UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF FLORIDA

PENSACOLA DIVISION

BRIAN WARD,	*	
	*	
Plaintiff,	*	
	*	
VERSUS	*	CIVIL ACTION 3:25cv930-TKW-ZCB
	*	
DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; FOOD AND DRUG ADMINISTRATION; and MARTIN A. MAKARY, M.D., M.P.H., in his official Capacity as Commissioner of Food and Drugs	*	
	*	
Defendants	*	

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COMPLAINT
FOR VACATUR, DECLARATORY, AND INJUNCTIVE RELIEF

GRAVAMEN OF THE CASE

1. The Secretary, acting through the FDA, issued a final rule that permits institutional review boards ("IRB") to authorize sponsors of clinical investigations to covertly conscript Plaintiff, Brian Ward, and the American people into biomedical experimental studies. The Rule permits the investigator to expose individuals to unapproved drugs, biologics, devices, and other testing articles,

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invade their body, establish secret medical records, extract biospecimens, or collect biometric data without informing them of their participation before, during, or after the study. Moreover, the Rule permits investigators to use the process of law to subject individuals to involuntary servitude. The final Rule violates the Constitution a thousand ways from Sunday.

PARTIES

2. The plaintiff, Brian Ward ("Mr. Ward"), is an individual, *sui juris*, who resides in Okaloosa County, Florida, and is a person who has been harmed by 21 C.F.R. § 50.22.

3. Mr. Ward has extensive knowledge relating to the biomedical research industry and the constitutional rights of individuals to refuse clinical investigations without incurring a penalty or losing a benefit to which they are otherwise entitled.

4. Mr. Ward asserts that the final rule allows any of the 30,000 estimated Federal Wide Assurance ("FWA") authorized entities[1] (see *infra*) to covertly subject him to clinical investigations without his legally effective informed consent. The rule has stripped him of his Constitutional rights to bodily autonomy, privacy, due process, and his right not to be subjected to involuntary servitude, while also burdening his freedom of religion.

[1] Persons authorized by the Health and Human Services to engage in biomedical and behavioral research activities funded or authorized by the United States Government, conditioned on compliance with the legally effective informed consent legal standard.

5. Defendants are United States governmental agencies and appointed officials of the United States government responsible for the challenged actions. The individual named defendants are all sued in their official capacities.

6. Defendant Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services ("Secretary"), has authority over the U.S. Department of Health and Human Services ("HHS") and its components, including the FDA, and has complete authority to establish the authorization conditions relating to the investigational use of drugs, biologics, devices, testing articles, and unapproved medical treatments.

7. Defendant Martin A. Makary, in his official capacity as Commissioner of Food and Drugs, exercises authority over the Food and Drug Administration ("FDA") ("Commissioner"), which agency has unlawfully interfered with Mr. Ward's constitutionally protected rights to refuse participation in the use of investigational drugs, biomedical experimentation, or unapproved medical treatments.

JURISDICTION AND VENUE

8. This Court has jurisdiction under 5 U.S.C. §§ 701-706, and 28 U.S.C. §§ 1331, 1346, 1361, 2201, under the U.S. Constitution, and pursuant to the equitable powers of this Court.

9. The Court is authorized to award the requested relief under 5 U.S.C. §§ 702, 706, and 28 U.S.C. §§ 1361, 2201, 2202, and pursuant to the equitable powers of this Court.

10. Venue is proper under 28 U.S.C. § 1391(e)(1)(B) because an officer of the United States in his or her official capacity, or an agency of the United States, is a Defendant, and a substantial part of the events giving rise to Plaintiff's claims occurred in this District. Venue is also proper under 28 U.S.C. § 1391(e)(1)(C) because an officer of the United States in his or her official capacity, or an agency of the United States, is a Defendant, and Mr. Ward resides in this District, and no real property is involved.

FACTUAL BACKGROUND

Legislative History of the Protection of Human Subjects

11. In 1972, the American public became aware of human rights atrocities perpetrated by the federal government's Executive Branch through what has become known as the Tuskegee Experiment, also referred to as the Tuskegee Syphilis Study, as documented in *The Tuskegee Syphilis Study*, 289 New England Journal of Medicine 730 (1973). This study involved medical researchers deliberately withholding effective treatments for syphilis to observe its impact on the subjects' anatomy. The investigators knowingly allowed approximately 100

African-American male participants to suffer until death. Additionally, 40 of their wives contracted syphilis, and 19 children were born with congenital syphilis as a result.

12. Enraged by the atrocity, Senator Edward Kennedy conducted hearings in 1973,[2] further exposing a series of abuses funded or authorized by the Executive Branch, revealing a disturbing pattern of unethical research practices. One notable example was Operation Sea-Spray, where the U.S. Navy sprayed San Francisco with a bacterial agent to study biological warfare, inadvertently harming many unsuspecting residents. Other cases included Chester M. Southam of Sloan-Kettering Institute, who injected live cancer cells into approximately 300 healthy female prisoners without their consent or knowledge, and Saul Krugman at Willowbrook State School, who deliberately infected children with viral hepatitis by feeding them extracts made from infected feces. The Atomic Energy Commission (AEC) and the Nebraska College of Medicine conducted experiments on healthy infants by injecting them with radioactive iodine to study its effects on the thyroid gland. Together, these revelations highlighted a systemic failure to protect human rights and underscored the need for stringent oversight in research. (*Id*).

[2] Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare United States Senate, titled, 'Quality of Health Care—Human Experimentation,' March 07-08, 1973

13. In 1974, Congress rewarded Senator Edward Kennedy's heroic efforts by enacting the National Research Act.[3] The Act established a commission tasked with examining "the nature and definition of informed consent in various research settings."[4] On April 18, 1979, the Commission for the Protection of Human Subjects released its findings in "The Belmont Report,"[5] a seminal document that outlined ethical principles for research involving human subjects.

14. The Belmont Report provides clarity on the "Voluntariness" of informed consent relating to investigational research practices, stating: (1) "An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable," (2) "Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially

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[3] Title II of the National Research Act, Public Law 93 - 348-July 12, 1974 https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf

[4] National Research Act Title II - PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH Part A Section 202. (a)(1)(B)(iv)

[5] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. - Belmont Report. Colorado, DC: U.S. Department of Health and Human Services, 1979

where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled."[6]

15. Acting on command from Congress under the National Research Act,[7] the Secretary promulgated regulations in 1980 to reflect the Commission's findings to end Executive Branch human rights abuses. The regulations are codified at 45 CFR part 46, subparts A through D. The statutory authority for the HHS regulations derives from 5 U.S.C. § 301; 42 U.S.C. § 300v-1(b); and 42 U.S.C. § 289. The regulatory scheme is known as the "Common Rule" within the $600 billion pharmaceutical industry.

16. The Common Rule, as informed by the Belmont Report, requires that potential research participants obtain a potential participant's "legally effective informed consent." This legal standard is constitutionally protected under the Due Process Clauses of the Fifth and Fourteenth Amendments, as recognized in *Board of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972) because the right to

[6] Belmont Report — Part C "Voluntariness." https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

[7] "The Secretary of Health, Education, and Welfare shall within 240 days of the date of the enactment of this Act promulgate such regulations as may be required to carry out section 474(a) of the Public Health Service Act." PUBLIC LAW 93-348-JULY 12, 1974 p. 353.

consent or refuse participation in unapproved medical testing or treatment is grounded in established legal principles that secure individuals' entitlement to such protections.

17. Neither the Legislative nor the Executive Branch can mandate consent unless it first confers upon the potential participant a property right to grant or withhold such consent, as noted in *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261 (1990) ("the logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment.") "Legally effective informed consent" constitutes a specific legal standard for unapproved medical products, experiments, or treatments, aligning with the ethical principles of the Belmont Report and detailed in 45 C.F.R. § 46.116 and the fundamental right to bodily autonomy recognized in *Cruzan*.[8]

18. The key distinction between informed consent and legally effective informed consent lies in the requirement that, for the latter, the individual offering participation in unapproved medical treatments or investigational articles must ensure the consent process occurs in a legally compliant environment, free from external pressures that could coerce the individual's decision to participate. Should a person be subjected to outside pressure and consent, even if given in writing, the

[8] The FDA incorporates the language of 45 CFR § 46.116 under 21 CFR § 50.20 stating, "no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject."

person offering participation has failed to obtain the individual's legally effective informed consent and is subject to liability for resulting injuries.

19. At bottom: Legally Effective Informed Consent, according to the Belmont Report and the Common Rule, can be broken down into its basic formula: (1) individuals must not come under pressure to participate in investigational research activities or unapproved medical treatments, (2) individuals freely consent in accordance to their personal health goals, and (3) the conditions of 1 and 2 are met before participation. Involving an individual in unapproved medical treatments outside of this legal standard renders the informed consent legally ineffective.

20. Research, for purposes of 45 C.F.R. Part 46, is broadly defined and "means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." (45 CFR 46.102(l)). Examples of research activities include college students studying the medical charts of patients at a local hospital to ascertain the effectiveness of a particular treatment; public health surveillance activities involving the collection of data relating to disease outbreaks; a clinical investigation to determine the safety and efficacy of a drug for purposes of marketing approval; or studying human biosamples to monitor the effects of a bacterial agent when their private

identifiable information of the individual is known or could be known through multiple sources of data.[9]

21. Should any federal entity, or persons acting on the Executive Branch's behalf, engage in research within the meaning of § 46.102(I), then that activity constitutes research "for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes." (*Id.*)

22. The federal budget, in its entirety, is subject to the Common Rule when any part of it is used to fund or authorize activities subject to the federal scheme. (45 C.F.R. § 46.122).[10] Congress has never amended this requirement for more than forty-five years, indicating its full intent regarding the subject.

23. On October 19, 1984, Congress established 10 U.S.C. § 980,[11] mandating that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless…the informed consent of the subject is obtained in advance…". Therefore, any use of DoD appropriated funding must prospectively obtain the informed consent of an individual when that funding is involved in research activities, irrespective of whether the DoD is the sponsor of the activity or not.

