Tales of Woe: How Federal Regulation Destroyed Entire Sectors of Biotechnology

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Biotech Regulatory Debacles

- "Ice-Minus" Bacteria – to prevent frost damage
- "FrankenFish" – fast-growing, farmed salmon
- Mosquitoes – for control of disease-carrying mosquitoes
- Bioremediation – cleanup of toxic wastes
- Biorational pesticides – to supplant chemical pesticides

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Preventing Frost Damage to Plants

- Frost damage to crops → billions in crop losses, lost jobs and increased consumer prices
- Frost damage promoted by *P. syringae* ("ice-plus")
- "Ice-minus" *P. syringae* effective in fields trials:

  lowers freezing point to 18^0 - 29^0 F

Regulatory Barriers

- EPA: "Products are. . . pesticides if they are intended for preventing, destroying, repelling, or mitigating any pest or intended for use as a plant regulator, defoliant, or desiccant.“
- EPA: “Ice-plus” bacteria are *pests*
- EPA: Therefore, “ice-minus” bacteria are *pesticides*

Regulatory Barriers

- Registering a pesticide:

  ~11 years

  ~US$286 million

- The "ice-minus" *P. syringae* was abandoned

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AquAdvantage® Atlantic Salmon

- Grows faster → reaches maturity 40% faster
- Consumes 25% less food
- Contains a growth hormone gene from Chinook salmon
- Sterile females
- Farmed inland

AquAdvantage® Salmon

Regulatory Timeline

- **Mid-1990s**: Company submitted dossier to FDA
- **2008**: FDA decided on regulatory pathway
- **2012**: Review hijacked by Obama White House
- **2015**: FDA decided AA salmon "safe to eat"
- **2018**: Still not sold in U.S.

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Genetically Engineered Mosquitoes

- *Aedes Aegypti* mosquitoes
- "Conditional lethal" mutation
- Successful field trials in several countries, commercial approval in Brazil
- FDA regulates them as a "new animal drug"
- FDA review: 2011-2016 → approved 1 field trial

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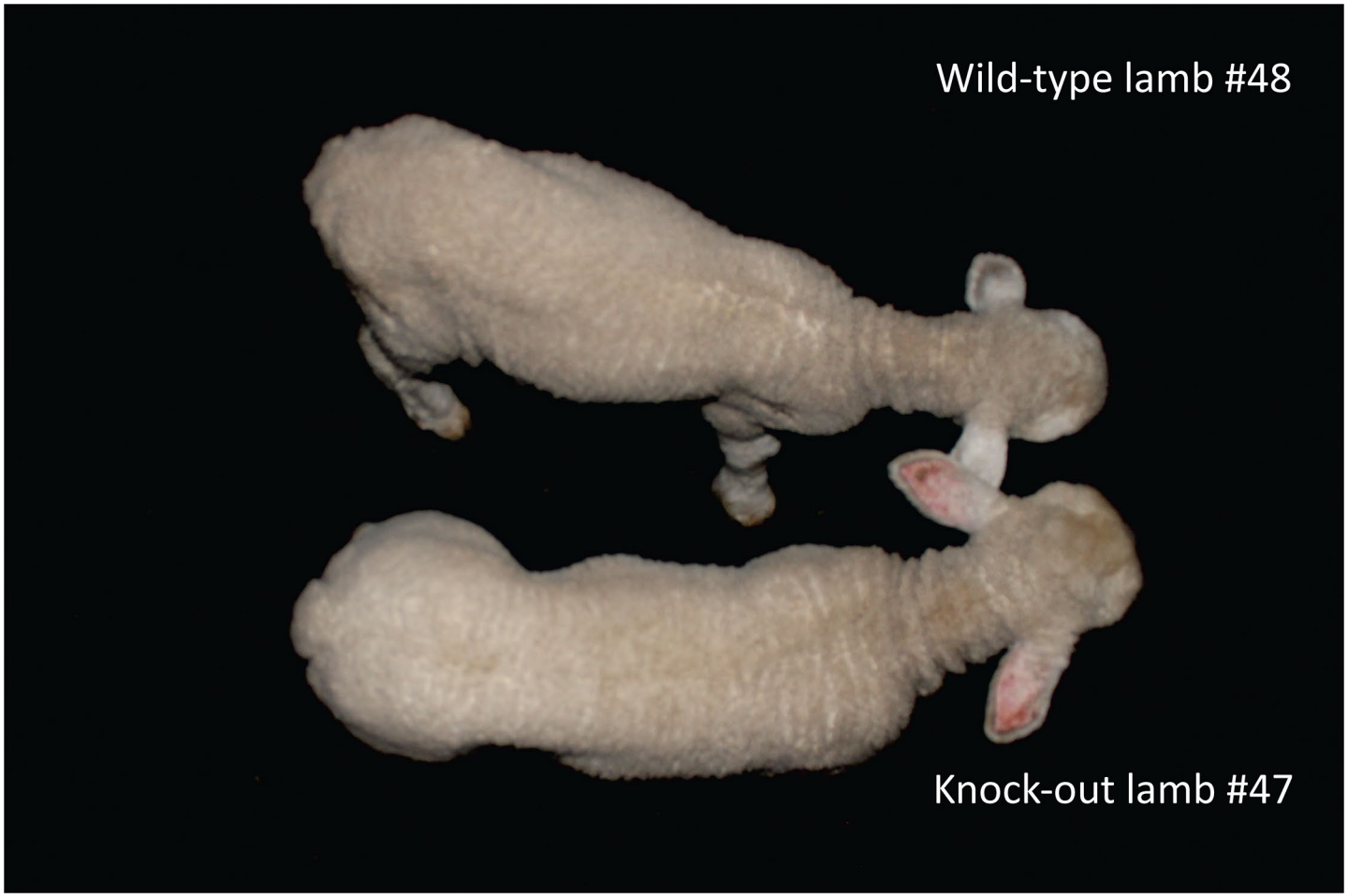
- FDA could not have approved the product for marketing! ("The U.S. Is Botching the Zika Fight," *Wall Street Journal*, Mar 14, 2016)

GE Mosquitoes: The Outcome

- FDA cedes jurisdiction to EPA (2017)

More Examples



More Examples

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Bioremediation

- "When I saw the full scale of the disaster in Prince William Sound in Alaska [1989]... my first thought was: '*Where are the exotic new technologies, the products of genetic engineering, that can help us clean this up?*'"

-- EPA Administrator William Reilly

Bioremediation

- EPA regulates microorganisms that contain DNA from different sources
- First oil cleanup microorganisms patented in 1980

Bioremediation

- None has been commercialized
- We still use 19th century technologies

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Biorational Pesticides

- Proposed field trial of *P. fluorescens* w/ *Bt* gene
- EPA denied permission for field testing
- Commercial interest evaporated

Conclusions

- Any of these sectors could have been biotech's Next Big Thing
- All are now moribund
- Heads should roll
- We need better congressional oversight of regulatory policy and regulators

Thank you!

Q&A

Regulation and R&D

- Excessive or uncertain regulation → less R&D → fewer products
- Compare semiconductors (no required testing/review) to ag & environmental biotech (years of testing and government approvals and uncertain outcome)