

rant increased reimbursement. The hope is that some of the pilot projects currently under way sponsored by the Center for Medicare and Medicaid Innovation (Innovation Center) or by private payers will provide insights to answer this question. For example, can the various models for medical homes and accountable care organizations (ACOs) or other strategies being tested consistently produce savings, and are any early savings that are produced by voluntary participants likely to be generalizable and sustainable? This is clearly a stretch goal, at least in the near term, since most evaluations are still in a relatively early stage, and some of the more advanced models of medical homes are only now beginning to be implemented.

Unfortunately, there are some important strategies that are not being piloted — most notably, projects that assess alternative ways to pay for physician services other than bundling them with institutional services (e.g., those

of hospitals or nursing homes) or strategies involving alternative ways to pay for specialty care (e.g., episode-based payments).

There are a few efforts under development that will begin to focus more systematic attention on changing incentives for specialists. Blue Cross Blue Shield of Michigan, for example, is planning to extend its “fee for value” incentive program to specialists in 2014, and the American Medical Association is in the early stages of developing a condition-based payment system for specialists. Obviously, the results for these activities are years off. Specialists may need to consider whether they will be able and willing to accept more financial risk than they have in the past. The success of physician-led ACOs may clarify their ability to do this successfully.

This year’s interest in fixing the SGR is more promising than it has been in the decade during which Congress has engaged in this year-end ritual. But as in so

much of health care, the devil is in the details, and those have yet to be spelled out.

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From Project HOPE, Bethesda, MD.

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1. Centers for Medicare & Medicaid Services. Estimated growth rate and conversion factor, for Medicare payments to physicians in 2014 (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/Downloads/sgr2014p.pdf>).
2. HR 2810: The Medicare Patient Access and Quality Improvement Act of 2013 (<http://energycommerce.house.gov/fact-sheet/reforming-sgr-prioritizing-quality-modernized-physician-payment-system>).
3. Discussion draft: SGR repeal and Medicare physician payment reform. October 30, 2013 ([http://waysandmeans.house.gov/uploadedfiles/sgr\\_discussion\\_draft.pdf](http://waysandmeans.house.gov/uploadedfiles/sgr_discussion_draft.pdf)).
4. CBO estimate of H.R. 2810. September 13, 2013 (<http://www.cbo.gov/sites/default/files/cbofiles/attachments/hr2810.pdf>).
5. Congressional Budget Office. The budget and economic outlook; fiscal years 2013 to 2023. February 2013:31 (<http://www.cbo.gov/sites/default/files/cbofiles/attachments/43907-BudgetOutlook.pdf>).

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## Asia’s Ascent — Global Trends in Biomedical R&D Expenditures

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The National Institutes of Health (NIH) has been a key enabler of the global dominance of the United States in biomedical research and development (R&D). In 2012, NIH funding accounted for \$30.9 billion of the R&D investment in the United States. U.S. government funding contributed to the development of 48% of all drugs approved by the Food and Drug Administration (FDA) and 65% of drugs that

have received priority review between 1988 and 2005.<sup>1</sup>

Owing to cuts mandated by the Budget Control Act of 2011, the NIH budget for fiscal year 2013 was reduced by \$1.7 billion, to \$29.2 billion — a 5.5% reduction that continued a trend of declining federal funding for biomedical research that began in 2003.<sup>2</sup>

A key consideration in NIH budget discussions is the country’s

competitive international standing in biomedical R&D funding.<sup>3</sup>

However, in determining that standing, policymakers have relied on historical trends within the United States and on data on gross expenditures for R&D in science and technology. Since the Global Forum for Health Research reported global expenditures of \$160.3 billion on biomedical R&D for 2005, no analysis, to our knowledge, has examined

