Truth and Consequences: Health R&D Spending in The U.S. (FY11-12)

RESEARCH AMERICA
AN ALLIANCE FOR DISCOVERIES IN HEALTH

Overall Gains Tempered by Stagnant Funding and Reclassifications

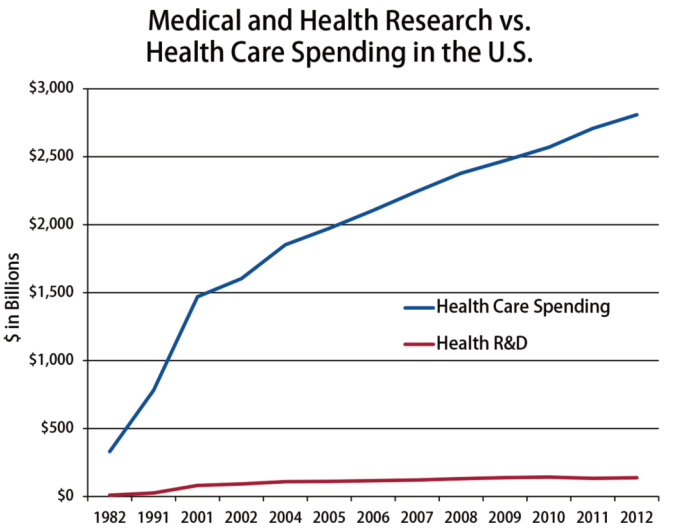
SPENDING BREAKDOWN

Industry and Other Non-Federal Spending on the Rise; Perception and Reality Diverge in Federal Funding "Increase"

After declining in FY10-11, health-related R&D spending in the U.S. increased by $4.3 billion (3.5%) in FY11-12, an increase largely driven by industry, philanthropy and voluntary health associations. Industry spending increased by $2 billion (3%), primarily due to a $1.3 billion (7.2%) increase in R&D spending by biotech companies. There was nominal growth in pharmaceutical and medical technology spending, at 1% and 2.5%, respectively. Pharmaceutical spending appears to be slowly climbing out of a deep dive (FY11 saw a 10.6% drop in spending in contrast to a 1.1% increase in FY12); the biotech industry is trending solidly upward (spending increased 4.7% in FY11 and 7.2% in FY12); and med tech R&D spending growth continued at a slightly slower pace (3.9% in FY11 compared to 2.5% in FY12).

Federal spending also contributed to the overall increase in the R&D spending reported for FY12, but the apparent increase in this category is misleading. The increase is largely due to changes in the classification of existing spending within the National Science Foundation and the Food and Drug Administration ($315 million at NSF and $152 million at FDA) rather than to an actual increase in dollars. At NSF, most of the increase is due to a reorganization that placed the formerly separate Office of Cyberinfrastructure within the Computer and Information Science and Engineering Directorate; at FDA, dollars that were formerly categorized under "Evaluation" were relabeled as "R&D."

The National Institutes of Health (NIH) budget grew by $181 million, or 0.6%. Funding for the Centers for Disease Control and Prevention (CDC) and the Agency for Healthcare Research and Quality (AHRQ), the agencies where much federal health services research, epidemiology and other health disciplines dollars are used or distributed, decreased in 2012 ($49 million, or 10.7%, for CDC and $4 million, or 1%, for AHRQ). The Patient-Centered Outcomes Research Institute (PCORI), established in 2010, increased its spending by $7 million as the new institute geared up to perform its mission of improving health care delivery and outcomes.