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[9] 45 CFR 46.102(e)(1)(ii)

[10] "Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied." 45 CFR 46.122.

[11] Public Law 98–525, the Department of Defense Authorization Act, 1985.

24. In 1992, the U.S. Senate ratified the International Covenant on Civil and Political Rights Treaty (ICCPR).[12] Article VII of the treaty states, "No one shall be subjected without his free consent to medical or scientific experimentation." *Id.* The legal definition of "experimentation" aligns with the FDA's definition under 21 C.F.R. § 312.3 "Clinical investigation," which states, "an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice." "In FDA parlance, experimental drugs that have not yet been approved for public use are deemed investigational drugs.' See 21 C.F.R. § 312.3(b)." *Abigail Alliance v. Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007).

25. To be clear, the administration of an investigational drug, biologic, or device during normal medical practice is lawfully considered an experiment for purposes of 21 U.S.C. Parts 50 & 56 and 45 C.F.R. Part 46.

26. All U.S. federal agencies, departments, military, and federal employees are subject to compliance with the Common Rule (45 C.F.R. § 46.101(a)). If any activity is exempt from the Common Rule, then that activity must still comply with the ethical principles of the Belmont Report (45 CFR §§ 46.101(c),(i)).

[12] Treaty Document 95-20, International Covenant on Civil and Political Rights, Ex. E, 95th Cong., 2d Sess. (1978). The Treaty came into force on September 8, 1992, for the U.S. The treaty is not self-executing under the terms of the Senate.

27. In 2001, the Executive Branch, under a lawful requirement (45 C.F.R. § 46.101(a)) to obtain an individual's legally effective informed consent,[13] including ensuring that persons acting on its behalf complied with the legal standard, established the FWA program.

28. The FWA program contractually obligates individuals or entities involved in the administration or use of federally funded or authorized investigational drugs, biologics, or devices to provide written assurance[14] to the Secretary that they will not pressure anyone into participating in federally funded unapproved medical treatments or related research activities. Currently, all U.S. states, territories, counties, and approximately 30,000 entities—including most major hospitals and universities—maintain active FWA agreements with the Office for Human Research Protections (OHRP) under the authority of the U.S. Department of Health and Human Services (HHS). The OHRP, under the authority

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[13] Informed Consent FAQs | HHS.gov. HHS.gov. Published 2018. Accessed June 12, 2025.https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

[14] "All of the Institution's human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. This statement of principles may include (a) an appropriate existing code, declaration (such as the World Medical Association's Declaration of Helsinki), or statement of ethical principles (such as the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research), or (b) a statement formulated by the institution itself." Office. FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS. HHS.gov. Published November 30, 2010. Accessed June 2, 2025. https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html

of the Assistant Secretary for Health, is solely responsible for ensuring that no individual is subjected[15] to investigational products or procedures without obtaining their legally effective informed consent.

29. No person may possess or administer an investigational medical treatment, nor conduct a clinical investigation, without being covered under the FWA program.

Judicial Precedent

30. The Supreme Court has long held that the right to refuse medical treatment or testing articles is a fundamental right protected by the Due Process Clause.

31. *Union Pacific Railway Co. v. Botsford*, 141 U.S. 250 (1891) ("[n]o right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others unless by clear and unquestionable authority of law").

32. The Supreme Court had well-established that the right to refuse medical treatment is a fundamental right: *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 273 (1990) ("On balance, the right to self-determination ordinarily outweighs any countervailing state interests, and competent persons

[15] Black's Law Dictionary (11th ed. 2019), means "to expose to liability, penalty, or the like."

generally are permitted to refuse medical treatment, even at the risk of death. Most of the cases that have held otherwise, unless they involved the interest in protecting innocent third parties, have concerned the patient's competency to make a rational and considered choice."); *Washington v. Glucksberg*, 521 U.S. 702 (1997 ("the right assumed in *Cruzan*, however, was not simply deduced from abstract concepts of personal autonomy. Given the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment, our assumption was entirely consistent with this Nation's history and constitutional traditions."); *Albright v. Oliver*, 510 U.S. 266, 272 (1994) ("[t]he protections of substantive due process have for the most part been accorded to matters relating to marriage, family, procreation, and the right to bodily integrity.").

33. The Supreme Court noted in *Cruzan, supra*, that "The informed consent doctrine has become firmly entrenched in American tort law" and "the logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment" because "a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages," (citing to *Schloendorff v. Society of New York Hospital,* 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914)).

34. Judge Sullivan of the D.C. Circuit, when vacating a Department of Defense mandate requiring civilians and service members to inject an investigational anthrax drug stated that "The Court is persuaded that the right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate." *Doe v. Rumsfeld* 341 F. Supp. 2d 1 (D.D.C. 2004).

35. The Supreme Court affirmed the right of individuals to be free from unwanted governmental intrusion, as established in *Griswold v. Connecticut*, 381 U.S. 479, which denies the FDA authority to promulgate a regulation allowing governments or persons acting under its authority to invade the bodily autonomy rights of individuals.

Fundamental Right

36. The right to refuse unapproved medical treatments and experimental clinical investigations is a fundamental right that is both "deeply rooted" in our nation's traditions and "implicit in the concept of ordered liberty," reaching a status so fundamental that "neither liberty nor justice would exist if [it was] sacrificed." *Washington v. Glucksberg*, 521 U.S. 702 (1997).

37. In addition to judicial precedent, federal programs, treaties, statutes, and regulations previously discussed, all States and Territories have agreed to

comply with 45 C.F.R. Part 46 and the Belmont Report's ethical guidelines through the FWA program. The totality of the federal and military budgets must comply with the legally effective informed consent requirement. (45 C.F.R. § 46.122; 10 U.S.C. § 980) Moreover, although the Common Rule is required of the entirety of the federal government (45 C.F.R. § 46.101(a)), the principle is directly incorporated within the regulatory framework of most of the USG's agencies: 22 C.F.R. Part 225 (Agency for International Development); 7 C.F.R. Part 1c (Dept. of Agriculture); 28 C.F.R. Part 46 (Dept. of Prisons); EO 12333, EO 13284, EO 13555, EO 13470 (Central Intelligence Agency); 15 C.F.R. Part 27 (Dept. of Commerce); 16 C.F.R. Part 1028 (Dept. of Product Safety Commission); 32 C.F.R. Part 219 (Dept. of Defense); 34 C.F.R. Part 97 (Dept. of Education); 10 C.F.R. Part 745 (Dept. of Energy); 40 C.F.R. Part 26 (Environmental Protection Agency); 28 C.F.R. Part 46 (Federal Bureau of Investigation); 45 C.F.R. Part 46 (Health and Human Services); 6 C.F.R. Part 46 (Dept. of Homeland Security); 24 C.F.R. Part 60 (Dept. of Housing and Urban Development); 28 C.F.R. Part 46 (Office of Justice Programs); 29 C.F.R. Part 21 (Dept. of Labor); 14 C.F.R. Part 1230 (National Aeronautics and Space Administration); 45 C.F.R. Part 690 (National Science Foundation); 20 C.F.R. Part 431 (Social Security Information); 49 C.F.R. Part 11 (Dept. of Transportation); 38 C.F.R. Part 16 (Dept. of Veteran Affairs); 42 C.F.R. Part 50 (Public Services Act-sterilization of persons in federally assisted

family planning projects); 48 C.F.R. Parts 297, 235, 252 (Defense Federal Acquisition Regulation Supplement—DFARS Case 2007-D008); DoDI 3216.02 (DoD: Research Integrity and Misconduct); DoDI 6200.02 (DoD: IND regulation for military and civilian use); DoDD 5400.11-R (DoD Privacy Program); AR 70-25 (U.S. Army: Research Protocols); ALARACT 031/2008, DTG 141557Z Feb 08 (Army Human Subjects Protection Requirements); HQ MRDC IRB Policies and Procedures (U.S. Army Medical Research and Development Command which is responsible for investigational and EUA drug administration DoD-wide).

38. Moreover, the legally effective informed consent standard governs the Executive Branch's agreements under the International Conference on Harmonization E-6 Guidelines, the Council for International Organizations of Medical Sciences Guidelines, the Canadian Tri-Council Policy Statement, and the Indian Council of Medical Research Ethical Guidelines.

39. It is unknown whether any other property right, based on valid acts of the Legislative and Executive Branches, is more ingrained into the fabric of society than that of the legally effective informed consent standard. The right to refuse unapproved medical treatments and clinical investigations is a fundamental right protected under the Due Process Clause that cannot be taken without cause.

21st Century Cures Act ("Cures Act")

40. In 2016, Congress enacted the '21st Century Cures Act.'[16] The Act stated that the Secretary "shall, to the extent practicable and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations in accordance with subsection (b)." (Cures Act — Section 3203).

41. Additionally, Section 3204 of the Act amended 21 U.S.C. 360j(g)(3), which pertains to informed consent requirements for devices, and 21 U.S.C. 355(i)(4), which pertains to informed consent requirements for drugs.

42. 21 U.S.C. § 355(i) provides exemptions from § 355 et seq., requirements when the use of the drug is only used for investigational purposes by "experts" on the condition that the subject gives their legally effective informed consent, "except" informed consent is not required as described under subsection 21 U.S.C. § 355(i)(4)) when certain conditions are met.

43. The Act struck from *Id.* § 355(i)(4) ''except where it is not feasible or it is contrary to the best interests of such human beings'' and replaced it with ''except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings."

[16] PUBLIC LAW 114–255—DEC. 13, 2016

FDA AGENCY ACTIONS

44. The Food, Drug, and Cosmetic Act ("FDCA") establishes the FDA as an agency within HHS. 21 U.S.C. § 393. The Secretary of Health and Human Services is responsible for executing the FDCA through the Commissioner of Food and Drugs. *Id.* § 393(d).

