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## TIMELINE — John P. Frawley, 1948–2007

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Interleaves (▪ pub) Frawley's publications · (◆ deminimis) the threshold proposal & FDA reaction · (✂ dioxin) the inter-company dioxin/herbicide events · (⚖ lit) the litigation. Tags: **[P]** primary, **[2]** secondary, **[abs]** absence-of-evidence. Dates in **bold** are documented to the day.

The point of laying these side by side: Frawley's **1983 sworn knowledge account** can be read against his **own contemporaneous 1960s record**. Watch the 1963–1965 rows.

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### FDA era (Division of Pharmacology)

- **1950** ▪[P] Fitzhugh, Nelson & Frawley, chronic toxicity of benzene hexachloride, *JPET* 100(1):59–66 — earliest located Frawley paper.
- **1951** ▪[P] Fitzhugh, Nelson & Frawley, "A Comparison of the Chronic Toxicities of Synthetic Sweetening Agents," *J. Am. Pharm. Assoc.* 40(11):583–586 (saccharin, cyclamate, dulcin) — the identity-anchor paper.
- **1952** ▪[P] Frawley, Hagan & Fitzhugh, organophosphate–anticholinesterase study, *JPET* 105(2):156–165.
- **1953** ✂/▪ **[disambiguation-contested]** A "John P. Frawley, 1st Lt., Medical Service Corps" serves on the **46th MASH** Surgical Research Team in Korea (with Howard & Artz). Frawley's *toxicology* publication record shows a **1953–55 gap** that coincides with this window — consistent with, but **not proof of**, the FDA toxicologist and the MASH officer being the same man. *Two workflow agents reached opposite conclusions; treated as OPEN.*
- **1957** ▪[P] Frawley, Fuyat, Hagan, Blake & Fitzhugh, "**Marked potentiation in mammalian toxicity from simultaneous administration of two anticholinesterase compounds**" (malathion–EPN synergism), *JPET* 121(1):96–106 — his FDA-era classic.

### Transition to Hercules

- **c. 1956** ⚖[P] Per his 1983 deposition (recited at 565 F. Supp. at 1273), Frawley "**has been with Hercules since 1956.**" (Note the partial overlap with late FDA-coauthored papers through 1958–59 — typical of a staged move.)
- **1958** ◆[P] Congress passes the Food Additives Amendment; rosin is swept in as (per Frawley) a "poisonous and deleterious substance," forcing 2-year studies on Hercules' food-grade rosins.
- **1959** ▪[P] Fitzhugh, Bourke, Nelson & Frawley, stearic-acid emulsifiers, *Toxicol. Appl. Pharmacol.* 1(3):315–331 (inaugural TAP volume).

## The rosin program → the de minimis idea (commercial driver)

- **1961** ♀[P] Hercules buys the **Jacksonville, Arkansas** plant (later Vertac). [Encyclopedia of Arkansas / EPA]
- **1963** ♀[P] Frawley, Weir, Tusing, DuBois & **Calandra** (IBT president), "Toxicologic investigations on Delnav," *TAP* 5:605–624 — **first IBT-linked co-authorship** (COI thread begins).
- **3 Jul 1963** ♀ [DOC A] Frawley writes **V.K. Rowe (Dow)** re USDA Dr. John Leary's request to test phenoxy herbicides. Per Frawley's 1983 affidavit, the health-hazard items concerned **2,4-D, not 2,4,5-T**. *Primary scan never located (absence)*. ← **compare to 1983 sworn account**
- **Oct 19–20 1964** ♀[P] Frawley delivers the **rosin safety paper** at the Naval Stores Work Conference (publ. 1965): >70 Hercules rosin products, 34 studied, studies "**conducted under contract by the Industrial Bio-Test Laboratories**"; ~5,000 rats + 138 dogs; the \$50k-per-compound cost is the explicit motive for a de minimis exemption.
- **19 Dec 1964** ♀[P-cite] Boehringer Ingelheim warns Dow the "extraordinary danger" of the dioxin "is not generally known." [Poison Papers 1A-1-563]

