution to gonadal tissues and consider potential effects on germline transmission.”

3. Human studies of all Pfizer and Moderna COVID-19 mRNA vaccines utilized non-validated clinical assays for primary efficacy endpoints

Both Pfizer’s and Moderna’s pivotal studies in humans utilize unvalidated assays for primary efficacy endpoints. Specifically, “Summary Basis for Regulatory Action” document for MNEXSPIKE shows that “RT-qPCR Assay by [redacted] for the Quantification of SARS-CoV-2 RNA [...] is an FDA Emergency Use Authorized In Vitro Diagnostic test for the qualitative detection of SARS CoV-2 nucleic acid in nasal and nasopharyngeal swabs from infected people.”⁹² For Comirnaty, “Summary Basis for Regulatory Action” document states that “Two clinical diagnostic assays (Cepheid Xpert Xpress RT-PCR assay for the detection of SARS-CoV-2 in clinical specimens and Roche Elecsys Anti-SARS-CoV-2 assay for the evaluation of serostatus to SARS-CoV-2) were used to assess clinical endpoints. Both assays have received FDA authorization under EUA.”⁹³

⁹²FDA, *Summary Basis for Regulatory Action* (MNEXSPIKE) (Section 6 p. 17 of 34) (May 30, 2025) <https://www.fda.gov/media/187164/download?attachment>

⁹³FDA, *Summary Basis for Regulatory Action* (November 8, 2021) (Comirnaty p. 9) <https://www.fda.gov/media/151733/download?attachment>

FDA's own nonclinical/clinical assay-validation guidances⁹⁴ highlight the need that before a BLA (or pivotal trial), all assays should be “fully validated and demonstrated to be suitable for their intended purpose.” Unvalidated (or partially validated/qualified) assays can be scientifically useful, especially in hypothesis-generating or mechanistic studies – but they are not suitable for primary endpoint for approval-level claims, efficacy demonstrations, or lot release for biologics.

Use of unvalidated assays for primary endpoints is unacceptable for BLA licensing due to potentially unreliable/non-reproducible results, uncertain clinical meaning, and false-positive and false-negative results can be deemed to be valid findings.

According to the relevant statutes and the FDA's own regulatory guidance,⁹⁵ the FDA may refuse to accept study results as “adequate and well controlled,” which are required for approval. 21 CFR standards for clinical trials and for biologics manufacturing expect reliable, validated measurements. Specifically, the statute establishing the legal standard of “adequate and well-controlled investigations” (21 U.S.C. § 355 (FD&C Act) – New drugs) states that “As used in this subsection . . . the term ‘substantial evidence’ means evidence consisting of adequate and well-controlled investigations, including clinical investigations, . . . on the basis of which it could fairly and responsibly be concluded . . . that the drug will have the effect it purports or is represented to have”

FDA may refuse to approve an NDA if there is a “lack of substantial evidence consisting of adequate and well-controlled investigations . . . that the drug product will have the effect it purports” (See 21 CFR § 314.125, and 21 CFR § 601.2)

4. Currently available BLA mRNA vaccines are EUA vaccines in disguise

As discussed above, non-investigational EUA countermeasures, including vaccines are not required to adhere to BLA standards, including, but not limited to: § 610.1 Tests prior to release of each lot or product; § 610.10 Potency; § 610.11 General safety; § 610.12 Sterility; § 610.13 Purity; § 610.14 Identity; § 610.9 Equivalent methods and processes; Product recall 42 U.S.C. § 262(d)(1), and Misbranding 21 U.S.C. § 352.

⁹⁴ FDA, *FDA CBER OTP Town Hall: Cell Therapy CMC Readiness for Late-Stage INDs* (September 5, 2024) <https://www.fda.gov/media/183285/download>

⁹⁵ FDA, *Bioanalytical Method Validation Guidance for Industry* (May 2018) <https://www.fda.gov/files/drugs/published/Bioanalytical-Method-Validation-Guidance-for-Industry.pdf>

a. FDA Did not Follow BLA Regulatory Standards

Under [42 U.S.C. § 262](#) – Regulation of biological products law, FDA can (only) license biologics that meet (purity, potency, safety, efficacy, manufacturing compliance and labeling disclosure/marketing compliance, and other applicable legal standards) requirements (ex. mfr, ingredients, disclosure, advertising, warnings, etc.) for investigational products, as discussed in this Petition. Products that reach consumers as EUA countermeasures under a declared emergency cannot satisfy BLA labeling standards retroactively, no matter how widely they have been distributed for emergency use. Full BLA licensing requires end-to-end, start-to-finish compliance with BLA standards. The BLA law is clear.

