



International Reference Pricing and the Impact on Patient Access and Future Innovation

BIO Patient & Health
Advocacy Summit

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C GRX

*Kenneth I. Moch
President & CEO
Cognition Therapeutics, Inc.*

International Reference Pricing and the Impact on Patient Access and Future Innovation



- Moderator:

Kenneth I. Moch, *President and Chief Executive Officer, Cognition Therapeutics*

- Panelists:

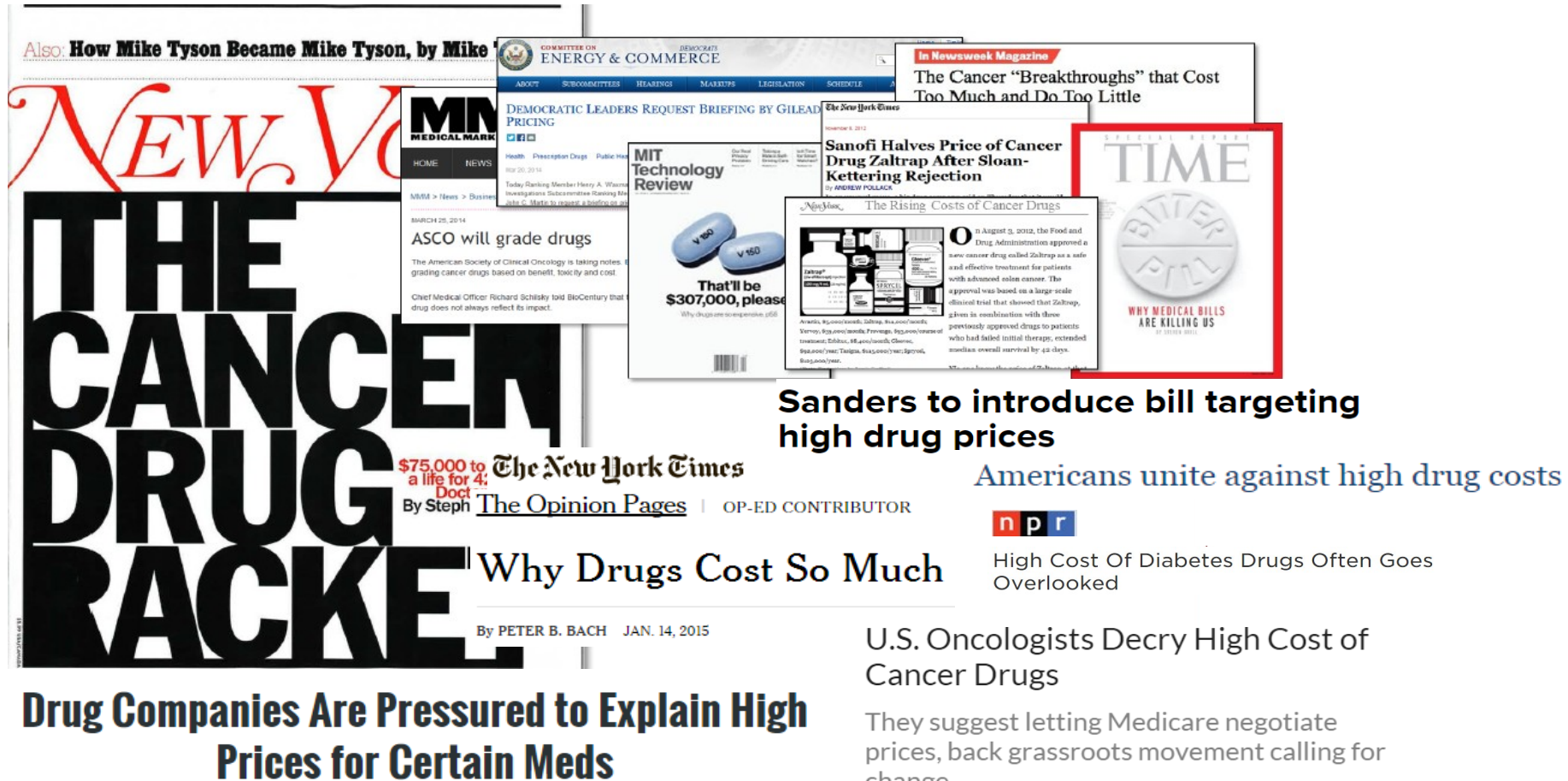
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Alexander Hardy, *Chief Executive Officer, Genentech*

Andrew Spiegel, JD, *Executive Director, Global Colon Cancer Association*

Erin Trish, PhD, *Associate Director, USC Schaeffer Center,
Assistant Professor, Department of Pharmaceutical and Health Economics
USC School of Pharmacy*

The External Environment: Intense Scrutiny of Drug Prices by Patients, Physicians and Politicians



Foreign Reference Pricing: *The Trump Administration Version*



- Last fall, the Centers for Medicare & Medicaid Services (CMS) issued an Advanced Notice of Proposed Rulemaking introducing an “**International Pricing Index (IPI)**” payment model that would dramatically change how prescription medicines are reimbursed under Medicare Part B
- Intended to be tested on half the Medicare program, the IPI model would:
 - Replace today’s Average Sales Price (ASP) reimbursement system with one based on prices in 12 foreign countries
 - Require physicians to acquire drugs from a third-party vendor
 - Replace the 6% add-on payment with a flat fee to physicians
- The IPI model would effectively impact the entire Medicare program as prices for drugs included in the model would be incorporated into the ASPs for drugs outside of the model

Foreign Reference Pricing: *The Democratic Version – H.R. 3*



- Would require the Secretary of Health and Human Services to directly negotiate the price up to 250 brand-name drugs annually that lack a generic or biosimilar competitor and have the greatest cost to Medicare and the U.S. health system.
- Would establish an upper limit for the price reached in any negotiation as no more than 120 percent of the volume-weighted average of the price of six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom). This price is known as the Average International Market (AIM) price.
- The goal is for HHS to negotiate a price that is below the AIM, called the “maximum fair price,” which would be applied to Medicare and even the commercial market. Health plans could use additional tools to negotiate even lower prices.

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Don't We All Want Lower Prices for Medicines? Yes of Course, But...



- **What are the implications of just focusing on the “price” of currently available medicines? And what “price/cost” are we talking about?**
- **What other levers can be changed which will lower the cost of developing new medicines or lower the costs to patients in need?**
- **Since price is a key component of return on investment, and thus a component of investment decisions and the cost and extent of development efforts, how do you compete for capital when the capital can go anywhere in the world for any product for any reason?**
 - **Have we abrogated drug development decisions to the investment world through the focus on capital allocation decisions?**
 - **How do we incorporate societal value to incentivize early stage investments for new medicines, when the return is uncertain?**

All Products are the Result of Risk/Reward Decisions – “What is the Return on the Investment”

