Vaccine and Related Biological Product Manufacturing as US Government-Licensed Poison Manufacturing.

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Evidence From November 1986 'Mandate for Safer Childhood Vaccines' Codified at 42 USC 300aa-27, and July 2018 Stipulation by HHS.

by <u>Katherine Watt</u>, <u>Bailiwick News</u> March 21, 2023

## Summary of legal history findings to date

The development since 1944, of American statutes and regulations governing US-Food and Drug Administration product licensing functions and non-functions, along with international Mutual Recognition Agreements and public health emergency/emergency use authorization/medical countermeasures law, support the conclusion that all biological products allegedly regulated by the FDA for compliance with manufacturing quality standards, distributed and used on the American population — and through MRAs, exported to countries around the world for use on populations worldwide — are in fact, unregulated.

Laws have been written to enable operators of biological product manufacturing facilities to legally make and distribute poisons. Legalized poisons are produced by US

military-public health contractors working under black box conditions inside pharmaceutical factories in the US and in countries occupied by US financial, public health and military forces.

FDA, DoD and military-pharmaceutical manufacturing contractors don't take every opportunity to adulterate every production run. They have vested interests in keeping the public in the dark about their legal access to production lines, and the availability of some harmless and/or beneficial products makes it more difficult for people to understand that the chemical and biological weapons emerging from the same factories are weapons.

The toxicity of vaccines and vaccine-related biological products has been incrementally increased over time.

Injuries and deaths caused by vaccines are falsely attributed to communicable disease, inherited genetic disorders and environmental exposures by the same public health, military and pharmaceutical manufacturing executives jointly running the intentional poisoning programs.

One of the most striking features of this almost-unimaginably vast military/public-health/pharmaceutical deception program is how the things that don't happen matter as much as — and often more than — the things that do happen.

The records that can't be located are as revealing as, and often more revealing than, the records that can be found.

One vivid example: blank pages enclosed as package inserts with Covid-19 vaccines.

Another example: if there had ever been any legal requirement for FDA to prevent Covid-19 vaccines from harming clinical trial subjects, and from later harming recipients in what many still irrationally insist is a consumer product market, FDA officials would have denied all of the Covid-19 vaccine manufacturers' licensing applications submitted starting in February and March 2020.

FDA would have denied the applications based on evidence accrued since genetic engineering research began, about harms caused to animal and human recipients of cell- and gene-based compounds, lipid nanoparticles, and other components listed on and/or redacted from application documents.

FDA did not deny manufacturers legal access to human targets.

Instead, FDA authorized legal access to several thousand targets in spring, summer and fall 2020, and then authorized legal access to everyone else in the world in December 2020.

Following FDA's failure to deny manufacturers' authorization to conduct what have since been revealed as <u>fake clinical trials</u>, if FDA had held a legal obligation to protect the public from biological product poisons, FDA officials would have immediately halted the alleged clinical trials in mid-2020 upon the first reported adverse effects and deaths.

Failing that, a drug manufacturing regulator with a legal obligation to protect people from harm would have immediately recalled all Covid-19 vaccines as soon as general public recipients in December 2020 and early 2021 started having anaphylactic reactions, developing heart damage and turbocancers and dropping dead; as soon as women started shedding decidual casts and miscarrying babies in the womb; and as soon as all the other injuries, diseases and deaths became clearly observable worldwide. (See, for example, Pfizer 5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports received through Feb. 28, 2021, Table 1 at p. 7)

FDA did not halt the pretend clinical trials, and has not recalled the vaccines, ordered the manufacturers to cease production, or ordered pharmacists, nurses and doctors to stop

### National Childhood Vaccine Injury Act

The "mandate for safer vaccines" section of the 1986 National Vaccine Act and the Vaccine Injury Compensation Program offers another good example of events that should have taken place but didn't, and records (recording those events) that should have been produced but weren't.

In November 1986, Congress and President Reagan passed the <u>State Comprehensive Mental Health Services Plan Act</u>.

The National Childhood Vaccine Injury Act section of the act (Title III) amended the 1944 Public Health Service Act to establish and fund a National Vaccine Program; grant vaccine manufacturers legal immunity for injuries and deaths caused by their products; and establish and fund a National Vaccine Injury Compensation Program, all of which was codified at 42 USC 300aa et seq.

At <u>42 USC 300aa-27</u>, Congress established a "mandate for safer vaccines."

- (a) General rule. In the administration of this part and other pertinent laws under the jurisdiction of the [HHS] Secretary, the Secretary shall—
- (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
- (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage,

administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

#### (b) Task force

- (1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.
- (2) The Director of the National Institutes of Health shall serve as chairman of the task force.
- (3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).
- (c) Report. Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

The 1986 National Childhood Vaccine Injury Act gave manufacturers immunity from liability for injuries and deaths caused by vaccines listed on the government-recommended childhood immunization schedule.

One of the justifications used to exempt manufacturers from liability was that the US government, through the Department of Health and Human Services, would monitor the childhood

vaccine program, collect safety data, report the data to Congress to provide oversight, and take harmful vaccines off the market.