Therefore, the FDA must withdraw licensure for lack of purity, potency, safety, efficacy, manufacturing compliance and labeling disclosure/marketing compliance, and other applicable legal standards violations.

In addition, manufacturers' liability typically induces the manufacturer to remedy issues even without FDA enforcement actions. The fact that the HHS and the United States Government shield manufacturers under the ongoing PREP Act declaration for COVID-19 emergency countermeasures adds to the unenforceability of expected consumer protections. Nondisclosure to the public of the numerous BLA violations and non-enforcement of the pharmaceutical law discussed in this Petition compound the injuries and harm attributable to the COVID-19 mRNA shots.

b. By law, vaccines that were developed and produced under EUA standards cannot retroactively satisfy BLA standards

The Northern District Court in Florida held: "FDA licensure does not retroactively apply to vials shipped before BLA approval." "[V]accines produced after August 23[, 2021] in unapproved facilities – remain product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act." The District Court continued, "Indeed, the Summary Basis for Regulatory Action lists a redacted excipient for BLA-approved Comirnaty that does not appear on the ingredient list in the EUA letter." The Court cited the Supreme Court's holding in [Generix](#); "two products with the same active ingredients were nonetheless not the same 'drug' under the FDCA where the district court had found that their different excipients created a reasonable possibility that the unlicensed drug was 'less safe and effective' than the licensed one." *Doe v. Austin*, 572 F. Supp. 3d 1224 (November 7, 2022)

The N.D. Fla., Court also found, "A fully approved FDA-compliant vaccine is not the same as its EUA version. There are restrictions on the manner and location of FDA-approved vaccines, for example, that do not apply to EUA products, which have more relaxed manufacturing specifications. See, e.g., 21 C.F.R. §§ 600.11, 600.20-.21." *Coker v. Austin*, 2022 U.S. Dist. LEXIS 240820, *13 (Nov. 8, 2022).

c. *Clinical trials were not conducted to satisfy BLA requirements*

According to the CDC:⁹⁶

Before vaccines are made available to people in real-world settings, FDA assesses the findings from clinical trials. Initially, they determined that [COVID-19 vaccines](#) met FDA's safety and effectiveness standards and granted those vaccines [Emergency Use Authorizations](#) (EUAs). The EUAs allowed the vaccines to be quickly distributed for use while maintaining the same high safety standards required for all vaccines. Learn more in this [video about EUAs](#).

FDA has granted full approval for some COVID-19 vaccines. Before granting approval, FDA reviewed evidence that built on the data and information submitted to support the EUA. This included:

- preclinical and clinical trial data and information,
- details of the manufacturing process,
- vaccine testing results to ensure vaccine quality, and
- inspections of the sites where the vaccine is made.

According to the FDA:

The EUA authority is separate and distinct from use of a medical product under an investigational application

....with regard to pre-EUA activities, an EUA is not a substitute for sponsor efforts to develop the product toward approval, including conducting clinical trials designed to determine whether the product is safe and effective for its intended use. When appropriate, FDA encourages sponsors to design and propose appropriately controlled clinical trials that could be conducted during the emergency response either to run in parallel with an EUA or instead of an EUA.

⁹⁶ CDC, *COVID-19 Vaccine Basics - Authorization or Approval* (September 3, 2024)

<https://www.cdc.gov/covid/vaccines/how-they-work.html#:~:text=Before%20vaccines%20are,vaccine%20is%20made>

The EUA authority is separate and distinct from use of a medical product under an investigational application (i.e., Investigational New Drug Application (IND)).⁹⁷

During a Vaccines and Related Biological Products Advisory Committee (“VRBPAC”) meeting, the transcript⁹⁸ reveals testimony that informed consent was explicitly waived/abandoned by Operation Warp Speed in October 2020. Without IRB and informed consent enforcement, and in accordance with the EUA pathway, Pfizer and Moderna Phase 3 “studies” completed by December 2020 were not legal investigational clinical trials.

