



# SRI Shenandoah Valley

*It doesn't get any better than this!*

*Tech Nite 7.0  
May 2007*

**Shenandoah Valley Technology Council**

**Tech Nite 7.0**

**May 30, 2007**

**Walter Moos**

Vice President

Biosciences Division

SRI International



# SRI Shenandoah Valley

*It doesn't get any better than this!*



**SVTC**  
**October 2013**

**Shenandoah Valley Technology Council**  
**Luncheon**  
October 24, 2013

**Walter Moos**  
Vice President  
Biosciences Division  
SRI International

# Drugs + Innovation = Dollars + “Sense”

*Saving lives through nonprofit R&D*

- *Introduction*
- Pharmaceutical math
- Innovation for impact
- What this means for the future

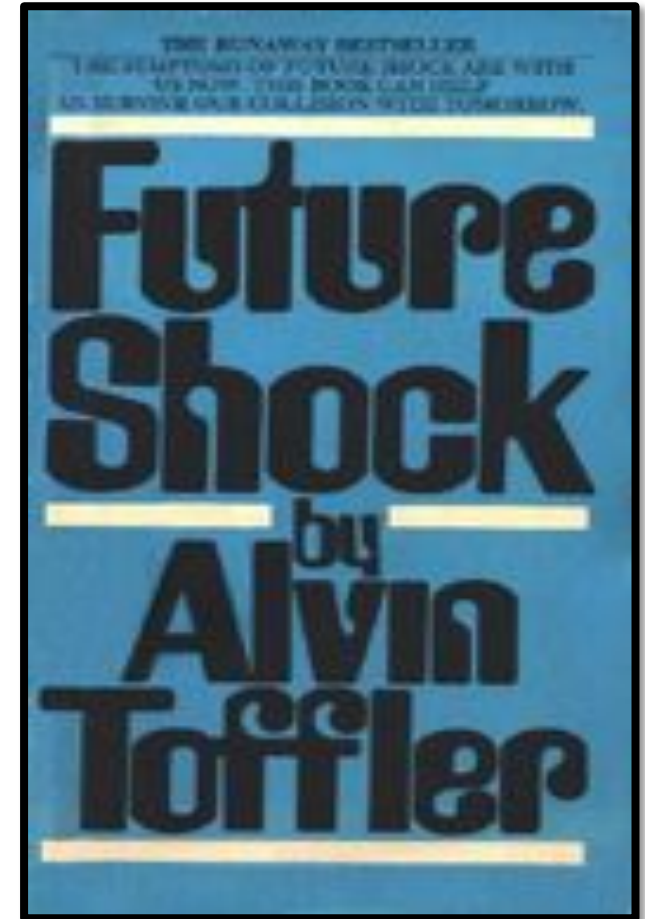


*“Unless someone like you cares a whole awful lot, nothing is going to get better. It's not.” Dr. Seuss*

# Future Shock

*Alvin Toffler ca. 1970*

- Future Shock = too much change in too short a period of time...
- Change is not merely necessary to life – it is life
- Technology feeds on itself – technology makes more technology possible
- *The illiterate of the future will not be people who can't read – it will be people who don't know how to learn*
- *The next major explosion is going to be when genetics + computers come together*

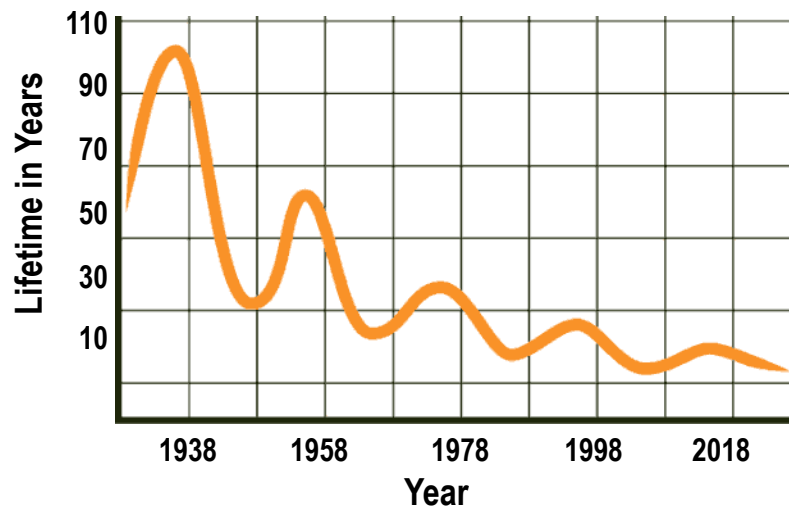


*Seuss + Toffler = Call to action for  
bioscience entrepreneurs*

# Creative Destruction = Fundamental Challenges to Survival

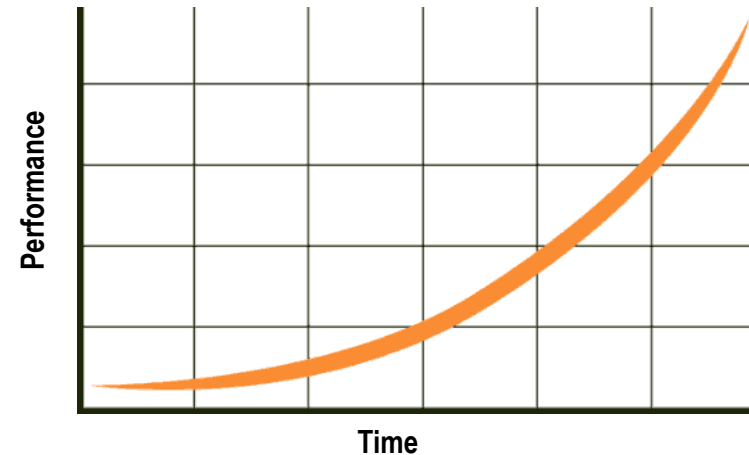
*Foster + Kaplan 2001*

Average Lifetime of  
S&P 500 Companies



Moore's Law

2x improvement in computer performance every 18 months



*"Standing still is going backwards"  
...exponentially*





# Innovation |ˌɪnəˈvā sh ən|

*Only path to survive creative destruction?*

- Noun
  - *New method, idea, product, etc.*
  - *Action or process of innovating*
  - *Example of use: Technological innovations designed to save energy*
- Origin
  - *Late Middle English*
  - *From Latin innovatio(n-), from verb innovare (see innovate)*

*Innovation = Creation + Delivery  
of New Customer Value in the Marketplace  
with a Sustainable Business Model for those producing it*

# SRI 5 Disciplines of Innovation (5DOI)

*The only way to survive creative destruction!*



Important Customer + Market Needs



High Value Creation



Innovation Champions



Innovation Teams



Organizational Alignment



*Big Idea = Train 1,000+ People in 5DOI @ SV*




**Success**

# Innovation by David or Goliath?

*Important roles for both large + small organizations*

**2008  
Revenues**

1.		• \$380,000,000,000
41.		• \$104,000,000,000
93.		• \$66,000,000,000
107.		• \$61,000,000,000
136.		• \$51,000,000,000
.....		• \$350,000,000





# **Big Pharma Needs Help with R&D**

***Big trouble for large healthcare organizations***

**Higher Costs**

**Longer Timeframes**

**Declining Productivity**

**Generics + Biosimilars**

**Increasing Competition**

**Expiration of Key Patents**

**Short-Lived Market Success**

**Growing Regulatory Hurdles**

**Entitlement to Good Health?**

# Drugs + Innovation = Dollars + “Sense”

*Saving lives through nonprofit R&D*

- Introduction
- *Pharmaceutical math*
- Innovation for impact
- What this means for the future

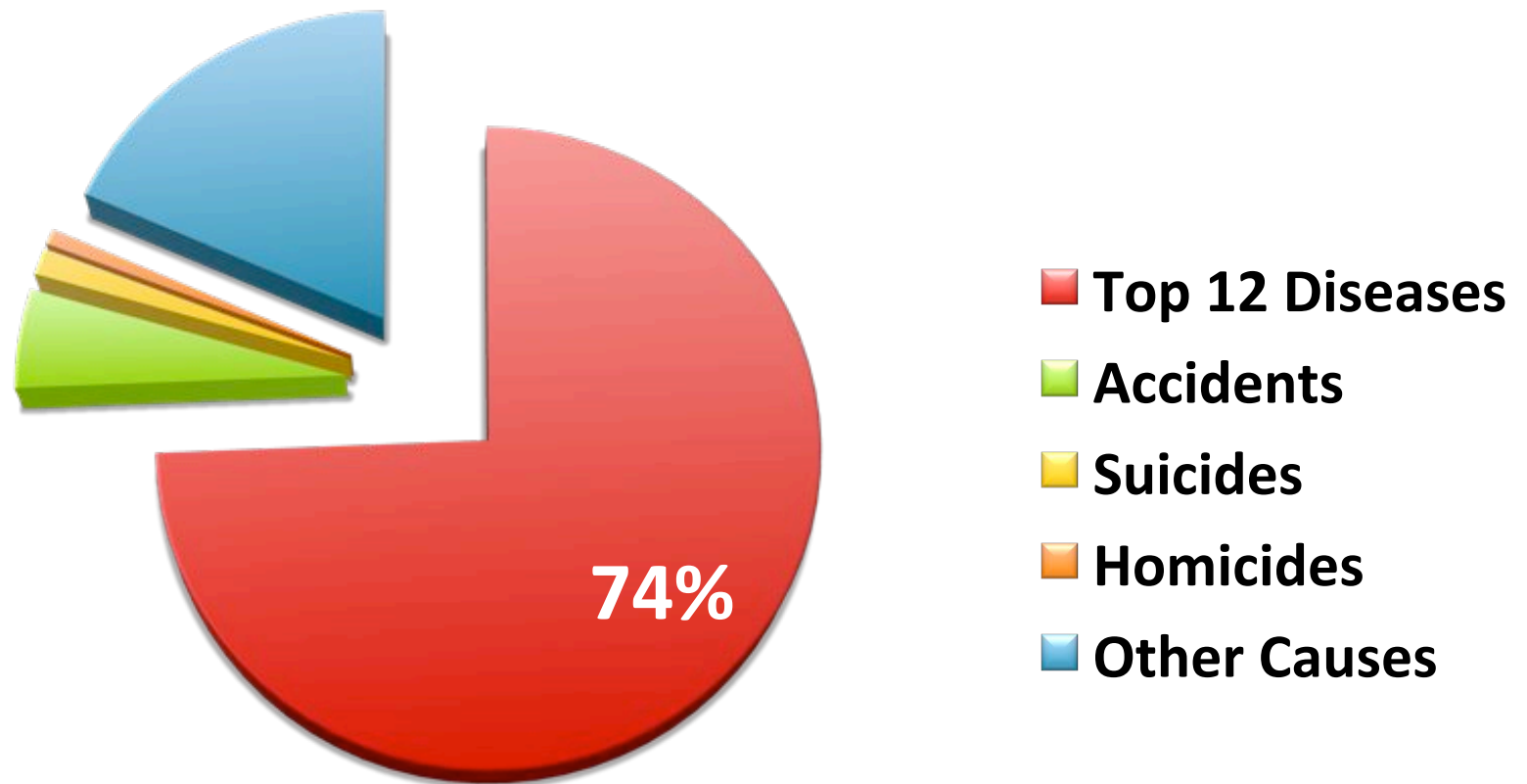


*High risk + high payoff  
= dollars + lives*

*Cancer  
claims 100s  
to 1,000s of lives  
every night...  
We must do  
better!*

