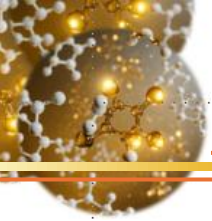


Stephen F. Bozer

Senior Vice President, Human Health
Flavine North America, Inc.

Email: Stephen.Bozer@flavine.com

Website: www.flavine.com



When Policy Gets the Chemistry Right

The Hatch-Waxman Act (1984) was a masterclass in balanced incentives:

- **For Innovators:** Favorable **marketing exclusivities** and **patent extensions** to reward R&D investment and risk-taking
- **For Generics:** **Abbreviated approval pathway** to bring **affordable medicines** to Americans
- **The Result:** A **thriving pharmaceutical ecosystem** that made the U.S. the global leader in drug innovation AND access

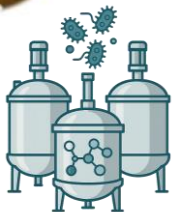
The Question Before Us Today:

Can we design a "Hatch-Waxman 2.0" that incentivizes not just innovation and affordability, but supply chain resilience and national security?



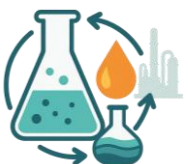
Keep the gains, close the gaps

The Chemistry Behind Your Medicine Cabinet



FERMENTATION:

- Biological production of antibiotics, insulin & vaccines
- Requires specialized vessels & contamination control
- *Think: brewing beer, but at pharmaceutical precision*



SOLVENTS:

- The "water" of chemistry used to dissolve, extract & purify
- Utilized in nearly every pharmaceutical reaction



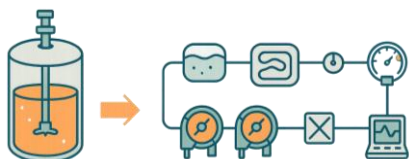
HIGH POTENCY CAPABILITY:

- Oncology & cytotoxic drugs, hormones and prostaglandins – active at microgram & picograms levels
- Requires contained facilities to protect workers



PETROLEUM INFRASTRUCTURE:

- Basic organic building blocks for many drug synthesis
- Common groups: Aromatics, Olefins & Aliphatics → complex molecules
- *The foundation of modern chemistry*



NEW TECHNOLOGY:

- Continuous Manufacturing & **Flow Chemistry**: continuous processing in tubes, not batches in tanks
- CRISPR-Cas9 Gene Editing → Cell Line Engineering
- **Artificial Intelligence (AI)** and Machine Learning
- These tech help make drug development faster, safer & more efficient – China and India are investing NOW

Respect the Chemistry – Three Hard Truths



THE COST REALITY – Building a resilient U.S. API supply chain will be expensive

- Not just factories but entire chemistry networks
- Solvents, catalysts, enzymes, intermediates & waste treatment
- Every pharmaceutical supply chain has 50-200 chemical steps



THE SAFETY IMPERATIVE:

- Bulk chemistry is inherently hazardous
- Proper handling, training, and infrastructure are non-negotiable
- Cutting corners on safety = cutting corners on communities



THE WORKFORCE CRISIS:

- Can't build API facilities without people who understand process chemistry
- China graduates 3 to 5 times more students in STEM fields than the U.S. with gap widening
- Onshoring APIs without onshoring expertise = Failure

Closing Remark: *Respecting the chemistry means respecting the complexity, the costs, the safety requirements, and the human expertise required. Half-measures won't work.*