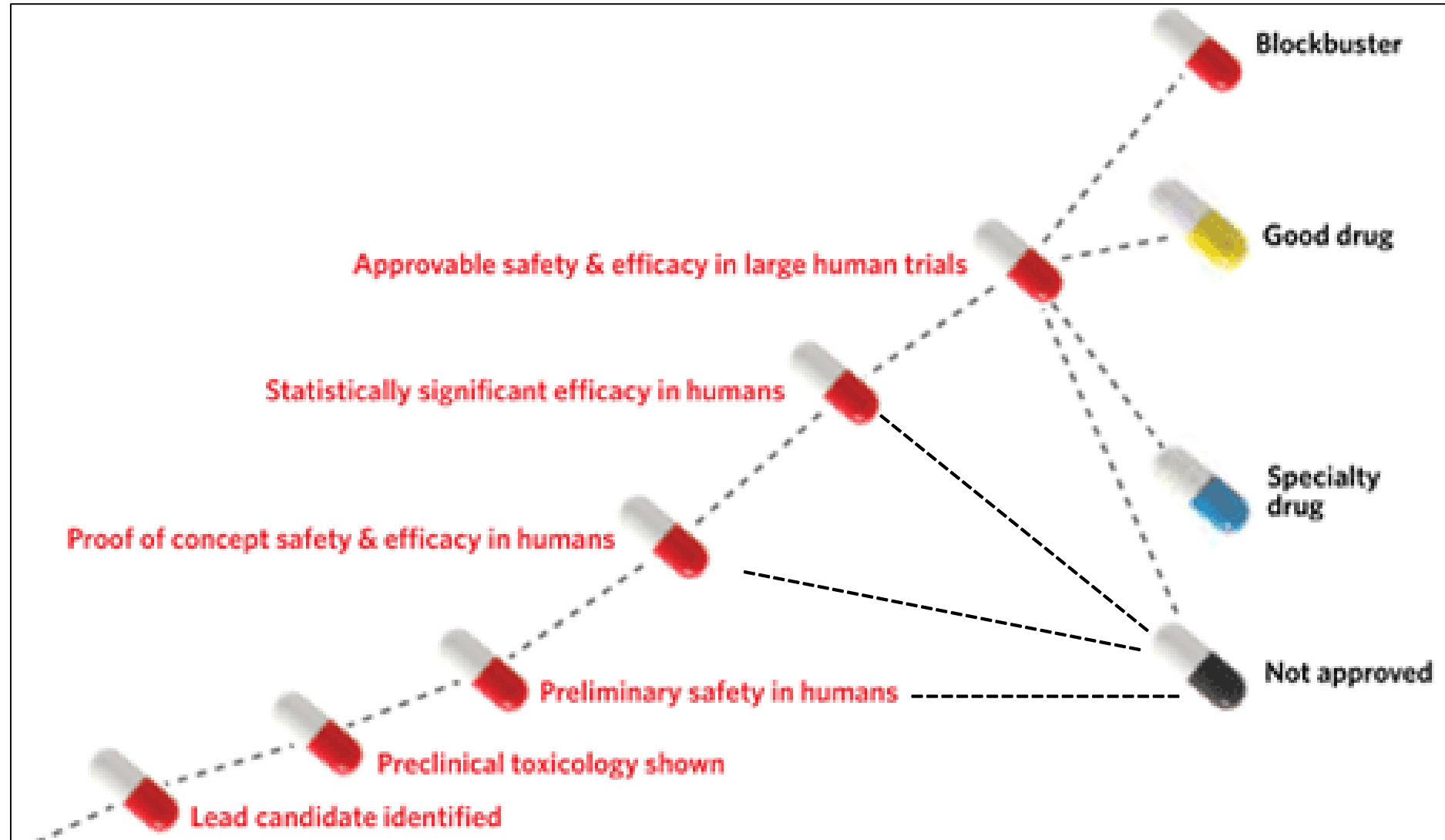


The Levers of Risk/Reward Need to be Considered From These Different Viewpoints



- **Uncertainty is Risk**
- **The riskier the science and/or therapeutic category, the harder it is to fund companies or projects to develop new medicines:**
 - Clinical Trial risk – probability of a successful development program
 - Regulatory risk – probability of approval based on acceptable endpoints
 - Patent risk – probability of reduction in patent terms globally, IPRs
 - Pricing risk – probability and impact of global and US price controls

A Basic Drug Development Risk: The Result and Thus the Return is Unknown Until the End of Development

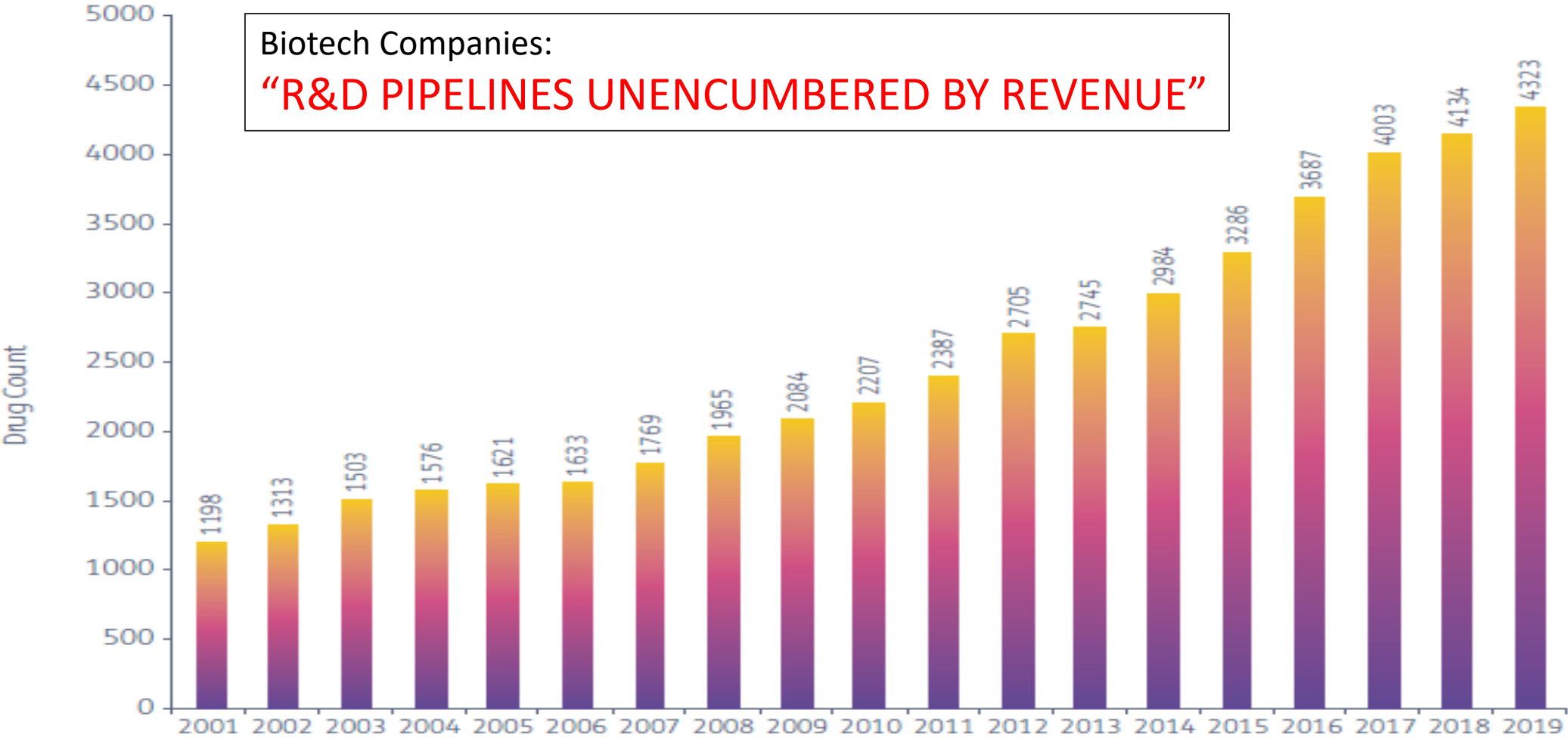


In Drug Development, Risk/Reward and Capital Allocation is Viewed Through the Lens of the Investing Entity



- **Large Companies:** focused on maximizing competitive returns from multiple products in multiple therapeutic categories
- **Investors (Venture Capitalists, Public Equity Investors, Individual Investors):** focused on maximizing returns to their pool of capital
- **Biotech Companies:** initially focused on a scientific idea, and then the ability to make an argument for a future return to investors through a liquidity event