Biomedical R&D Expenditures by the Public Sector and Private Industry in the United States, Canada, Europe, and the Asia-Pacific Region, Adjusted for Inflation, 2007–2012.*						
Region	2007	2008	2009	2010	2011	2012
	<i>billions of U.S. \$</i>					
United States	131.3	123.8	119.1	126.3	120.0	119.3
Public	48.0	46.9	47.9	51.4	50.6	48.9
Industry	83.3	76.9	71.2	74.9	69.4	70.4
Canada	6.0	6.1	5.6	5.6	5.6	5.3
Public	4.0	4.1	3.8	3.5	3.4	3.3
Industry	2.0	2.0	1.8	2.1	2.2	2.0
Europe	83.6	90.0	85.6	80.9	84.9	81.8
Public	27.7	31.1	29.0	28.0	28.4	28.1
Industry	55.9	58.8	56.7	52.9	56.5	53.6
Asia-Oceania	41.1	45.6	49.3	52.9	59.8	62.0
Total						
Public	13.5	14.4	15.9	17.3	19.1	19.3
Industry	27.6	31.3	33.4	35.6	40.7	42.7
China	2.0	2.9	4.6	4.0	7.0	8.4
Public	0.6	1.1	1.2	1.1	1.7	2.0
Industry	1.5	1.8	3.4	2.9	5.4	6.3
Japan	28.2	31.3	33.1	34.9	37.5	37.2
Public	7.3	7.6	8.6	9.0	9.6	9.5
Industry	20.9	23.7	24.5	26.0	27.9	27.6
South Korea	3.5	3.6	3.4	4.3	4.9	6.0
Public	0.9	0.9	0.8	1.0	1.0	1.1
Industry	2.6	2.7	2.6	3.3	3.9	4.9
India	1.4	1.7	1.7	1.8	1.8	2.0
Public	0.4	0.4	0.4	0.4	0.4	0.4
Industry	1.1	1.3	1.3	1.3	1.4	1.6
Australia	4.4	4.3	4.6	5.8	6.3	6.1
Public	3.3	3.1	3.6	4.4	4.9	4.7
Industry	1.1	1.2	1.0	1.4	1.4	1.4
Other Asia-Pacific	1.6	1.8	1.9	2.1	2.2	2.4
Public	1.2	1.2	1.3	1.4	1.5	1.6
Industry	0.5	0.5	0.6	0.7	0.7	0.8
Total	262.1	265.6	259.6	265.7	270.3	268.4
Total in nominal values	226.6	240.4	241.8	254.9	266.6	268.4

\* Unless otherwise noted, all values are shown in billions of U.S. dollars, adjusted for inflation to 2012, with the use of the National Institutes of Health Biomedical Research and Development Price Index according to the mean exchange rate for U.S. dollars for each year.

those expenditures in particular (although commentators have described government funding of biomedical R&D in key Asian countries<sup>4</sup>).

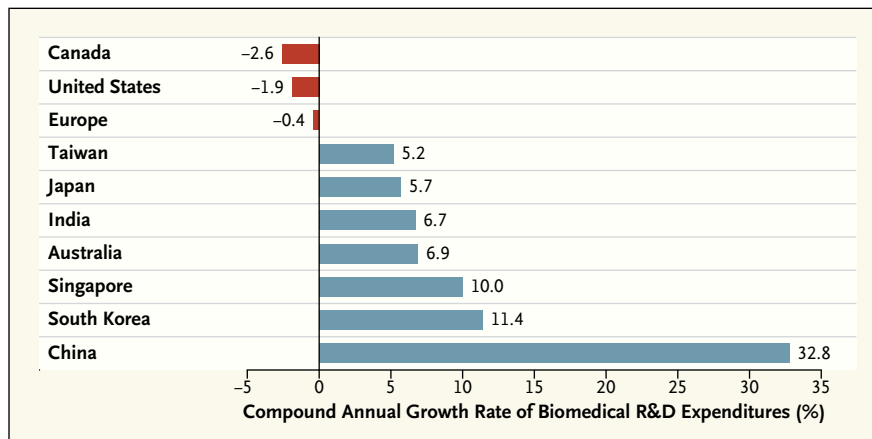
Although a sizable fraction of funding for biomedical R&D in such countries as China, South Korea, Taiwan, and India comes

from national economic-development programs, industry also shoulders a substantial proportion of these costs. To clarify the trends in spending levels, we compared biomedical R&D expenditure levels in the public sector and private industry in the United States, Canada, Europe

(the European Union, Switzerland, Norway, and Iceland), and Asia-Oceania (Australia, China, India, Japan, Singapore, South Korea, and Taiwan) for the period between 2007 and 2012.