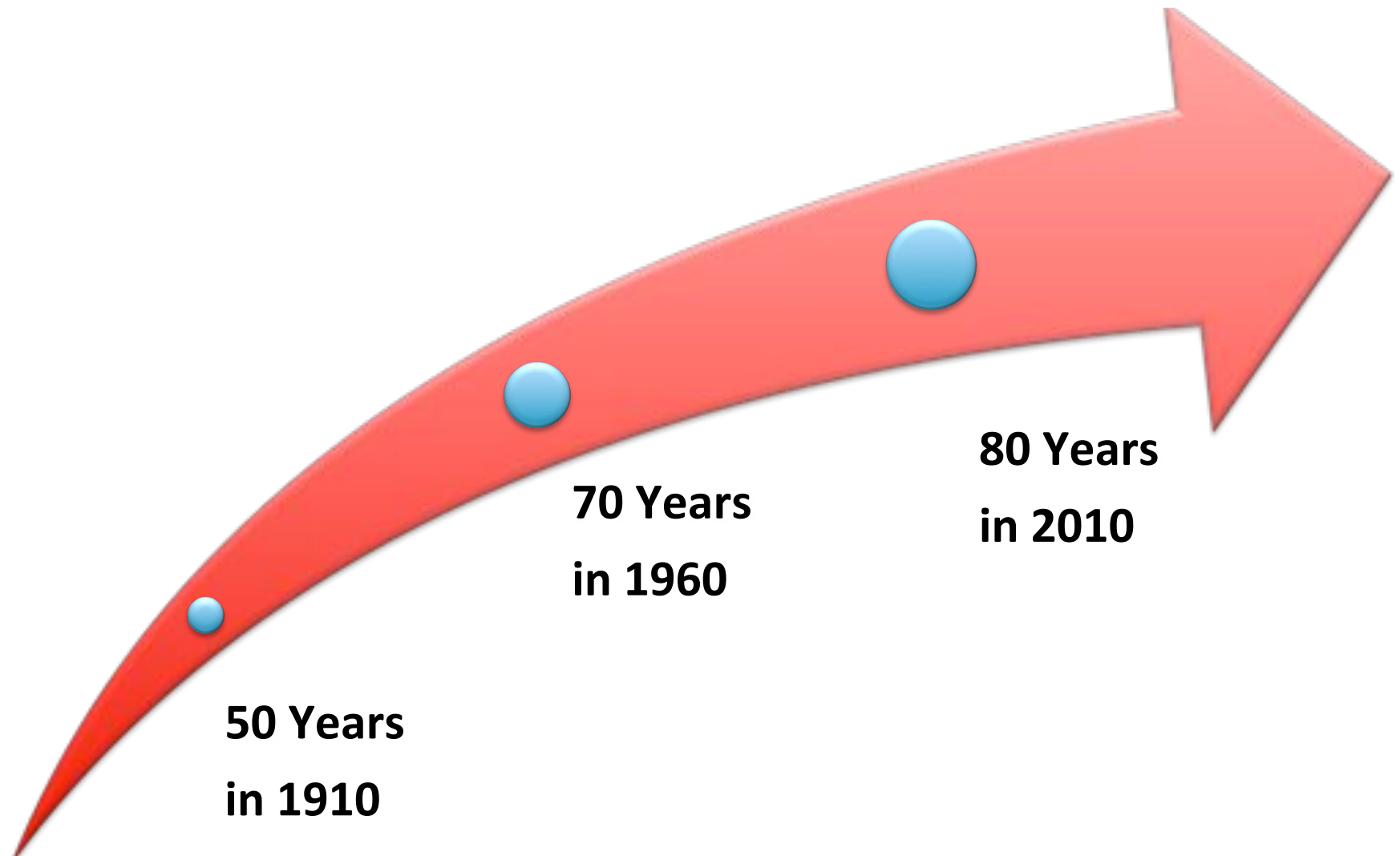
**Diseases = 1,800,000+ Deaths per Year**

*Leading causes of death in US (2006)*



**Life Expectancy = +60%**

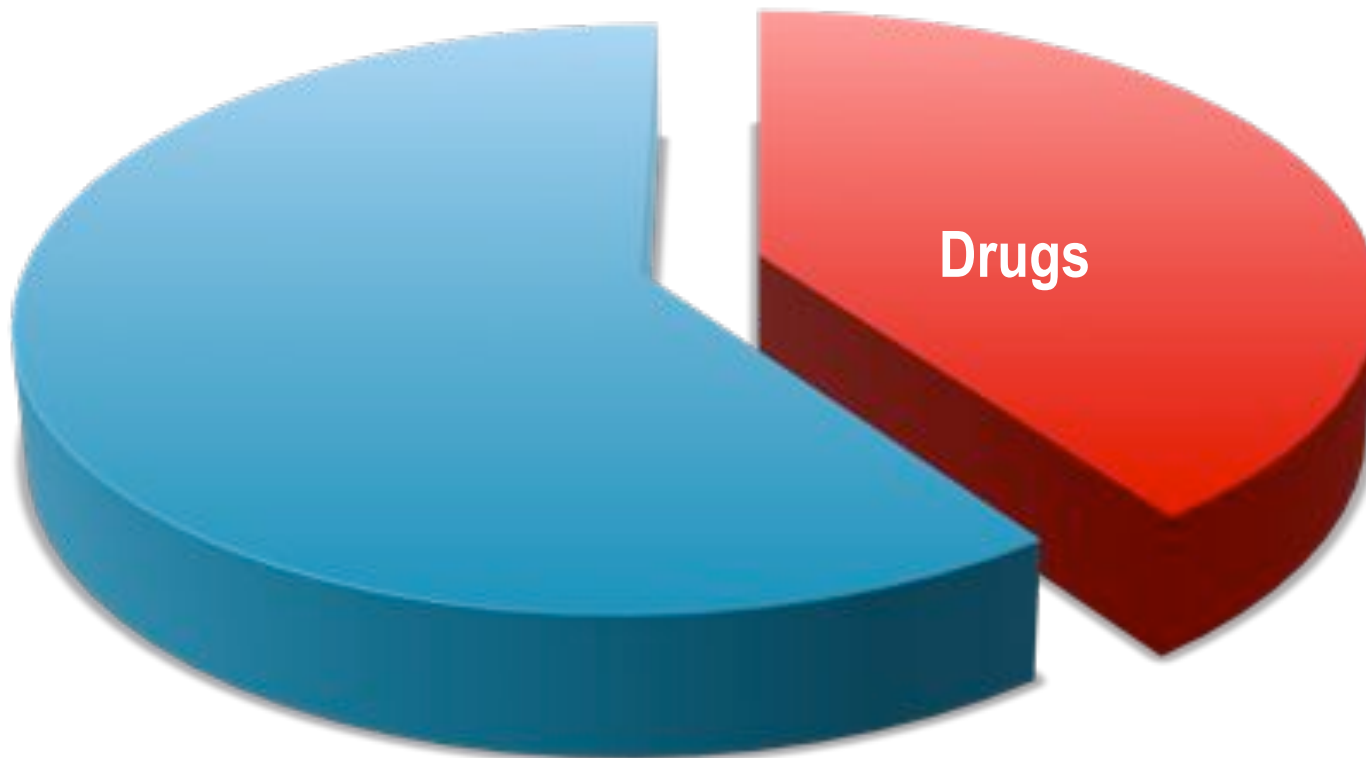
***Last 100 years in US***



**Drugs = 40% of +60%**

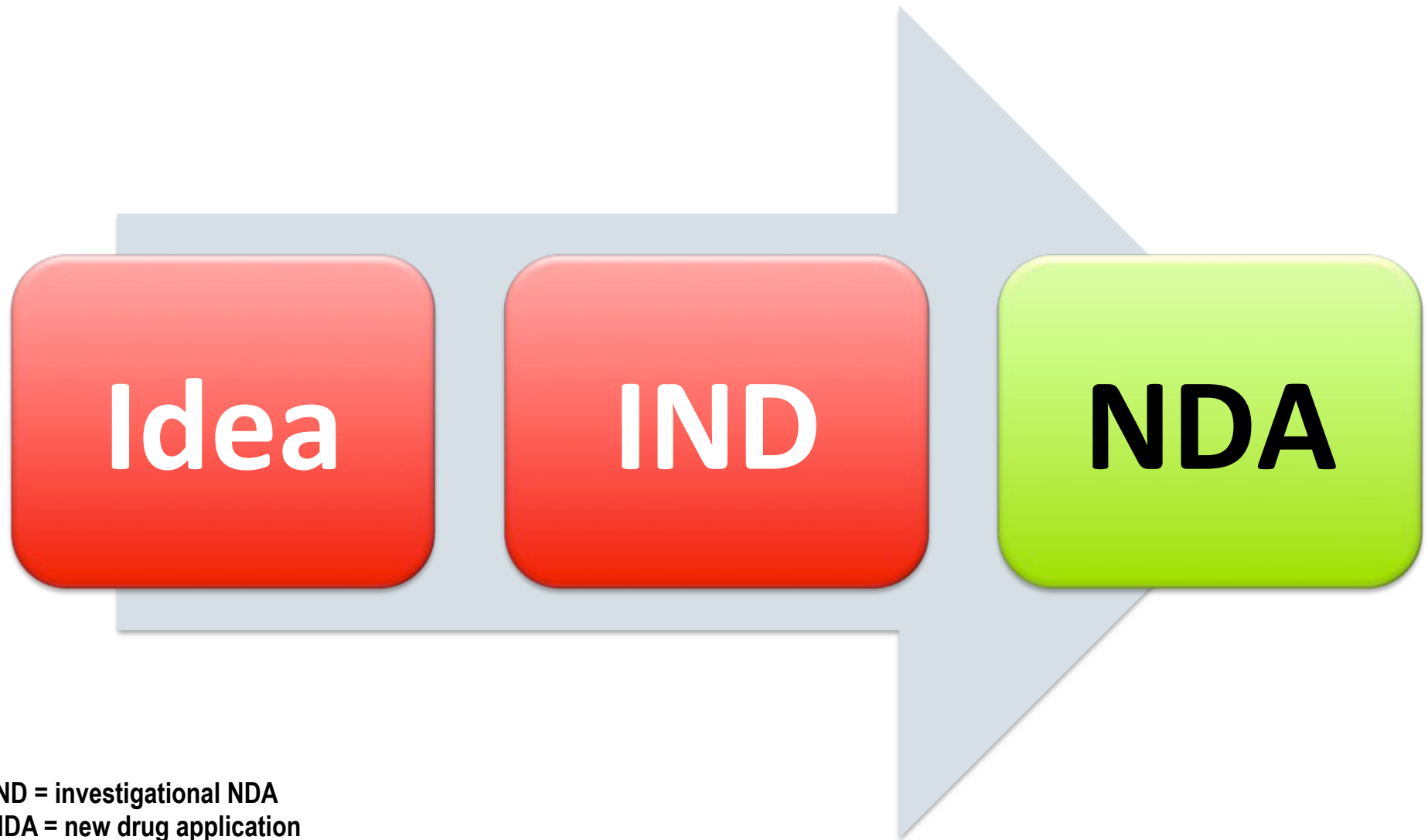
***Average in US  $\approx$  +12 years per person***

