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Office of the Secretary
Health and Human Services
200 Independence Avenue, S.W. Washington, DC 20201

RE: Inclusion of COVID-19 Investigational Drugs on CDC 2024-25 Vaccine Immunization Schedule

Dear Secretary Kennedy:

The Centers for Disease Control and Prevention (CDC) included the Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine investigational new drugs (IND) within the latest CDC Vaccine Immunization Schedule (Schedule). The inclusion of unlicensed drugs in the Schedule is without precedent and lacks lawful authority.

The Schedule is published after the Advisory Committee on Immunization Practices (ACIP) finalizes its annual recommendations. The ACIP is relegated to recommending licensed vaccines within the meaning of 21 U.S.C. § 355. The ACIP derives its authority, in part, from the Social Security Act § 1928,[1] the Cures Act § 309,[2] and the Charter of the Advisory Committee on Immunization Practices.[3]

Notably, the ACIP makes recommendations, but it is the CDC Director's prerogative to adopt or reject the committee's recommendations. The Schedule provides a structured reference for medical providers on the vaccine dosing schedules and recommended ages, and it impacts several federally funded programs, thus carrying national significance within the medical and legal communities.

The Schedule is automatically adopted by the Vaccines for Children program (42 U.S.C. § 1396s), which provides licensed vaccines at no cost to eligible children. 42 U.S.C. § 300gg-13 requires the Schedule to be included in group health insurance plans. The Schedule is included in the Immigration and Nationality Act (8 U.S.C. § 1182), which makes certain foreign nationals inadmissible if they have not completed the schedule. The Schedule is included in the Vaccine Injury Compensation Program (VICP) (42 U.S.C. § 300aa-14). No federal agency, department, or military can subject individuals to investigational drugs by valid acts of the U.S. Congress. Therefore, including investigational drugs and presenting them as licensed with a legal indication, the Schedule creates liability for your office and the U.S. Government.

The Pfizer-BioNTech and Moderna INDs were purchased by the United States Government (USG) and distributed within the U.S. through the CDC COVID-19 Vaccination program under federally funded research protocols.[4] These drugs are subject to the CDC's Federal Wide Assurance (FWA00001413) agreement, which requires the CDC to ensure that no person is pressured to use the INDs nor punished for such refusal.

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[1] https://www.ssa.gov/OP_Home/ssact/title19/1928.htm#ftn358; the SSA Act requires only licensed vaccines to be considered for federal programs.

[2] https://www.congress.gov/114/statute/STATUTE-130/STATUTE-130-Pg1033.pdf; § 3091 (c)(2) states any "vaccines that" "could be used in a public health emergency." This requires licensure of a drug as a vaccine and it does not extend to unlicensed drugs.

[3] https://www.cdc.gov/acip/downloads/acip-charter.pdf; the charter states that one of the committee's duties is to provide "Guidance for use of unlicensed vaccines may be developed if circumstances warrant." However, establishing "guidance" for other purposes does not grant the committee authority to recommend unlicensed drugs in the Schedule.

[4] 45 C.F.R. § 46.101 requires adherence by all federal agencies, departments, and the military, and every appropriated dollar must comply with 45 C.F.R. § 46.116 as noted in § 46.122.

Additionally, the HHS Secretary only introduced the drugs into commerce for emergency use (21 U.S.C. 360bbb-3). Those programs require strictly voluntary participation, requiring providers to inform potential recipients of the potential risks, benefits, and alternatives and ensure awareness of their right to accept or refuse, which duty the Secretary delegated first to a state's health agency and then to whomever the state recruited to help it administer the drugs.

When an individual accepts the Schedule's INDs via injection into their body, they volunteer as human subjects in federally funded research activities. Individuals willfully surrender their private identifiable and health information to unknown persons for collecting, monitoring, and studying for unknown purposes. They also agree to assume more than minimal risk to their safety and health. (45 CFR 46.102(j)).

Moreover, individuals must surrender their Fifth and Fourteenth Amendment due process rights to judicial relief if injured by the drugs or their administration because they are currently listed as covered countermeasures under the PREP Act—the U.S. or other governments cannot condition public benefits (e.g., education, unemployment, public employment, etc.) on an individual relinquishing constitutional rights.[5] The inclusion of the INDs within the Schedule gives governments the false impression that these drugs are not under constitutional protections that provide potential users the explicit right to refuse without consequence.

The CDC COVID-19 Vaccination Program requires all program providers to promise to comply with "any Emergency Use Authorization (EUA)" (see CDC Provider Agreement line 12(a)). The HHS Secretary was unambiguous when issuing EUA mandating "All descriptive printed matter, advertising, and promotional material **relating to the use** of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state: 'This product **has not been approved or licensed by FDA**, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus'"[6] (emphasis added). The same statement exists for Moderna's IND.