Biotech Companies Are Clearly the “Feedstock” of New Medicine Development



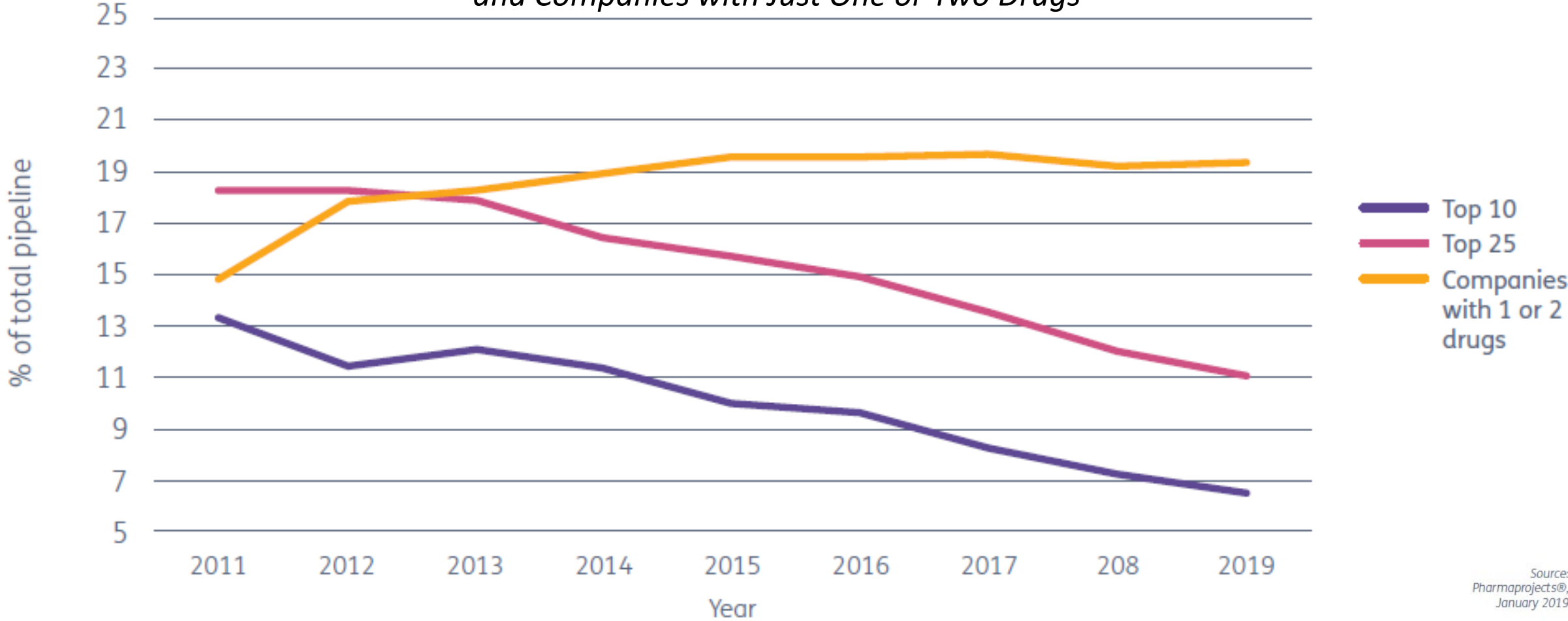
Total Number of Companies with Active Pipelines – 2001 - 2019

Source:
Pharmaprojects®,
January 2019

Share of New Medicine Pipeline by Largest Pharma Companies Declining as More Biotech Companies Evolve



Share of the Pipeline Contributed by Top 10 and Top 25 Pharma Companies, and Companies with Just One or Two Drugs

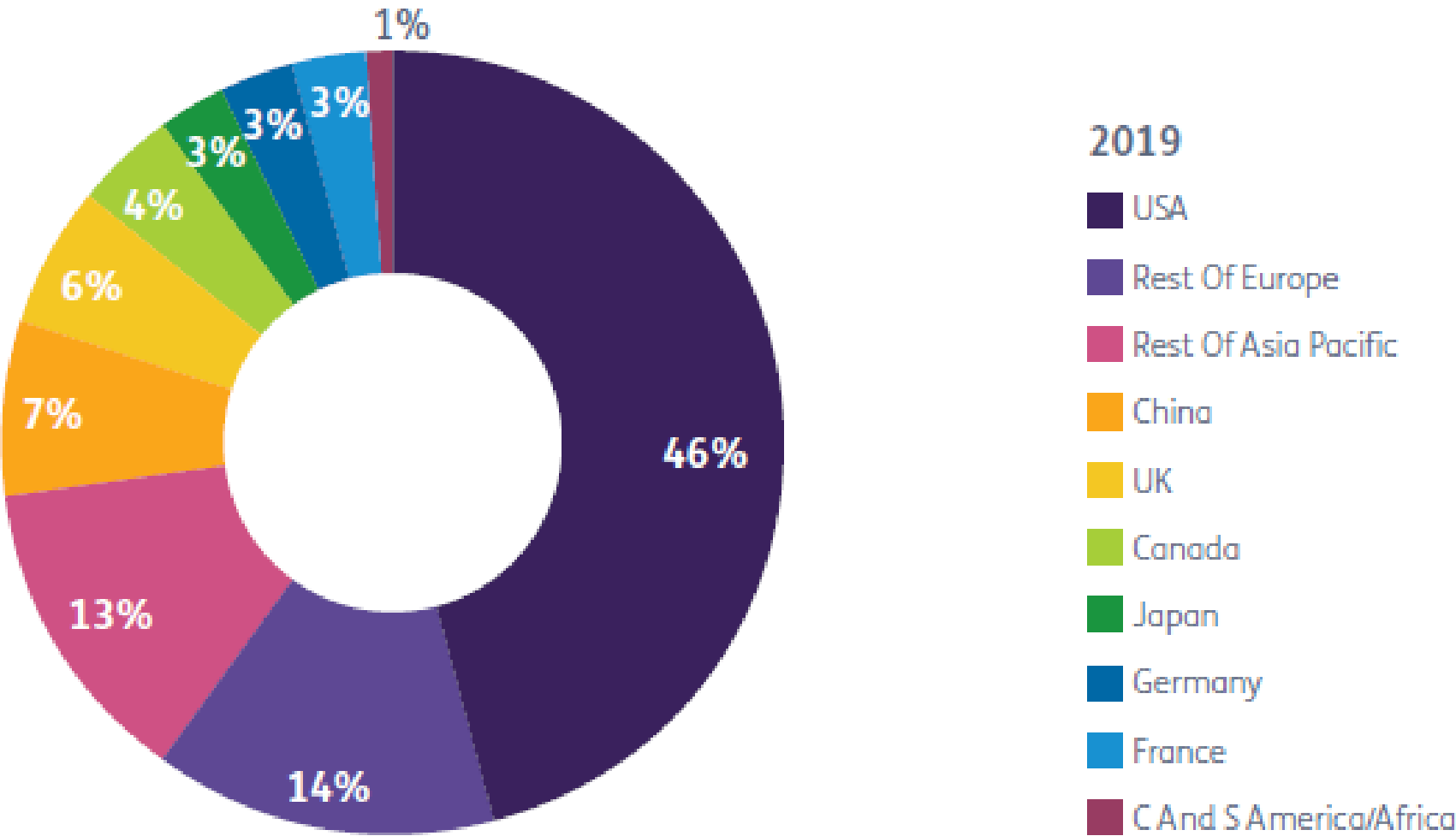


Source:
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The US Remains the Focal Point for Innovative Biotech Companies, but Not Without Competition

