Healthcare Innovation and Intellectual Property

Florida Tech and Innovation Summit 2022

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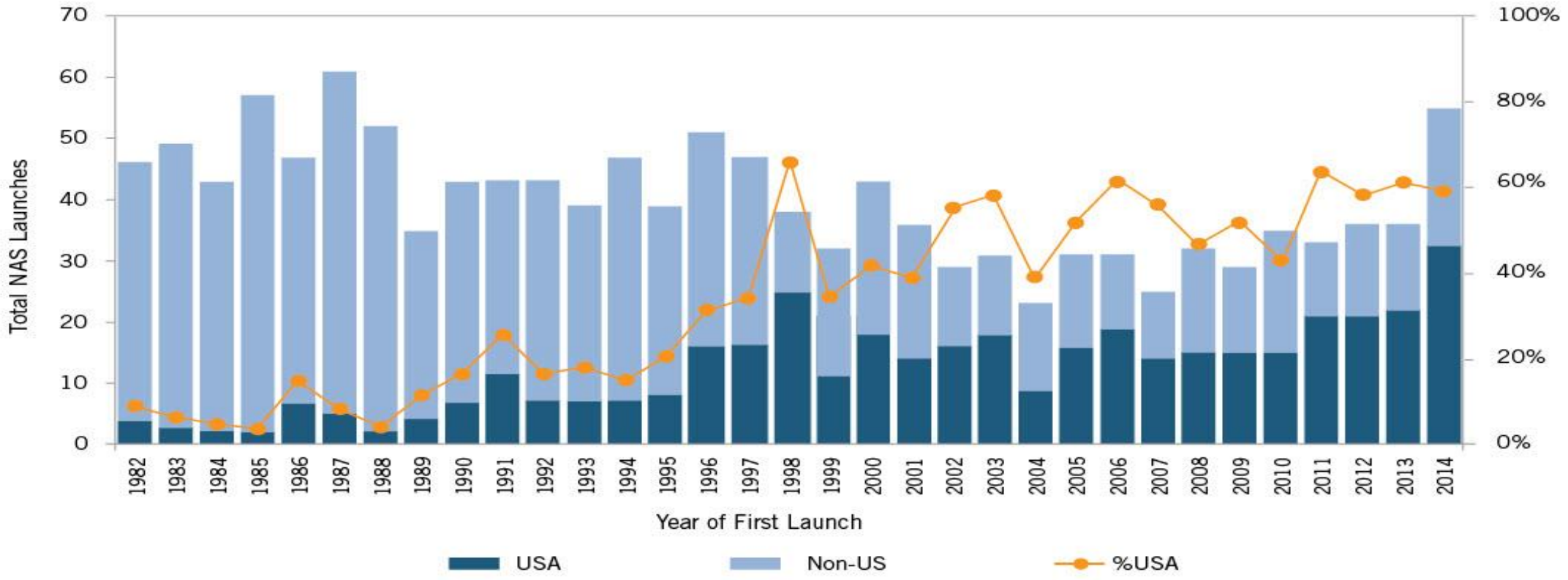
U.S. Was Once a Global "Also Ran" in Biomedical Innovation