### Reasons for Increased Life Expectancy



# Pharma Long Timelines

*10-20 years = 1 approved drug*

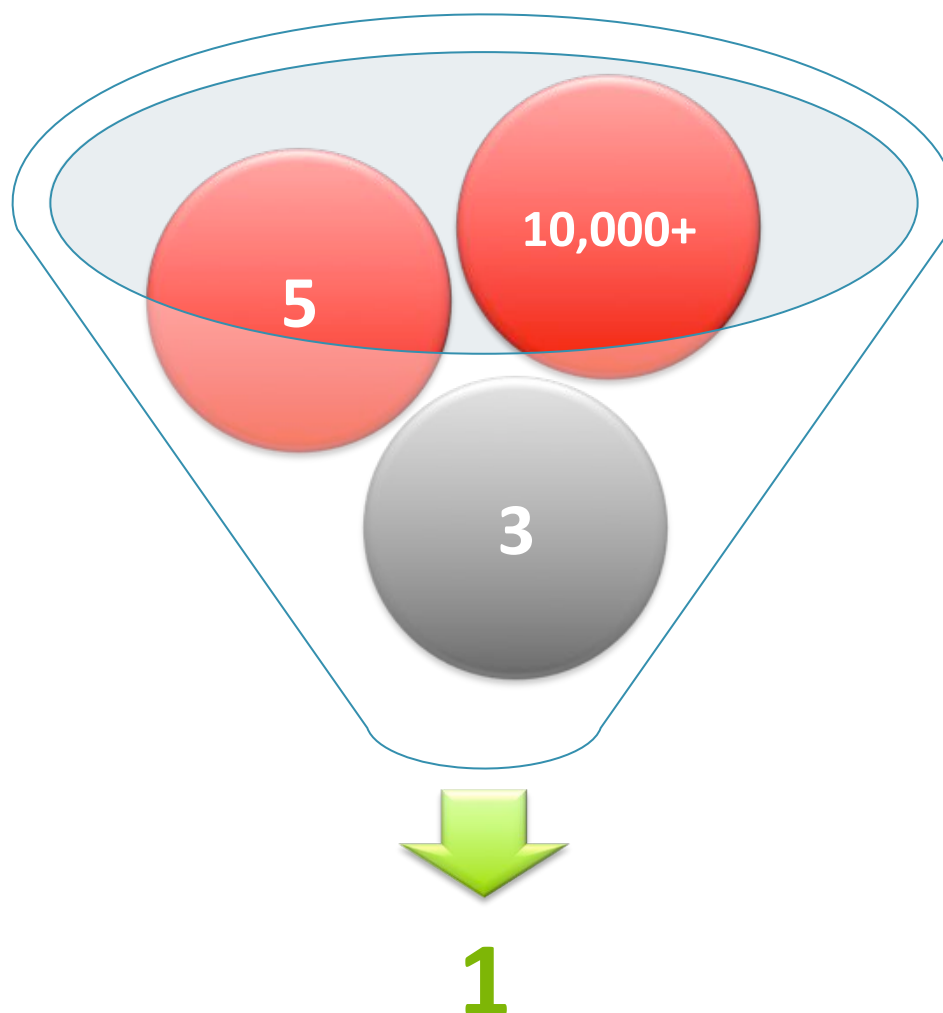


IND = investigational NDA  
NDA = new drug application



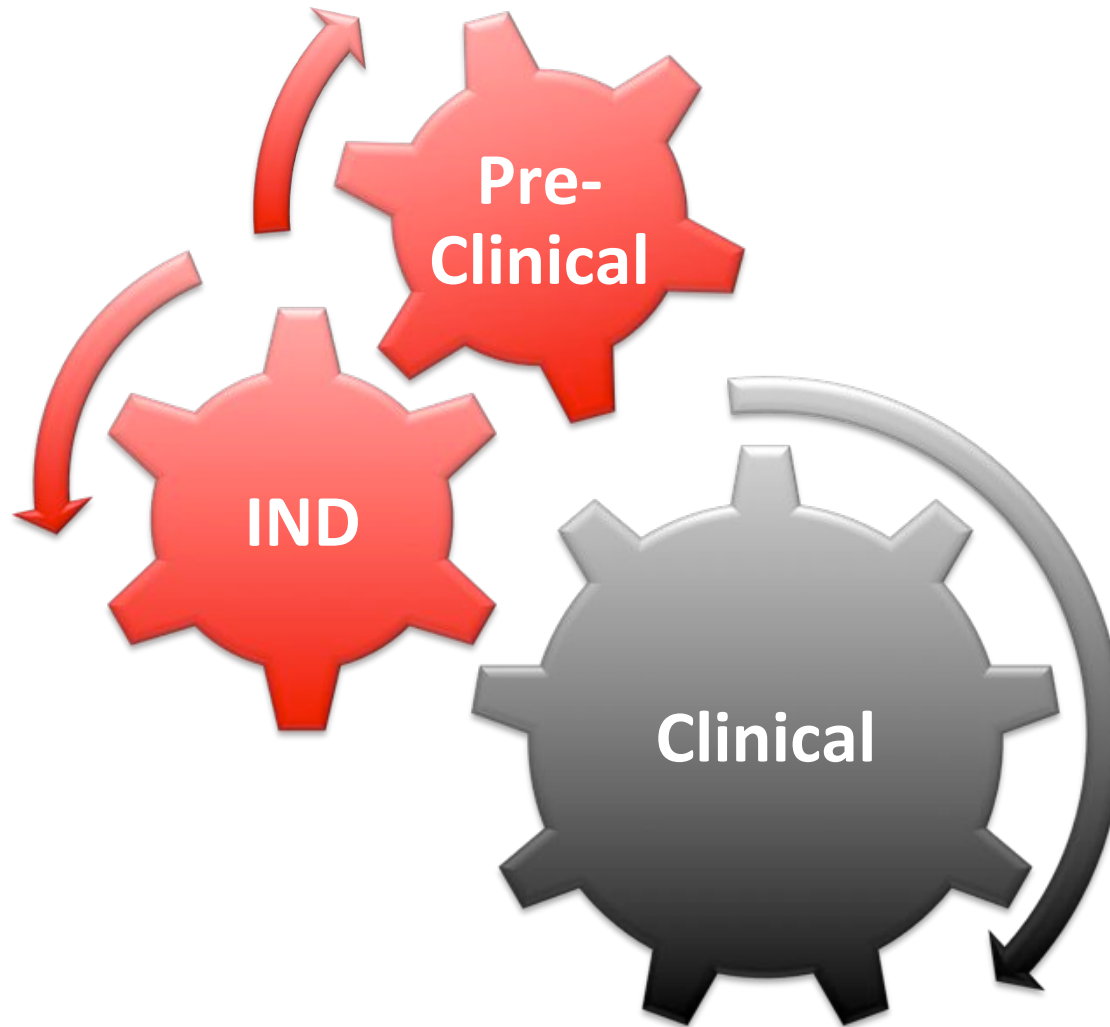
# Pharma Low Success Rate

*10,000+ screened = 1 approved drug*



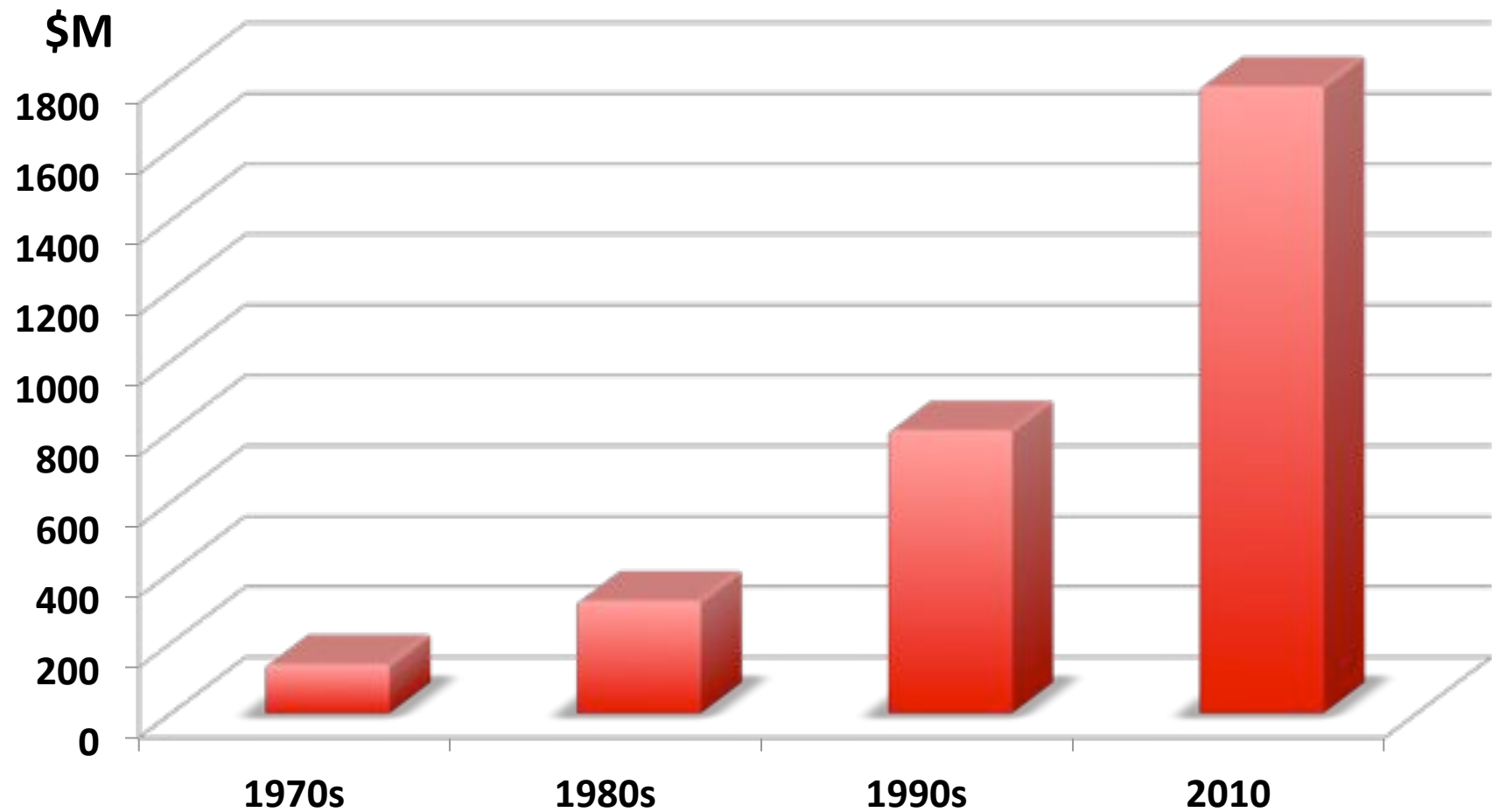
# Pharma High Costs

***\$500,000,000+ = 1 IND***



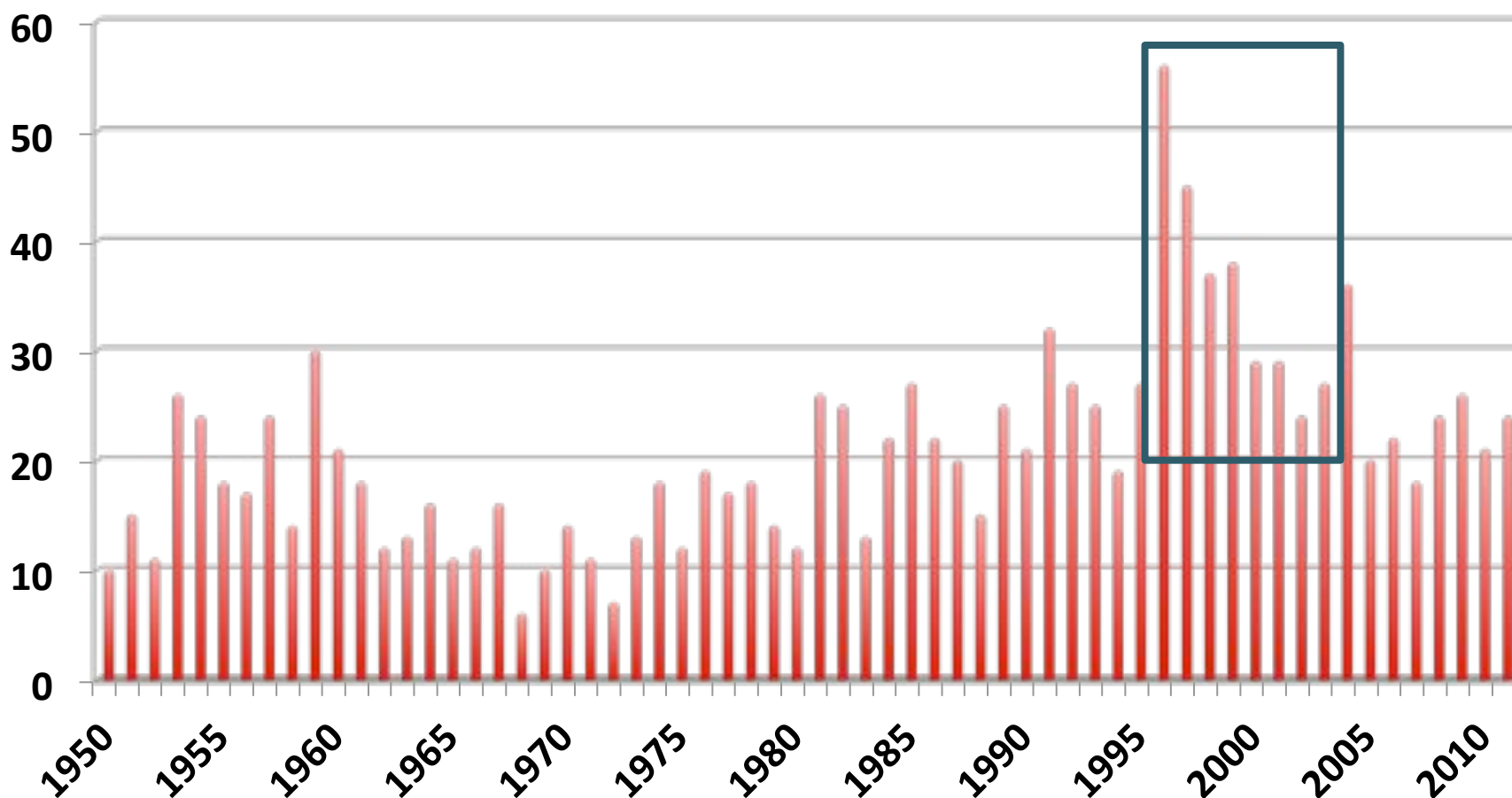
# Pharma Drug Development Costs

*Higher x 10*



# Pharma Success = New Drug Approvals

*FDA-approved NMEs + BLAs trending upward... slowly*



NME = drugs (chemicals)