## 1965 — the pivotal dioxin year

- **Feb 1965** ♀/♂[P] Per Frawley's 1983 affidavit: his "**first knowledge... of industrial health problems associated with the production of 2,4,5-T occurred in February 1965, when he was told by Dow of its chloracne problem**"; he says he did **not** learn of Monsanto's **1949 Nitro** chloracne until then.
- **19 Mar 1965** ♀ [P — CROWN-JEWEL DOCUMENT] **V.K. Rowe (Dow) letter to "Dr. John P. Frawley, Hercules Powder Company"** (+ Monsanto's Emmet Kelly, Hooker, Diamond Alkali) convening a meeting on "highly toxic impurities" in 2,4,5-trichlorophenol. **Poison Papers Bates B 1575 · DocumentCloud 3253794.**
- **24 Mar 1965** ♀[2/♂P] Frawley **attends the Dow "Chloracne Problem Meeting"** (Midland; Dow, Diamond Alkali, Hooker, Hercules); receives Dow's analyses showing Hercules' product had "**a very low level of dioxin**" (565 F. Supp. at 1273). A Hercules memo of the meeting (Poison Papers) records Dow "fearful of a congressional investigation"; Hercules: PHS "happy to get in the act." [**DOC B is most likely a paraphrase of this memo + C3 below.**]
- **24 Jun 1965** ♀[2] **V.K. Rowe (Dow) → Ross Milholland**: dioxin "exceptionally toxic... chloracne and systemic injury"; whole 2,4,5-T industry would be "hard hit" by restrictive legislation; "**Under no circumstances may this letter be reproduced... outside of Dow.**"
- **later 1965** ♀[P] Hercules improves its 2,4,5-T process and begins testing its own product for dioxin (per affidavit).
- **1965** ♀[P] Two IBT/Calandra **BHT** papers (*FCT* 3:377–386; 3:471–474) and two FCT opinion pieces ("Our sacred food"; "Suds and sensitivity").

## The de minimis proposal goes public

- **14 Sep 1966** ♦[2] At the **152nd ACS National Meeting, New York**, Frawley first publicly advances the **0.2% / <0.1 ppm "toxicologically insignificant"**

exemption (carve-outs for carcinogens, pesticides, heavy metals, and anything toxic  $\leq 40$  ppm); companion attack-on-FDA paper by packaging attorney **Jerome H. Heckman**. (Frawley's data base: 143 chronic studies.) [Keller & Heckman history]

- **1966** •[P] Kinoshita, Frawley & DuBois, DDT/**toxaphene** microsomal-enzyme induction, *TAP* 9:505–513 (toxaphene = a Hercules product).
- **25 Jan 1967** ♦[P] Frawley delivers the mature version at the **BIBRA Fifth Annual Scientific Meeting, London** (220 chronic studies), published as *Food Cosmet. Toxicol.* 5(3):293–308. States FDA "**authorized me to tell you that they are giving it serious consideration, but could not reach a decision prior to this meeting.**" Appendix cites unpublished **Hercules** (ref. 3) and **IBT** (ref. 26) data.
- **1967–68** ♦[P-cite] Frawley corresponds with the **NAS Food Protection Committee** (letters to Paul Johnson, the FDA Hearing Clerk, Richard Hall) — UCSF Darby Papers.
- **13 Feb 1968** ♦[P] FDA's **National Conference on Indirect Food Additives** (Washington D.C.; opened by Commissioner Goddard) — the agency's response to Rep. Dingell's unanswered Aug-1967 questions. **Frawley presents his "Reasoned Approach"** address (245 chronic studies; 0.1 ppm / 0.2% rule; "24 toxicologists endorsed it to FDA"; "I personally had spent over a million dollars... all wasted"), printed as *Food Drug Cosm. Law J.* 23(5):260–270. **FDA Bureau of Science chief W. H. Summerson rebuts it** the same day — "soundness... but... sheer nonsense" (*Food Chem. News*, 19 Feb 1968). [Frawley's text = local PDF; Summerson = 08\_VINYL\_CHLORIDE §4]
- **12 Jul 1968** ♦[P-cite] Frawley writes the NAS "**Ad Hoc Committee on Insignificant Levels**" that he will **not** take an active part in drafting its report. [UCSF yhgd0228]
- **1968** •[P] (the **Fitzhugh tribute**, *FCT* 6(2):121–122; Frawley's "Reasoned Approach" FDCLJ paper is now dated above to the 13 Feb 1968 conference.)
- **1969** ♦[P-cite] The NAS/NRC Food Protection Committee publishes "**Guidelines for Estimating Toxicologically Insignificant Levels of Chemicals in Food**" (0.1 ppm threshold, carcinogen/pesticide/heavy-metal exclusions). DOI 10.17226/20376.
- **1969** ♦[2] FDA's "serious consideration" crystallizes as the **Ramsey Proposal** ( $\leq 50$  ppb migration exemption).
- **Aug 1968 / released 1969** ✖[P] Per affidavit, Hercules learns of possible 2,4,5-T **teratogenicity** only when the government releases the **Bionetics Report** (commissioned 1963).