U.S. Share of New Active Substances (NAS) Launched First on World Market



Source: John K. Jenkins, M.D., "CDER New Drug Review: 2015 Update

Keys to Today's U.S. Life-Sciences Innovation Leadership

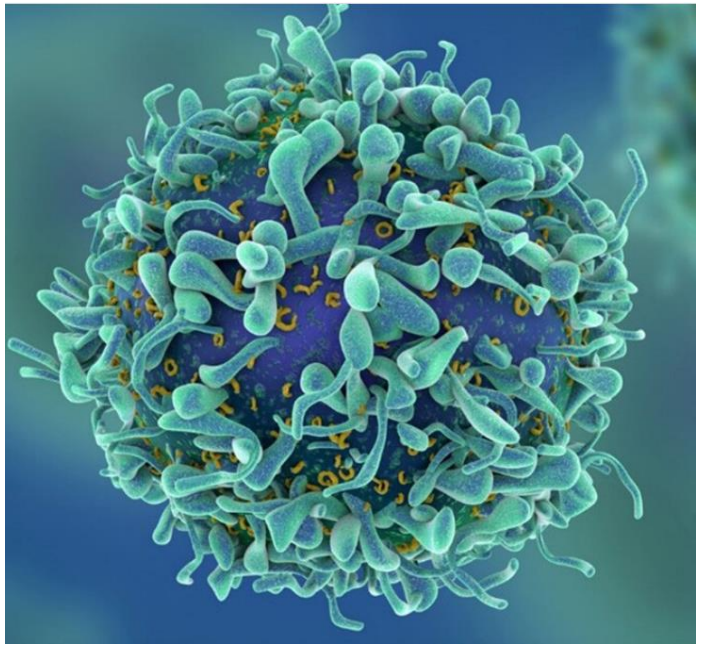
1. Robust public/private investment in biomedical research.

2. Aggressive incentives to encourage investment. (E.g., R&D tax credit, Orphan Drug tax credit.)

3. Effective regulatory/drug approval system (PDUFA).

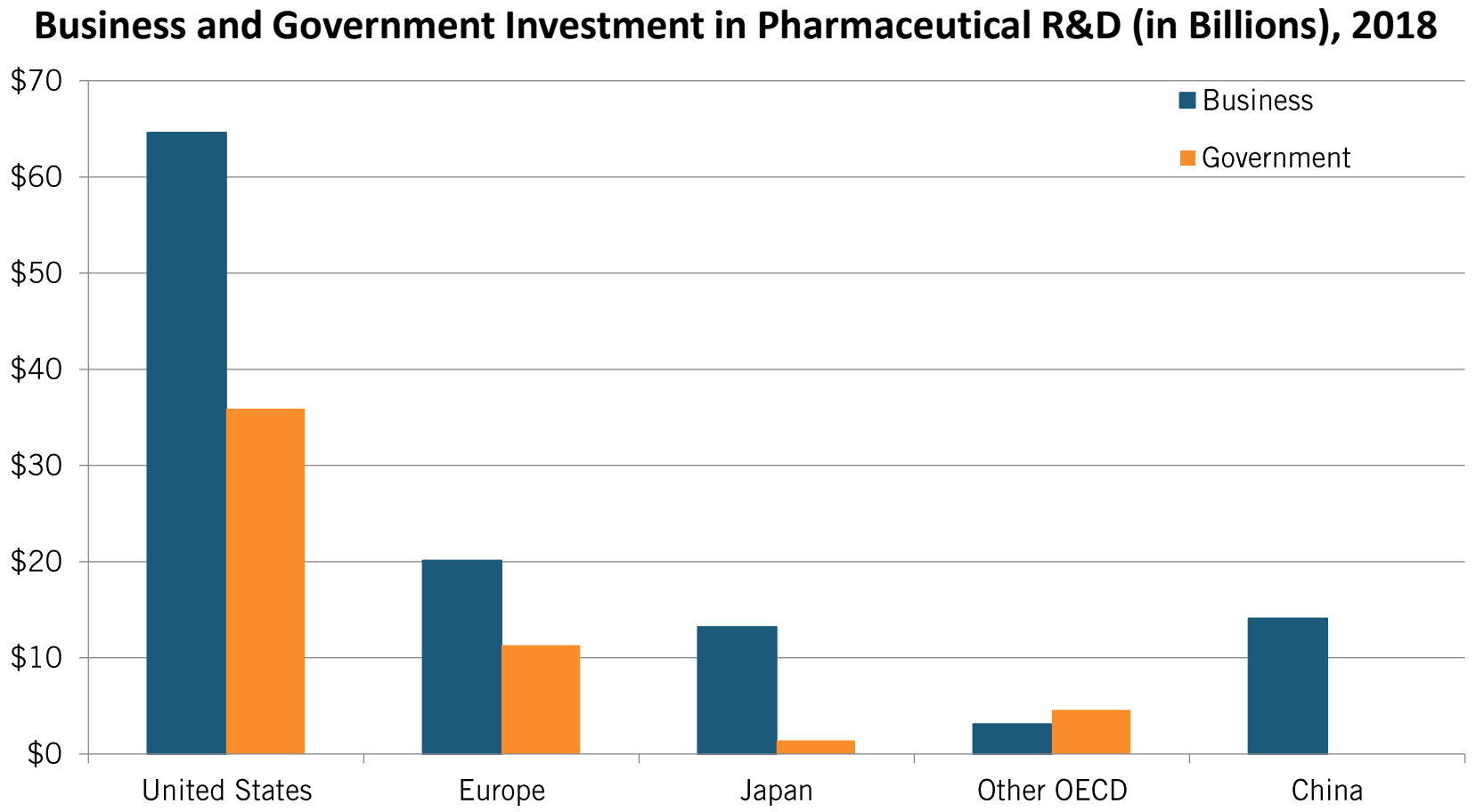
4. Pricing/reimbursement system allowing innovators to earn sufficient revenues.