Other Sources of Funding Increasing

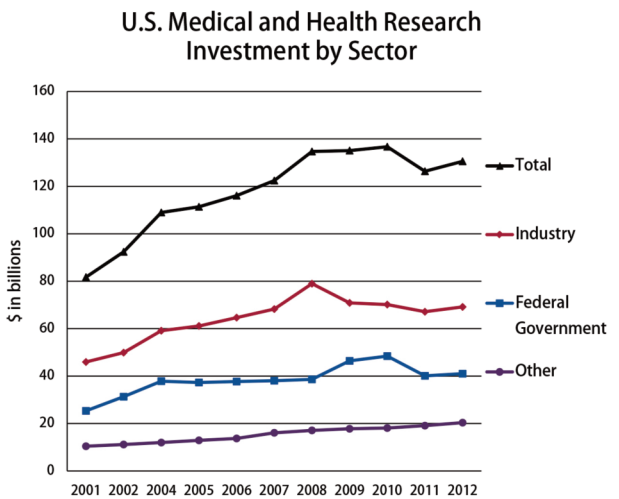
Philanthropic and voluntary health association spending contributed to the overall jump in spending — largely due to a single $150 million grant awarded by the W.M. Keck Foundation. In total there was an increase of 7.5% ($1.42 billion) in FY12 in "other" spending. This includes an increase in use of institutional funds at universities (4.6%), independent research institutes (19.7%), foundations (79.4%) and voluntary health associations (6.5%). Funding from state and local governments declined slightly (0.9%), the only non-federal and non-industrial source that decreased. Of note is that the rate of growth in expenditure of institutional funds from universities — the largest share of this category — slowed in FY11 (4.6%) over FY10 (6.2%). Overall spending in these areas increased 7.5%, continuing to outpace growth in both industry and the federal government, albeit from a much lower starting point.

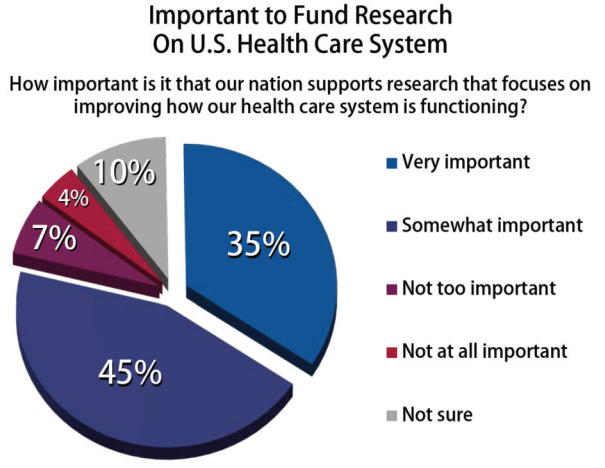
WHAT STORIES DO THESE NUMBERS TELL?

Federal Government

For a decade, medical and health research supported by federal health agencies has been characterized by stagnant funding. Following a two-year uptick due to the American Recovery and Reinvestment Act, investment is now shrinking; the 2011 Budget Control Act imposed sequestration (across-the-board budget cuts beginning

Continued on Page 3





A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics, with support from the American Society of Hematology, in November 2013.

