Key documents supporting argument that FDA functions pertaining to vaccines are non-regulatory, for regulatory simulation purposes only.

**1910**

*The Federal Control of Serums, Vaccines, Etc*. (Milton J. Rosenau, *Journal of the American Medical Association*, Jan. 22, 1910)

Milton Rosenau, the second director of the Hygienic Laboratory (1899-1909), described the 1902 Virus-Toxin law as having established an inspection and licensing program that he claimed was operated by the staff of the Hygienic Laboratory division of pathology and bacteriology, including purchase of samples from manufacturing establishments and "on the open market" for "examination as to potency and purity." Rosenau further claimed that the licensing process applied to individual products and that "general licenses authorizing the manufacture of any and all biologic products are not issued," even though the 1902 law only addressed the licensing of establishments and did not define or authorize the Treasury department to adopt or enforce product standards. After describing inspectors inquiring into "methods of manufacture," the "competency" of employees and the "efficiency of the material equipment," Rosenau concluded: "At present every confidence may be had in all biologic products made under government license."

The last section of Rosenau's paper on federal control is titled "Government Guarantee" and states:

> "The government does not guarantee that each vaccine point or each package of antitoxin will produce its full therapeutic effect and be free from all danger. This would be impracticable with the extent and variety of the business in biologic products now carried on in this country and abroad..."

**1910**

*Vaccine Virus* (Milton J. Rosenau, *Journal of the American Medical Association*, Jan. 22, 1910)

Rosenau described *vaccine virus* as

> "the specific principle in the material obtained from the skin eruption of calves having a disease known as vaccinia [cowpox]..." and stated "both the pulp and the lymph are mixtures containing epithelial cells, serum, blood, leucocytes, products of inflammation, debris, bacteria, etc., in varying proportions."

Rosenau admitted

> "the specific principle of vaccinia [cowpox] is unknown;" stated that "it is impossible to obtain vaccine virus free from the bacteria of the skin;" and stated "the fact that a serum or vaccine is granted a license does not mean that it is a valuable curative or prophylactic; in fact, it may have little or no therapeutic value."

He stated:

> "it is evidently the province of the medical profession to determine for itself whether a certain substance has therapeutic value or not. The chief concern of the government is to protect the practitioner against sophistications, impurities, faults or mislabeling."

Rosenau ended his paper with an argument for adding *vaccine virus* to the US Pharmacopeia, from which it is possible to infer that US Pharmacopeia officials were resisting such efforts:

> The objection, that vaccine virus is an indefinite substance, the 'active principle' of which is not known, is no longer valid, for the Pharmacopeia contains many such substances, including the ferments, against which similar objection holds.
>
> The objection that vaccine virus cannot be "assayed" [quantitatively and qualitatively analyzed to determine the presence, amount or functional activity of a substance] by the average druggist also lacks force when we recall that the potency and purity of vaccine virus in interstate traffic is cared for by the federal government under the law of July 1, 1902, which relieves the pharmacist of this responsibility...

The words *potency*, *purity* and *vaccine* do not appear in the July 1902 Virus-Toxin law, nor do the words *adulteration* or *misbranding*. Rosenau did not point out to JAMA readers that the 1902 Virus-Toxin law was silent on identity, purity and labeling of products by physical and chemical composition and ingredients; the 1902 law did not prohibit adulteration and misbranding; and the 1902 law did not establish prosecutorial procedures. Rosenau understood that *vaccine virus* was "an indefinite substance" that could not be identified, purified or subjected to any measurable standards for product identity, purity or potency; that no such standards had been established by federal officers or by the US Pharmacopeia acting as a private-sector product quality monitor in partnership with government agencies; that no tests had been developed or were being used by Hygienic Lab workers to test *vaccine virus* specimens for compliance with non-existent identity, purity and potency standards; and that no criminal prosecution of propagation, sale and use of adulterated or misbranded *vaccine virus* was authorized or carried out. The real purpose of the 1902 Virus-Toxin law was to create initial false public confidence in vaccines.

**1924**

*Regulation of Sale of Viruses, Serums, Toxins and Analogous Products, Etc*, record of hearings before subcommittee of US House Committee on the District of Columbia, chaired by Henry Rathbone (Rathbone hearings, Feb. 21, 1924 to May 6, 1924)

William H. Park, Director of Bureau of Labs, NYC, 1924 Rathbone hearing record, at p. 110:

> "By putting 'No U.S. standard of potency' on such material it shows all who are intelligent that that has not yet been shown to be an effective remedy. It might have value, and it might not have value."