5. Robust intellectual property protections.



Source: ITIF, "Why Life-Sciences Innovation is "Politically Purple"—And How Partisans Get It Wrong"

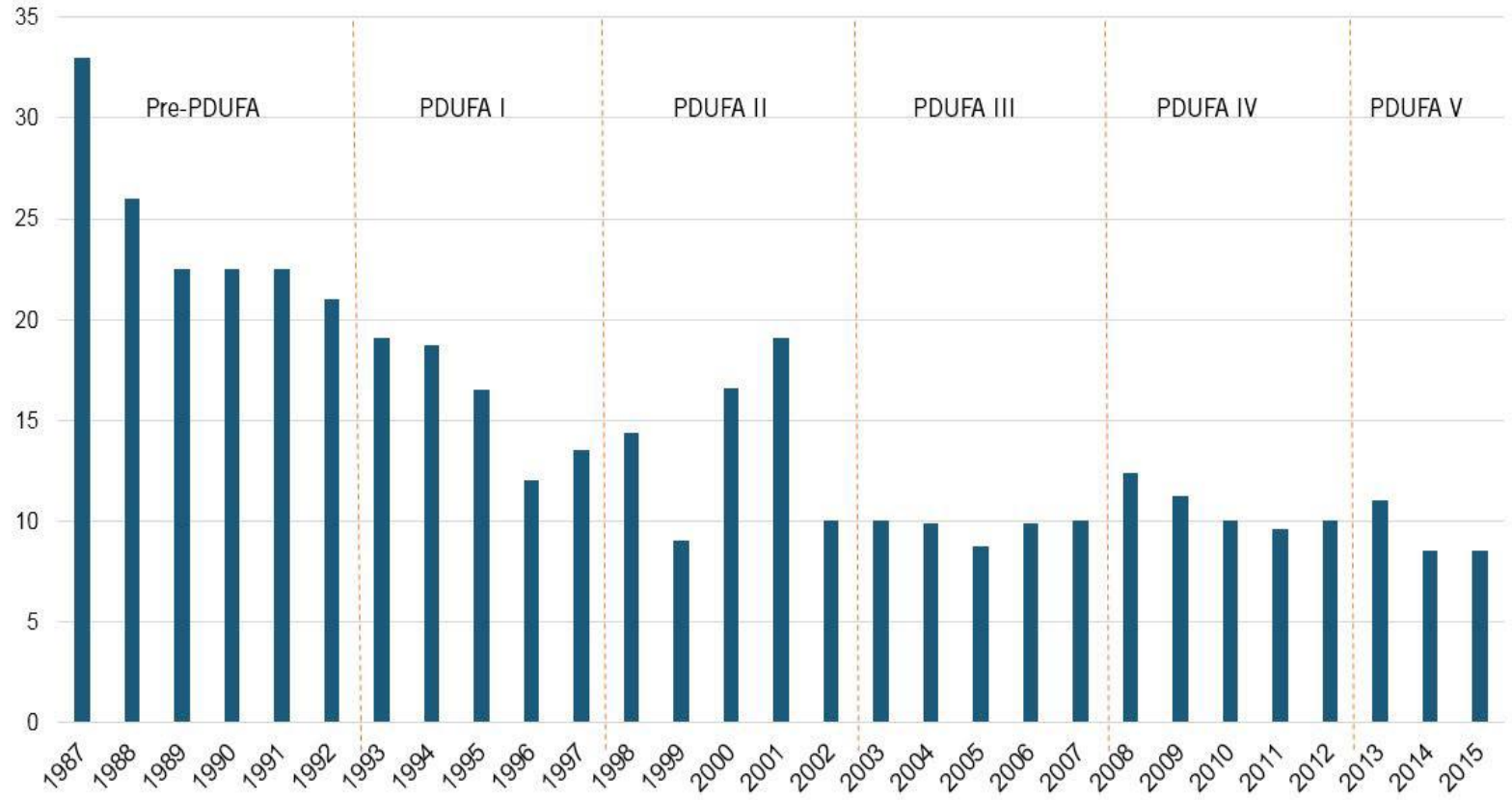
United States Leads World in Biopharmaceutical R&D



