119th CONGRESS: Vaccine Trial Transparency, Accountability, and Integrity Act (VTAI Act)

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H.R. XXXX

To mandate transparency, accountability, whistleblower protections, and criminal liability in vaccine clinical trials to ensure public trust, scientific integrity, and regulatory oversight.

IN THE HOUSE OF REPRESENTATIVES
[Date Introduced]

Mr./Ms. [Sponsor's Name] introduced the following bill; which was referred to the Committee on Energy and Commerce and the Committee on Oversight and Accountability.

A BILL

To establish standards for transparency, accountability, and integrity in vaccine clinical trials, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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SECTION 1. SHORT TITLE.

This Act may be cited as the "Vaccine Trial Transparency, Accountability, and Integrity Act" (VTAI Act).

SECTION 2. PURPOSE.

The purpose of this Act is:

1. To mandate full public disclosure of raw data from vaccine clinical trials.
2. To establish independent third-party auditing mechanisms for vaccine trial data.
3. To provide robust legal protections for whistleblowers reporting fraud, negligence, or misconduct in vaccine trials.

4. To criminalize the manipulation, falsification, or suppression of vaccine trial data and impose penalties on those responsible.

SECTION 3. DEFINITIONS.

For the purposes of this Act:

1. "Vaccine Clinical Trial" refers to any study conducted to evaluate the safety, efficacy, or immunogenicity of a vaccine candidate involving human participants.
2. "Raw Data" refers to all original, unprocessed datasets from a vaccine clinical trial, including individual participant records, adverse event logs, mortality reports, and statistical analyses.
3. "Whistleblower" refers to any individual with direct knowledge of unethical practices, misconduct, or fraud in vaccine trials who discloses such information to an oversight body or authorized authority.
4. "Data Manipulation" refers to any intentional act to falsify, conceal, misrepresent, or distort clinical trial data.
5. "Third-Party Auditor" refers to an independent entity, unaffiliated with the vaccine manufacturer or regulatory bodies, authorized to review clinical trial data and ensure compliance with regulatory requirements.

SECTION 4. MANDATED RAW DATA DISCLOSURE.

(a) Full Disclosure Requirement:

- Vaccine manufacturers shall release all raw data collected during clinical trials within 12 months following the completion of the trial.
- Data shall include participant records, adverse event logs, statistical models, mortality data, and immunogenicity reports.

(b) Accessibility and Transparency:

- All disclosed data shall be published in a machine-readable format on a publicly accessible database managed by the Department of Health and Human Services (HHS).
- Data must comply with Federal Open Data Standards to ensure accessibility and usability.

(c) Oversight Mechanism:

- A Transparency Review Board (TRB) shall be established under the HHS to oversee compliance with data transparency requirements.
- The TRB will have the authority to audit vaccine manufacturers' raw data submissions and enforce compliance through administrative penalties.

(d) Exemptions:

- Personal identifying information (PII) of trial participants shall be redacted in compliance with HIPAA regulations.

SECTION 5. THIRD-PARTY AUDITS FOR TRIAL INTEGRITY.

(a) Mandatory Independent Auditing:

- All vaccine clinical trials shall undergo independent third-party audits to ensure the accuracy, integrity, and completeness of reported data.

(b) Scope of Audits:

- Auditors shall examine:
    - Raw datasets
    - Adverse event logs
    - Mortality reports
    - Statistical methodologies used in analysis

(c) Publication of Audit Results:

- Full audit findings must be published concurrently with clinical trial results in publicly accessible formats.

(d) Selection of Auditors:

- Third-party auditors shall be certified by the Government Accountability Office (GAO) and appointed independently to avoid conflicts of interest.

(e) Reporting Mechanisms:

- Auditors shall report any evidence of data manipulation, suppression, or fraud directly to the FDA, HHS Inspector General, and Congress.

SECTION 6. WHISTLEBLOWER PROTECTIONS.

(a) Federal Legal Safeguards:

- Whistleblowers disclosing unethical practices, misconduct, or fraud in vaccine trials shall be protected under federal whistleblower laws.

(b) Prohibition of Retaliation:

- Any form of retaliation—such as termination, harassment, demotion, or blacklisting—against whistleblowers shall be considered a federal offense.

(c) Financial Incentives:

- Whistleblowers whose disclosures result in successful prosecution or regulatory action may be eligible for financial rewards up to 10% of collected penalties, capped at $1 million per case.