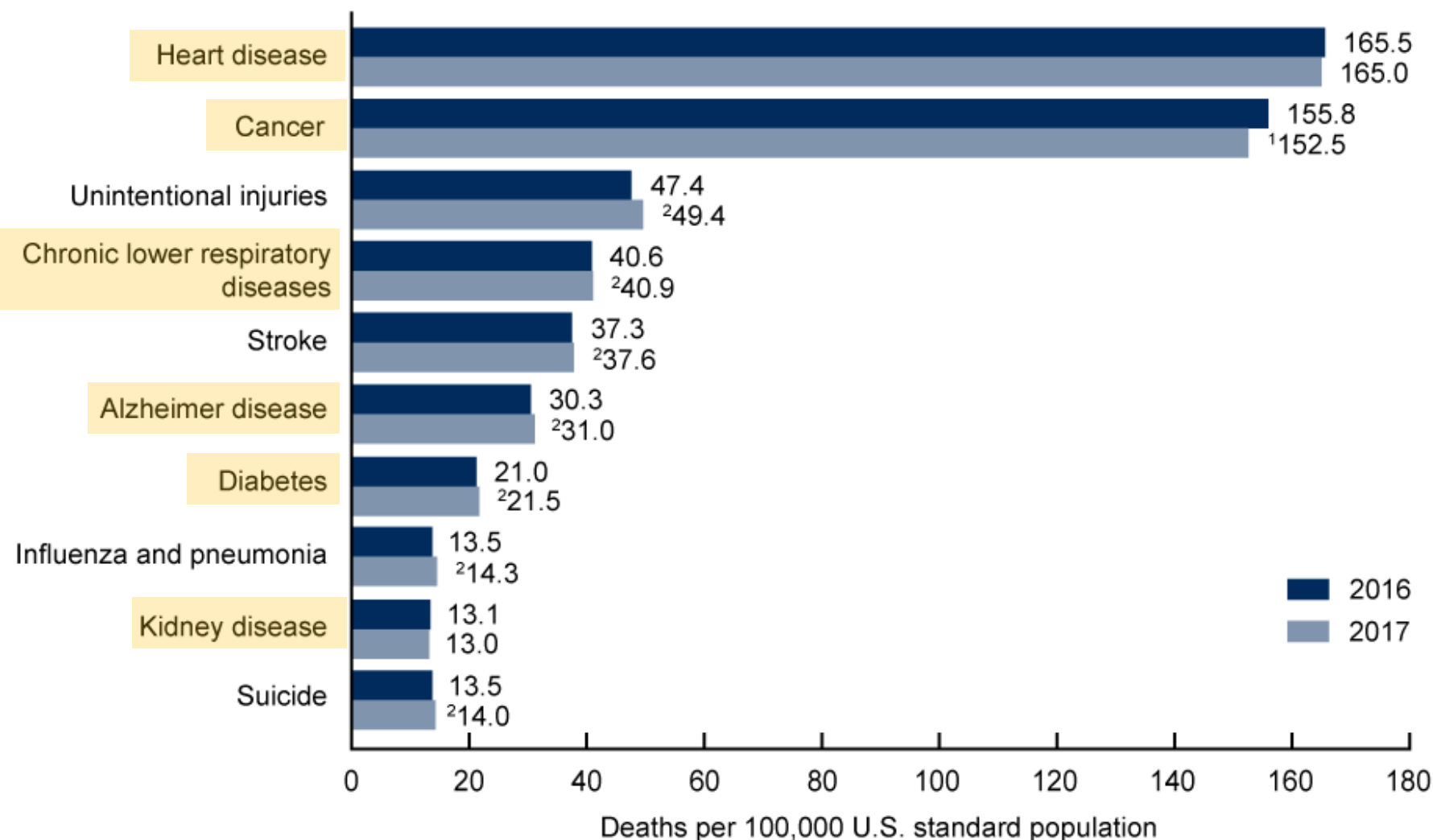


Distribution of R&D Companies by HQ Country/Region - 2019



Source:
Pharmaprojects®,
January 2019

Age-Adjusted Death Rates for the 10 Leading Causes of Death: United States, 2016 and 2017



Source: NCHS, National Vital Statistics System, Mortality

The Risk/Reward Investment Decision/Dilemma Through the Lens of Highly Prevalent Chronic Diseases (HPCDs)



Where would you invest?

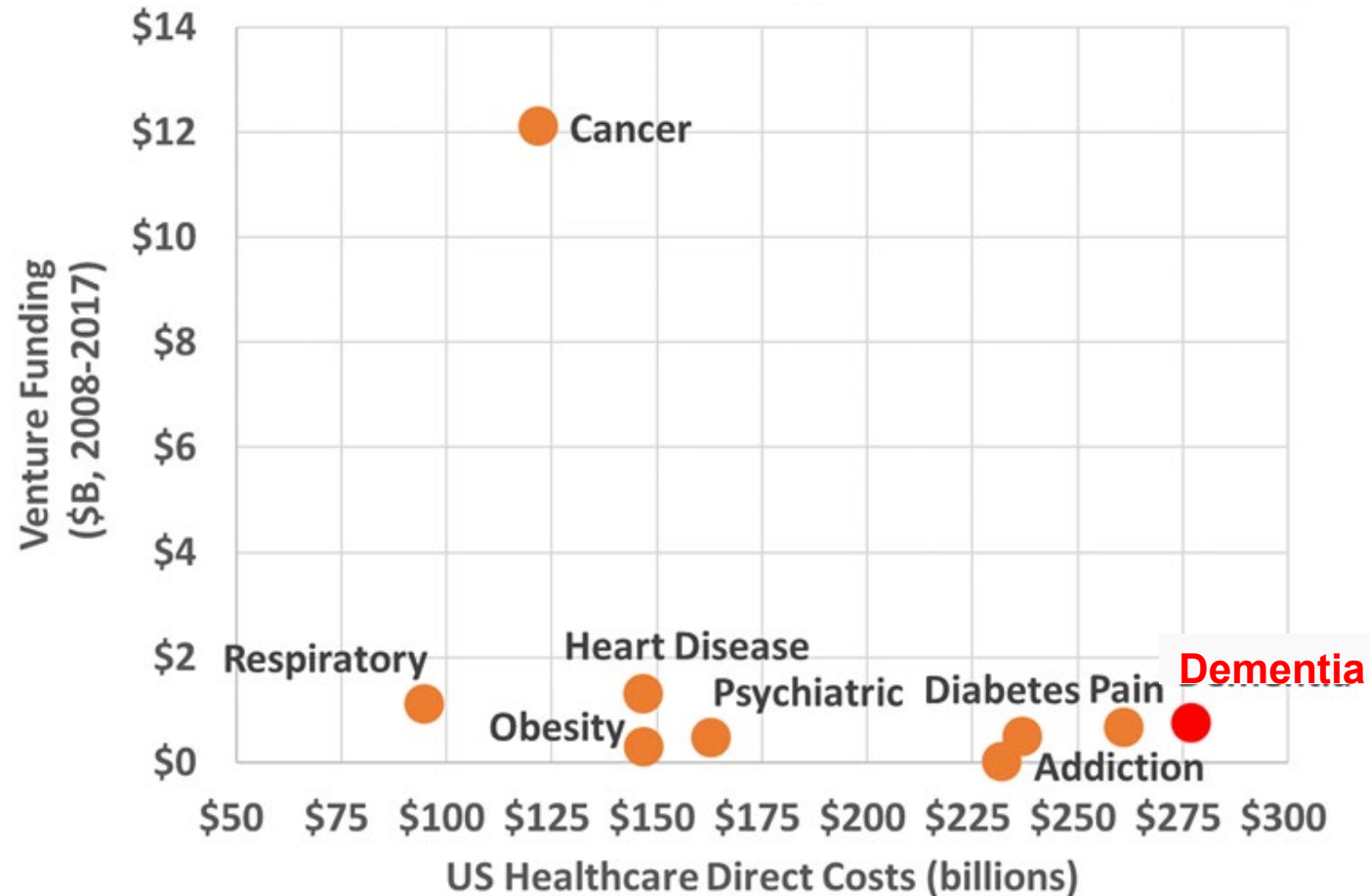
- Oncology; Gene Therapy; Rare Diseases:
 - Genetically defined patient population (increasingly)
 - Defined endpoints
 - Increasing success rates

- Alzheimer's:
 - Heterogeneous patient population
 - Subjective and imprecise clinical endpoint
 - 15 year probably of success = asymptotic towards 0%

Many of the Diseases with the Highest Societal Costs Have the Lowest Relative Venture Funding