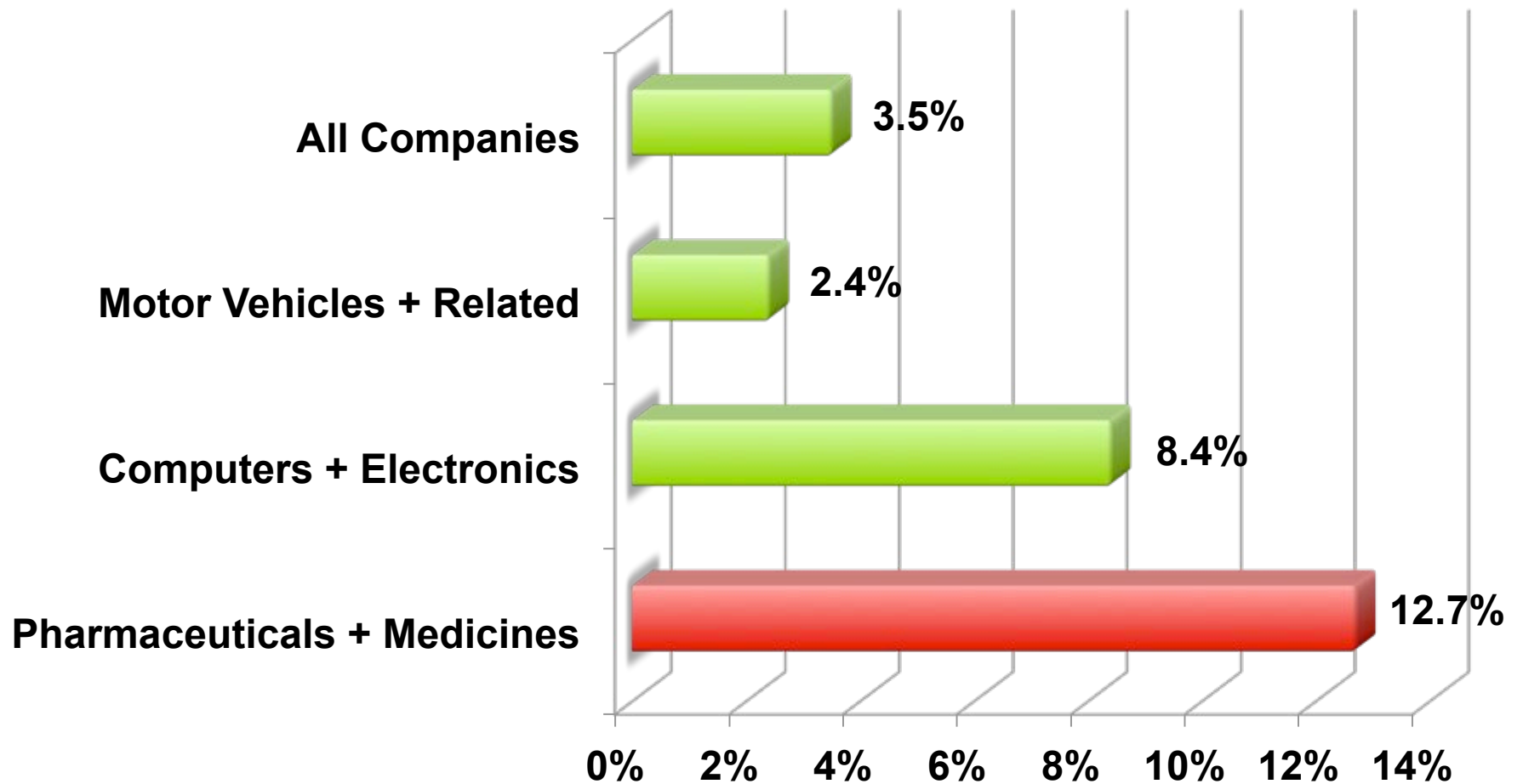
BLA = biologics

See: Osborne, Nat Biotechnol 2013; Scannell et al., NRDD 2012

# Pharma Investments

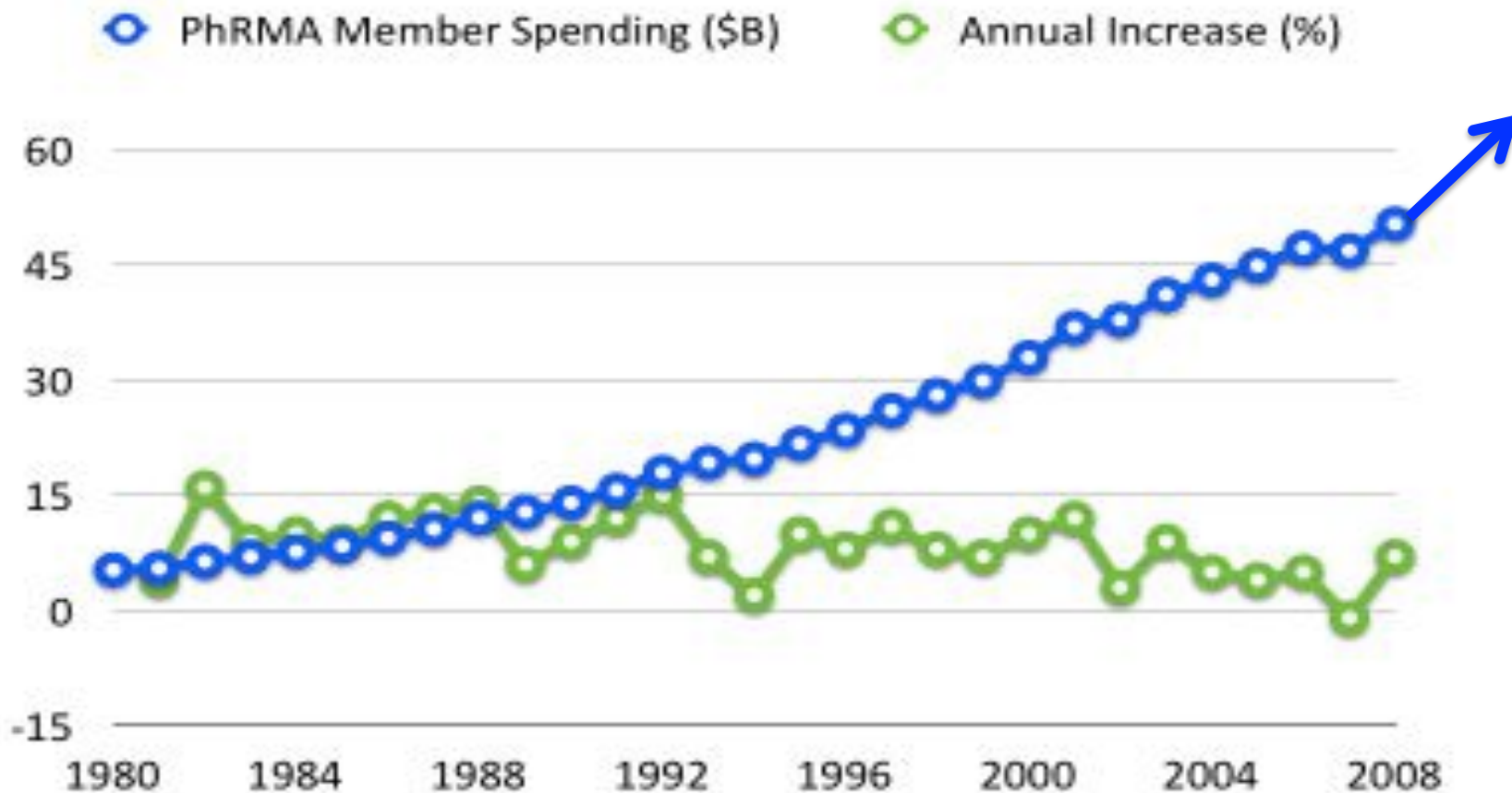
*R&D-intensive industry*

**R&D Funding as % of Net Sales**



# Pharma R&D = \$50,000,000,000+

*CPI-adjusted PhRMA member company annual spending*

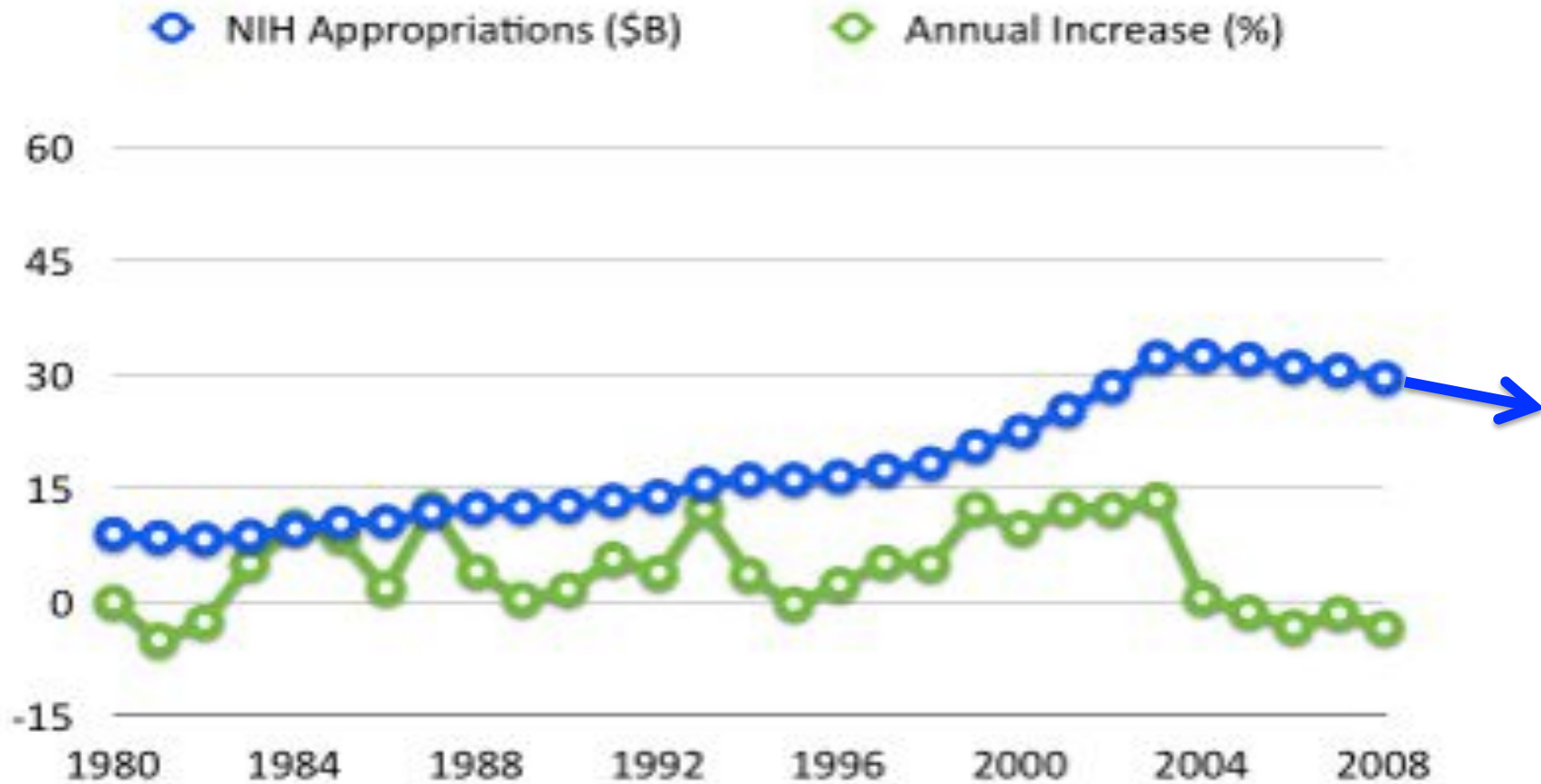


CPI = Consumer Price Index (2008 \$)  
PhRMA = Pharmaceutical Research Manufacturers of America



