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> ***Public health and regulatory systems have consistently hidden those truths behind false claims about the effects of vaccines, and behind legalized non-regulation of biological product manufacturing.***

by **Katherine Watt**, *Bailiwick News*
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The US Food and Drug Administration and other drug manufacturing regulators claim that drug manufacturing regulation is about assessing product purity, sterility, potency, safety and efficacy to protect humans and animals from impure, adulterated, contaminated, impotent, harmful, and/or ineffective products.

Biological products can be defined as a subset of the larger category of drugs. Biological products are drugs manufactured through biological processes that take place within living organisms. Drugs that aren't biological products are manufactured through chemical processes. Vaccines are included in the biological products class of drugs.

A defining characteristic of biological products, in legal terms, is their rule-governed exemption from regulatory oversight that applies to and is enforceable for drugs manufactured using chemical processes.

One of several defining characteristics of biological products as murder weapons, is their ability to biologically incorporate into the target's body, such that weapons become indistinguishable from victims. Empty vials, syringes and other residual evidence disappears into garbage dumps and medical waste incinerators.

Eleanor McBean published a book in 1957 called *Poisoned Needle*.

She carefully documented the history of vaccination lies prior to and since Edward Jenner's cow-pox and smallpox lies. She collected dozens of doctors' observations throughout the 1700s, 1800s and early 1900s, supporting the conclusion that vaccines have always been nothing more than toxic slurries introduced into healthy people and animals for the purpose of making them weaker and sicker and dead, while enabling the poisoners to lie to themselves and to their victims about what they're doing, how and why.

One example from *Poisoned Needle*:

> Dr. J. W. Hodge had considerable experience with vaccination before he denounced it and wrote a book on his collected data. In his [1902] book *The Vaccination Superstition* (p. 41) he states:
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> *"After a thorough investigation of the most authentic records and facts in harmony with the physician's daily observations and experiences, the conclusion is drawn that instead of protecting its subjects from contagion of smallpox, vaccination actually renders them more susceptible to it.*
>
> *"**Vaccination is the implantation of disease – that is its admitted purpose**. Health is the ideal state to be sought, not disease . . . Every pathogenic disturbance in the*

> *infected organism wastes and lowers the vital powers, and thus diminishes its natural resisting capacity.*
>
> *"This fact is well known and so universally conceded that it seems superfluous to cite authorities. Nevertheless, I shall mention one. The International Textbook of Surgery – Vol. 1. p. 263, is authority for the following statement: 'Persons weakened by disease or worn out by excessive labor yield more readily to infection than healthy individuals.'*
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> *"If this is true, it explains why, in various epidemics, smallpox always attacks the vaccinated first, and why these diseases continue to infest the civilized world while its allied (unvaccinated) 'filth diseases' have disappeared before the advance of civilization, through the good offices of sanitation, hygiene and improved nutrition."*

For the last few years, I've been documenting the development of American public health emergency anti-law as a distinct layer of statutes, regulations, executive orders and court cases that overrides and suspends good laws criminalizing (among other crimes) intentional use of poisons, including vaccines, to injure and kill people.

Public health emergency law as a tool to enable deniable, spatially-distant, time-shifted homicide became more visible because public health emergency law was used to start the Covid-19 killing programs and is still being used to maintain the Covid-19 killing programs.

Public health emergency statutes, regulations, executive orders and court cases govern, among other things, non-regulation of poisons (i.e. emergency use authorization/EUA countermeasures) during declared emergencies.

In December 2023, I located a *Federal Register* Notice of Final Rule through which then-FDA Commissioner Scott Gottlieb shut the doors of all biological product manufacturing facilities to FDA inspections, effective May 2, 2019, eight months before public announcement of Covid-19, and more than a year and a half before the Covid-19 mass vaccination campaign got underway in December 2020.

This fact helps to answer the question: How could hundreds of millions of doses be manufactured, shipped and ready for use a few weeks after the FDA's December 2020 "emergency use authorization" decisions? Manufacturing began well before Covid was announced, inside factories not subject to inspection. That's how.

Reading Gottlieb's rule-change a few months ago, I realized that non-regulation of biological product manufacturing under routine, non-emergency conditions, had been in effect – or, rather, non-effect – since long before Covid, and will still be in effect/non-effect even if emergency declarations about Covid and other fake communicable disease and public health threats are revoked someday.

So for the last couple of months, I've been thinking about and collecting more legal evidence that biological product anti-law under non-emergency conditions *also* suspends or overrides good laws criminalizing (among other crimes) intentional use of poisons to injure and kill people, just as effectively as public health emergency anti-laws do.

The legal history of routine non-regulation of all biological products can be assembled in the same way the legal history of emergency-predicated non-regulation of EUA countermeasures has been assembled.

Such a collection would document how, over time, built-in exemptions from otherwise applicable, enforceable manufacturing rules, along with rule changes, and explicit

notices from FDA to manufacturers (called Guidance for Industry) that FDA would not, will not and does not enforce rules, have rendered biological product non-regulation more non-regulatory as each year has passed.