in millions

2012 Total: Estimated U.S. Medical and Health Research Expenditures					130,383
Industry	**2010**	**'10-'11 Change**	**2011**	**'11-'12 Change**	**2012**
Pharmaceutical (research and development, estimate)	40,700	-10.6%	36,400	1.1%	36,810
Biotechnology (research and development)	17,200	4.7%	18,000	7.2%	19,300
Medical Technology (research and development)	12,265	3.9%	12,738	2.5%	13,059
Subtotal	**70,165**	**-4.3%**	**67,138**	**3.0%**	**69,169**
Federal Government					
National Institutes of Health	34,829	-14.4%	29,831	0.6%	30,012
Department of Defense (medical research, chemical and biological defense)	2,667	-12%	2,346	2.8%	2,412
Department of Homeland Security (biodefense)	2,372	-91.0%	213	9.9%	234
Department of Agriculture (Agricultural Research Service, National Institute of Food and Agriculture, Economic Research Service)	2,188	-19.8%	1,754	11.3%	1,953
National Science Foundation (biological sciences, bioengineering, behavioral sciences, computer and information science and engineering)	1,753	0.4%	1,760	17.9%	2,075
Department of Energy (biological and environmental research, advanced scientific computing research)	1,037	-3.1%	1,005	1.5%	1,020
Environmental Protection Agency (clean air, clean water, health and human ecosystems, pesticides and toxics)	596	-2.3%	582	-2.4%	568
National Institute of Standards and Technology	588	-9.5%	532	4.7%	557
Department of Veterans Affairs (medical and prosthetic research)	581	-0.2%	580	0%	580
Agency for Healthcare Research and Quality	420	-5.2%	398	-1.0%	394
Centers for Disease Control and Prevention (disease control, research and training)	363	25.9%	457	-10.7%	408
Food and Drug Administration	248	2.4%	254	59.8%	406
NASA (Human Research Program)	182	-14.8%	155	1.9%	158
U.S. Agency for International Development	158	0%	158	19.0%	188
Administration for Children and Families (children's research)	43	-4.7%	41	-75.6%	10
Ctrs. for Medicare & Medicaid Services (health services research, demonstration, evaluation)	27	33.3%	36	-47.1%	21
Health Resources and Services Administration	8	42.9%	12	0%	12
Patient Centered Outcomes Research Institute	—	—	1	700%	8
Subtotal	**48,222**	**-16.8%**	**40,115**	**2.2%**	**41,016**
Other Sources					
Universities (Institutional Funds) (2011)	11,198	6.2%	11,897	4.6%	12,445
State and Local Government (2011)	3,647	5.7%	3,854	-0.9%	3,819
Independent Research Institutes (institutional funds)	1,259	2.1%	1,285	19.7%	1,538
Philanthropic Foundations (2011)	854	-13.7%	737	79.4%	1,322
Voluntary Health Associations	887	14.9%	1,008	6.5%	1,074
Subtotal	**17,835**	**5.3%**	**18,781**	**7.5%**	**20,198**
Total U.S. Biomedical and Health R&D Spending	136,222	-7.5%	126,034	3.5%	130,383
Total U.S. Health Spending (health care spending + biomedical and health R&D spending)	2,706,222	4.7%	2,834,034	3.7%	2,939,383
Biomedical and Health R&D as a Percentage of Total U.S. Health Spending	5.03%	-11.5%	4.45%	-0.2%	4.44%

Compiled by: Adam M. Katz

Analysis, from Page 1

January 1, 2013, and mandated each year through 2021) and lower limits on discretionary spending. Sequestration slashed non-defense discretionary accounts (such as NIH, CDC and FDA) by approximately 5% beginning in March 2013.

Overall federal R&D investments are a mixed bag, with some R&D increases borne of accounting changes at key federal agencies. This phenomenon tracks all too closely to the situation on Capitol Hill, where there is vocal support for medical research but actual investment in research has gone from increasing to stagnant to declining. The increases in industry and other funding, including a large increase in philanthropic funding, are positive developments, but there are caveats to the interpretation of those findings as well.

Industry

While promising, none of the increases in industry funding appear to signal the beginnings of a significant upward trend in private sector R&D. The med tech industry is contending with a 2.3% excise tax that took effect January 1, 2013, and both the biotech industry and the pharmaceutical industry face continued uncertainty regarding future reimbursement levels and other policy concerns, including intellectual property and regulatory issues. In such a climate of uncertainty, investors are attracted to nations with stable, predictable regulatory environments.

In addition, positive biotech funding increases may not be a good barometer of the marketplace. Venture capital funding for the U.S. biotech industry dropped 15% in FY12, from $4.9 billion to $4.1 billion. In contrast, venture capital for all sectors of the economy dropped 10% to $26.5 billion in 2012. The decline in venture capital for biotech is consistent with warnings by industry leaders that if the U.S. takes a passive stance on U.S. medical innovation, venture capital will begin — and has begun — to flow to other countries.