Journalist Norman Hapgood, editor of Hearst International Magazine, 1924 Rathbone hearing record, at p. 7, describing the system established by the 1902 Virus-Toxin law:

> "The law regulating the sale of these serums and toxins for human beings makes but one requirement, and that is that this stuff, whether dirt or dung, or whatever it is, shall be put up in a laboratory which is hygienically conducted. An inspector can go in and say that the methods are clean, and on that basis alone they are regulated..."

**1958**

*Federal Regulation of Biologicals Applicable to the Disease of Man* (Parke M. Banta, General Counsel, Dept. of Health, Education and Welfare, *Food, Drug, Cosmetic Law Journal*, Vol. 13, No. 4, April 1958, pp. 215-221

> "[T]here has not been since the enactment of the statute in 1902 any litigation directly involving its application or interpretation; no one has been penalized for its violation nor, so far as I know, charged under its any penalty provisions with any violation of any of its provisions. Moreover, I am informed that no license has been suspended or revoked over the protest of the licensee."

**1962**

Memo dated Sept. 18, 1962, from Joseph Smadel, director of NIH Division of Biologics Standards, Laboratory of Virology and Rickettsia, to J. Anthony Morris, NIH-DBS virology and vaccine researcher charged with "lot release" duties. Smadel order, cited by Nicholas Wade, *Division of Biologics Standards: In the Matter of J. Anthony Morris* (*Science*, 175 Sci. 861, Feb. 25, 1972):

> "The manufacturer will provide full data on the potency assay of his lots which are submit- ted for release. Furthermore, release by the DBS will be on the basis of data submitted by the manufacturer and not on the basis of results obtained in this institution."

**2011**

*Bruesewitz v. Wyeth* (US Supreme Court, 562 US 223, Feb. 22, 2011)

SCOTUS affirmed lack of FDA regulatory functions pertaining to product design.

> "Design defects…do not merit a single mention in the [1986 National Childhood Vaccine Injury Act] or the FDA's regulations. Indeed, the FDA has never even spelled out in regulations the criteria it uses to decide whether a vaccine is safe and effective for its intended use." (562 US 223, 237)

SCOTUS affirmed status of FDA as a "passive agency," citing *Hurley v. Lederle* (1988, 863 F. 2d 1173, 1177).

> "[T]he FDA is a passive agency: it considers whether to approve vaccine designs only if and when manufacturers come forward with a proposal" (562 USC 223, 270 at FN19)

**2011**

*Manual for the Establishment of National and Other Secondary Standards for Vaccines* (World Health Organization, Department of Immunization, Vaccines and Biologicals, Quality, Safety and Standards unit, WHO/IVB/11.03)

> "*Biologicals* are substances which cannot be fully characterized by physico-chemical means alone, and which therefore require the use of some form of *bioassay*...a laboratory procedure for the estimation of the nature or potency of a material by means of the reaction that follows its application to some elements of a living system (examples include animals, tissues, cells, receptors and enzymes)..."

**2017**

*New quality-control investigations on vaccines: micro- and nanocontamination* (Antonietta Gatti and Stefano Montinari, *International Journal of Vaccines & Vaccination, 2017;4(1):7–14).* Researchers report that samples of vaccines contained organic matter, but could not specify its identity, source or quantity.

> "So, organic entities are visible and easy to distinguish from inorganic ones. The method cannot distinguish between proteins and organic adjuvants (e.g. squalene, glutamate, proteins, etc.) or viruses, bacteria, bacteria's DNA, endo-toxins and bacteria's waste, but their comparatively low atomic density allows us to identify these entities as organic matter."

**2018**

*Informed Consent Action Network (ICAN) v. US-HHS*, (USDC, Southern District New York, 18-cv-03215, July 9, 2018). ICAN requested records of safety monitoring for the national childhood vaccination program, under the 1986 NCVIA law, between 1986 and 2017. HHS responded:

> "The [HHS Department]'s searches for records did not locate any records responsive to your request."

**2021**

*Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination (*US-FDA statement, May 19, 2021)

> "The U.S. Food and Drug Administration (FDA) is reminding the public and health care providers that results from currently authorized SARS-CoV-2 antibody tests should not be used to evaluate a person's level of immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination...Currently authorized SARS-CoV-2 antibody tests...are not validated..."

**2022**

US-Department of Health and Human Services, Food and Drug Administration, Form 483 inspection report, Rentschler Biopharma SE, Laupheim, Germany, inspections conducted Feb. 7, 2022 to Feb. 15, 2022, by Wayne Siefert, Ralph Bernstein and Jose Melendez.

> "On February 11, 2022, we (WS and JM) observed the simulated fill process [redacted] simulation of the [redacted] drug substance..."