Source: ITIF, "Ensuring U.S. Biopharmaceutical Competitiveness"

An Effective Regulatory/Drug Approval System

Median Approval Times for New Medicines, Months (CDER NME NDAs/BLAs)

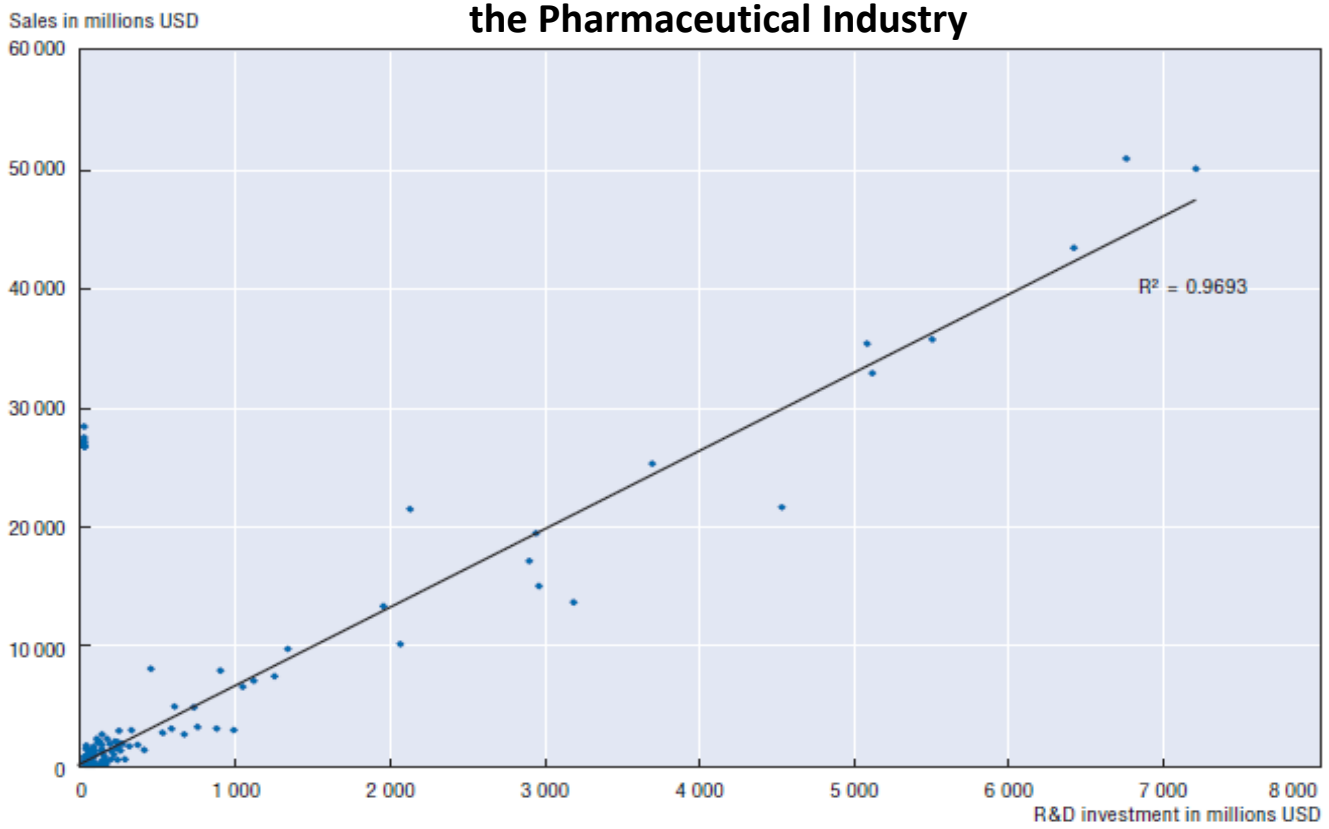


Source: John K. Jenkins, M.D., "CDER New Drug Review: 2015 Update"

Reasonable Profits Are Vital to Biopharmaceutical Innovation

- OECD: "There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures."
- Every $2.5 billion of additional revenue leads to a new drug approval.