Other Sources of Funding

While the increase in non-federal, non-industry sources of funding is welcome, it is important to note that the results are highly influenced by a $150 million grant awarded by the W.M. Keck Foundation to the University of Southern California for groundbreaking education, medical, clinical and translational research. There was also an increase in the number of multi-million dollar grants awarded by the Bill & Melinda Gates Foundation in the field of medical research during 2011. As federal funding becomes more competitive, applications to foundation sources continue to increase, stiffening the competition in the already challenging non-government environment. Some philanthropic funders have been in a position to increase support in recent years, but these grants are often more competitive than federally supported grants, and many are not open to competition.

KEY IMPLICATIONS

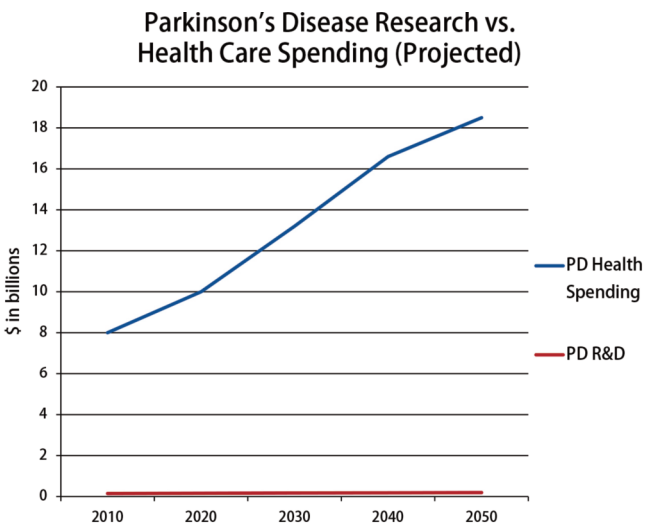
Health Care Costs

Federal health care spending is expected to explode over the coming decades, propelled by our aging population, returning veterans, and the associated increase in the number of Medicare and Medicaid enrollees with disabling and deadly conditions like cancer and Alzheimer's disease. The largest cost burden associated with these and other chronic diseases is often not a result of new treatments or technologies. Rather, it is often due to labor-intensive care — home health care, physical therapy, hospital readmissions, etc. Medical and health research each play a critical role in addressing these costs: Medical research uncovers preventive measures, treatments and cures that can reduce the incidence or delay the onset of chronic diseases and minimize the disabling symptoms associated with them. Health research helps optimize health care protocols to assure patients are seeing the right provider at the right time in the right setting, improving the return on health care spending in terms of quality of care, patient satisfaction and outcomes while reducing spending. Yet, in the name of long-term deficit reduction, policy makers are not sufficiently powering our medical and health research capacity to meet the challenge.

Parkinson's Disease Case Study

Cutting federal funding for Parkinson's disease research is one example of a deficit reduction strategy that will, in all probability, prove counterproductive. The Parkinson's Action Network estimates that upwards of 1.5 million Americans currently live with the disease and that nearly 60,000 new cases are diagnosed every year. The costs associated with Parkinson's disease alone are projected to skyrocket to $18.5 billion per year by

Continued on Page 4



METHOD AND RATIONALE

Pharmaceutical R&D was reported by PhRMA; biotechnology research expenditures were reported by Ernst & Young; and medical technology spending was provided by the Advanced Medical Technology Association (AdvaMed) to Research!America.

Figures for the U.S. Agency for International Development (USAID), Centers for Medicaid and Medicare (CMS), Health Resources Services Administration (HRSA), and the Administration for Children and Families were obtained from agency budget reports to Congress.

The Department of Homeland Security figure was obtained from an article on national biodefense spending in the journal Biosecurity and Bioterrorism.

The Department of Agriculture estimate includes intramural and extramural research funded by the Agricultural Research Services, the National Institute of Food and Agriculture, and Economic Research Service. Research was determined to be health-related based on the research objectives of each agency.