45. Based on the Cures Act, on November 11, 2018, the agency proposed a new rule, 'Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations,"[17] to implement "a provision of the 21st Century Cures Act (Cures Act)." (*Id*). It is from this proposed 2018 rule that the FDA issued its final 2024 Rule ("Rule")[18] that is the cause of Plaintiffs' Complaint.

46. The FDA claimed that the new rule, "if finalized, would allow an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects." (*Id.*)

47. The FDA stated that it would harmonize 21 C.F.R. Part 50 with 45 C.F.R. Part 46, where applicable. Still, it publicly stated that "At this time, we are not proposing to adopt the new fifth criterion in the revised Common Rule, which

[17] 2018-24822 (83 FR 57378)
[18] 2023-27935 (88 FR 88228)

has a general compliance date of January 21, 2019; however, we invite comments on this issue."[19]

48. The "fifth criterion" under 45 C.F.R. Part 46 relates to exemption from informed consent of certain research activities when IPI is known as defined under the Common Rule. Therefore, the FDA, in its proposed rule to the public, did not consider whether to allow exemption from legally effective informed consent for clinical investigations involving IPI; it was only accepting comments for the sake of discussion.

49. However, on December 21, 2023, the agency issued its final Rule[20] that specifically allowed persons to conduct clinical investigations on unsuspecting victims even when their IPI was known. The Rule promulgated 21 C.F.R. § 50.22(c) outside of notice and comment, which promulgation is not in accordance with the Administrative Procedures Act ("APA") (5 U.S.C. § 706). The agency abused its "discretion" (§ 706(1)(A)) when issuing the final Rule by not providing stakeholders notice of a proposed rule that would subject the American people to clandestine biomedical experimentation.

50. By introducing § 50.22(c) in the final rule without explicitly proposing it earlier, the FDA arguably engaged in a form of bait-and-switch rulemaking. The agency solicited public comments on a narrower set of criteria but

[19] https://www.federalregister.gov/d/2018-24822/p-53
[20] 2023-27935 (88 FR 88228)

implemented a broader exemption, undermining transparency and public trust. While the FDA justified this addition based on comments received and alignment with the Common Rule, the lack of prior notice about this specific criterion is misleading, as accepting comments only for purposes of discussion while plainly stating it is not considering adoption violates APA standards. Stakeholders were not given an adequate opportunity to address the implications of waiving informed consent for clinical investigations involving IPI, a first for the agency and the nation, because such final implementation was not being considered. A busy professional would not typically take the time to discuss the potential implications of such exemptions when they could wait to address an actual proposed rule.

51. However, the agency failed to promulgate any regulations as required under 21 U.S.C. § 355(i)(4). The FDA, under 21 C.F.R. § 50.22, only parroted the statute's language and referred to it as regulations. However, in reality, the regulations delegate the final policymaking function to clinical investigators, violating the nondelegation doctrine.

52. Congress was unambiguous when stating that "The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts" (21 U.S.C. § 355(i)(1) on the condition "that such exemption shall be conditioned upon…[the] sponsor [] will inform any human beings to whom such drugs, or any

controls used in connection therewith, are being administered…that such drugs are being used for investigational purposes and will obtaint he consent of such humans beings…"(Id. § 355(i)(4)) "except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings." (*Id*) (emphasis added).

53. The FDA, promulgated regulations under 21 C.F.R. § 50.22 stating that "The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent…provided the IRB finds and documents the following:"

1. "The clinical investigation involves no more than minimal risk to the subjects;"
2. "The clinical investigation could not practicably be carried out without the requested waiver or alteration;"
3. "If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;"

4. "The waiver or alteration will not adversely affect the rights and welfare of the subjects; and"

5. "Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation."

54. The Secretary neglected to define "minimal risks" in relation to an individual's privacy, religious liberties, financial well-being, and due process rights. No clear criteria were established for determining when obtaining informed consent is impracticable. The Secretary failed to specify conditions under which a clinical investigation might adversely impact a subject's rights and welfare, including the nature, timing, and manner of such effects. Furthermore, no specific guidelines were provided on when or how subjects should be notified of their involvement in covert clinical investigations, nor was a minimum timeframe for such notifications established.

55. The final Rule was arbitrarily and capriciously implemented outside of APA standards because it wholly failed to "appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings" (21 U.S.C. § 355(i)(4)). Factually, the Secretary removed all safeguards by not defining meaningful boundaries, allowing IRBs to determine the meaning of the Rule, which directly implicates the subject's fundamental rights.

The Regulation (21 U.S.C. § 50.22)

56. The FDA, claiming authority under the 21st Century Cures Act,[21] violated 21 U.S.C. § 355(i)(4) when issuing the new Rule that promulgated 21 C.F.R. § 50.22 ("Regulation"), which permits Institutional Review Boards ("IRB")[22] to authorize sponsors of clinical investigations to include humans in such investigations without obtaining their legally effective informed consent,[23] even if the subject's IPI is known on the basis that the investigation only involves minimal risk. However, by knowing the IPI, the investigation will always exceed the minimal risk threshold.

57. Clinical investigation "means any experiment that involves a test article and one or more human subjects…" (21 CFR 50.3(c)).

58. Test article "means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n)." (21 CFR 50.3(j)).

59. "Drugs" as defined under 21 U.S.C. § 321(g)(1), mean, in part, articles "intended for use in the diagnosis, cure, mitigation, treatment, or

[21] PUBLIC LAW 114–255—DEC. 13, 2016
[22] 21 C.F.R. Part 56
[23] "The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent…" 21 C.F.R. § 50.22

prevention of disease in man" (*Id.*) and/or "intended to affect the structure or any function of the body of man…" (*Id.*).

60. Human subject "means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient." (21 CFR 50.3(g)).

61. 21 C.F.R. § 312.3 further clarifies "Clinical investigations," involving investigational new drugs, means "an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice." "In FDA parlance, experimental drugs that have not yet been approved for public use are deemed investigational drugs. See 21 C.F.R. § 312.3(b)." *(Abigail Alliance v. Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007)).

62. Therefore, clinical investigations under 21 C.F.R. § 50.22 involve experiments testing unapproved articles for their intended use, invasively administered to human subjects to study their impact on the body's structure or function, or the use of articles to collect biometric data and biospecimens for secondary research purposes.[24]

63. Invasive procedures, for purposes of clinical investigations, can include, but are not limited to, supplemental surgical procedures (investigations on

[24] Secondary research involves using data or biospecimens (like medical records or tissue samples) that were originally collected for something else, like clinical care or a different study. If the data is identifiable (can be linked to a person), it's considered secondary research.

persons already undergoing surgery), biopsies, endoscopic procedures, catheterization, injection, infusion, device insertion, needle aspiration, biometric/biospecimen collection, electrophysiological procedure, topical application, aerosolized inhalation, and phototriggered drug delivery systems (PDDS) (drugs that are activated or released when exposed to a specific light waveform, enabling spatiotemporal control over drug activity).

64. A clinical investigator can justify nearly any procedure under the new Rule if they piggyback on an agreed-upon procedure, such as when a patient undergoes surgery for one medical procedure but is also enrolled in an investigative procedure that involves minimal risk under the current condition and can be conducted during the surgery. Knee surgery is not considered a minimal risk, but testing an unapproved drug or device on a patient during that surgery can be subjectively argued as only involving minimal risk.

65. Minimal risk, according to the Secretary, subjectively "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 21 CFR 50.3(k).

66. In everyday life, individuals commonly experience minor injuries, such as paper cuts, bruises, burns, bumps, or scrapes. The FDA authorizes

investigators to subject individuals to similar injuries without obtaining informed consent, as long as the research meets specific exemption criteria. This regulatory framework enables such actions to be conducted lawfully, potentially protecting investigators from civil liability for harms that would otherwise constitute tortious injuries outside the research context.

67. However, no clinical investigation can ensure minimal risk when a subject's IPI is known but collected covertly, as this knowledge introduces legal, financial, religious, privacy, and other risks to the subject's welfare not accounted for during informed consent. The new Rule permits investigators to gather an individual's biometric data,[25] extract biospecimens, expose the individual to testing articles for study, and linking the IPI to this data to create a secret medical record for permanent storage and retrieval without the individual's awareness. Such exemptions are not granted under the Common Rule.

68. The Regulation provides exemptions from legally effective informed consent conditioned upon the following:

69. **§ 50.22(a)):** "The clinical investigation involves no more than minimal risk to the subjects."

[25] Examples of biometric data include DNA, voice, fingerprints, facial recognition, digital signature, hand geometry, gait, iris, retina, biological biometrics, keystroke patterns and rhythms, and other behavioral biometrics.

70. Clinical investigations must involve a human being with unapproved test articles under experimental conditions. The only means to study the effects of the test article on human anatomy is to expose humans to the article through invasive procedures to determine how the article affects the structure and function of the body. A test article has not been approved for its safety, and therefore, it involves an unknown number of potential contraindications,[26] all of which pose more than minimal risk.

71. The MalaCards Human Disease Database[27] identifies over 19,000 known diseases. The FDA regulates approximately 23,000 approved prescription drugs, 7,000 medical devices, 1,600 animal products, 753 biological products, and 100,000 tobacco products.[28] However, the number of test articles used in clinical investigations remains unknown, as does the number of studies conducted by the 30,000 entities operating under an FWA agreement, each involving an unspecified number of investigators and investigations.

72. A clinical study[29] revealed that, on average, each U.S.-licensed drug carries 4.6 absolute contraindications[30] and 1.54 relative contraindications.[31] A

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[26] "A condition which makes a particular treatment or procedure potentially inadvisable." Medical Definition of Contraindication. RxList. Published March 29, 2021.