- CBO: Price controls would reduce the number of new drugs 3-5% over the next decade.

Relationship Between Sales and R&D Expenditures in the Pharmaceutical Industry



Sources: OECD, "Pharmaceutical Pricing Policies in a Global Market"; Dubois, "Market size and pharmaceutical innovation";
CBO: "Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare"

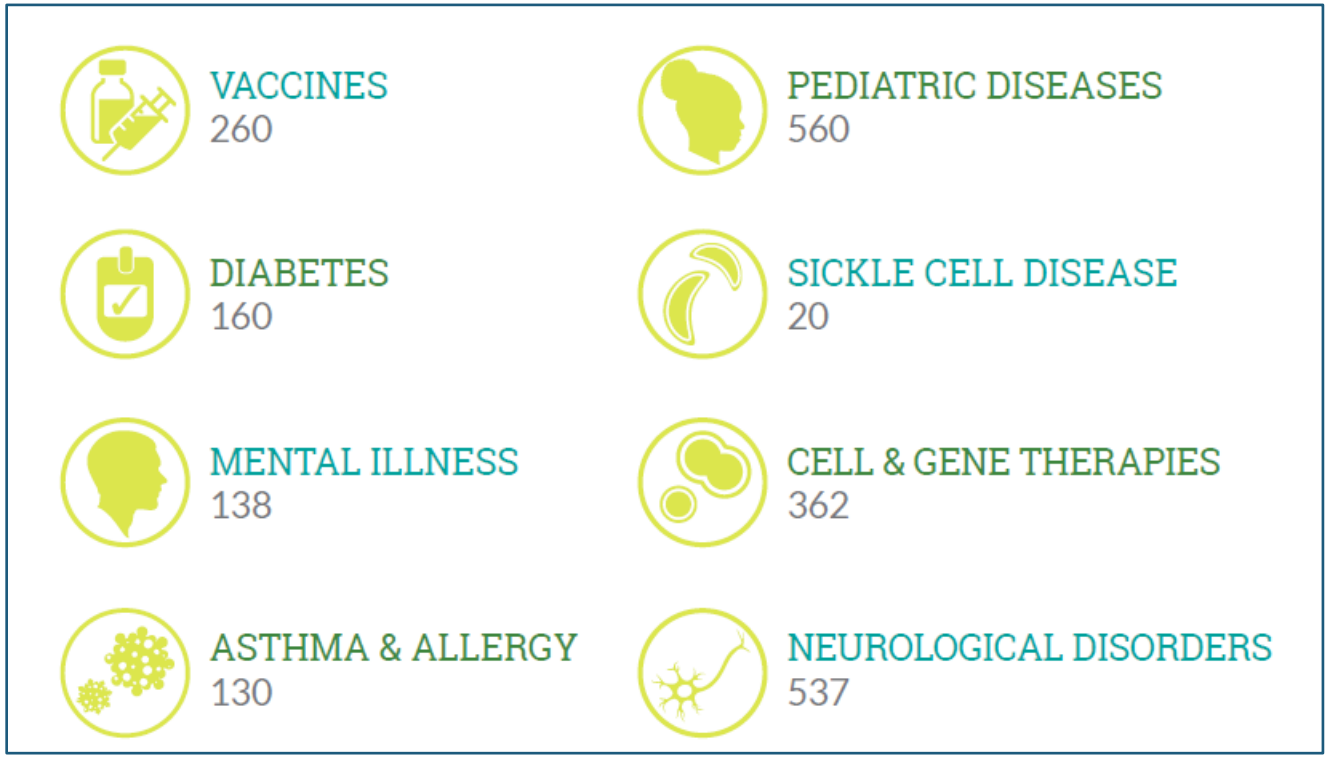
Robust IP Rights Essential for Life-sciences Innovation