## Regulatory fights & winding down

- **Apr 7 & 15 1970** ⚡[P] Senate "**Effects of 2,4,5-T on Man and the Environment**" hearings — **Frawley absent** from the witness index (Dow's Rowe testifies). [read directly]
- **3 Jun 1971** ♦[2] FDA tells Ramsey it cannot go forward with his proposal — "scientifically sound" but legally unworkable. *The de minimis idea dies inside FDA for a generation.*

- **4 Mar 1971** ✂[P-cite] Frawley & **E. Ross Hart** (Hercules) → EPA/USDA's **Upholt** re the Bionetics 2,4,5-T study. [UCSF **rxfb0228**]; **5 May 1971** the 2,4,5-T Advisory Committee "Objections" doc names Frawley + Hercules [UCSF **zkcb0228**].
- **1971** •[P] Su, Kinoshita, Frawley & DuBois (18 organophosphates), *TAP* 20:241–249; Borzelleca, ..., Frawley, ..., Hayes, McCollister & Scala letter, *Science* 174:545–546.
- **1973** •[P] Kennedy, Frawley & **Calandra** (IBT), multigeneration pesticide reproduction, *TAP* 25(4):589–596 — the last and most IBT-entangled study (the kind later central to the IBT fraud findings). (*A secondary source renders a co-author "Frawley MP"; PMID 4795382 gives JP.*)

### Late career, litigation, legacy

- **Jun 1981** •[P] Frawley, "**The 1980s — A decade of change**," *Regul. Toxicol. Pharmacol.* 1(1):3–7 — the inaugural-issue article (he is an associate editor).
- **May 1982** → **14 Oct 1982** ⚡[2] Special Master **Schreiber's PTO 43 / 96 F.R.D. 582** seals all MDL 381 documents and depositions (Frawley's among them).
- **20 May 1983** ⚡[P] **565 F. Supp. 1263**: Judge **Pratt** grants **Hercules summary judgment** on the government-contractor defense, resting on **Frawley's deposition + affidavit** (dioxin-free product; no worker chloracne 1961–70; first knowledge Feb 1965; the 1963 letter "relate[s] to 2,4-D, not... 2,4,5-T"). Rearg. denied **22 Jun 1983**.
- **(post-1983)** ⚡[2] **Chief Judge Weinstein WITHDRAWS Pratt's opinion** and reinstates the defendants — the SJ win is **vacated before trial**. [recited in 516 U.S. 417]
- **May 1984** ⚡[P] Hours before trial, defendants create the **\$180M** settlement fund; **Hercules' share = \$18,772,568**.
- **1985** •[P] Frawley, "Editorial," *RTP* 5(3):239.
- **1987** •[P/♦] **Rulis (FDA)** publishes "De Minimis and the Threshold of Regulation," **crediting Frawley 1967** as precursor. Same year, SOT gives Frawley the **Arnold J. Lehman Award** (named for his own FDA mentor/co-author).
- **1987** ⚡[P-cite] *U.S. v. Vertac*, 671 F. Supp. 595 cites "**Frawley deposition p. 45**" (PX 213) — a second deposition appearance.
- **1988–90** •[2] Frawley is **ISRTP** VP then **president** (W. Gary Flamm as VP); runs **Health & Environment International Ltd.**, Wilmington.
- **1989** •[P] Frawley reprises "**Our sacred food — a perspective**," *RTP* 9(3):209–211.
- **Mar–Apr 1994** ⚡•[P] A "**Statement of John P. Frawley, Ph.D.**" is **drafted** (by/with **Covington & Burling**) for the House **Waxman tobacco hearings** — Frawley as a **tobacco-industry consultant** — but is a **DRAFT never delivered** (zero "Frawley" in the printed record). [UCSF IDL zqxb0104, lhyg0018, ...]
- **1996** ⚡[P] **Hercules, Inc. v. United States**, 516 U.S. 417 — Supreme Court denies Hercules recovery of its settlement/defense costs from the U.S.
- **1995** ♦[P] FDA's **Threshold of Regulation rule (21 CFR 170.39, 60 FR 36582)** — the de minimis idea finally codified (0.5 ppb), via the **Rulis** line; the

rule cites Rulis, **not Frawley** directly.

- ~**2003–2004** Frawley **dies** (bracketed by SOT deceased-asterisk convention; exact date **unconfirmed**, no obituary located).
- **1998 / 2007** 砵[2] Hercules pays **102.9M(1998) \* \*and \* \*124M (2007)** Vertac-site Superfund judgments — the long tail of the Jacksonville 2,4,5-T/dioxin operation.

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*The 1963–1965 cluster is the analytic heart: see **06\_ANALYTIC\_MEMO** for the consistency assessment of Frawley's 1983 sworn account against these contemporaneous rows.*