[27] MalaCards - human disease database. Malacards.org. Published 2017. https://www.malacards.org/

[28] *FDA Regulated Products and Facilities*. Accessed June 6, 2025. https://www.fda.gov/media/182749/download

[29] Then MI, Wahram Andrikyan, Fromm MF, Maas R. Comprehensibility of Contraindications in German, UK and US Summaries of Product Characteristics/Prescribing Information—A

National Institutes of Health study reported that 54% of prescription drugs have at least one known contraindication. [32] Additionally, a study on anaphylaxis identified drugs as the leading cause of anaphylactic reactions in adults.[33] Furthermore, the CDC reports that 1 in 3 adults suffers from some allergy.[34]

73. Assessing whether an investigation exceeds minimal risk when covertly exposing a subject to a test article involving an astronomical number of potential adverse reactions relating to an unknown number of combinations of drugs, foods, diseases, and medical products is literally incalculable. While a test article or its associated invasive procedure may be deemed to pose minimal risk under current medical standards, its interaction with other factors unknown to the sponsor of the activity, because they are not involved in the informed consent process of the subject who alone can inform them of such conditions, can never be assumed to pose only minimal risk. **The lack of informed consent creates conditions exceeding minimal risk.**

Comparative Qualitative and Quantitative Analysis. *Journal of Clinical Medicine*. 2022;11(14):4167-4167. doi:https://doi.org/10.3390/jcm11144167

[30] "An absolute contraindication is a situation which makes a particular treatment or procedure absolutely inadvisable." Medical Definition of Contraindication. RxList.

[31] A relative contraindication is a condition which makes a particular treatment or procedure possibly inadvisable. (*Id.*)

[32] Blankart KE, Lichtenberg FR. Prevalence and relationship with health of off-label and contraindicated drug use in the United States: a cross-sectional study. *Journal of Pharmaceutical Policy and Practice*. 2025;18(1). doi:https://doi.org/10.1080/20523211.2025.2472221

[33] Wood RA, Camargo CA, Lieberman P, et al. Anaphylaxis in America: The prevalence and characteristics of anaphylaxis in the United States. *Journal of Allergy and Clinical Immunology*. 2013;133(2):461-467. doi:https://doi.org/10.1016/j.jaci.2013.08.016

[34] Ng A, Boersma P. Diagnosed Allergic Conditions in Adults: United States, 2021. *PubMed*. Published online December 17, 2022. doi:https://doi.org/10.15620/cdc:122809

74. Involving an individual in a testing article under these conditions means that the individual cannot, according to their knowledge, determine whether the article will pose more than minimal risk to their life, liberty, or property, nor can they convey to the investigator relevant information, as they are unaware of the invasive procedure. Therefore, the Regulation is arbitrary and capricious because the application of the Regulation, by its inherent nature, always involves more than minimal risk to the physical body (not including secondary research). The FDA "failed to present an adequate basis and explanation for" (Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29 (1983)) allowing investigators to involve individuals in invasive clinical investigations under conditions that always involve more than minimal risk without their legally effective informed consent.

75. When the FDA was pressed about allowing covert invasive procedures, it stated, "In general, we do not believe that a study involving an invasive procedure being used for research purposes would qualify as presenting no more than minimal risk to subjects."[35] (emphasis added). This statement raises several issues. First, § 50.22 only relates to "clinical investigations" as the title of the subsection denotes, which means that a human must be exposed to a test article that enters the body through an invasive process. Second, it purports that a clinical

[35] https://www.federalregister.gov/d/2023-27935/p-77

investigation, under 21 C.F.R. § 50.22, can only involve minimal-risk activities, which is false because it only addresses physical risk, not risks relating to a subject's legal, financial, or religious welfare. Third, the agency's use of "believe" introduces ambiguity, as it lacks a clear standard because it is a position that can and will evolve. The term was intended to pacify public concerns about the new Regulation, thereby undermining regulatory clarity, while providing the agency plausible deniability in future legal proceedings, as what they believed in the past regarding the Regulation can be legally changed to reflect their current beliefs. "Believe" is an ever-moving goalpost.

76. The FDA's use of "believe" to state its official position affirms that it does not know what its Regulation restricts or permit. Therefore, it must be deemed arbitrary and capricious, as it lacks an intelligible principle[36] guiding it, nor does it provide definable boundaries for persons operating under its authority.

77. However, because the Regulation allows individuals to be covertly subjected to clinical investigations when their IPI is known, minimal risk applies to more than just the risk to one's physical body; it now applies to their financial affairs, religious freedoms, medical records, property rights, and other

[36] J.W. Hampton, Jr. & Co. v. United States (1928) requires that Congress establish defined boundaries that the agency must conform to for purposes of the nondelegation doctrine. The agency must establish the boundaries of conduct among persons it intends to regulate and cannot simply parrot the wording of the statute, which shifts the responsibility to the person being regulated to make final policymaking decisions, violating the nondelegation doctrine.

considerations relating to the individual's welfare not considered under legally effective informed research activities.

78. No one can reasonably argue that biometric collection[37] poses more than minimal risk to the physical body. However, it undeniably presents more than minimal risk to an individual's legal, privacy, and personal welfare.

Religious Liberty

79. It is well-established that many testing articles rely on fetal-derived cell lines, such as HEK-293 or PER.C6, in their development, testing, and production. Similarly, porcine (i.e., pig) tissues or cell lines, such as PK-15 (derived from a pig's kidney) or porcine islet cells, are frequently utilized in the research, testing, and development of pharmaceuticals. Consequently, the Regulation contravenes 42 U.S.C. § 2000bb-1(a), the Religious Freedom Restoration Act (RFRA), by permitting federally authorized investigators to expose Orthodox Jews, who strictly adhere to kashrut, and Muslims who follow halal dietary laws, which both strictly avoid pork, to be covertly subjected to pork imbedded testing articles without their consent. The Rule unduly burdens their religious practices. Additionally, the same holds true for Christians who would not

[37] Examples of biometric data include DNA, voice, fingerprints, facial recognition, digital signature, hand geometry, gait, iris, retina, biological biometrics, keystroke patterns and rhythms, and behavioral biometrics.

desire to participate in testing articles that were infused with tissue derived from aborted human babies.

80. It is an absurd result that a healthcare practitioner can sue their employer under Title VII, because they were terminated for refusing to be involved in products that violate their faith, but under the Regulation, they can be covertly involved without the employer (i.e., acting on behalf of the sponsor) being required to inform them.

81. Additionally, the Regulation contravenes 42 USC 300a-7(d) by denying participants in clinical investigations the opportunity to choose whether to participate based on their "religious beliefs or moral convictions" (*Id*) because their involvement is undisclosed. Therefore, covert clinical investigations will always pose more than minimal risks to individuals' liberty to practice their religious faith freely.

Financial and Legal

82. Suppose an individual's health insurance policy does not cover biomedical research participation, and the covert activity injures them; this undeniable fact denotes more than minimal risk to their financial sustainability.

83. Suppose the research data, attached to the individual's IPI, is shared, sold, or stolen. Such data could implicate them in civil or criminal matters, or impact their employability or tarnish their reputation. Therefore, clinical

investigations under § 50.22 pose more than minimal risk to a person's privacy, reputation, and economic sustainability.

84. Suppose a subject is injured, but does not know the injury results from the research activity. The financial requirement to treat that injury is now placed upon the subject, violating their due process rights, which exceeds minimal risk.

85. Suppose the testing article is immunized from liability under the PREP Act (42 U.S.C. § 247d-6d) and the subject is injured involving the covered countermeasure. Even when the subject is informed that his injury derives from the covert research activity, the investigator would claim PREP Act immunity, financially ruining the subject's livelihood. Secretary Kennedy Jr. could not provide this Court with a definitive list of covered countermeasures immunized from liability due to the volume of products covered and the vague wording of amendments to the current PREP Act declaration. The threat of irreparable injury under the Rule is not hypothetical, but an ever-present danger to the American people.

86. However, the Regulation permits an IRB to approve the covert theft of a subject's Constitutional guarantees, which fact demonstrates that minimal risk activity is unattainable and such IRB approval always involves irreparable harm. *Elrod v. Burns*, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms for even minimal periods of time, unquestionably constitutes irreparable injury.");

Statharos v. N.Y. City Taxi and Limousine Comm'n, 198 F.3d 317, 322 (2d Cir.1999) ("Because plaintiffs allege deprivation a constitutional right, no separate showing of irreparable harm is necessary.") The Secretary ignored calls for a renewed definition of minimal risk[38] because covert clinical investigations involve irreparable harm.

87. **§ 50.22(b)** "The clinical investigation could not practicably be carried out without the requested waiver or alteration."

88. This provision is problematic, as it improperly authorizes public or private persons to override individuals' fundamental rights to bodily integrity. Factually, the FDA is asserting dominion over the human race to bargain as chattel under the Regulation. The FDA lacks the authority to waive informed consent requirements merely because an investigator—whether acting in the interests of pharmaceutical companies or the Executive Branch—deems such consent "impracticable." The regulation is arbitrary and capricious, as it subordinates individuals' fundamental rights to the discretionary or profit-driven motives of parties not empowered to take individuals' property rights without procedural due process. The FDA allows investigators to strip individuals of their rights if they deem it impractical to obtain informed consent, but the agency does not define the boundaries of what constitutes impracticable. Therefore, the investigator, not the

[38] https://www.federalregister.gov/d/2023-27935/p-102

agency, is the final policymaker of what is considered impracticable, in violation of 21 U.S.C. § 355(i), stating that "The Secretary shall promulgate regulations" establishing when a clinical investigation does not require informed consent, where it is not practicable, violating the nondelegation doctrine.

89. **§ 50.22(c)** "If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format."

90. As previously discussed, the FDA stated that it was not considering exemptions from legally effective informed consent when IPI is known or could be known. § 50.22(c) should not have been promulgated under the new Rule.

91. Historically, the IPI served as a barrier protecting humans from non-consensual participation in clinical investigations. Now, under the new Rule, investigators can covertly **touch** the subject with testing articles for the first time because they can proceed when the subject's IPI is known.