- Robust IP rights incent investment in expensive, risky, lengthy innovation.
  - Takes 12-14 years to bring new drugs to market at a cost of $2.5 billion.
- IP constitutes as much as 80% of a life-sciences company's value.

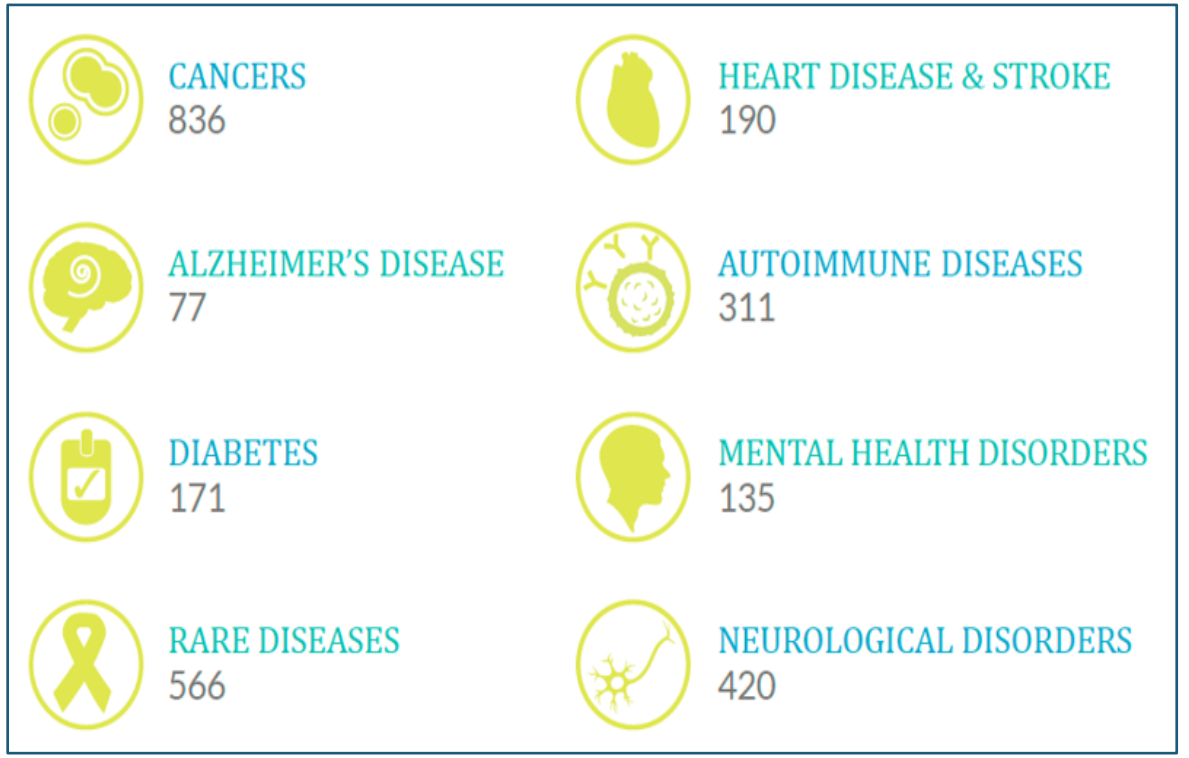
- Requires clear standards for patentability and subject-matter eligibility.
- 12 years of data exclusivity for biologics clinical trial data.
- Bayh-Dole Act allows licensing of IP resulting from federally funded research.