Safety monitoring and reporting as called for in the 1986 law did not occur.

In August 2017, the <u>Informed Consent Action Network</u> (ICAN) filed a FOIA request with HHS, requesting copies of the biennial reports that should have been prepared and submitted to House and Senate committees between 1987 and 2018.

In June 2018, HHS responded to ICAN's request:

"The [Department]'s searches for records did not locate any records responsive to your request. The [HHS] Immediate Office of the Secretary (IOS) conducted a thorough search of its document tracking systems. The Department also conducted a comprehensive review of all relevant indexes of HHS Secretarial Correspondence maintained at Federal Records Centers that remain in the custody of HHS. These searches did not locate records responsive to your request, or indications that records responsive to your request and in the custody of HHS are located at Federal Records Centers."

Informed Consent Action Network v. US-HHS, (1:18-cv-03215-JMF), resulted in <u>a July 9, 2018 stipulation</u> signed by Attorney Robert F. Kennedy Jr.

The stipulation quoted the June 2018 acknowledgement, by HHS, that HHS had no record of any safety monitoring activity or public, Congressional reporting of the childhood vaccination program, under the 1986 law, between 1986 and 2018.

Later two reports were located, filed on May 4, 1988 and July 21, 1989 (partial, no appendices). The 1988 and 1989 reports addressed vaccine promotion, vaccine supply, vaccine research activity (see, for example, pp. 67-78 of 1988 report), and

set-up of reporting and data analysis programs.

Since 1989: nothing.

HHS has never systematically collected or reported information from parents, pediatricians, toxicologists, manufacturers, or anyone else about harms caused by childhood vaccines administered in single doses, combined doses (i.e. measles-mumps-rubella), or cumulative doses (the childhood schedule), and HHS has never collected or reported information about the harmful effects of biological components, chemical adjuvants, preservatives or any other ingredients.

# What would a true vaccine monitoring, reporting and product safety program have looked like?

It would have included detailed records of:

- Date, time and location of vaccine administration, including the name of the nurse or other health care worker who administered the vaccine, and the doctor who ordered the vaccine.
- Parent and doctor observations of symptoms of injury in the baby and child post-vaccination: what the symptoms were, when they occurred in relation to the vaccine, how long they lasted, how severe they were, whether they were transient or chronic, and whether the parent was subsequently advised to refrain from further vaccination of the child.
- Serial number of the vaccine vial, identifying the manufacturing facility by name and address, lot number, batch number, date of manufacture, and names of production line workers who prepared the batch, separated out the lot, and filled the vial.
- Dates, times and shipping methods through which the vaccine vial was shipped from the factory and received by the doctors' office, hospital or pharmacy.

- Storage and handling of the vaccine vial by the employees at the doctors' office, hospital or pharmacy.
- Each chemical and biological component listed or not listed on the vaccine label, including chemical and molecular structure, raw materials, cell lines, active ingredients, adjuvants, preservatives and all other components.
- Each manufacturing protocol used at each step in the production process, fully describing the chemical and biological reactions, procedures and methods used to make each component of the vaccine, including the final, finished product.
- Names of the suppliers of each chemical and biological ingredient; date and time at which each ingredient was delivered to the vaccine factory; name of the employee who received the delivery.
- FDA inspections of the manufacturing facility during the period when the vaccine was manufactured, including date and time of inspections and names of the inspectors.
- Samples and protocols from the lot, submitted by the manufacturers to the FDA Bureau of Biologics, including date, time, shipping method and name of the person who submitted the samples and protocols.
- Samples and protocols from the lot, received by the FDA Bureau of Biologics, including date, time, shipping method and the name of the person who received the samples and protocols.
- Results of sample and protocol testing, by FDA inspectors, validating that the sample contained the compounds listed on the label; did not contain any compounds (adulterations or contaminants) not listed on the label; and that the protocol the manufacturer reported using, in fact yielded a chemically and biologically identical final product when applied by an FDA inspector to the same ingredients in the same sequence using the same methods.
- FDA written certification of each lot for release,

distribution and use, including names of FDA inspectors, signatures and dates of lot-release.

The July 2018 ICAN-HHS stipulation supports the conclusion that none of those regulatory functions have been performed, no records of vaccine manufacturing regulation have been produced by FDA or regulated manufacturers, and no records have been collected, assessed or used by HHS.

No vaccine manufacturing safety regulation has been conducted by FDA, NIH, CDC or any other HHS department, at any time since Congress passed the 1986 "mandate for safer vaccines."

Or, if such evidence has been collected, it's been collected under classified military data collection systems, to confirm and refine national vaccination programs as an effective chemical and biological weapons production and distribution system capable of deniably inducing rapid death (i.e. Sudden Infant Death Syndrome) and chronic diseases including asthma, allergies, neurological disorders, gastrointestinal disorders, autoimmune disorders, heart disease, diabetes, obesity, cancer and other immune-mediated diseases.

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