US Healthcare Spending vs. US Venture Funding

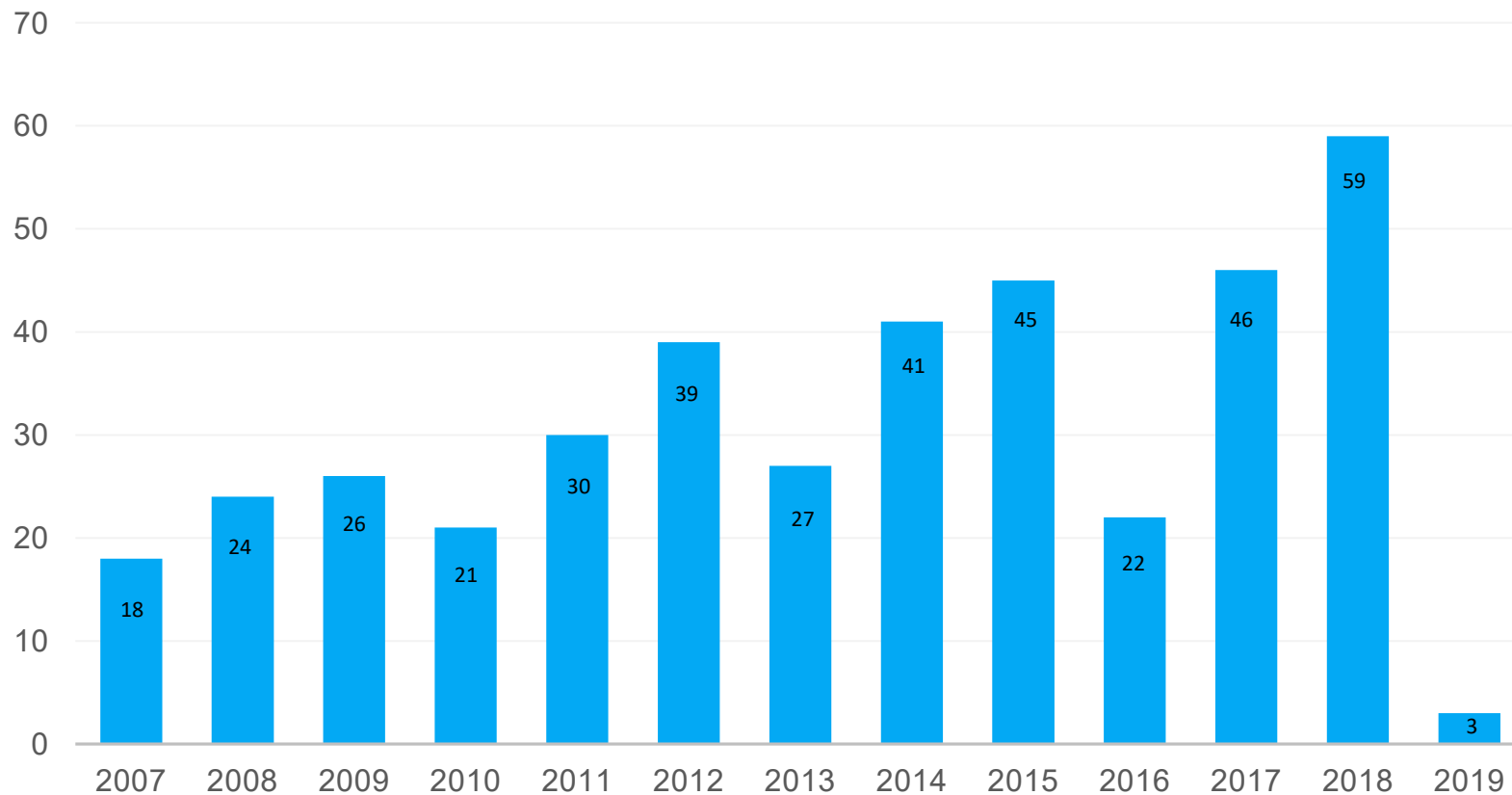


Source: BIO Industry Analysis, 2019

FDA Novel Drug Approvals Reached a Record High in 2018, Focused on Oncology and Rare Diseases



**In 2018, the FDA approved 59 novel drugs
1/3 in oncology; 1/3 in rare diseases; 1/6 in infectious disease**

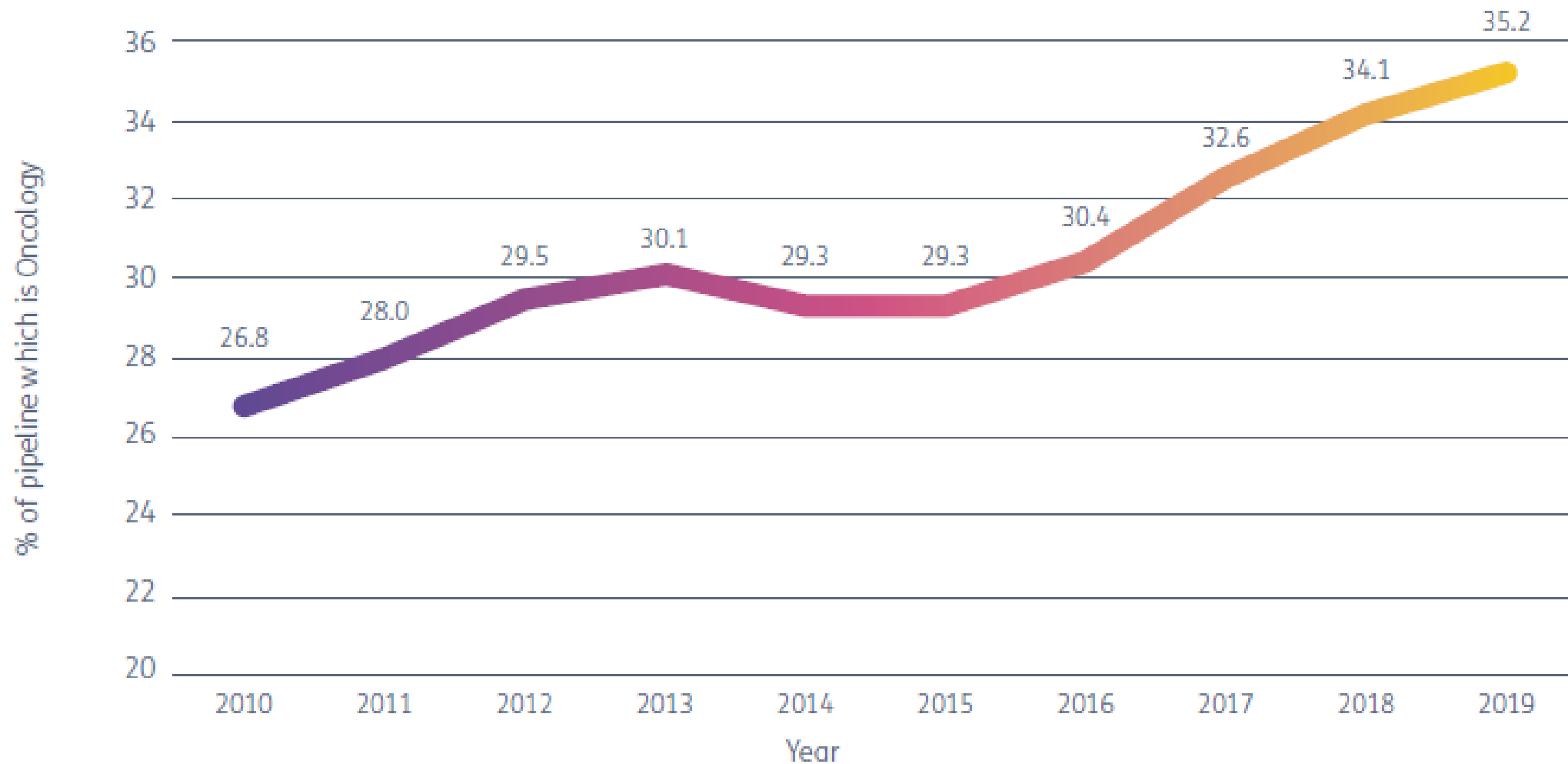


Source: William Blair

With Increased Investment, There Has Been a Concurrent Expansion of Oncology Clinical Trials