# National Institutes of Health Losing Ground

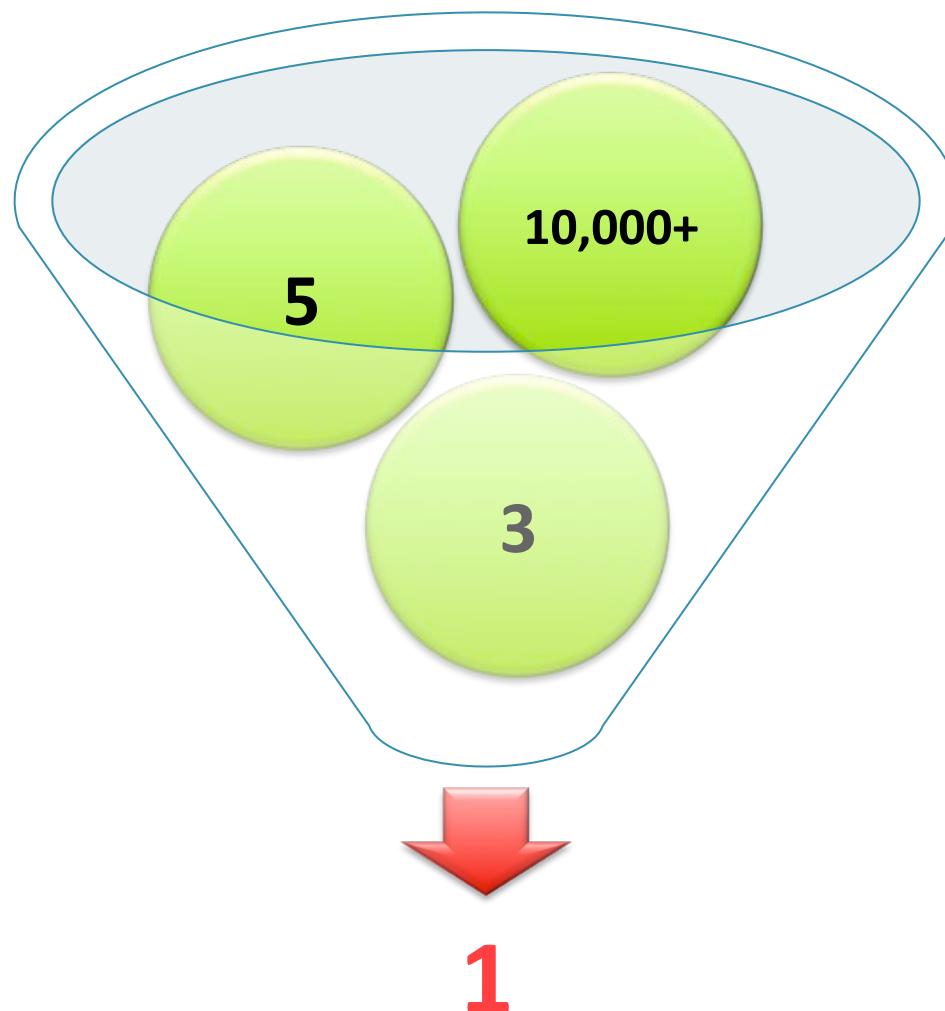
*End result = Fewer lives saved*



CPI-Adjusted 2008 \$

# Miracles Do Happen

*\$ billion drugs like Lipitor®*



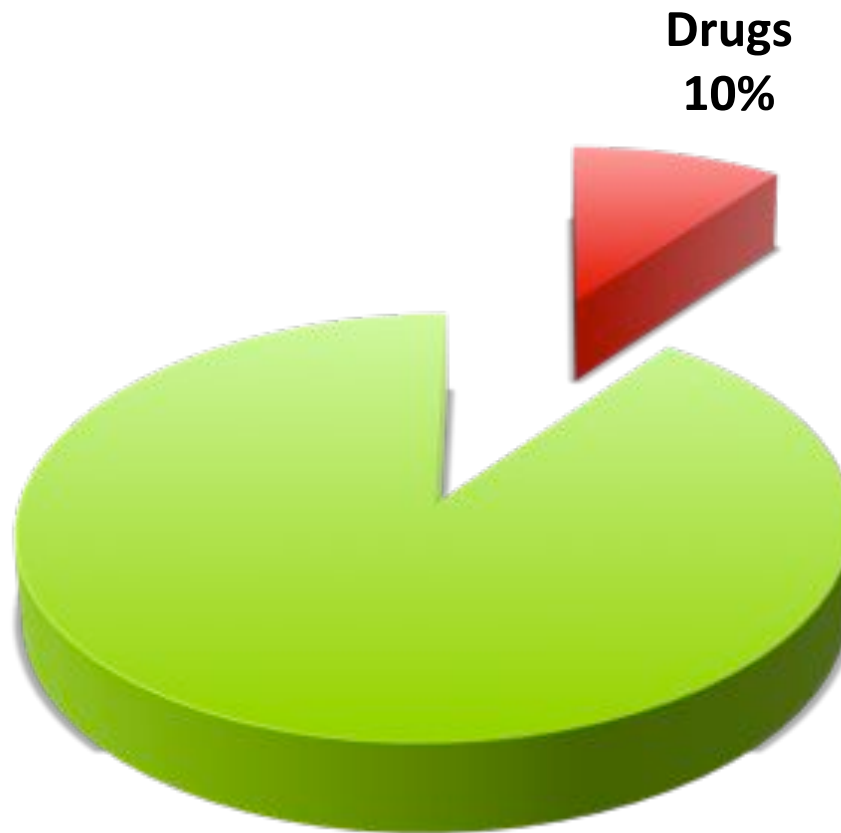
# Rich Returns for Licensors

*5% royalties = \$50,000,000 per year*



# Drugs Not as Costly as Some People Think

*10¢ per health care \$1*



# Drugs + Innovation = Dollars + “Sense”

*Saving lives through nonprofit R&D*

- Introduction
- Pharmaceutical math
- *Innovation for impact*
- What this means for the future



*Success = lives saved*

*Pandemic H5N1  
bird flu could kill  
50M+ worldwide =  
nearly everyone in  
VA + adjoining  
states (MD, NC,  
WV, etc.)*

**Malaria = Every 30 Seconds another Child Dies**

*Doing well by doing good*





# Mosquito-Borne Maladies = e.g., Malaria + West Nile Virus

## *SRI SV R&D = Protection from deadly disease transmission*

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## SRI International


R&D for Government and Business

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### Press Releases

#### Common U.S. Mosquitoes Can Transmit Disease-Causing Virus from Asia



MENLO PARK, Calif.–August 22, 2012–New research from SRI International finds that mosquitoes commonly found in the United States can be infected with a disease-causing virus from Asia. The research findings are from a recent study that modeled how mosquito-borne infections can become introduced. Study findings are published in the August 2012 issue of the journal *Vector-Borne and Zoonotic Diseases*.

In laboratory experiments, researchers demonstrated that mosquitoes from Virginia and Georgia can transmit a virus called Chikungunya (CHIKV), which has infected more than 2 million people in Asia, Africa, and parts of Europe since 2005. The U.S. has never witnessed an outbreak of CHIKV, although a number of infected people have been identified with a CHIKV infection acquired from travel to Asia.

Although CHIKV infection is rarely fatal, patients may suffer persistent complications, such as debilitating arthritis that can last from months to years. Currently, there is no drug to treat CHIKV and no vaccine is available.

"The findings underscore the importance of control measures, such as eliminating mosquito breeding sites, to prevent mosquito-borne viral infections for which there are no cures," said [Rajeev Vaidyanathan, Ph.D.](#), associate director of Vector Biology and Zoonotic Diseases in the [Biosciences Division](#) of SRI and lead study author.

"We are the first group to look at multiple field populations of mosquitoes with a recent epidemic strain of Chikungunya virus. This is relevant because the populations we sampled are what you would find in the real world."

**FILTER**

Filter by Date

From: 2007 Jan To: 2013 Mar

Filter by Type

☐ Event ☐ In the News  
☐ Podcast ☐ Press Release  
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#### Related R&D

Disease Focus Areas  
Infectious Diseases

# Partnership on Diagnostics for Global Health

*SRI SV R&D = Industry alliance to create faster + cheaper tools for emerging nations (including terrible diseases now in America too)*



The screenshot shows the SRI International website with a news release titled "SRI International and CTK Biotech Developing Low-Cost Diagnostic for Hard-to-Diagnose Chikungunya Virus". The release is dated May 5, 2011, from Menlo Park, Calif. The text describes the partnership between SRI and CTK Biotech, Inc. to develop a low-cost, sensitive diagnostic for Chikungunya virus. It mentions that the test will be a "point-of-care" diagnostic that won't need expensive reagents requiring refrigeration. The release also includes quotes from Krishna Kodukula, Ph.D., executive director of SRI's Center for Advanced Drug Research (CADRE), and Catherine Chen, M.D., Ph.D., chief executive officer of CTK Biotech. A large, semi-transparent watermark for CTK Biotech, Inc. is overlaid on the center of the page, featuring the company logo and the tagline "The New Wave of Diagnosis". To the right of the text is a photograph of a mosquito on a mesh screen. The left sidebar of the website lists various navigation links such as "Newsroom", "Media Contacts", "News Release Archive", "Events", "Story Kits", "Speaker Bureau", "Expert Source List", "SRI in the News (by date)", "Books about SRI", "Image Bank", "Featured Videos", "Podcasts", "Image & Material Request Form", "SRI Digest", "SRI Management", "Board of Directors", "SRI Corporate Brochure", "SRI Timeline of Innovations", "Facts and FAQs", and "Spin-off Ventures".

**SRI International**

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**SRI International and CTK Biotech Developing Low-Cost Diagnostic for Hard-to-Diagnose Chikungunya Virus**

**MENLO PARK, Calif. — May 5, 2011**—In parts of the world where dengue fever is common, other viral infections are often misdiagnosed. Such misdiagnosis is a waste not only of time and money. It can be especially problematic for sufferers of another mosquito-borne viral infection called chikungunya. Symptoms may be similar to dengue fever, but the infection can take from 3 to 7 days to appear. "Silent" infections can take from 3 to 7 days to appear. "Silent" infections can take from 3 to 7 days to appear. "Silent" infections can take from 3 to 7 days to appear.

**CTK Biotech, Inc.**  
*The New Wave of Diagnosis*

To solve the problem, SRI and CTK are working with the U.S. Centers for Disease Control and Prevention (CDC) to develop a "point-of-care" diagnostic that won't need expensive reagents requiring refrigeration.

"Our collaborative program focuses on developing a series of low-cost, sensitive diagnostics for neglected diseases of global importance," said [Krishna Kodukula, Ph.D.](#), executive director of SRI's [Center for Advanced Drug Research \(CADRE\)](#) in Shenandoah Valley, Virginia. "With CTK, we expect to develop a diagnostic test that will be easy to use in developing nations in the battle against infectious diseases such as chikungunya."