92. First, the IPI of subjects involved in activities exempt from 21 U.S.C. § 355 *et seq.*, obligations has always been known as the FDA requires that "Patients to whom the drug is administered will be under his [i.e. sponsor] personal supervision, or under the supervision of investigators responsible to him" (21 U.S.C. § 355 (i)(1)(B)). (emphasis added).

93. Exemptions from legally effective informed consent relating to invasive procedures historically applied to life-threatening emergency conditions or a presidential waiver relating to military service members, and they never applied to invasive investigations when the IPI of the subject was known or could be known (21 CFR 50.23).

94. Therefore, the inclusion of § 50.22(c) was specifically designed to allow clinical investigators to covertly subject humans to nonconsensual participation in a clinical investigation, violating the Due Process Clause.

95. Second, a federal agency is not constitutionally empowered to provide unfettered access to the private lives of the American citizenry through its rulemaking authority. An agency is not Congress and cannot be used by Congress to achieve a result that Congress cannot command directly (*Speiser v. Randall*, 357 U.S. 513, 526 (1958)), and Congress cannot "manipulate" the Constitution "out of existence" (*Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593- 94 (1926)) through its agencies. Specifically, this would include situations where the investigator establishes medical records and shares those records with unknown individuals, for unknown reasons, and for an unspecified duration.

96. Nothing in the Cures Act allows the FDA to promulgate regulations that permit sponsors of clinical investigations to covertly establish and collect

private health information from individuals under nonconsensual conditions, nor to attach their IPI to the research data.

97. The Regulation is also problematic because it allows investigators to attach the IPI to experimental results, including secondary research, without obtaining informed consent, which the Common Rule explicitly prohibits.[39] Therefore, neither the Cures Act nor 45 C.F.R. Part 46 provides the FDA with such rulemaking authority.

98. Suppose an individual is covertly involved in a clinical investigation where the individual's biospecimens reveal they have a medical condition, or are prone to a medical condition. Disclosure (e.g., sharing, selling, theft) of that data might reasonably damage the subject's financial standing, employability, educational advancement, or reputation. Moreover, disclosure of other research outcomes might place the individual at risk of criminal or civil liability, all of which pose more than minimal risk to the subject beyond physical risk. These conditions exist solely because the IPI can now be attached permanently to the research data, a condition not allowed by Congress or the Constitution and not considered by the FDA when promulgating the Regulation.

[39] Storage and maintenance of IPI or biospecimens of known IPI requires "broad consent" under 45 C.F.R. Part 46, which is never exempt from informed consent requirements, including secondary research uses.

99. The fundamental rationale for limiting exempt research to noninvasive activities, such as retrospective studies or public health surveillance, is to ensure that IPI is detached from research data, thereby safeguarding individuals' privacy rights. For example, if a patient is diagnosed with HIV, the physician, acting on a public health surveillance request, reports the diagnosis to the Centers for Disease Control and Prevention (CDC) without including the patient's IPI, preserving the individual's constitutional right to privacy. However, the Regulation fails to adhere to such protocols when deemed impracticable for investigators. This violates the Constitution and exceeds the agency's rulemaking authority, as Congress mandated that exemptions include "appropriate safeguards…to protect the rights, safety, and welfare of such human beings" (21 U.S.C. § 355(i)(4)). The Regulation lacks provisions to ensure these safeguards, instead enabling investigators to undermine the rights, safety, and welfare of individuals. The Rule is the clinical version of the wild west, where it empowers investigators to establish what is or is not permitted under the Regulation and thus under the Constitution, federal law, and state law.

100. **§ 50.22(d)** "The waiver or alteration will not adversely affect the rights and welfare of the subjects." The regulation is arbitrary and capricious because it is legally impossible for an investigator to achieve this result, as discussed herein. The term "adversely" is excessively vague and subjective, shaped

by the investigator's personal beliefs, moral values, financial interests, health priorities, or privacy concerns, which are unlikely to align with those of the test subject. The FDA failed to establish the boundaries defining such rights as required by Congress, and allows the investigator to become the final policymaker.

101. One cannot covertly involve an individual, their biometric data, or biospecimens in a clinical investigation without "adversely" (*Id*) affecting their rights. It is constitutionally impossible to achieve such a result.

102. Moreover, research sponsors and IRBs, lacking the expertise of constitutional or tort lawyers, are unqualified to evaluate whether their covert activities violate the rights of research subjects. These indisputable facts underscore the FDA's reckless disregard for human rights.

103. An individual holds the fundamental right to privacy, due process, freedom of religion, freedom from involuntary servitude, procedural due process, and bodily autonomy rights, of which some or all of these rights are adversely affected when involved in covert clinical investigations.

104. The FDA was warned that the Rule potentially violated the federal constitution, that would adversely impact an individual's rights, as noted by the agency stating, "One comment argues that 'invasive procedures, interventions or intrusions' into a person's 'body, cognition, or otherwise' without consent is a violation or a potential violation of the Fourth, Fifth, Eighth, and Fourteenth

Amendments."[40] The agency's misdirecting reply is breathtaking, stating, "we note that the rule does not require an IRB to waive or alter informed consent, nor does it require any entity, including a government entity, to conduct or support any research."[41]

105. The constitutional question presented to the FDA did not concern what the Regulation mandates, but rather what it permits. The agency's interpretation of the Regulation is untenable and intentionally misleading, as it suggests that the agency may authorize any conduct, no matter how egregious or contrary to constitutional protections, so long as the agency does not mandate participation. This position leads to absurd and constitutionally impermissible outcomes. Such a doctrine would allow the agency to sanction conduct that violates the Constitution, provided such unconstitutional conduct remains voluntary among the clinical investigators the agency regulates. However, this result cannot, or should not, withstand judicial review because the agency is not empowered to permit any person to violate the constitutional rights of any other person. The FDA's reply is linguistic sophistry and attempts to establish a new legal precedent, arguing that a government can permit unconstitutional conduct as long as it does not mandate it, thereby upending the well-settled Unconstitutional

[40] https://www.federalregister.gov/d/2023-27935/p-74
[41] https://www.federalregister.gov/d/2023-27935/p-76

Conditions doctrine.[42] The Regulation allows governments to take an individual's privacy, property (e.g., private health data, biospecimens, biometrics), and fundamental rights under covert conditions, and thus it permits an unconstitutional condition to exist. (See *Nollan v. California Coastal Commission*, 483 U.S. 825 (1987)).

106. At bottom, the Rule purports that the FDA holds dominion over Mr. Ward's bodily autonomy, privacy, labor, property, and agency as chattel, which it authorizes clinical investigators to covertly exploit for their interests at Mr. Ward's expense.

107. **§ 50.22(e)** "Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation."

108. This regulation is arbitrary and capricious because it fails to establish a minimum or maximum framework for investigators to comply with. The regulation is ambiguous because it does not define what it considers "appropriate," thereby allowing the investigator to become the final policymaker of the Regulation, rather than the Secretary, as required by Congress under 21 U.S.C. §

[42] The U.S. Supreme Court first used the phrase "unconstitutional condition" in *Doyle v. Continental Ins. Co.*, 94 U.S. 535, 543 (1876) (Bradley, J., dissenting) ("Though a State may have the power, if it sees fit to subject citizens to the inconvenience, of prohibiting foreign corporations from transacting business within its jurisdiction, it has no power to impose unconstitutional conditions upon their doing so.") See, *Speiser v. Randall*, 357 U.S. 513, 526 (1958); *Sherbert v. Verner*, 374 U.S. 398 (1963); *Shapiro v. Thompson*, 394 U.S. at 634.

355(i). Moreover, the sponsor of the research will never deem it appropriate to inform an injured subject that their injury resulted from covert biomedical experimentation. If the subject's IPI is stolen, when is it appropriate to inform the individual of such theft, which subjects the sponsor to liability? When does due process deem it appropriate to inform the individual of their involuntary participation in a private business activity impacting their fundamental rights? We do not know because the Secretary does not establish or define those boundaries as required by Congress.

ARGUMENT

Administrative Procedure Act and Implementing Regulations

109. The Administrative Procedure Act ("APA") provides a right to judicial review for any "person suffering legal wrong because of agency action." 5 U.S.C. § 702. The reviewing court must "hold unlawful and set aside agency action" that it finds "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; contrary to constitutional right, power, privilege, or immunity; in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or] without observance of procedure required by law . . . ." 5 U.S.C. § 706(2)(A)–(D) (cleaned up).

FACTUAL ALLEGATIONS

110. Mr. Ward possesses inviolable fundamental rights under the U.S. Constitution: (1) to refuse participation in unapproved medical treatments, clinical investigations, medical experimentation, and biologic or behavioral research; (2) to give legally effective informed consent; (3) to privacy in matters of bodily autonomy and protected health information; (4) to freely exercise his religion without government interference; and (5) to be free from involuntary servitude.

111. The FDA, through its Rule, has unconstitutionally stripped Mr. Ward of these fundamental rights without due process, leaving him vulnerable to grave physical, psychological, and constitutional injuries. This regulation exposes Mr. Ward to the unchecked power of federal agencies, including the FDA, other departments, or military branches, as well as private entities, which may conduct clinical investigations on him under the Regulation without his knowledge. Bereft of constitutional protections, Mr. Ward stands defenseless, akin to a sheep among wolves, with no recourse but to challenge the Regulation's legality and constitutionality before this Court, which has the power to restore that which the FDA stole from Mr. Ward—his fundamental constitutional guarantees.

112. Congress does not require the investigator to prospectively notify the Secretary of investigational uses of drugs.[43] The FDA does not require the investigator to inform Mr. Ward of his involvement before, during, or after involving him with experimental drugs. (21 CFR 50.22(e)). This egregious regulatory gap permits investigators to subject Mr. Ward to test articles without his legally effective informed consent, exposing him to severe risks of irreparable physical harm, including bodily injury or long-term health damage, as well as legal, financial, and psychological trauma. Moreover, should the test article incorporate tissue from aborted babies, it will violate his religious convictions, compounding the injury to his dignity and autonomy.