Proportion of Drug Pipeline in Development for Cancer, 2010 - 2019

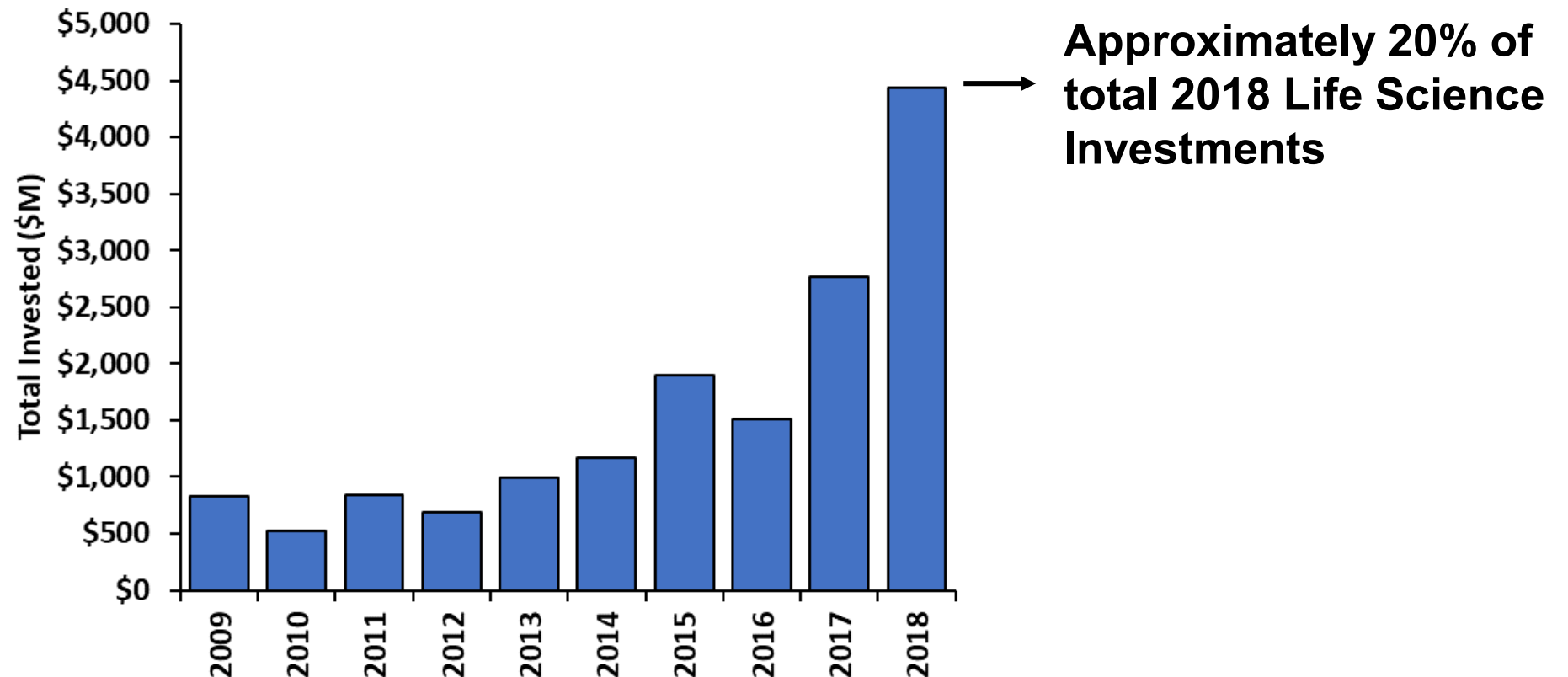


Source:
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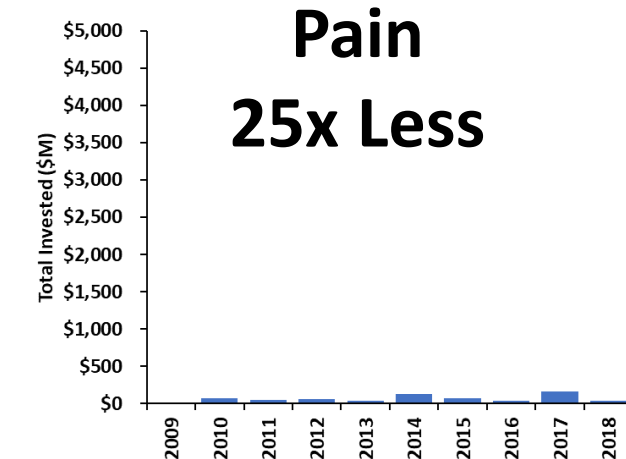
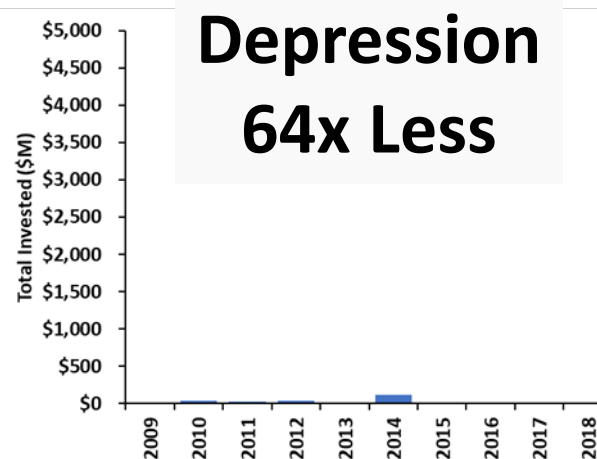
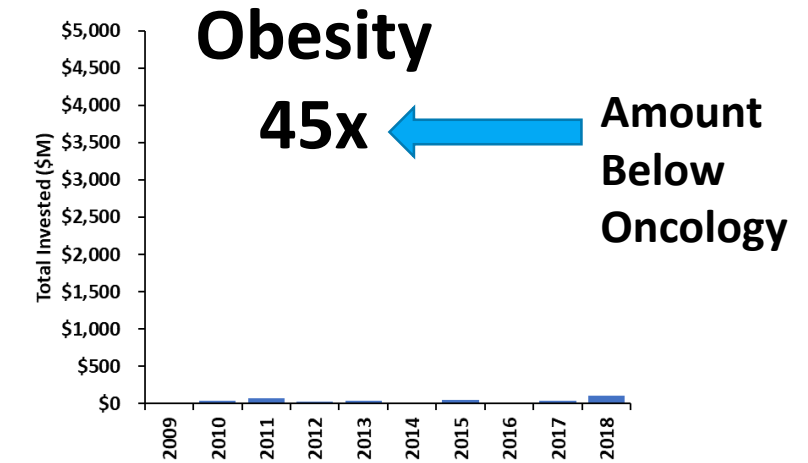
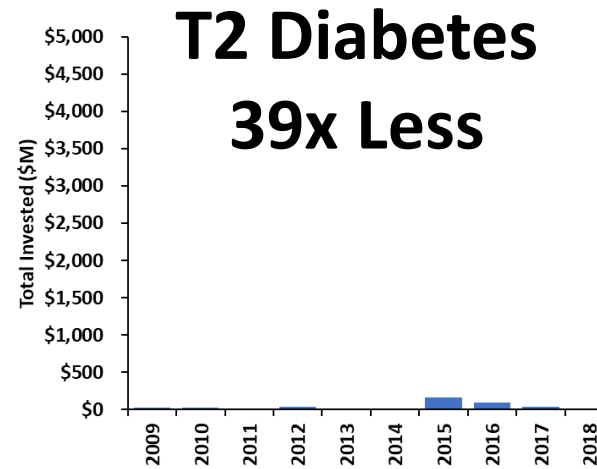
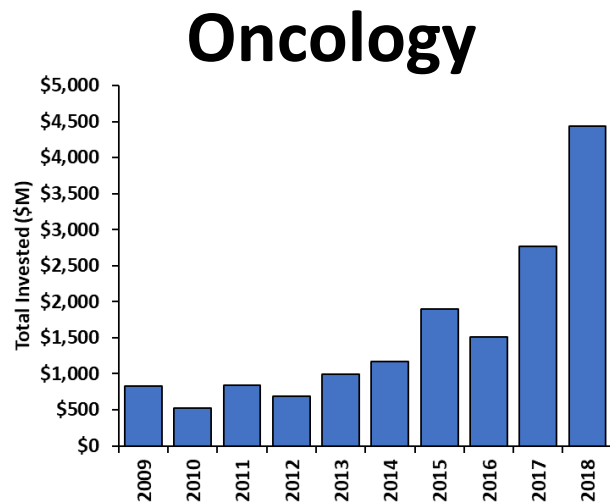
Capital Flows to the Highest Perceived Present Value – Particularly Oncology