"We are delighted to form an alliance with SRI International to develop point of care diagnostic kits," said Catherine Chen, M.D., Ph.D., chief executive officer of CTK Biotech. "A collaborative approach like ours, combining SRI research with CTK's manufacturing capabilities, will result in products that will benefit people throughout the world."

First isolated in the 1950s, chikungunya virus has been responsible for numerous outbreaks in Africa and Asia and more recently in parts of Europe. Once the CTK-SRI chikungunya test is developed and distributed, it will provide an important and low-cost public health tool that may help limit the spread of the disease to other regions. CTK Biotech and SRI will also work to develop diagnostics for other diseases.

**About CTK Biotech**

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# Grant for Probiotic Vitamin Delivery

*SRI SV R&D = Improved immunity against diarrheal diseases, which cause 5,000,000 childhood deaths/year*



The screenshot shows the SRI International website with a news article titled "SRI International Receives \$100,000 Grand Challenges Explorations Grant for Innovative Global Health Research". The article, dated May 13, 2010, reports that SRI has received a US\$100,000 grant from the Bill & Melinda Gates Foundation to support research by Douglas Watson, Ph.D., on "Vitamin A-Secreting Probiotics to Activate Mucosal Immunity." The article includes a photo of a petri dish with orange bacterial colonies and a large blue overlay with the text "BILL & MELINDA GATES foundation". The left sidebar contains a navigation menu with links such as "Newsroom", "Media Contacts", "News Release Archive", "Events", "Story Kits", "Speaker Bureau", "Expert Source List", "SRI in the News (by date)", "Books about SRI", "Image Bank", "Featured Videos", "Podcasts", "Image & Material Request Form", "SRI Digest", "SRI Management", "Board of Directors", "SRI Corporate Brochure", "SRI Timeline of Innovations", and "Facts and FAQs".

**SRI International**

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## SRI International Receives \$100,000 Grand Challenges Explorations Grant for Innovative Global Health Research

Menlo Park, Calif. —May 13, 2010—SRI International announced today that it has received a US\$100,000 Grand Challenges Explorations grant from the Bill & Melinda Gates Foundation. The grant will support an innovative global health research project conducted by Douglas Watson, Ph.D., protein biochemist in SRI's [Center for Advanced Drug Research \(CADRE\)](#), titled "Vitamin A-Secreting Probiotics to Activate Mucosal Immunity."

Watson's project is one of 78 grants announced by the Gates Foundation in the fourth funding round of [Grand Challenges Explorations](#), an initiative to help scientists around the world explore bold and largely unproven ways to improve health in developing countries. The grants were provided to scientists in 18 countries on six continents.

To receive this grant, Watson's project was selected from over 1,000 proposals submitted outside current SRI research areas. The Gates Foundation's Grand Challenges Explorations initiative is designed to fund research on some of the world's most pressing health problems, such as infectious diseases, malaria, and HIV/AIDS. Watson's project focuses on poor gut health, which increases susceptibility to acute and chronic diarrhea. Vitamin A supplementation can reduce childhood mortality by 30 percent; however, studies have shown that fewer than 60 percent of children in affected areas receive the recommended dose.

To facilitate delivery of vitamin A to children who may not otherwise receive enough of it, SRI researchers will plan to engineer a probiotic bacterium that produces vitamin A for direct delivery to mucosal immune cells in the gastrointestinal tract. If successful, this therapy could restore protective mucosal immunity while simultaneously combating other consequences of vitamin A deficiency, including blindness and susceptibility to measles and malaria. The new therapy, which should reduce the duration of symptoms while also reducing the impact of future infections, could be developed for distribution during clinic visits for the treatment of diarrhea.

**BILL & MELINDA GATES foundation**

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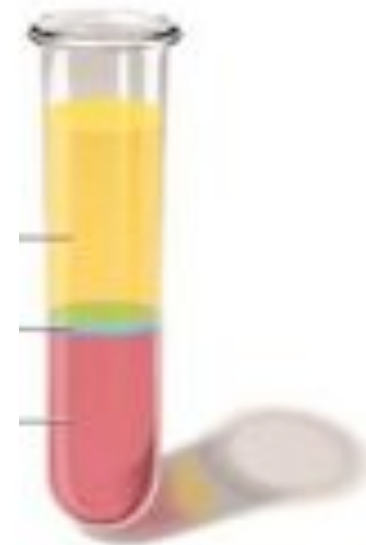
# Tobacco Exposure Biorepository Samples

***SRI SV R&D = Reducing lung disease + heart disease + cancer***

- Important Problem = Leading Cause of Preventable Illness + Death
  - Cigarette smoking causes >400,000 deaths/year, including 50,000 deaths due to exposure to secondhand smoke
  - Lung cancer leading cause of cancer death in men + women in US
  - Smokers up to 6 times more likely to suffer heart attacks than nonsmokers
  - Despite proven risk, >20% of US adults smoke cigarettes
- Valuable R&D Resource
  - International CRO conducted study for large tobacco company
  - 39 sites in 31 states at cost of perhaps >\$70M
  - Samples transferred to SRI SV via nonprofit VTHRR in Richmond, VA

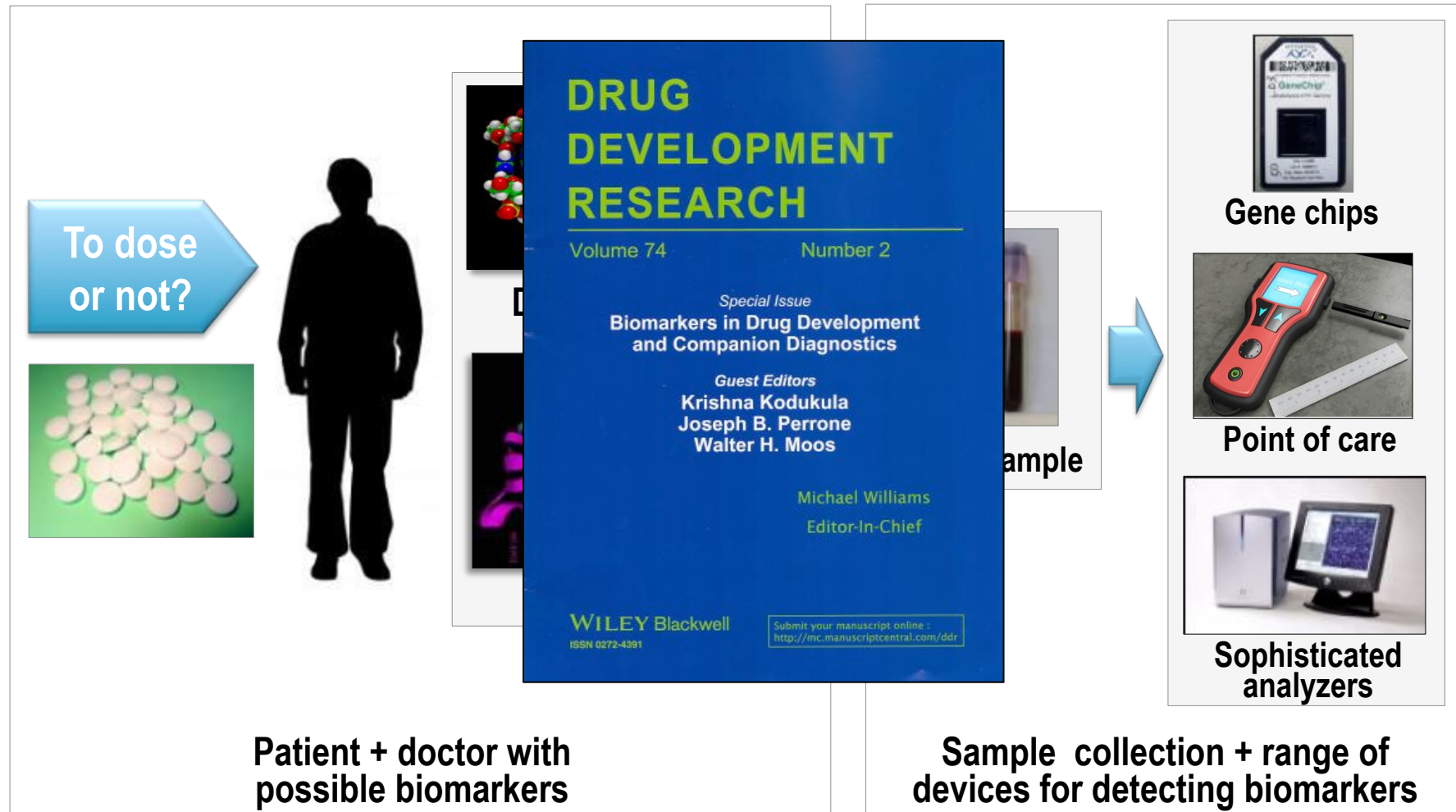


Plasma (55%)  
White blood cells  
+ platelets (<1%)  
Red blood cells (45%)



# Biomarkers + Personalized Therapies = Future of Medicine

*SRI SV R&D = Precision medicine*



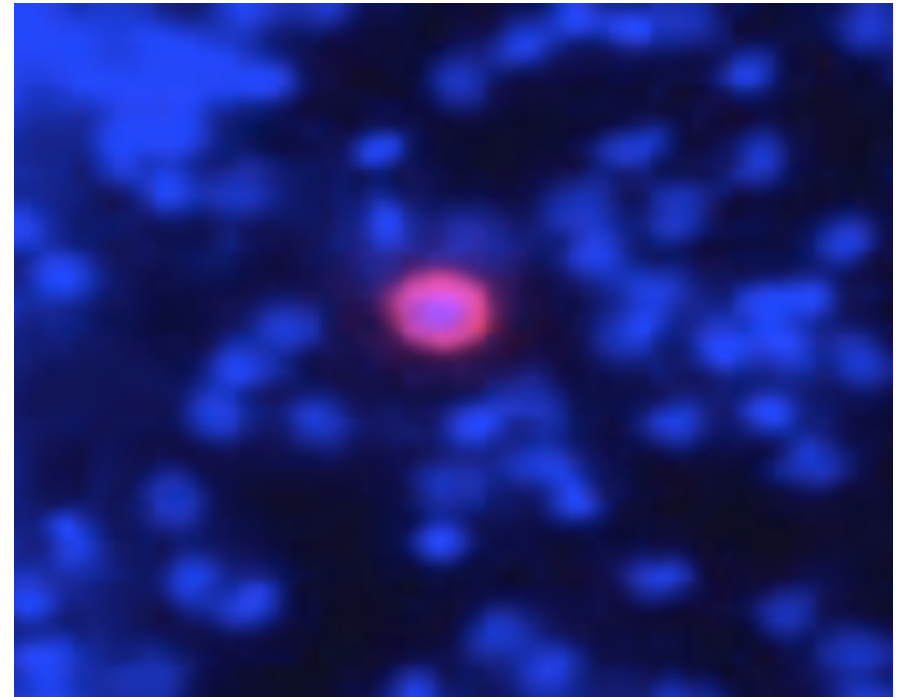
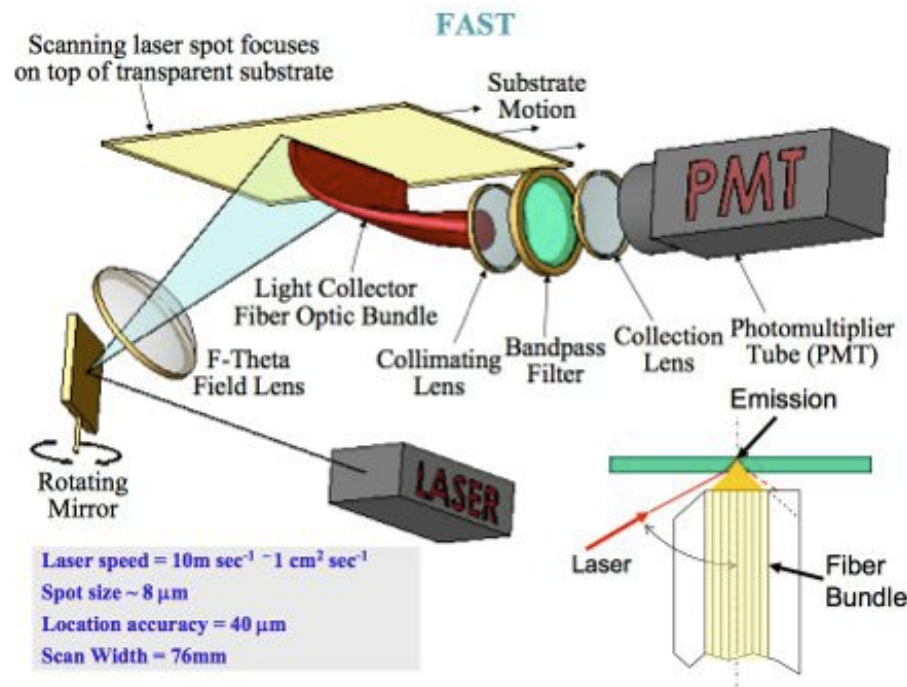
*Predictive medicine = same diagnosis + same drug?  
No... Different people, different results!*