(d) Anonymous Reporting Portal:

- An anonymous whistleblower reporting system shall be established and managed by the HHS Inspector General's Office.

SECTION 7. CRIMINAL PROSECUTION FOR DATA MANIPULATION.

(a) Federal Criminal Offense:

- Intentional falsification, suppression, or manipulation of clinical trial data shall be considered a federal felony.

(b) Penalties:

- Individuals found guilty under this section shall face:
    - Up to 20 years in federal prison
    - Fines of up to $10 million

(c) Executive Accountability:

- Senior executives of pharmaceutical companies proven to have knowledge of or involvement in data manipulation shall face equal liability and penalties as the direct perpetrators.

(d) Statute of Limitations:

- Criminal liability under this section shall have a 10-year statute of limitations from the date of trial completion.

SECTION 8. ENFORCEMENT MECHANISMS.

(a) Oversight Authorities:

- The Food and Drug Administration (FDA) and the Department of Justice (DOJ) shall jointly oversee the enforcement of this Act.
- The HHS Inspector General shall serve as an additional oversight authority for whistleblower protections and compliance monitoring.

(b) Audit and Compliance Teams:

- Each vaccine clinical trial shall be assigned an FDA Compliance Officer responsible for ensuring adherence to this Act.

- Compliance Officers shall have unrestricted access to trial sites, datasets, and personnel for investigation purposes.

(c) Reporting Mechanisms:

- A secure, confidential portal shall be established by the HHS Office of Inspector General to allow whistleblowers, trial participants, and auditors to report violations of this Act anonymously.
- All submitted reports shall be reviewed within 30 days of receipt, with preliminary findings communicated to the FDA and DOJ for further action.

(d) Corrective Action Plans:

- In cases of non-compliance or suspected data manipulation, the FDA shall have the authority to issue Corrective Action Plans (CAPs) to manufacturers.
- Failure to adhere to CAPs within 60 days will result in:
    - Suspension of clinical trials.
    - Fines of up to $500,000 per day until compliance is achieved.

(e) Judicial Review:

- Any enforcement actions taken under this Act shall be subject to judicial review in federal courts.

SECTION 9. ANNUAL CONGRESSIONAL REPORT.

(a) HHS Reporting Requirement:

- The Department of Health and Human Services (HHS) shall submit an Annual Report to Congress detailing:
    1. Compliance with raw data disclosure requirements.
    2. Findings from independent third-party audits.
    3. Whistleblower reports and their outcomes.
    4. Criminal prosecutions under this Act.
    5. Recommendations for further legislative improvements.

(b) Public Access:

- The Annual Report shall be made publicly accessible on the HHS website within 30 days of submission to Congress.
- A summary version of the report shall be published in plain language for broader accessibility.

(c) Congressional Oversight Hearings:

- The House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions (HELP) shall hold annual oversight hearings to review the report and question key stakeholders.

SECTION 10. IMPLEMENTATION TIMELINE.

(a) Immediate Effect:

- Sections 4 (Mandated Raw Data Disclosure), 5 (Third-Party Audits), and 6 (Whistleblower Protections) shall take effect immediately upon enactment of this Act.

(b) Phase-In Period:

- Section 7 (Criminal Prosecution for Data Manipulation) and Section 8 (Enforcement Mechanisms) shall be fully implemented within 18 months of enactment.

(c) Regulatory Framework Development:

- The FDA and HHS shall develop and publish regulatory guidelines to support the implementation of this Act within 6 months of enactment.

SECTION 11. SEVERABILITY CLAUSE.

If any provision of this Act, or the application of any provision to any person or circumstance, is held unconstitutional or otherwise invalid, the remainder of this Act and the application of the provisions to other persons or circumstances shall not be affected.

SECTION 12. FUNDING.

(a) Authorization of Appropriations:

- Congress authorizes an annual appropriation of $500 million for the implementation, enforcement, and oversight of this Act.

(b) Use of Funds:

- Funds appropriated under this section shall be used for:
    1. Hiring and training FDA Compliance Officers and Third-Party Auditors.
    2. Developing and maintaining public data disclosure platforms.
    3. Supporting whistleblower protection programs.
    4. Investigating and prosecuting cases of data manipulation.

(c) Financial Accountability:

- An independent financial audit of funds allocated under this section shall be conducted annually by the Government Accountability Office (GAO).

SECTION 13. EFFECTIVE DATE.

This Act shall take effect 60 days after its enactment unless otherwise specified in individual sections.