United States Leads the World In New Drugs Developed

4,500 New Medicines Under Development in the United States



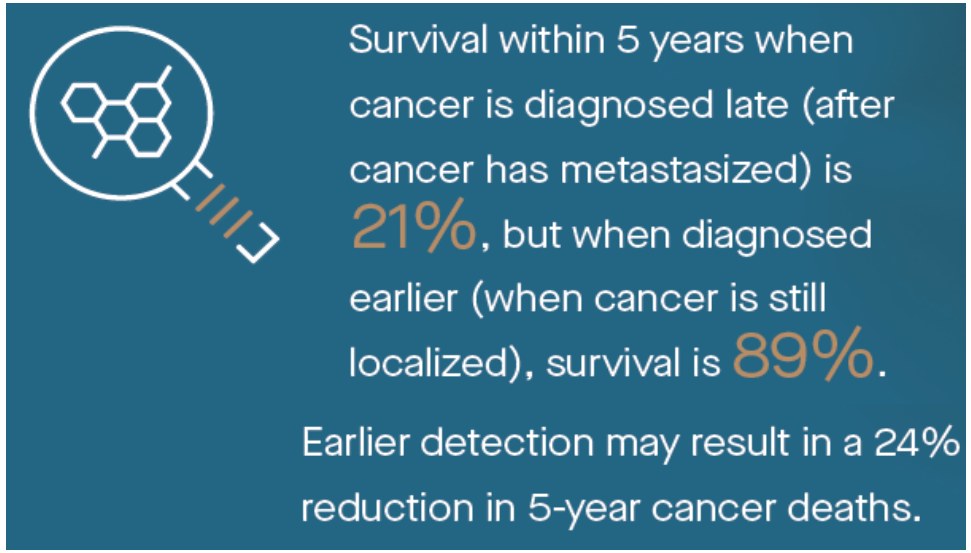
8,000 New Medicines Under Development Globally



Source: PhRMA, "Chart Pack: Biopharmaceuticals in Perspective, Fall 2020"

Multicancer Early Detection (MCED)

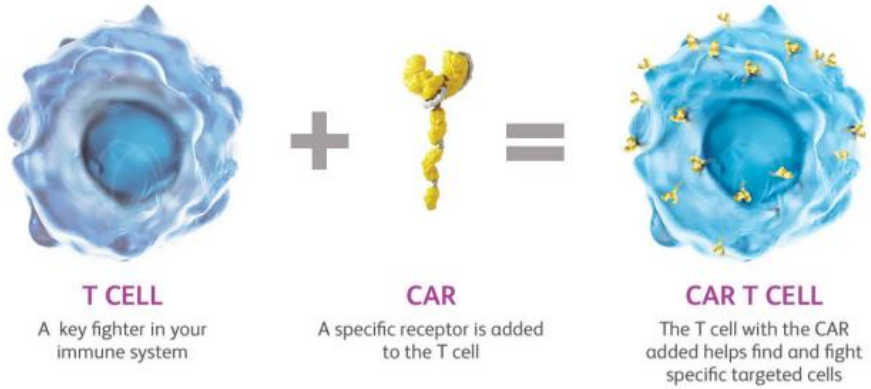
- Convergence of AI/ML and genomics transforming cancer detection.
- MCEDs like GRAIL can detect as many as 50 different types of cancers from a single blood draw.
- GRAIL's test identifies cancerous tissue with 97.1% accuracy and a false positive rate of less than 1%.