We obtained data on biomedical R&D expenditures from government agencies, statistical bureaus, and industry associations and separated them into public spending and industry spending (see Table S1 in the Supplementary Appendix, available with the full text of this article at NEJM.org). Public spending included expenditures by government agencies, educational or research institutions, and charitable organizations, whereas industry spending included expenditures by biotechnology, medical-device, and pharmaceutical firms. We converted all currencies into U.S. dollars using the mean daily exchange rate for each expenditure year and interpolated data where values were missing (see Supplementary Appendix). We adjusted values for inflation using the NIH Biomedical Research and Development Price Index and for differences in the relative value of currencies when calculating percentage share using “purchasing-power parity” data from the International Monetary Fund.

Overall nominal (unadjusted for inflation) R&D expenditures in the United States, Canada, Europe, and Asia-Oceania increased by \$41.8 billion (18.4%), from \$226.6 billion to \$268.4 billion, between 2007 and 2012 (see table). Overall inflation-adjusted expenditures (calculated on the basis of 2012 currency values) increased by \$6.3 billion (2.4%), from \$262.1 billion to \$268.4 billion. But these expenditures increased only in Asia-Oceania (from \$41.1 billion to \$62.0 billion), whereas



**Compound Annual Growth Rate of Biomedical R&D Expenditures by Country, Adjusted for Inflation, 2007–2012.**

The compound annual growth rate was calculated on the basis of total inflation-adjusted biomedical R&D expenditures in U.S. dollars for 2007 and 2012.

they decreased in the United States (from \$131.3 billion to \$119.3 billion), Europe (from \$83.6 billion to \$81.8 billion), and Canada (from \$6.0 billion to \$5.3 billion).

Japan's increase of \$9.0 billion was the largest in absolute dollars. China showed the largest percentage increase — 313.0%, from approximately \$2.0 billion in 2007 to just over \$8.4 billion in 2012, for a compound annual growth rate of 32.8% (see graph). The United States' share of biomedical R&D expenditures among these regions fell from 51.2% in 2007 to 45.4% in 2012 (see Fig. S1 in the Supplementary Appendix). Europe's share remained essentially unchanged — it was 28.5% in 2007 and 29.2% in 2012 — while the proportion spent by Asia–Oceania increased from 18.1% to 23.8%.

Public-sector expenditures (adjusted for inflation) increased in all regions — by \$859 million in the United States, \$452 million in Europe, and \$5.8 billion in Asia–Oceania, driven primarily by a \$2.2 billion increase in Japan and a \$1.4 billion increase in

China. U.S. public-sector R&D spending kept pace with inflation over this period, with decreases in NIH spending being offset by increases from the American Recovery and Reinvestment Act. In 2013, however, the effects of this stimulus were diminished because of sequestration. The United States continued to contribute the largest share of total global public-sector expenditures — 52.9% in 2007 and 50.8% in 2012 — followed by Europe with 26.7% in 2007 and 27.4% in 2012; Asia–Oceania increased its share from 16.6% to 19.1%.

The decline of \$12.0 billion in inflation-adjusted U.S. expenditures from 2007 to 2012 was therefore driven by a \$12.9 billion reduction in industry's investment in R&D. The U.S. share of global industry R&D expenditures decreased from 50.4% in 2007 to 42.3% in 2012. In Europe, industry R&D expenditures decreased by \$2.3 billion, but Europe's share was essentially unchanged (from 29.6% to 30.2%) because its purchasing power increased by 7%. In Asia–Oceania, an increase of

\$15.1 billion in industry's R&D expenditure (from 19.0% to 26.5%) was driven primarily by a \$6.7 billion increase in Japan and a \$4.8 billion increase in China.

The balance between public-sector and industry expenditures changed little over this period: 35.6% public-sector and 64.4% industry in 2007 and 37.1% public-sector and 62.9% industry in 2012. In an analysis adjusting for the size of a region's economy as defined by nominal gross domestic product (GDP), we found that in 2012, the biomedical R&D expenditure as a percentage of GDP was greatest in the United States — approximately 0.76%, as compared with 0.46% in Europe and 0.28% in Asia–Oceania (see Table S2 in the Supplementary Appendix). As a percentage of GDP, U.S. public expenditures actually increased by 5.7%, while U.S. industry expenditures decreased by 12.3%. However, even after adjustment for Asia–Oceania's GDP growth, which was six times that of the United States, overall U.S. expenditures grew 13% more slowly than those in Asia–Oceania.