However, sifting through hundreds of rule changes to track each rule as it's become increasingly inapplicable and unenforceable, is an exercise in grasping at smoke. So I'm not planning to pursue it further, unless an attorney contacts me with a credible proposal for a case that would be strengthened by detailed accounts of FDA *Federal Register* rule-making activities over the past half-century or so.

As an example, in November 1973, just after regulation of biological products transferred from NIH Division of Biologics Standards to the FDA Bureau of Biologics, FDA published a revised, consolidated set of biological product manufacturing regulations at 21 CFR 600 to 21 CFR 680.

At 21 CFR 610.11, the 1973 FDA rules established that the only "general safety" test (GST) required to claim a biological product was safe, was to inject a sample into two mice and two guinea pigs. If the two mice and two guinea pigs didn't get "significant symptoms" or die within seven days, "the product meets the requirements for general safety."

FDA authorized "exceptions to this test…when more than one lot is processed each day" and "variations of this test…whenever required." Manufacturers were directed to apply to the Bureau of Biologics (now the Center for Biologics Evaluation and Research) for exemptions.

After a series of revisions, FDA eliminated general safety test requirements for biological products, effective Aug. 3, 2015 (80 FR 37971).

FDA has made dozens of similar rule changes, weakening and eliminating rules about samples, protocols and lot-by-lot release; establishment and product licensing applications;

post-approval manufacturing process changes; mixing, diluting and repackaging and more, including the elimination of facility inspections Gottlieb put in place effective May 2, 2019.

It’s important to understand that the acts FDA officials have committed, to eliminate applicability and enforceability of drug manufacturing regulations for biological product manufacturing, have not been acts to eliminate actual regulation of medicines.

They have been acts to eliminate what has, from the start, been pretend-regulation to enable unimpeded manufacture, distribution and use of intentional poisons, so that their true character as poisons could be hidden from and invisible to the public.

A few weeks ago, I located Mutual Recognition Agreements. MRAs are international trade treaties. When signed and ratified by national governments, MRAs authorize national regulators – including drug regulators – to be “relieved of” their regulatory obligations and instead, recognize and rely on the regulatory decisions of other countries’ regulators, especially the US Food and Drug Administration.

The two systems interlock.

Under the legal terms of MRA treaties, US-FDA can be legally construed as the sole regulator for worldwide drug manufacturing and distribution systems.

Under the legal terms of the US-FDA drug regulation system, all biological product manufacturing can be legally conducted with no substantive disclosure, monitoring or enforcement of rules controlling purity, sterility, safety, potency,

efficacy, raw materials, manufacturing processes, or chemical and biological composition of finished, packaged, distributed products.

Also note, the legal structure of Mutual Recognition Agreements plus FDA-non-regulation-of-biological-products, operates separate from and in addition to the UN-World Health Organization, International Health Regulations system.

National governments interested in shielding their populations from intentional poisoning must withdraw from the United Nations and WHO treaties; must withdraw from the IHR treaty; and also must withdraw from each Mutual Recognition Agreement treaty that subordinates their own federal drug regulation to other countries' regulators, including the US-FDA non-regulation, poison-facilitation system.

It's plausible that some simpler biological products (insulin, for example) may have historically been manufactured, and may still today be manufactured, to meet measurable, achievable standards of safety and batch-to-batch consistency, because doing that would help US-FDA and pharmaceutical companies maintain public confidence and reduce the likelihood that the public would begin to see and understand the biological-product-based intentional poisoning program.

It's also plausible that biological products labeled as vaccines have had, for many decades and still today, a high degree of batch-to-batch variation ranging from low to high toxicity, because that also would be a sensible way for US-FDA and pharmaceutical companies to maintain high levels of public ignorance, complacency and compliance with vaccination programs.

Related Bailiwick reporting and analysis

- Dec. 19, 2023 – Legalized FDA non-regulation of biological products effective May 2, 2019, by Federal Register Final Rule, signed by then-FDA Commissioner Scott Gottlieb.
- Jan. 25, 2024 – Law and Antilaw: 1995 report by Constitution Society
- March 5, 2024 – Four questions and four responses "…Due to changes in US law, acts that are crimes in other legal contexts, such as poisoning, battery, torture and homicide, if carried out by vaccines (and many other drugs, devices and biological products) are legal. Perpetrators cannot be held liable under civil tort law and cannot be prosecuted under criminal law. This intentional poisoning is much more visible to the public because of the Covid-19 events since 2020, so there are more possibilities for stopping the programs. One of the main methods to carry out the mass deception is false attribution of cause and effect…"
- March 8, 2024 – Mutual Recognition Agreements. First in series on legal links connecting domestic and international non-regulation of non-medicines.
- March 12, 2024 – Statutory and regulatory definitions for drugs, biological products, and biosimilars.
- March 15, 2024 – Deregulation of biological product manufacturing, mid-1990s to present.

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