The National Institute of Standards and Technology (NIST) estimate includes research spending on chemical science and technology, physics, materials science and engineering, information technology, electronics and electrical engineering, the Center for Nanoscale Science and Technology, and technology services.

The Patient-Centered Outcomes Research Institute (PCORI) figure was taken from its 2012 annual report.

University institutional funds are reported by the National Science Foundation (NSF) as part of the Survey of Research and Development Expenditures at Universities and Colleges for FY2011. Institutional funds may include endowment income, tuition or gifts/donations. Figures for institutional funds of independent research institutes were provided by the Association of Independent Research Institutes (AIRI).

R&D investment by voluntary health associations was calculated using data available from research grant-making organizations.

Health research grants made by philanthropic organizations and foundations of all sizes were reported by the Foundation Center.

Parkinson's disease research expenditures are modeled for out-years based on average spending on Parkinson's disease research by the National Institutes of Health between 2011 and 2012.

Research!America produces this investment report annually to assist policy makers and stakeholders in analyzing budget and policy options in order to make the healthiest possible decisions for our nation.

This is the 10th annual Investment in Research report. Previous reports are available online at http://bit.ly/1fe2Qse.

Analysis, from Page 3

2050. Yet critical federally funded research in this area is stagnant, handcuffed by arbitrarily tightened appropriations budget caps and squeezed even further by sequestration. Some proposed entitlement reforms, such as cuts to prescription drug and biologic reimbursements under Medicare, would likely stifle the capital needed for pharmaceutical and biotech firms to advance the work of NIH-funded researchers and complete the significant development needed to turn initial medical discoveries into viable medical advances. If federal policy makers choke off funding for research and development in both the public and private sectors, what alternatives will be at our disposal to overcome Parkinson's disease?

Underestimating the Value of Health Research is a Costly, even Deadly, Mistake

As noted earlier, medical research is not the only research discipline that plays a critical role in reducing health care spending. Health research, a small percentage of overall medical research, distinguishes effective cost-saving strategies from ineffective ones. Whether it is used to evaluate public health interventions like smoking cessation programs, health care financing and delivery models like cost savings, and health care quality strategies like the medical home concept, health research is a necessary field for assuring both our prosperity as a nation and our health as individuals. Health economics, health services, social science and public health research — all under the umbrella of health research — help us to shed light on these and related questions.

Case in point: The 2012-13 flu season in the U.S. was markedly deadlier than in previous years. According to the CDC, 149 laboratory-confirmed influenza-associated pediatric deaths were reported for the season. Influenza-associated pediatric deaths have previously ranged from 34 to 123 per season. Epidemiology, a form of public health research, tracks the prevalence of the flu and other infectious diseases in communities across the nation and assists health care professionals in making the right diagnoses and determining the most effective treatment. Yet federal policy makers are cutting funding for some health research disciplines and trying to eliminate funding for others. It is the implementation of findings from this class of research that resulted in the dramatic reduction of health care-associated infections by 66%, saving more than 1,500 lives and $200 million during the first 18 months of a pilot program in Michigan.

Global Competitiveness and the Future

As federal funding for medical and health R&D remains effectively stagnant, other countries are rapidly and doggedly increasing their capacity. China, Japan, Singapore, Sweden, Mexico, the U.K. and Germany are among those accelerating investment in medical and health R&D. Over the past year, China has increased its health R&D investment by 15%. Germany's federal investment in health R&D spending has increased by 60% since 2005 and is now approaching 3% of GDP. Not only are other nations investing at a rapid pace, they are building public policy frameworks that are decidedly more conducive to medical innovation. U.S. R&D tax incentives have not kept pace with other countries including China, South Korea, India and much of Europe. Among the incentives being offered are a "super tax deduction" of 150% for eligible R&D expenditures in China, an investment tax credit on R&D equipment in South Korea, and a new 35% tax credit for recruiting highly skilled researchers to Italy. All are compelling reasons for venture capitalists to focus their attention overseas.