# Rare Cancer Cell Detector for Cancer

**SRI SV R&D = Spin-off AxonMD for new age of precision medicine**

- Detect + characterize rare circulating tumor cells
  - Novel assays to diagnose + follow disease
  - Guide personalized therapy in real time
- Specificity = ability to find + distinguish 1 in 25,000,000 cells
- Paired with 'omics = even more powerful biomarker platform





# Drugs + Innovation = Dollars + “Sense”

*Saving lives through nonprofit R&D*

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- *What this means for the future*

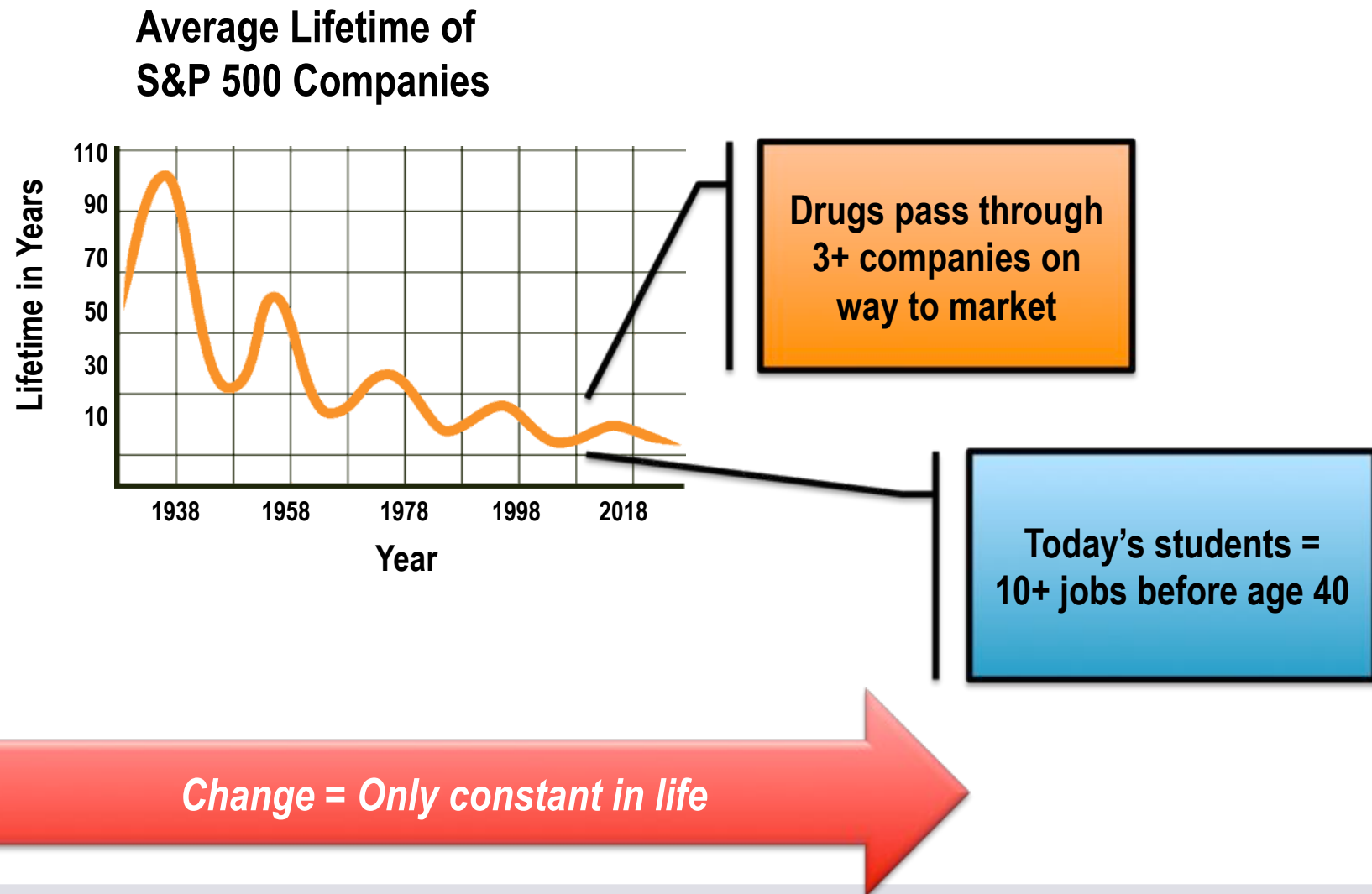


*Preparing for the unknown*

*Future Shock is upon us... How will you avoid Creative Destruction?*

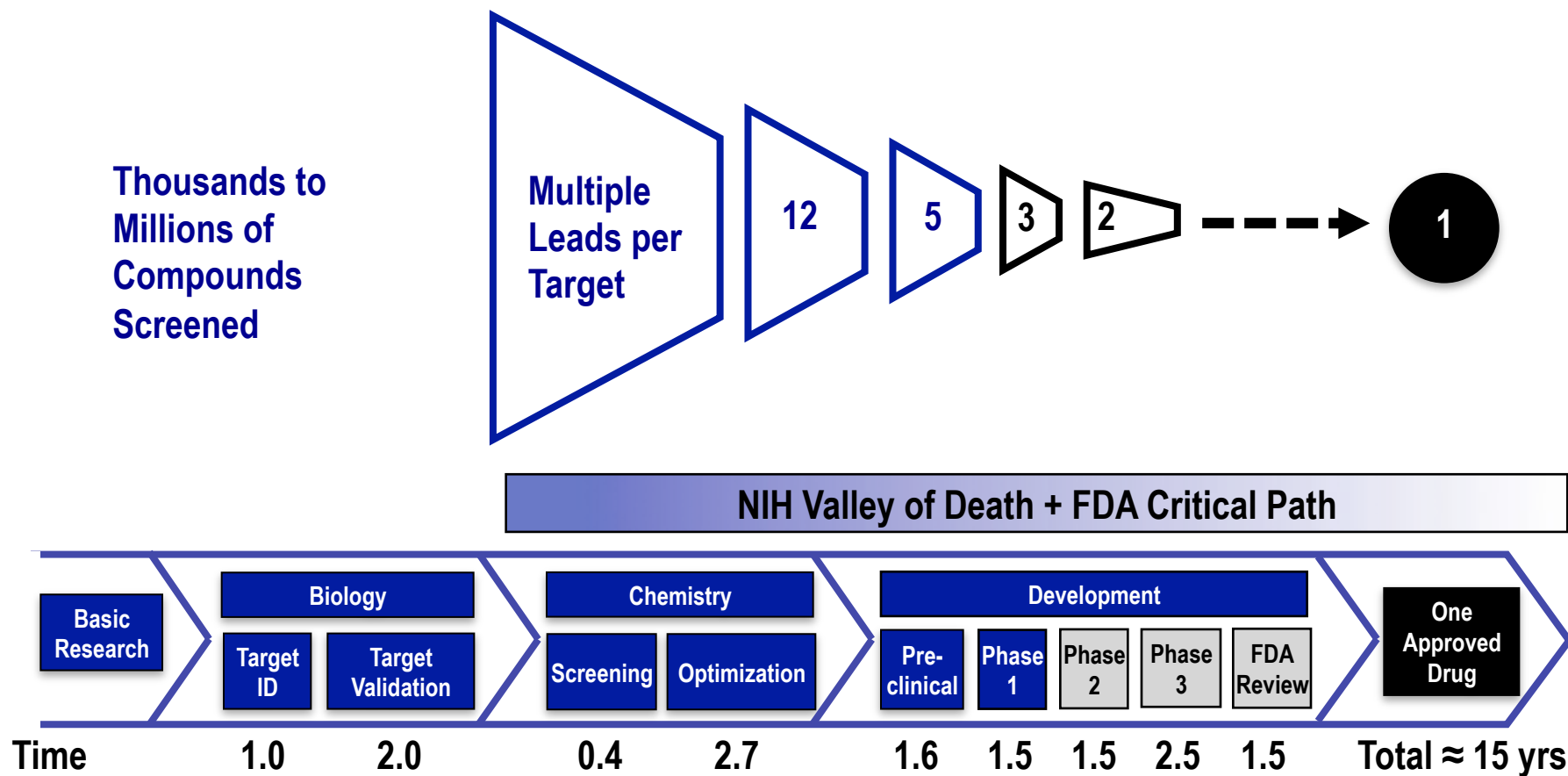
# Life-Long Learning + Doing = Key to Survival

*Keep up with accelerating rates of change*



# Cross-Disciplinary Partnerships Required

*Pharmaceutical R&D = Team sport*



*Important Need = Bridging the Valley of Death*

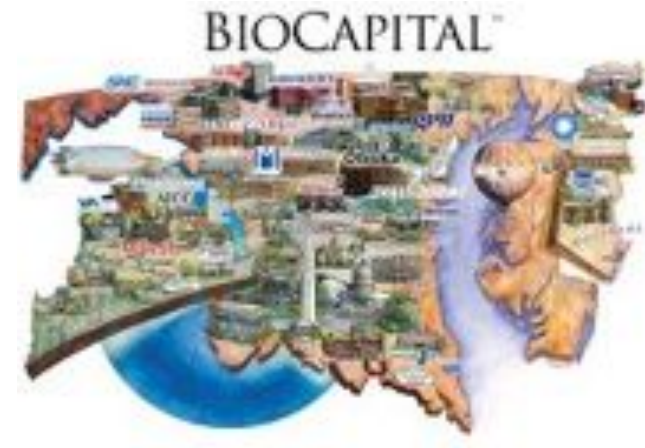
# Everyone Needs a Partner

***SRI SV + Virginia = Winning team***

- Virginia #1 = “Best State for Business”
- Major funding >\$10 billion = short drive away
- Base for growth in biosciences + other important areas