113. Mr. Ward has a known allergy to Formaldehyde, which is commonly utilized in the medical field in various ways, including the sterilization of medical equipment, as a preservative for biological specimens, tissue fixation in histopathology (stabilization of tissue for microscopic examination), vaccine production, and other applications. Should Mr. Ward be exposed to Formaldehyde, specifically in its aerosolized state, it would cause an adverse reaction impacting his physical body, potentially irreparable harm, leading to a loss of labor and financial stability. The inability to inform the clinical investigator of this medical condition poses a significant physical risk to Mr. Ward.

[43] "Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs." 21 U.S.C. 355(i)(4).

114. Mr. Ward has covertly been, is, or will be subjected to involuntary servitude to act as a test subject for the benefit and profit of others without compensation or an agreement to engage in such labor, which violates his rights under the Thirteenth Amendment to be free from such human rights abuse.

115. Mr. Ward has suffered concrete and ongoing injuries: the loss of his constitutional protections, the imminent threat of unauthorized medical interventions and clinical investigations, and profound emotional distress stemming from the uncertainty of when, where, or how he is being subjected to clinical investigations. He reasonably believes he has been, is currently, or will be involved in such activities without his knowledge, as investigators are not required to disclose the nature of the test articles or the scope of his involvement. This pervasive fear and lack of control over his own body, religion, and due process right to life, liberty, and property constitute a direct assault on his bodily autonomy, inflicting severe psychological harm through the loss of dignity and his fundamental rights.

116. The Regulation, 21 C.F.R. § 50.22, has inflicted, is inflicting, and will continue to inflict irreparable harm on Mr. Ward—physically through unauthorized medical interventions, emotionally through profound distress and fear, financially through potential medical or legal costs, and legally through the erosion of his constitutional rights—unless this Court intervenes. By permitting clinical

investigations without informed consent or notification, the regulation violates Mr. Ward's fundamental rights to bodily autonomy, privacy, and equal protection under the Fourteenth Amendment, exposing him to severe and ongoing injuries. Without judicial relief, Mr. Ward remains defenseless against federal agencies wielding unchecked power to subject him to experimental test articles, risking bodily harm, psychological trauma, and violations of his religious convictions.

117. At bottom, the FDA has taken ownership of Mr. Ward's person, permitting others to do unto him as they deem practicable under its authority. The FDA, through the issuance of the final Rule, has assumed an authority outside of its Constitutional and delegated powers, which conduct has, is, and will cause irreparable harm to him and the public at large.

118. Should such a regulation be permitted to erode the rights of an entire nation, history warns of dire consequences. When governments deny due process and equal protection, citizens, stripped of legal recourse, may resort to extralegal measures to secure their liberties, as seen in past societal upheavals. This Court stands as the final guardian of civil society, uniquely positioned to prevent such chaos by striking down this unconstitutional Regulation. By intervening, the Court will affirm the rule of law, protect Mr. Ward from further irreparable harm, and ensure that the nation's commitment to equal protection and bodily autonomy endures, which is of significant societal importance.

LEGAL STATEMENT

119. It has been the public health policy of the United States Government since Congress enacted the 1974 National Research Act and the Executive Branch promulgated regulations based on that Act that "Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative" (45 CFR 46.116(a)(1)) and that "A statement [be provided] that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." (*Id.* (b)(8)) (emphasis added). The Rule ensures that sponsors of clinical investigations can bypass this duty, which is designed for the protection of human subjects.

CLAIMS FOR RELIEF

COUNT ONE
5 U.S.C. § 706(2)(A)
APA Violation: Arbitrary or Capricious

120. The allegations in each of the preceding paragraphs are expressly incorporated herein as if restated in full.

121. The APA authorizes judicial review of "final" agency actions, 5 U.S.C. § 704, and requires courts to "hold unlawful and set aside any "action, findings, and conclusions found to be . . . arbitrary" or "capricious." 5 U.S.C. § 706(2)(A).

122. Agency actions are "arbitrary" or "capricious" under the APA if the agency fails to engage in "reasoned decision making." *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998) (internal quotation omitted).

123. This necessarily means that "[n]ot only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational." *Id.* More specifically, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

124. **Statutory Mandate**: Under 21 U.S.C. § 355(i)(4), the Secretary of Health and Human Services (the "Secretary") is required to promulgate regulations exempting investigational drugs from certain requirements, provided such exemptions are conditioned on obtaining informed consent unless:

a) Obtaining consent is not feasible;

b) Consent is contrary to the best interests of the subject;

c) The investigation poses only minimal risk; or

d) Appropriate safeguards are in place to protect the rights, safety, and welfare of subjects.

125. **Agency Action**: The Secretary promulgated regulations at 21 C.F.R. § 50.22, allowing waivers or alterations of informed consent requirements under certain conditions. However, these regulations are arbitrary and capricious for the following reasons:

126. **Failure to Define "Not Feasible"**: The regulation at 21 C.F.R. § 50.22(b) permits waivers when an investigation "could not practicably be carried out without the waiver" but the Secretary failed to define what constitutes "practicable" nor the boundaries of "not feasible" as required by 21 U.S.C. § 355(i)(4). The Secretary unlawfully delegated this determination to clinical investigators without establishing clear standards, contrary to Congress's mandate that the Secretary define such conditions.

127. **Failure to Define "Contrary to Best Interests"**: The Secretary failed to establish clear criteria for when obtaining informed consent is "contrary to the best interests of such human beings" under 21 U.S.C. § 355(i)(4), leaving the regulation vague and subject to arbitrary application.

128. **Failure to Define "Minimal Risk"**: The regulation at 21 C.F.R. § 50.22(a) allows waivers for investigations involving "minimal risk" but does not

define the scope of minimal risk, including risks to privacy, religious practices, constitutional protections, or financial well-being, rendering the standard impermissibly vague that will result in irreparable harm to human subjects.

129. One person commented plainly that "the vagueness of the term 'minimal risk' would precipitate misuse of the rule."[44] The concern fell upon deaf ears at the FDA.

130. The FDA stated: "We do not believe that a study involving an invasive procedure being used for research purposes would qualify as presenting no more than minimal risk to subjects." Yet, the Regulation permits waivers of informed consent for investigations exceeding the minimal risk threshold defined in 21 C.F.R. § 50.3(k), directly contradicting the FDA's own position. This inconsistency violates the statutory requirement under 21 U.S.C. § 355(i)(4) to protect subjects' rights, safety, and welfare.

131. The FDA's reliance on the term "believe" in its rationale for promulgating the Regulation demonstrates a lack of clear, objective standards, rendering it arbitrary and capricious. By stating, "We do not believe that a study involving an invasive procedure being used for research purposes would qualify as presenting no more than minimal risk to subjects," the FDA informs the public that it does not know what the Regulation permits. This ambiguity fails to provide the

[44] https://www.federalregister.gov/d/2023-27935/p-102

reasoned decision-making required by the APA, as it lacks a rational connection between the regulation and its intended protections. Federal agencies must regulate within defined boundaries, not subjective beliefs subject to change with agency leadership. The FDA's failure to establish clear criteria violates 21 U.S.C. § 355(i)(4), which mandates specific conditions for waiving informed consent. By substituting vague beliefs for objective standards relying on valid acts of Congress, the FDA, through ambiguity, assumes powers reserved for the Legislative Branch.

132. **Unauthorized Waiver of Rights**: The regulation permits waivers even when IPI is involved (21 C.F.R. § 50.22(c)), despite no statutory authority in 21 U.S.C. § 355(i)(4) or the 21st Century Cures Act to waive informed consent for invasive clinical investigations or the loss of privacy and property rights related to private health information and biospecimens. The waiver is a legal process that clinical investigators can use to take from individuals their fundamental rights to bodily autonomy, privacy, property (i.e., private health information, biospecimens, etc.), and agency without procedural due process.

133. **Failure to Define "Adverse Effects"**: The regulation at 21 C.F.R. § 50.22(d) mandates that waivers of informed consent not adversely affect subjects' rights and welfare but fails to define what constitutes an "adverse effect," rendering the standard vague and unenforceable. This ambiguity violates the APA's requirement for reasoned decision-making, as it lacks a rational basis for

ensuring subject protections. Furthermore, the regulation unlawfully delegates to investigators the authority to determine what constitutes an adverse effect, without clear criteria, thereby depriving subjects of consistent safeguards who must bear the burden of the adverse result alone.

134. **Failure to Define Notification Standards**: The regulation at 21 C.F.R. § 50.22(e) requires that subjects be provided information about their participation "whenever appropriate" but does not establish when such notification is appropriate or impose a minimum timeframe for notification, depriving subjects of meaningful protections for their rights and welfare.

Arbitrary Decision Making

135. Public comments on the Regulation urged the inclusion of more explicit "definitions or criteria descriptions" [45] to establish boundaries for investigators, ensuring compliance with human subject protection standards. The FDA disregarded ALL REQUESTS.

136. The FDA recognizes that individual factors shape informed consent decisions, stating, "individual decisions to participate in research often depend on different factors, such as the recruitment method used (Ref. 5) and health literacy (Ref. 6). Additionally, an individual's trust (or distrust) in their healthcare provider and/or in the institution conducting the research may also contribute to their

[45] https://www.federalregister.gov/d/2023-27935/p-87

willingness to participate."[46] However, and concerning, is the FDA's statement that requiring the investigator to determine if the subject might refuse participation based on such information "would be unduly burdensome" and thus they can bypass a subject's legally effective informed consent rights based on the fear that the subject might refuse. Despite acknowledging that some individuals would refuse consent under certain conditions, the FDA perversely uses this perceived fact to justify allowing investigators to covertly involve humans in clinical investigations, citing fear of nonparticipation as legal authority. This directly contravenes *Canterbury v. Spence* (464 F.2d 772, D.C. Cir. 1972), which holds, "it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie." The FDA's claimed authority to bypass informed consent on such grounds is arbitrary, capricious, and a flagrant violation of individual agency. By reducing individuals to mere objects of research—akin to chattel—the FDA's policy obliterates the foundational principles of autonomy and consent, resulting in a morally bankrupt and legally indefensible travesty that can only be described as debased madness.