VC Investment in Oncology



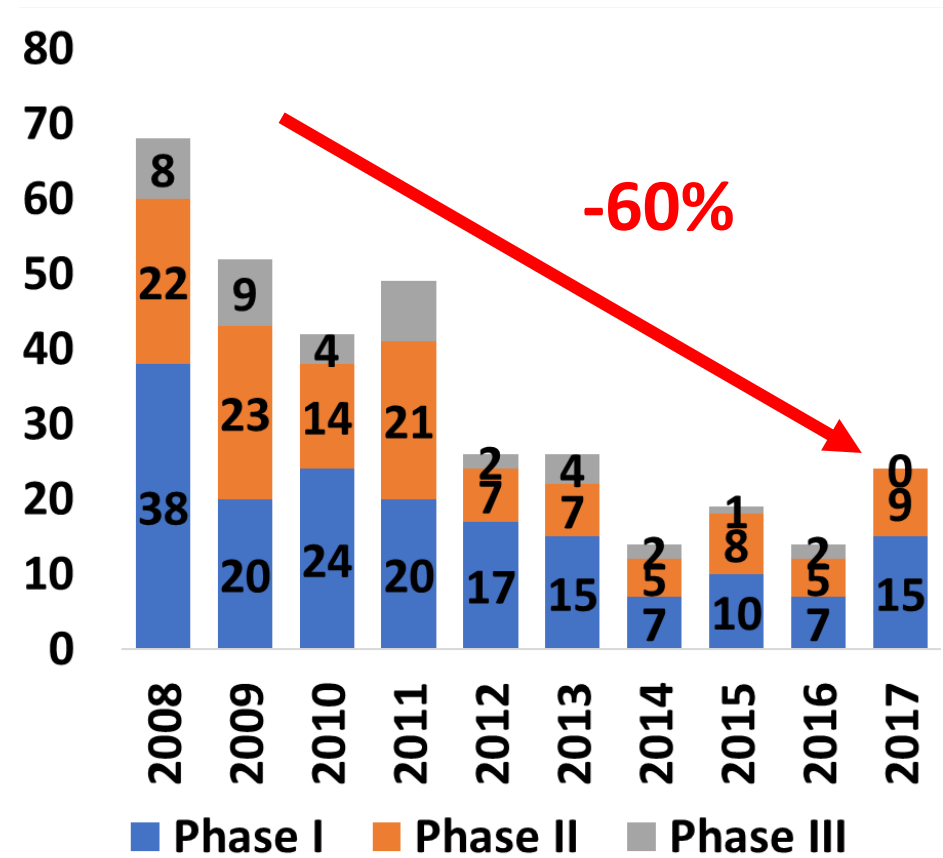
Venture Funding for Highly Prevalent Chronic Diseases is Significantly Less Than Oncology (Part 1)



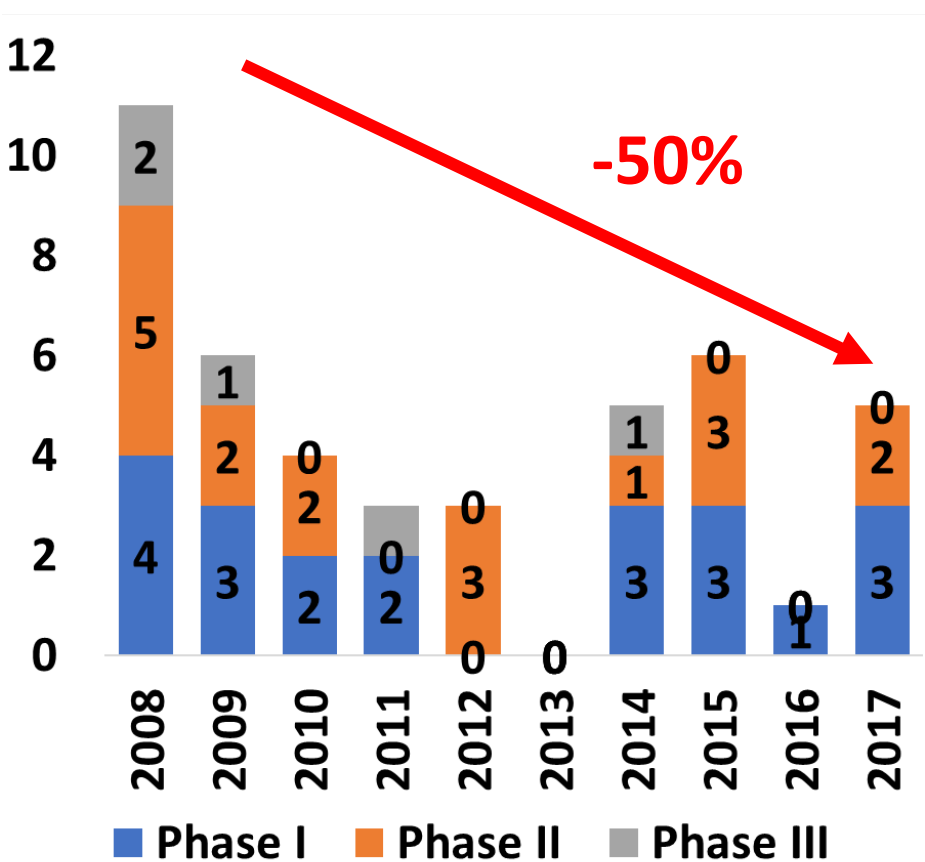
Clinical Trial Activity is a Proxy for Investment in Specific Highly Prevalent Chronic Diseases



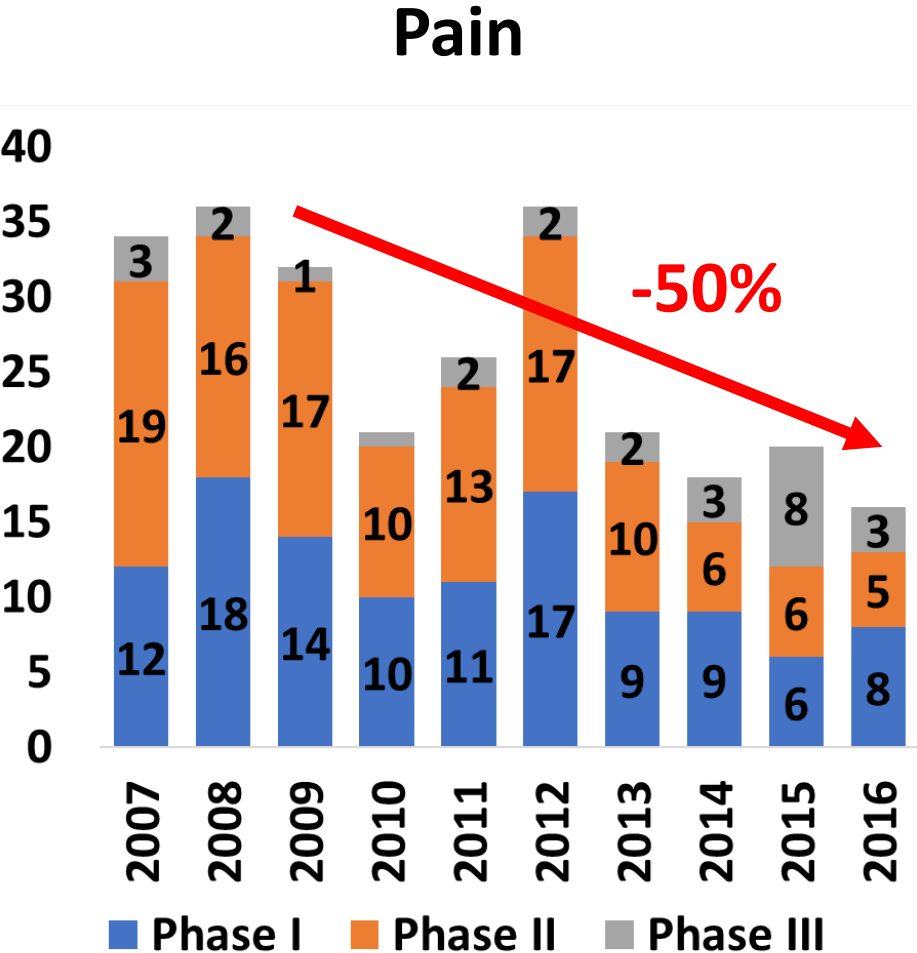
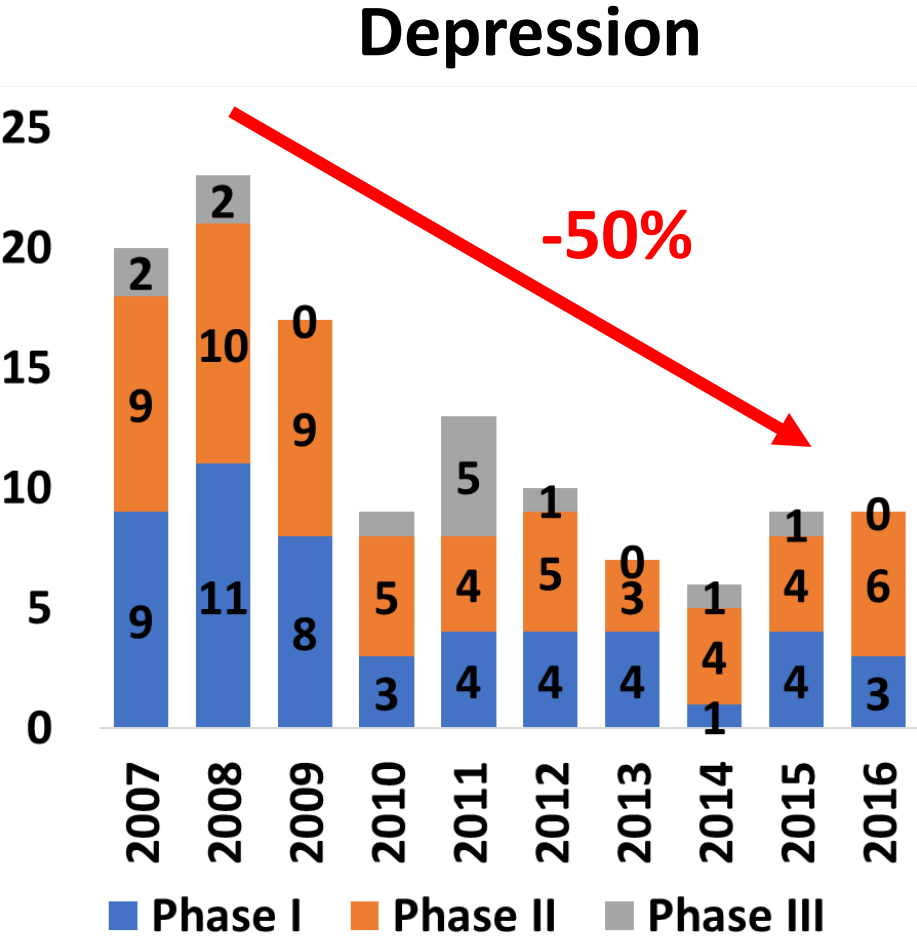
T2 Diabetes