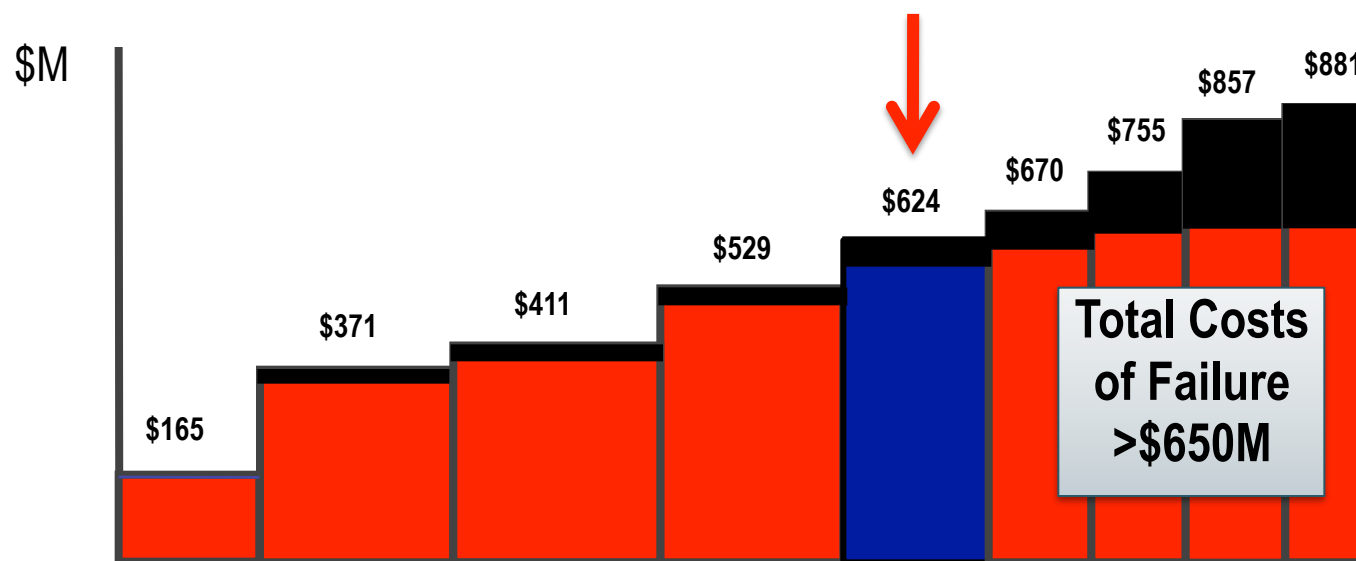
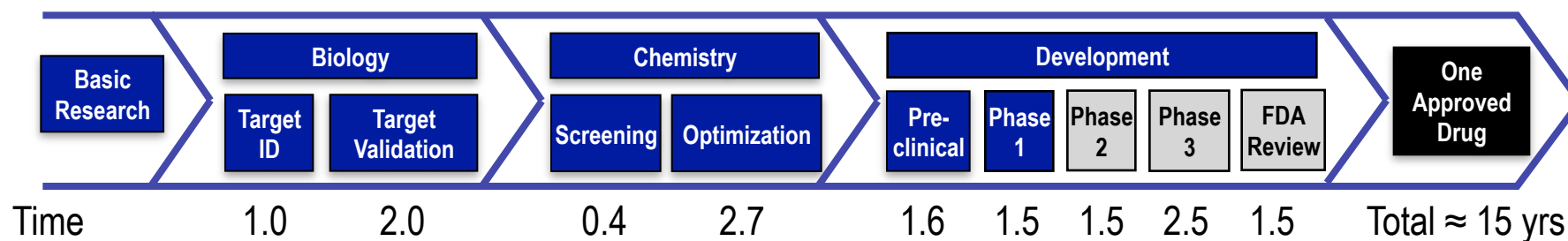


RADFORD UNIVERSITY



# Keep Doing Good Things Till Good Things Happen

*The difficult we do immediately... The impossible takes a little longer*

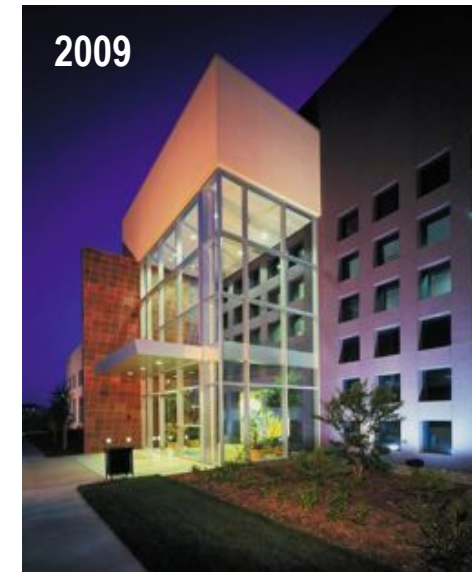


**Important Value Proposition = \$100M+ De-Risking**

# SRI SV Win-Win Plans on Day 1

*2007-2013 + beyond*

- Continue **partnerships** with you all
- Accelerate **commercialization** of VA technologies
- Create new **jobs** at SRI SV
- Initial focus on **advanced drug research**
- Investment **magnet** for new high-tech clusters
- Host **VC** meetings
- High-tech jobs for VA **students + postdocs**
- SRI staff **seminars** as adjunct **professors**
- Conduct SRI Value Creation **workshops**
- Submit **proposals** worth \$ millions each year
- **Reinvest** profits back into SRI SV
- Pay portion of **royalties** to VA





# SRI SV Win-Win Plans Continued

*2013 + beyond = More + more value propositions realized*

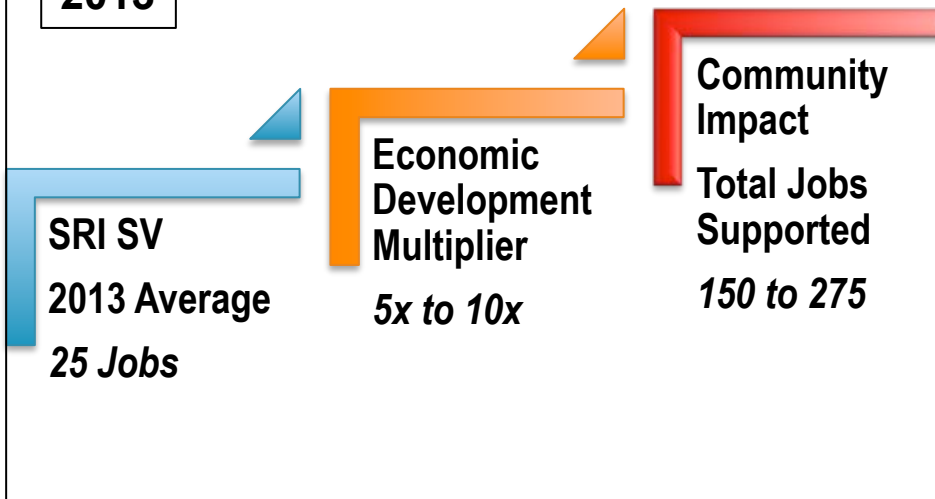
2009



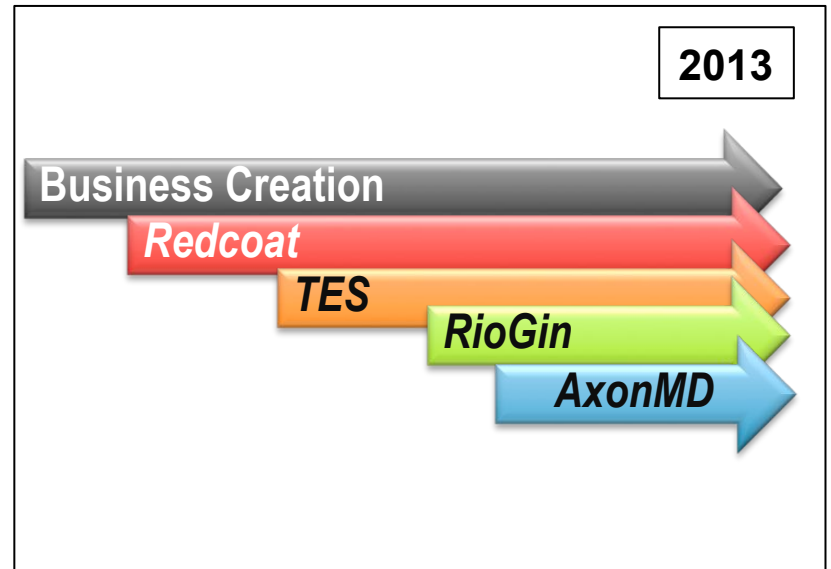
2012



2013



2013





# SRI SV Win-Win Plans by the Numbers

*2007-2013 + beyond = Wow!*

**\$200M**

Value of Proposals  
Submitted with >6  
Virginia Insitutions

**25**

Student Interns  
from 6 Colleges  
(4 Virginia)

**12**

Advanced to  
Grad or Med School

**\$5M**

SRI 2013 Investments  
in Building + Staff

**70 + 50**

VA Lectures @  
JMU, SVTC, et al.  
+ Annual Visitors

**16**

Postdoctoral +  
International  
Fellows

**7**

@ Merck Nearby  
+ Virginia Spin-Outs

**6**

Local College Faculty  
Summer Sabbaticals

**60**

Employees Since  
Inception

**8**

New Positions in Universities, Returned to  
School, or Made Career Changes

**3**

Retired, Plan to  
Retire, or Returned to  
Native Country

**\$22M + 25**

VA Support +  
Funded Projects

**10**

5DOI Workshops

**2 + 1**

Moved from SRI MP  
to SRI SV + the  
Reverse

**40K + 25**

Building Square  
Footage + Acres

# SRI SV = Impact Despite “New Normal”

*Good, bad, ugly... This too shall pass*

NIH  
post-  
doubling  
cliff

VA  
SRI  
MOA

SRI SV  
opens  
@ JMU

Great  
Recession  
begins

New  
labs  
open

ARRA  
funding  
cliff

Sequestration  
+ gov't delays  
+ debt ceiling

'05

'06

'07

'08

'09

'10

'11

'12

'13



# Drugs + Innovation = Dollars + “Sense”

*Saving lives through nonprofit R&D*

- Introduction
- Pharmaceutical math
- Innovation for impact
- What this means for the future

*Remember...*

*“Unless someone like you cares a whole awful lot, nothing is going to get better. It's not.”*



# Thank You for Making SRI SV Possible

*The original team... We couldn't have done it without you!*

- Richard Abramson
- Charles Ahrend
- Jim Barnes
- Jerry Benson
- Keith Boswell
- John Bramer
- David Brakke
- Michael Breeden
- Doug Brown
- Rae Lyn Burke
- Ted Byrd
- Curt Carlson
- John Chichester
- Aneesh Chopra
- Pablo Cuevas
- Rodney Eagle
- Dee Floyd
- Tom Furst
- Patrick Gottschalk
- Emmett Hanger
- Phil Harman
- Tim Kaine
- Krishna Kodukula
- William Kyger Jr.
- Steve Landes
- Matt Lohr
- Jake Meyers
- John Noftsinger
- Mark Obenshain
- Joe Paxton
- Len Polizzotto
- Liz Povar
- Alice Resnick
- Lin Rose
- Chris Saxman
- Brian Shull
- John Sternlicht
- Robin Sullenberger
- Nicky Swayne
- Louise Temple
- Billy Vaughn





# Innovation + Solutions + Life

**Harrisonburg**



**Arlington**



**Menlo Park**



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# Suggested Reading

## *SRI Biosciences + SRI International*

- **Biomarkers:** Essential Tie that Binds Future of **Drugs & Diagnostics**  
*Perrone et al., Drug Development Research 2013*
- Nonprofit Pharma: **Solutions for What Ails Industry**  
*Moos + Kodukula, Current Medicinal Chemistry 2011*
- Nonprofits & **Valley of Death** in Drug Discovery  
*Moos, Xconomy 2010*
- **Nonprofit Organizations** & Pharmaceutical R&D  
*Moos + Mirsalis, Drug Development Research 2009*
- Nonprofit Research Institute Perspective on **Outsourcing R&D**  
*Moos, bioLOGIC 2008*
- Nonprofit Model for **Drug Discovery & Development**  
*Frank et al., Drug Development Research 2007*
- Intersection of **Strategy** & Drug Research  
*Moos, Comprehensive Medicinal Chemistry II 2007*
- **Innovation: Five Disciplines for Creating What Customers Want**  
*Carlson + Wilmot, Crown Business 2006*
- **Nanobiotechnology:** It's a Small World after All  
*Moos + Barry, Drug Development Research 2006*
- **Ethical Issues** in Biotechnology & Pharmaceutical Industries  
*Aronson et al., Drug Development Research 2005*
- Estrogens & **Neuroprotection:** Desperate Housewives, Lost & Survivor  
*Howell et al., Drug Development Research 2005*
- Defining Mandate of **Proteomics** in Post-Genomics Era  
*Kenyon et al., Molecular Cellular Proteomics 2002*
- **Biotechnology** Industry in Period of Opportunity & Uncertainty  
*Moos + Feldbaum, Drug Development Research 2002*
- Diagnosing Decline of Major Pharmaceutical Research Laboratories: **Prescription for Drug Companies**  
*Weisbach + Moos, Drug Development Research 1995*