Source: ITIF, "Seizing the Transformative Opportunity of Multicancer Early Detection"

Innovative Cancer Technologies and Platforms

- Gene editing through tools like CRISPR-KAS enables alterations to an organism's DNA.
  - Tackling inherited blindness; childhood leukemia.
- Cancer immuno- (or "cell-") therapy: Treatments manufactured uniquely for each individual patient, using a patient's own T cells as the starting material.





CRISPR Gene Editing

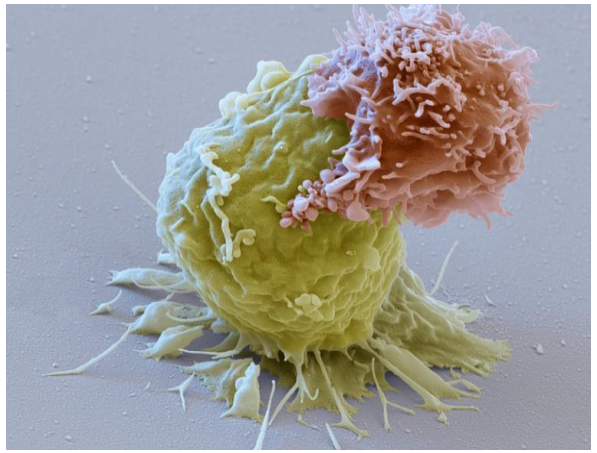
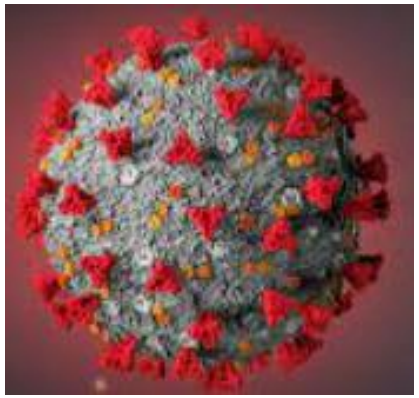
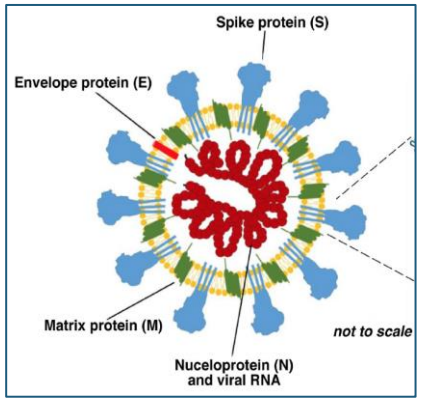


Image of a CAR-T cell (reddish) attacking a leukemia cell (green).

mRNA Unlocks Vast Potential for New Drugs and Therapies

- Before COVID-19, it took an average of 14 years to develop a new-to-the-world vaccine.
- mRNA carries instructions for cells to make specific proteins; COVID-19 vaccines are made of mRNA (wrapped in a coating) that teaches cells how to make copies of the COVID-19 spike protein.
- There are currently 520+ ongoing clinical trials testing mRNA across more than 20 disease categories.





Sources: CDC, "How mRNA COVID-19 Vaccines Work"
Ernst & Young, "How mRNA Medicines Might Change the Drug Landscape"

Thank You!

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