Testimony by Marion Gruber, Ph.D., formerly of the FDA, explained: “Use of an investigational COVID-19 vaccine under an EUA is not subject to informed consent requirements.” “Under EUA, it is your choice to receive or not receive the vaccine.”⁹⁹ This was admitted in 2021 during the time when only EUA versions of the product were being shipped in the United States.

Doran Fink (Operation Warp Speed (“OWS”)) also testified that the COVID-19 vaccines were not going to utilize the investigational regulatory pathways. Specifically, responding to the question whether OWS considered using the Expanded Access Use (EAU) pathway, Fink replied: “So among many other things, those regulations require use of an institutional review board and also obtaining informed consent from recipients of the investigational vaccine according to regulations for clinical investigations -- research use of investigational vaccines. And so operationally speaking, an expanded access protocol would add some complexity, and that is why Emergency Use Authorization is being considered primarily as the mechanism for addressing the public health emergency that has been declared.”¹⁰⁰ OWS was not going to use an investigational pathway and instead would utilize the non-investigational EUA pathway, citing the desire of OWS not to be bound by the requirements of the IRB and informed consent.

[21 U.S. Code § 360bbb-3\(k\)](#) *Relation to other provisions*, confirms:

⁹⁷ FDA, *Emergency Use Authorization of Medical Products and Related Authorities Guidance for Industry and Other Stakeholders* (January 2017) (see p. 30 Footnote 35)

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities>

⁹⁸ FDA, *FOOD AND DRUG ADMINISTRATION (FDA) Center for Biologics Evaluation and Research (CBER) 161st Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting transcript* (October 22, 2020) <https://www.fda.gov/media/143982/download>,

⁹⁹ *Ibid.* at p. 36

¹⁰⁰ *Ibid.* at p. 203-204

If a [product](#) is the subject of an authorization under this section, the use of such [product](#) within the scope of the authorization shall not be considered to constitute a clinical investigation for purposes of section [355\(i\)](#), [360b\(j\)](#), or [360j\(g\)](#) of this title or any other provision of this chapter or section 351 of the [Public Health Service Act](#) [[42 U.S.C. 262](#)].

Thus, the clinical trials for COVID-19 vaccines were not subject to IRB review and did not undergo clinical trials sufficient to satisfy the statutory BLA requirements.

C. Conclusion to Statement of Grounds

The FDA's mission is "protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products...."¹⁰¹ President Roosevelt's signing of the FD&C Act closed many safety and efficacy loopholes and improved the landscape of consumer protection forever.¹⁰²

After the devastation of Thalidomide, President John F. Kennedy signed into law landmark legislation that established the scientific framework used today by the FDA that "required drug manufacturers to prove scientifically that a medication was not only safe, but effective."¹⁰³ The 1962 Kefauver-Harris amendment set in motion regulatory standards for biologics licensure that require proven efficacy "to ensure that consumers will not be the victims of unsafe and ineffective medications."

The FDA published proposed procedures for the review of safety, effectiveness, and labeling of biological products in the Federal Register on August 18, 1972. The preamble stated, "The importance to the American public of safe and effective vaccines...and other biological products cannot be understated."¹⁰⁴ These historic advances require reflection.

Biologics, as with all drugs and devices, must have adequate directions for use and be proven safe and effective before FDA approval and licensure. The FDA erred with the anthrax vaccine,

¹⁰¹ FDA, *What We Do* (November 21, 2023) <https://www.fda.gov/about-fda/what-we-do#mission>

¹⁰² FDA, *80 Years of the Federal Food, Drug, and Cosmetic Act* (Nov. 7, 2018), <https://www.fda.gov/about-fda/fda-history-exhibits/80-years-federal-food-drug-and-cosmetic-act>

¹⁰³ FDA, *Kefauver-Harris Amendments Revolutionized Drug Development* (Oct. 9, 2012), https://www.gvsu.edu/cms4/asset/F51281F0-00AF-E25A-5BF632E8D4A243C7/kefauver-harris_amendments.fda.thalidomide.pdf