137. The FDA stated that "§ 50.22(b) requires the reviewing IRB to find that the waiver or alteration will not adversely affect the rights and welfare of the

[46] https://www.federalregister.gov/d/2023-27935/p-94

subjects."[47] However, the Regulation fails to provide clear definitions, criteria, or boundaries to guide IRBs in assessing what constitutes an adverse effect on subjects' rights or welfare. This lack of clarity creates significant challenges for IRBs, as they must evaluate complex and individualized factors—such as a subject's medical conditions, religious beliefs, legal rights, or insurance coverage—without the benefit of informed consent or direct communication with the subject.

138. The FDA's assertion that "the balance between respect for persons and beneficence should come out in favor of facilitating research that satisfies the criteria in § 50.22 by permitting waiver or alteration of informed consent requirements to advance the public health" [48] undermines the core purpose of 21 C.F.R. Part 50. The regulation is designed to prioritize the protection of human subjects in unapproved medical treatments and clinical research, mandating that their safety, welfare, and rights take precedence over all other objectives, including scientific and public health considerations. By advocating for a waiver or alteration of informed consent to expedite research, the FDA's stance arbitrarily **shifts** the focus of the Regulation from safeguarding individuals to promoting perceived scientific progress. The excuse of "scientific progress" is what led to untold hundreds of thousands of Americans being subjected to human rights abuses by the

[47] https://www.federalregister.gov/d/2018-24822/p-63
[48] https://www.federalregister.gov/d/2023-27935/p-72

Executive Branch and the murder of the *Tuskegee* participants. The FDA attempts to bypass protections that Senator Kennedy fought hard to establish through regulatory powers, under *ultra vires* acts.

139. The FDA's approach to the Regulation is flawed, as it overlooks the inherent risks of entrusting human safety and rights to decision-makers whose judgments will be swayed by personal interests, financial incentives, or institutional pressures. The purpose of 21 C.F.R. Part 50 demands unwavering commitment to protecting research subjects, not compromising their autonomy for potential public health gains and corporate profits. The FDA's Rule is thus untenable, as it conflicts with the foundational ethical obligation to prioritize human dignity and welfare in medical research.

140. The public comments focused on the need for the new rule to address concerns of dignity, constitutional protections, definable boundaries, examples of permitted and prohibited research, safety, privacy, and the loss of bodily autonomy rights, which the FDA refused to provide a logical basis for not effectively addressing. The Regulation is arbitrary and capricious.

141. Most concerning is that the Rule permits clinical investigations on large populations without informed consent. In 1996, the U.S. Army conducted biological experiments in New York City's Seventh and Eighth Avenue subway lines, releasing 87 trillion Bacillus globigii organisms to study their impact on

large groups (Cole, L. A. (1990). Clouds of Secrecy: The Army's Germ Warfare Tests Over Populated Areas). Initially deemed harmless, these bacteria were later classified as disease-causing pathogens.

142. Unlike 45 C.F.R. Part 46, the Rule enables egregious overreach: a mayor could authorize clinical investigations of an entire city workforce for a sponsor, a school could mandate student biometric data collection, and a hospital could impose unapproved medical treatments on patients or collect and sequence the DNA of each newborn. The use of this Rule to undermine the Constitutional guarantees of privacy cannot be overstated. This Rule constitutes a profound and unprecedented assault on the constitutional rights of Americans, threatening fundamental liberties on an unparalleled scale.

143. The Rule is overly broad, vague, and prone to abuse, enabling unconstitutional actions and posing a direct threat to national security. It facilitates the covert collection, storage, and perpetual sharing of private health information linked to IPI, undermining privacy and security.

COUNT TWO
APA Violation
5 U.S.C. §§ 706(2)(A)
APA Violation: Not In Accordance With Law

144. The allegations in each of the preceding paragraphs are expressly incorporated herein as if restated in full.

145. Under the APA, courts must "hold unlawful and set aside agency action" that is "not in accordance with law" 5 U.S.C. § 706(2)(A). The Rule is not in accordance with the following laws:

A. The Regulation exempts investigators from complying with 42 U.S.C. § 2000bb-1 by permitting them to bypass an individual's legally effective informed consent, thereby obstructing the individual's ability to freely exercise their religious beliefs in accordance with the Religious Freedom Restoration Act.

B. The Regulation exempts investigators from complying with 42 U.S.C. § 300a-7(d) by permitting them to bypass notifying individuals of nonconsensual research activities, thereby obstructing individuals' ability to not "assist" in activities that interfere with their religious beliefs.

C. The Regulation violates 10 U.S.C. § 980 when DoD appropriated funding is involved.

D. The Regulation violates 45 C.F.R. § 46.122 when federal funds are involved.

E. The Regulation violates 10 U.S.C. §§ 1107, 1107(a) when involving service members.

F. The Regulation violates Article VII of the International Covenant on Civil and Political Rights Treaty (ICCPR), stating, "no one shall be subjected without his free consent to medical or scientific experimentation." Although the treaty is not self-executing, the FDA is not authorized to promulgate a regulation that conflicts with the Senate's ratified treaty, which the Regulation does. The Senate clarified that "it is the view of the United States that States Party to the Covenant should wherever possible refrain from imposing any restrictions or limitations on the exercise of the rights recognized and protected by the Covenant, even when such restrictions and limitations are permissible under the terms of the Covenant."[49]

G. The Regulation violates 42 U.S.C. § 241(d)(3) by enabling clinical investigations without informed consent or mandatory notification, thereby obstructing research subjects' statutory right to access information collected about themselves during their participation. The statute explicitly states that nothing in 42 U.S.C. § 241(d) shall limit an individual's access to their own research data, ensuring transparency and autonomy in HHS-supported research. However, the Regulation permits investigators to covertly include individuals in studies, even when IPI is involved, and only requires notification "whenever appropriate," without clear standards. This ambiguous approach means subjects will remain

[49] https://www.congress.gov/treaty-document/95th-congress/20/all-info

unaware of their participation, effectively preventing them from exercising their right to request and obtain their research data, such as test results or biospecimen analyses. By undermining the transparency guaranteed by 42 U.S.C. § 241(d)(3), the regulation directly conflicts with the statute's mandate to protect research subjects' access to their personal information.

H. 21 C.F.R. § 50.22 conflicts with Title VII of the Civil Rights Act of 1964 (42 U.S.C. § 2000e et seq.) by permitting covert clinical investigations that may involve employees or patients in research activities contrary to their religious beliefs, without their knowledge or consent. Title VII prohibits employment discrimination based on religion and requires employers to reasonably accommodate employees' sincerely held religious practices unless doing so imposes an undue hardship (42 U.S.C. § 2000e-2, § 2000e(j)). By allowing investigators to covertly involve employees with test articles (e.g., those derived from fetal or porcine tissues) that may violate the religious convictions of employees (e.g., healthcare workers handling such articles) or patients (e.g., subjects unknowingly exposed), the regulation risks creating discriminatory conditions or a hostile work environment under Title VII. The covert nature of these investigations, enabled by the regulation's waiver of informed consent and lack of mandatory notification, prevents individuals from objecting or seeking

accommodations, thereby undermining Title VII's protections against religious discrimination in the workplace.

COUNT THREE
5 U.S.C. §§ 706(2)(B)
APA Violation: Contrary to Constitutional Rights

146. The allegations in each of the preceding paragraphs are expressly incorporated herein as if restated in full.

147. Under the APA, courts must "hold unlawful and set aside agency action" 5 U.S.C. § 706(2)(A), that is "contrary to constitutional right, power, privilege, or immunity" *Id.*, § 706(2)(B).

148. The Rule, as applied, purports ownership of the human race. An individual is subjected to irreparable harm under each use of 21 U.S.C. § 50.22 because involvement in covert clinical investigations means the subject is no longer protected by constitutional rights relating to due process, privacy, bodily autonomy, and religious freedoms, which rights have been taken without procedural due process. The Rule is contrary to the following constitutional rights:

A. The Due Process Clause of the Fifth Amendment ensures that no person shall be deprived of life, liberty, or property without due process of law. The Rule permits clinical investigators to conduct biomedical experiments on Mr. Ward and the public under covert conditions, thereby depriving them of their fundamental

right to bodily autonomy. This right extends to the right to refuse participation in clinical investigations.

In *Joint Anti-Fascist Refugee Committee v. McGrath*, 341 U.S. 123, 170 (1951), Justice Frankfurter emphasized that "a democratic government must therefore practice fairness, and fairness can rarely be obtained by secret, one-sided determination of facts decisive of rights." As applied, the Regulation permits clinical investigators to unilaterally determine the scope of Mr. Ward's rights in relation to their activities, making these decisions in secret without his knowledge or participation in the decision-making process. This clandestine process violates the core principle of procedural due process, which requires transparent and participatory procedures to ensure fairness in the eyes of the affected individual.

B. The Rule violates the Fifth Amendment's Takings Clause. The Takings Clause applies to a "government [that] physically takes possession of property without acquiring title to it" (Cedar Point Nursery v. Hassid, 141 S. Ct. 2063 (2021)) (emphasis added). Further, "Government action that physically appropriates property is no less a physical taking because it arises from a regulation." (*Id*). The question of whether government conduct is considered a taking "is whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner's

ability to use his own property" because "Whenever a regulation results in a physical appropriation of property, a per se taking has occurred" (*Id*).