Our analysis reveals that U.S. inflation-adjusted R&D expenditures and the U.S. share of global expenditures decreased from 2007 through 2012. The decline is remarkable because the United States has provided a majority of the funding for biomedical R&D globally for the past two decades — a share that some previous analyses suggested was as high as 70 to 80%.<sup>2</sup> Moreover, the decline was driven almost entirely by reduced investment by industry, not the public sector, between 2007 and 2012. Sequestration of NIH funding in 2013 and beyond will exacerbate this reduction by causing U.S. public-sector expenditures to decline.

One explanation for the shift in global R&D expenditures may be the attractive cost of conducting R&D in Asia–Oceania, where labor is cheaper and greater government subsidies are available, especially as the development costs per FDA drug approval have increased considerably.<sup>4,5</sup> Accordingly, we found that the U.S. share declined even as global R&D investments by industry remained flat (after adjustment for inflation), which suggests that industry is simply reallocating R&D funding to Asia–Oceania. Because U.S. public-sector expenditures as a percentage of GDP are already 200 to 300% the size of those in Europe and Asia, increasing NIH funding alone may not be a sustainable way of retaining long-term R&D leadership. Instead, even as it boosts NIH funding, the U.S. government might also develop strategies to

provide incentives to industry for investing in biomedical R&D.

Although our data set has its limitations, our findings reveal a decline in U.S. financial competitiveness in biomedical R&D and may have implications for the debate over appropriate federal policy in this area. The lack of a coordinated national biomedical R&D strategy is disappointing, at a time when mature economies such as those of Japan and Europe have maintained their level of investment in this area.

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1. Sampat BN, Lichtenberg FR. What are the respective roles of the public and private sectors in pharmaceutical innovation? *Health Aff (Millwood)* 2011;30:332-9.
2. Dorsey ER, de Roulet J, Thompson JP, et al. Funding of US biomedical research, 2003-2008. *JAMA* 2010;303:137-43.
3. Collins FS. Fiscal Year 2014 budget request. Fiscal Year 2014 testimony before the Senate Subcommittee on Labor–HHS–Education Appropriations. May 15, 2013 (<http://www.nih.gov/about/director/budgetrequest/fy2014testimony.htm>).
4. Sun GH, Steinberg JD, Jagsi R. The calculus of national medical research policy — the United States versus Asia. *N Engl J Med* 2012;367:687-90.
5. Morgan S, Grootendorst P, Lexchin J, Cunningham C, Greyson D. The cost of drug development: a systematic review. *Health Policy* 2011;100:4-17.

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## The Road toward Fully Transparent Medical Records

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Forty years ago, Shenkin and Warner argued that giving patients their medical records “would lead to more appropriate utilization of physicians and a greater ability of patients to participate in their own care.”<sup>1</sup> At that time, patients in most states could obtain their records only through litigation, but the rules gradually changed, and in 1996 the Health Insurance Portability and Accountability Act entitled virtually all patients to obtain their records on request. Today, we’re on the verge of eliminating such requests by simply providing patients online access. Thanks in part to federal financial incen-

tives,<sup>2</sup> electronic medical records are becoming the rule, accompanied increasingly by password-protected portals that offer patients laboratory, radiology, and pathology results and secure communication with their clinicians by e-mail.

One central component of the records, the notes composed by clinicians, has remained largely hidden from patients. But now OpenNotes, an initiative fueled primarily by the Robert Wood Johnson Foundation, is exploring the effects of providing access to these notes.<sup>3</sup> Beginning in 2010, at Beth Israel Deaconess Medical Center (which serves ur-

ban and suburban Boston), Geisinger Health System (in rural Pennsylvania), and Harborview Medical Center (Seattle’s safety-net hospital), more than 100 primary care doctors volunteered to invite 20,000 of their patients to read their notes securely online.<sup>4</sup>

Although only a small minority of these doctors’ patients used the portals, the initial findings were striking. At the end of a year, four of five patients had read the notes, and among those who responded to a survey, large majorities reported having better recall and understanding of their care plans and feeling more in control of their health care. More-