CONCLUSION

Overall, medical and health R&D spending in the U.S. edged upward in FY12, but virtually all of the federal contribution to that increase is the result of changes in how federal spending is classified, rather than an increase in the dollars devoted to R&D. And while the increase in private sector spending is a positive sign, access to venture capital is shaky; policy makers must pay attention to the statutory and regulatory environment under which that industry operates to assure U.S. companies remain attractive to investors.

Medical and health R&D holds enormous potential for our nation in its capacity to improve individual and population health and ignite our economy. Research and innovation are needed to help stabilize health care spending, whether by delaying or preventing costly chronic diseases, enabling earlier diagnosis or by squeezing needless red tape out of our health care system. If our nation is to maintain its global leadership in medical and health R&D for the sake of economic stability and national security; if policy makers are truly serious about resolving our nation's budget problems and do not want to squander past investments in our nation's unrivaled research infrastructure; if medical progress that leads to longer and healthier lives is truly a national priority, then policy makers must reverse course and actively champion research to improve health. The consequences of ill-conceived policies that hamper medical innovation will be felt for many generations to come.

Sources and Acknowledgements

Budget table sources (click to learn more):

- PhRMA, 2013 Profile Pharmaceutical Industry
- Ernst and Young, Beyond Borders: Matters of Evidence. Biotechnology Industry Report 2013
- U.S. Medical Technology R&D numbers provided by the Advanced Medical Technology Association (AdvaMed)
- American Association for the Advancement of Science Report XXXVIII, R&D FY 2014
- "Federal Agency Biodefense Funding, FY2012-FY2013." Franco C and Sell TK. *Biosecurity and Bioterrorism*. 2012;10(2):162-181
- U.S. Agency for International Development, Report to Congress: Health-Related Research and Development strategy 2011-2015
- Centers for Medicare and Medicaid Services (research funding at CMS)
- Patient-Centered Outcomes Research Institute (PCORI)
- National Science Foundation (University Institutional Funds & State and Local Governments)
- Association of Independent Research Institutes, Survey of Members
- The Foundation Center, Distribution of Foundation Grants by Subject Categories
- Research!America survey of annual reports of voluntary health associations
- Centers for Medicare and Medicaid Services, National Health Expenditure Data

Additional sources (click to learn more):

- Internal Revenue Service FAQ on the Medical Device Tax
- MoneyTree venture capital funding: Double-digit dip. Pricewaterhouse Coopers LLP (2013)
- Kowal, et al. The Current and Projected Economic Burden of Parkinson's Disease in the United States, *Movement Disorders*, Volume 28, No. 3, 2013
- National Institutes of Health Research Portfolio Online Reporting Tools: Estimates of Funding for Various Research, Condition, and Disease Categories (NIH sponsored Parkinson's disease Funding)
- United States, 2012-13 Season and Composition of the 2013-14 Influenza Vaccine. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report (MMWR) June 14, 2013 / 62(23);473-479
- The American Association of Critical Care Nurses
- N Engl J Med. 2006 Dec 28;355(26):2725-32
- Macilwain, C. Biology Boom Goes Bust. *Cell*, 2013 Jul3;154(1):16-9
- Schiermeier, Q. Germany hits science high. Nature. 19 September 2013. Vol 501. P.289-90
- International Tax Incentives: 2012 Global Survey of R&D Tax Incentives. Deloitte Global Services Limited (2012)

Photo credit:

National Human Genome Research Institute

RESEARCH AMERICA
AN ALLIANCE FOR DISCOVERIES IN HEALTH

1101 King Street, Ste. 520; Alexandria, VA 22314-2960
703.739.2577 phone / 703.739.2372 fax
800.366.CURE; *www.researchamerica.org*