The Supreme Court is on point in the instant action stating, "Rather than restraining the growers' use of their own property, the regulation appropriates for the enjoyment of third parties the owners' right to exclude" and as the Court holds the right to exclude is "one of the most treasured rights of property ownership." (*Id.*)

Mr. Ward's biometric data, body, biospecimens, and health information are private property that cannot be taken without cause. Mr. Ward is entitled under the Fifth Amendment to dispose of his private property as he determines, not as the FDA determines. The Rule permits takings by regulation because it specifically denies Mr. Ward and the American people the right to exclude others from invading their bodies and taking their biometric data and biospecimens. Rather, it permits takings under the most incredulous conditions—namely, secrecy. A biospecimen not freely given is the owner's private property.

C. The Due Process Clause of the Fifth Amendment guarantees that a person's "private property [shall not] be taken for public use, without just compensation." (emphasis added). By promulgating a regulation allowing clinical investigators to include Mr. Ward's private property (i.e., private health data, research labor, biospecimens) for public use (e.g., federally funded research,

products and services derived from Mr. Ward's data) without compensation, the Regulation is contrary to the Fifth Amendment. Moreover, the FDA places the burden of scientific progress on the shoulders of a few, whereas research should be a burden borne by the public as a whole. *Armstrong v. United States*, 364 U.S. 40 (1960) ("The Fifth Amendment's guarantee that private property shall not be taken for a public use without just compensation was designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole.")

D. The Fourth Amendment guarantees Mr. Ward's right to be secure in his person, home, papers, and effects against unreasonable searches and seizures, encompassing a reasonable expectation of privacy in his personal affairs. Under 21 U.S.C. § 355, a clinical investigator's authority is strictly regulated by the Secretary of Health and Human Services, requiring explicit permission to access or examine any individual's biological material, including a single cell. If the Secretary authorizes an investigator to seize Mr. Ward's private health information, biomedical data, or labor—whether at his home, workplace, medical facility, or educational institution—this federal authorization, pursuant to the process of law, enables the investigator to infringe upon Mr. Ward's Fourth Amendment privacy rights. Such government-sanctioned action constitutes a

deprivation of his constitutional protections against unreasonable searches and seizures into his personal and private domains.

Boyd v. United States, 116 U.S. 616 (1886) referenced James Otis stating that colonies issuing writs was "the worst instrument of arbitrary power, the most destructive of English liberty, and the fundamental principles of law, that ever was found in an English law book" because it placed "the liberty of every man in the hands of every petty officer." (Cooley's Constitutional Limitations, 801-303 (5th ed. 368, 369)).

Here, no one is issuing writs, but the FDA is placing the liberty of every man into the arbitrary hands of self-serving clinical investigators. Like a thief in the night, the FDA and its authorized investigators come and go, rummaging through Mr. Ward's life as if 'We the People' endowed the agency with such power.

Mr. Ward has a reasonable expectation that when he visits the doctor's office, he is not being involved in a covert clinical investigation, or when he gives blood for charitable reasons, that his blood will not be used for covert DNA sequencing. Mr. Ward has a reasonable expectation to determine when, where, and how he participates in a clinical investigation, as well as how his private health information will be collected, stored, shared, or sold. Mr. Ward has no expectation that a private medical file will be established, stored, shared, or added to by

unknown persons for unknown reasons over an unspecified period, resulting from the unconstitutional seizure of private health information by clinical investigators.

Mr. Ward has a reasonable expectation that he is in control of his bispecimens and can dispose of them as he sees fit.

Mr. Ward has a reasonable expectation that his life is fully protected from the invasion of his privacy, regardless of his location, whether in private or public spaces.

"The Fourth Amendment protects people" (Katz v. United States, 389 U.S. 347 (1967)) from government-authorized search and seizures, period. "Wherever a man may be, he is entitled to know that he will remain free from unreasonable searches and seizures." (*id.* 389 U.S. at 359).

The FDA is not empowered to achieve a result that Congress can not command directly, and the forfeiture of the nation's privacy through the Rule represents a willful and intentional design to achieve an unconstitutional result. The Rule is contrary to the Fourth Amendment.

E. The Thirteenth Amendment, which prohibits slavery and involuntary servitude except as punishment for a crime, is directly implicated by the Regulation's morally and legally indefensible design. When individuals, or their property (i.e., biospecimens), are covertly enrolled as human subjects in a corporation's clinical investigations, such as those for a marketing license under 21

U.S.C. § 355 or 42 U.S.C. § 262, they are compelled to provide labor without informed consent or compensation. This labor, encompassing the physical and psychological burdens of experimental treatments and the generation of valuable data for corporate profit and or the interest of others, constitutes involuntary servitude.

In *United States v. Kozminski*, 487 U.S. 931 (1988), the Supreme Court defined "involuntary servitude" as "a condition of servitude in which the victim is forced to work for the defendant by the use or threat of physical restraint or physical injury, or by the use or threat of coercion through law or the legal process." (emphasis added). Here, the Regulation's authorization of covert enrollment exploits legal processes to bypass consent, effectively coercing individuals into forcible servitude by denying them the choice to refuse participation. By leveraging regulatory mechanisms to conceal the laborious experiment, the Regulation mirrors the coercive legal coercion *Kozminski* condemns, as individuals are stripped of autonomy over their bodies and data for corporate gain. Such covert conscription into medical experimentation, without meaningful choice or transparency, violates the Thirteenth Amendment's prohibition on involuntary servitude, as it transforms individuals into unwitting tools of corporate research without regard for their dignity or agency.

Moreover, the Regulation enables the entity to extract labor from Mr. Ward[50] for shareholder profit, treating them not as autonomous beings, but as slaves subject to the whims of an unknown master, in direct violation of the Thirteenth Amendment's guarantee of personal liberty. No person should be compelled to serve another's interests against their will. The FDA has become a master of human exploitation.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court issue an order and judgment:

(1) Enjoin the final rule as published under **2023-27935 (88 FR 88228)**;

(2) Declare that the Secretary's actions in implementing the final rule were arbitrary and capricious, were not in accordance with law, and contrary to Plaintiff's Constitutional rights, constituting a violation of the APA;

(3) Set aside and vacate the Rule;

(4) Order the Secretary to promulgate new regulations in compliance with the Constitution and applicable laws;

[50] The investigator might require Mr. Ward to run on a treadmill, take supplements, fast for 24 hours, or engage in other physical activities not required for the purpose of the visit to the doctor's office or a school activity, etc. The activity is ordered specifically for the investigation, but for reasons unknown to the subject.

(5) Make the following declaratory judgments pursuant to *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) because the instant action involves an actual controversy that exists because the Secretary holds that Mr. Ward is property of the FDA that can be covertly delegated to others for their personal use. The issuance of a declaratory judgment will clarify Mr. Ward's constitutional rights in relation to FDA's legal claims, which will stop current harm and prevent future harm when the Secretary promulgates new regulations. Moreover, the declaration serves the public interest by protecting the public at large from nonconsensual and/or covert, unapproved medical treatments and clinical investigations, upholding due process, privacy, and preventing the erosion of trust in governance. This Court's intervention will avert societal chaos that arises when citizens, denied their constitutional protections without cause, seek extralegal remedies, as historical precedents caution.

A. Declare that the Due Process Clause of the Fifth Amendment guarantees that no government shall "deprive any person of life, liberty, or property without due process of law" (U.S. CONST. amend. XIV, § 1, cl. 3) and that individuals hold a liberty interest in bodily autonomy, which is a fundamental right pursuant to *Cruzan*, *Glucksburg*, *Oliver*, and *Union Pacific Railway Co.*, *supra*.

B. Declare that an individual's liberty interest in bodily autonomy rights affords them the unqualified right to refuse unapproved medical treatments, participation in clinical investigations, or biomedical and behavioral research activities, and such liberty interest cannot be taken without due process nor deprived of through covert means by any governmental agency or regulation.

C. Declare that the legally effective informed consent standard is a property right subject to the Due Process clause that cannot be taken without cause pursuant to *Roth, supra*.

E. Declare that covert clinical investigations unduly burden Mr. Ward's religious beliefs under 42 U.S.C. § 2000bb-1(a) and deprive him of his religious right not to "assist" in a research activity contrary to his faith under 42 U.S.C. § 300a-7(d).

F. Declare that covert clinical investigations deprive Mr. Ward of his due process right to seek judicial remedy if injured by the research due to the lack of informed consent.

G. Declare that covert clinical investigations deprive Mr. Ward's fundamental right to privacy and allow unwanted governmental intrusion into his life pursuant to *Griswold*, *supra*.

H. Declare that covert clinical investigations subject Mr. Ward to involuntary servitude in violation of the Thirteenth Amendment pursuant to *Kozminski*, *supra*.

I. Declare that Mr. Ward's health information, biometric data, and his biospecimens are his private property subject to the Due Process Clause that cannot be taken without cause nor covertly to avoid procedural due process obligations.

(6) Direct the FDA to issue a formal directive to all clinical investigators, mandating public disclosure of all clinical investigations conducted under 21 C.F.R. § 50.22 without obtaining informed consent, including those involving Mr. Ward. This directive must require investigators to promptly notify Mr. Ward and all other individuals covertly involved in such research, providing detailed information about their participation, including the nature of the involvement (e.g., invasive procedures, biospecimen use, or data collection), the specific test articles used, and any associated risks or outcomes, to ensure transparency and compliance with statutory (42 U.S.C. § 241(d)(3)) and constitutional protections.

(7) Order the destruction of all research data obtained under the Rule to ensure equitable relief for the nation.

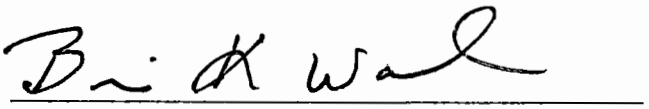
(8) Direct the Secretary to issue a revised definition of "minimal risk" across all regulations pertaining to the proection of Human Subjects that explicitly

excludes any physical contact with the subject's body or exposure to a test article, and that comprehensively addresses the subject's welfare, including their constitutional, legal, financial, and religious interests.

(9) Granting any other relief that the Court deems just, proper, and equitable.

Dated: July 03, 2025

Respectfully submitted,



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