¹⁰⁴ HHS, FDA, *Biological Products March 1936-March 1978*, (August 18, 1972) Preamble, p. 56, [37 Fed. Reg. 16679](#)

and it took a Citizen Petition¹⁰⁵ and a federal court decision to make it comply with the FD&C Act.¹⁰⁶ At other times, the FDA has upheld its mission to make tough regulatory rulings, as the Supreme Court has acknowledged.¹⁰⁷ With this Petition, we look forward to the FDA's appropriate, tough regulatory action to remove COVID-19 mRNA vaccine licensure due to FDA's failure to follow federal law and its own regulatory guidance for BLA products.

We ask the FDA to be ever cognizant of its longstanding, statutory mission and duty to protect the public health and to ensure that the American public receives only safe and effective vaccines. Most Americans are not aware of the strict compliance requirements for licensed (BLA) COVID-19 vaccines and the numerous violations of the BLA standards that are currently allowed for the marketed COVID-19 vaccines, as described in this Petition. They do not know that the FDA has fully approved these vaccines as safe and effective under the FD&C Act when they do not meet licensed (BLA) standards. Americans are unaware that the FDA, even though it is responsible for protecting public health, has failed to enforce the law. Reversing these licensures or granting EUA status is imperative.

Acting on this Citizen Petition will enhance the FDA's credibility with the public. Given the obvious safety, effectiveness, labeling, and branding concerns over mRNA COVID-19 vaccines detailed above, along with anticipated comments on this docket, we respectfully appeal to the FDA to implement the actions requested in this Citizen Petition.

III. ENVIRONMENTAL IMPACT

The undersigned hereby state that the relief requested in this Petition will have no environmental impact, and therefore an environmental assessment is not required under 21 C.F.R. §§ 25.30 and 25.31.

IV. ECONOMIC IMPACT

¹⁰⁵ **62.1** *Dingle/Rempfer Citizen Petition 01P-0471/CPI* (October 12, 2001)

<https://img1.wsimg.com/blobby/go/4fa7f468-a250-4088-926e-3c56a998df1f/downloads/citizen%20petition%20ava%20rempfer%20dingle.pdf?ver=1620969217312>,

62.2 HHS, Response (August 8, 2002) https://downloads.regulations.gov/FDA-2001-P-0119-0003/attachment_1.pdf.

¹⁰⁶ *Doe # 1 v. Rumsfeld*, 297 F. Supp. 2d 119, 135 Order

¹⁰⁷ U.S. Reports: *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609 (1972), <https://tile.loc.gov/storage-services/service/l1/usrep/usrep412/usrep412609/usrep412609.pdf>.

Economic impact information will be submitted upon request of the Acting Commissioner.

V. CERTIFICATION

The undersigned certify that, to their best knowledge and belief, this Petition includes all information and views on which the Petition relies, and that it includes representative data and/or information known to the Petitioners that are unfavorable to the Petition. Further, the undersigned certify that they have taken reasonable steps to ensure that any representative data and or information which are unfavorable to this petition were disclosed to them.

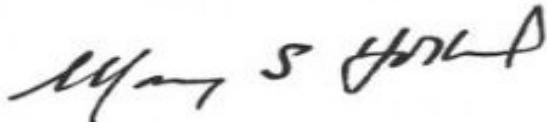
They further certify that the information upon which they have based this action requested herein first became known to the parties on or about the following date: December 2020.

The undersigned do not expect to receive payments, including cash and other forms of consideration, to file this information or its contents.

We verify under penalty of perjury that the foregoing is true and correct as of the date of this submission of this petition.

December 8, 2025

Sincerely,

A handwritten signature in black ink, appearing to read "Mary S. Holland".

**Mary S. Holland, Esq.,
Chief Executive Officer**

A handwritten signature in black ink, appearing to read "Brian S. Hooker".

**Brian S. Hooker, Ph.D.,
Chief Science Officer**

A handwritten signature in black ink, appearing to read "Kim Mack Rosenberg".

**Kim Mack Rosenberg,
CHD General Counsel**

A handwritten signature in blue ink, appearing to read "Ray L. Flores II".

**Ray L. Flores II,
Senior Outside Counsel**