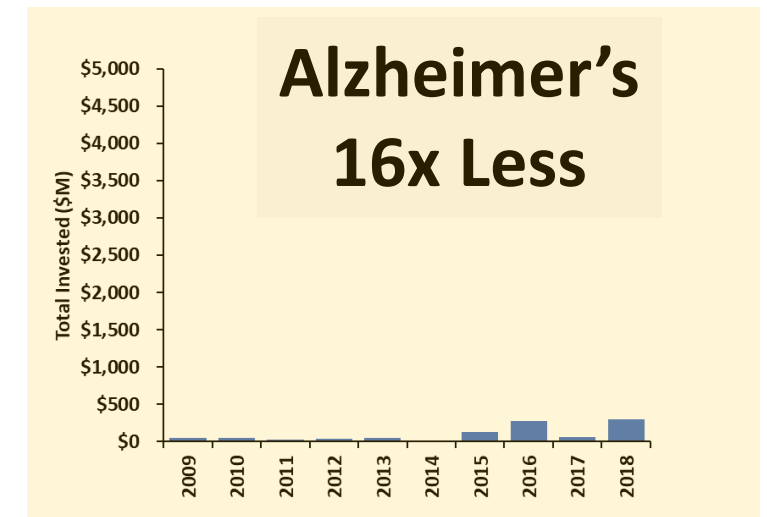
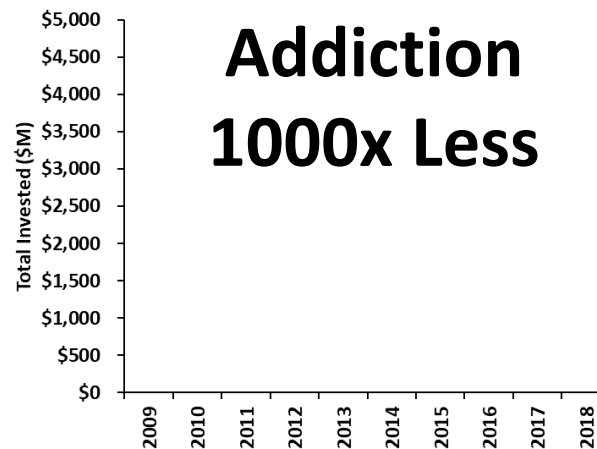
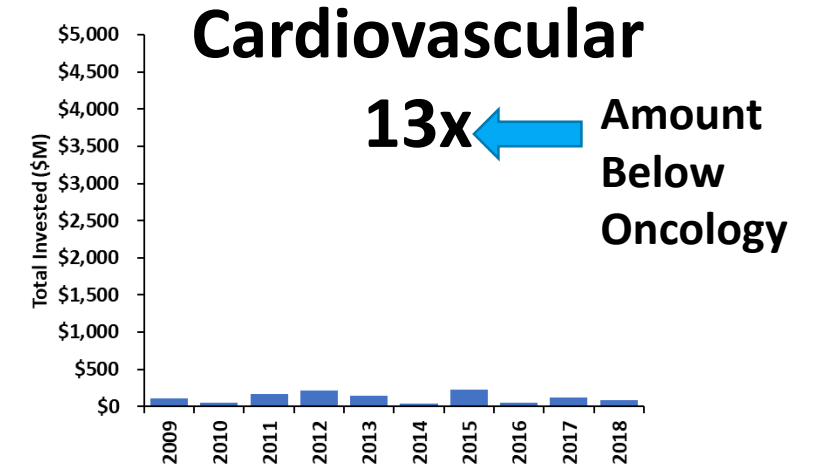
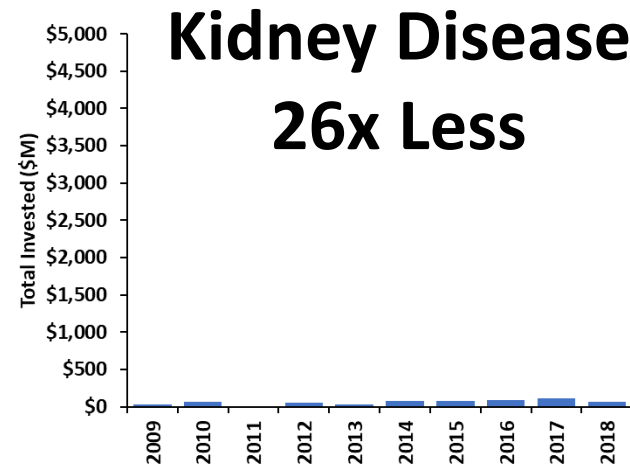
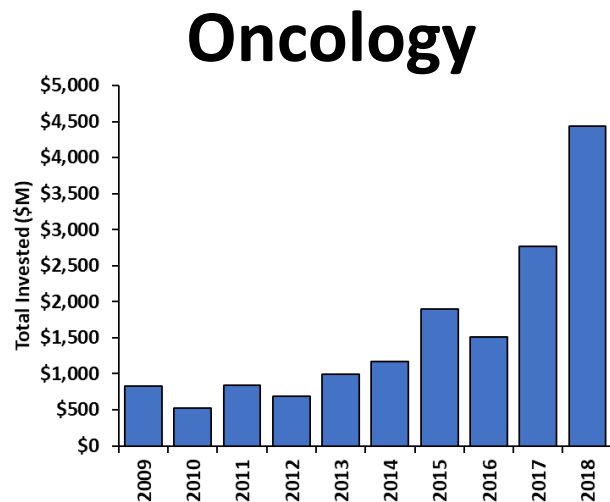
Obesity



Clinical Trial Activity is a Proxy for Investment in Specific Highly Prevalent Chronic Diseases



Venture Funding for Highly Prevalent Chronic Diseases is Significantly Less Than Oncology (Part 2)



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