Therefore, "legally effective informed consent" (45 CFR 46.116(a)(1)) requires the individual considering the use of any IND to consent in a knowing, voluntary, and intelligent manner. That notwithstanding, suppose individuals are misled into believing the drugs are FDA-licensed with a legal indication to safely and effectively inoculate them from a disease and not informed that they are volunteering to become human subjects in federally funded research and forfeiting their right to sue if injured. In such cases, it is legally impossible for individuals to knowingly and intelligently consent to the administration of the drugs under the required legal conditions. The lack of transparency by the CDC of the drug's legal classification establishes liability for the federal agencies under your authority.

The inclusion of unlicensed drugs within this year's Schedule is disturbing for the following reasons:

(1) The drugs are not licensed with a legal indication by the FDA nor approved for their safety and efficacy for individuals 0 through 11 years of age or immunocompromised persons. By what authority can the CDC include unlicensed drugs in the Schedule?

(2) The CDC's graphic[7] of the Schedule does not "conspicuously" or otherwise indicate that the drugs have "not been approved or licensed by FDA." This is cause for concern because the Schedule violates EUA authorization conditions and the well-established regulation that "A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." (21 C.F.R. 312.7)

(3) The CDC does not inform the public that participants must volunteer to become human subjects in

[5] "For at least a quarter-century, this Court has made clear that even though a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis that infringes his constitutionally protected interests." Perry v. Sindermann, 408 U.S. 593, 92 S.Ct. 2694, 33 L.Ed.2d 570 (1972)

[6] FDA, EUA letter to Pfizer, August 23, 2021, p. 11, letter "Y"

[7] https://www.cdc.gov/vaccines/covid-19/downloads/covid-19-immunization-schedule-ages-6months-older.pdf

federally funded research activities and that they must surrender their constitutional rights to due process if the drugs or their administration injures them.

(4) The CDC does not inform the healthcare community that the investigational drugs require providers to inform potential users that the FDA does not approve the drugs as vaccines for their intended emergency use.

(5) The CDC does not inform the public of the drugs' risks, benefits, and alternatives, nor does it inform individuals that it is their private health choice whether to participate in the drug's administration.

(6) Notably, neither Pfizer nor Moderna is required to manufacture the EUA drugs in accordance with their Biologics License Application as they do for their licensed drugs, nor are they required to maintain a specific formulation of their investigational drugs, as the word "investigational" means they can investigate by changing the formulation. How can the CDC recommend injecting into children drugs whose formulations the FDA does not approve for safety and efficacy and can change without notice while also willfully failing to notify parents that their children will become human subjects in research activities, which data Moderna and Pfizer will use for their profit? This is a morally corrupt condition.

(7) The CDC's promotion of an investigational drug as a vaccine through its Schedule raises serious legal concerns regarding potential misbranding. By presenting this drug in a manner that suggests FDA vaccine licensure, the CDC creates a misleading impression for ordinary citizens viewing their graphic. This presentation potentially conflicts with established legal precedents. Under well-settled law, when medical professionals promote drugs beyond their approved labeling with intent to mislead regarding legal indications, they violate federal misbranding statutes, as confirmed in *U.S. v. Arlen*, 947 F.2d 139 (5th Cir. 1991). (See 21 C.F.R. §201.128; 21 U.S.C. § 331) The Department of Justice regularly prosecutes misbranding as a felony offense, creating a troubling double standard. To maintain legal and ethical integrity, the CDC must ensure complete transparency in its communications about investigational drugs. CDC materials should unambiguously clarify which drugs have not received vaccine licensure as the HHS Secretary requires in each issued EUA.

Mr. Secretary, the Biden administration previously used the HHS agency to manipulate Americans out of their Constitutional, statutory, and programmatic rights to refuse INDs without consequence. They were successful, in part, due to the judicial branch of government's lack of knowledge of IND regulation and administration. My letter serves to help you restore the integrity of the HHS agency.

I recommend issuing an emergency public notice, a "Dear Health Care Provider" Letter, and internal communications to all federal departments under your authority. These communications should clarify that the Schedule includes drugs not licensed by the FDA for any legal indication and are under specific legal conditions requiring legally effective informed consent.

Please ensure that healthcare providers inform potential recipients about the risks, benefits, and alternatives of Pfizer-BioNTech and Moderna INDs. Additionally, individuals should fully understand that by participating, they assume more significant risks to their health and safety, that they must release private health information to unknown persons for unknown reasons, and that they forfeit their right to sue the manufacturer and persons administering the drug for related injuries as required under the PREP Act.

In closing, I recommend that you require the CDC to inform your office by what authority they can include unlicensed drugs and present them as having a legal indication as a vaccine in the Schedule. The Schedule should never include unlicensed investigational drugs.

With regard,
Brian Ward