

Medicare, Medicaid, and Pharmaceuticals: The Price of Innovation

Daniel J. Kevles*

INTRODUCTION

Through much of the last half century, Medicare and Medicaid have not for the most part supported research intended to lead to new drugs. For their role in drug development, we need to look to infrastructure and incentives. The record of the National Institutes of Health (NIH) illustrates the potential of both for pharmaceutical innovation. The current budget of NIH, the big elephant in the zoo of the federal biomedical enterprise, is \$30 billion, but apart from a dozen small programs devoted to targeted drug development, most of these billions are not aimed directly at pharmaceutical innovation.¹

Yet the NIH investment in biomedicine has indirectly fueled drug development in the private sector to a huge degree. It has paid for the training of biomedical scientists and clinicians, many of whom went on to staff the drug industry, especially its laboratories. NIH-sponsored research has also generated basic knowledge and technologies and it has encouraged universities to spin out their potentially useful findings into the industry by allowing for the patenting and licensing of the findings.²

Like NIH, Medicare and Medicaid have helped fuel drug development indirectly by supporting selected experimental cancer treatments, medical

* Professor of History, Yale University; Senior Research Scholar in Law, Yale Law School.

This essay was originally published on Health Affairs Online, in conjunction with this symposium. See Daniel Kevles, *Medicare, Medicaid, and Pharmaceuticals: the Price of Innovation*, Health Aff. Blog, Nov. 20, 2014, <http://healthaffairs.org/blog/2014/11/20/medicare-medicaid-and-pharmaceuticals-the-price-of-innovation/>, Copyright (c)2010 Health Affairs by Project HOPE - The People-to-People Health Foundation, Inc.

* Professor of History, Yale University; Senior Research Scholar in Law, Yale Law School. This essay was originally published on Health Affairs Online, in conjunction with this symposium. See Daniel Kevles, *Medicare, Medicaid, and Pharmaceuticals: the Price of Innovation*, Health Aff. Blog, Nov. 20, 2014, <http://healthaffairs.org/blog/2014/11/20/medicare-medicaid-and-pharmaceuticals-the-price-of-innovation/>, Copyright (c)2010 Health Affairs by Project HOPE - The People-to-People Health Foundation, Inc.

1. OFFICE OF TECH. ASSESSMENT, OTA-H-522, PHARMACEUTICAL R&D: COSTS, RISKS AND REWARDS 234 (Feb. 1993), http://govinfo.library.unt.edu/ota/Ota_1/DATA/1993/9336.pdf [hereinafter PHARMACEUTICAL R&D].

2. *Id.*

education, and some clinical research and training.³ But investment in these activities has been small and their impact on drug development apparently very limited. In contrast to NIH, the Medicare and Medicaid stimulus to drug innovation has resided not in the production of new scientists or the patented uses of new knowledge but principally in markets and pricing.

The sizable expansion in the medical market that came with Medicare and Medicaid drew a number of companies into the generic drug business, a type of innovation, many of them from outside the pharmaceutical sector. The *Sunday Herald Tribune* noted in January 1966: “Whatever the future trend of generic-drug sales may be, many companies are jumping into the swim. Only last week Cott Corp., chiefly a dispenser of soft drinks, announced it was forming a unit to sell ‘a full line’ of generic drugs.”

Not long after the passage of Medicare and Medicaid, the U.S. Department of Health, Education, and Welfare called for the use of generic drugs “whenever it is practicable and economical.” Champions of generic substitutes predicted that the shift from brand names would save taxpayers some \$100 million annually.⁴ Generics now comprise some 80% of U.S. prescriptions.⁵

During the latter third of the twentieth century U.S. pharmaceutical companies devised hundreds of new drugs that won Food and Drug Administration (FDA) approval. One might think that the growth was stimulated in part by the increase in the size of the population over 65, which rose from about 18 million in 1965 to about 46 million in 2013, an increase of 28 million people, or 255%. The effective measures and drugs for overcoming infectious disease helped extend life spans and allowed for the expression in much higher frequencies of chronic disease. During this period, pharmaceutical companies stepped up their investments in research and development (R&D)—between 1975 and 1990, in constant dollars from \$2 billion to \$6.6 billion.

But neither the general increase in the size of the senior population nor Medicare and Medicaid was responsible for this output, or within it for new drugs for the treatment of diseases that occur with greater frequency among older or impoverished Americans.⁶

3. *Id.* See also *Medicare and the American Social Contract: Final Report of the Study Panel on Medicare's Larger Social Role: Restructuring Medicare for the Long Term Project*, NAT'L ACAD. OF SOC. INS., 16 (1999), http://www.nasi.org/usr_doc/med_report_soc_contract.pdf.

4. JEREMY A. GREENE, *GENERIC: THE UNBRANDING OF MODERN MEDICINE* 67, 295 n.8 (2014).

5. John Lechleiter, *Beyond the Fiscal Cliff, Pharmaceutical Innovation is the Key to Long-term Fiscal Health*, FORBES (Dec. 11, 2012), <http://www.forbes.com/sites/johnlechleiter/2012/12/11/beyond-the-fiscal-cliff-pharmaceutical-innovation-is-the-key-to-long-term-fiscal-health>.

6. PHARMACEUTICAL R&D, *supra* note 1, at 30, 43; Daron Acemoglu et al., *Did Medicare Induce Pharmaceutical Innovation?*, 96 AM. ECON. REV. 103, 103–07 (2006).

I. WHY THE WEAK ROLE OF MEDICARE AND MEDICAID IN PHARMACEUTICAL INNOVATION?

It is difficult to explain a negative and the data is sketchy, but enough is available to suggest that a plausible answer lies in Medicare and Medicaid policies for prescription drugs. In the case of Medicare, the reason seems to have been a restricted market; in the case of Medicaid, it was seemingly limitations on pricing. Federal support of prescription drugs for Medicare patients was for the most part confined to drugs that were incidental to in-patient medical services provided in hospitals and approved clinics.⁷ Otherwise, resources for prescription drug payments were limited. In 1987, family funds paid the costs of 56% of pharmaceuticals; private insurance, which presumably involved negotiated prices and by and large did not likely cover seniors, only 27%.⁸

As for Medicaid, federal policies established between 1990 and 1992 compelled drug manufacturers to negotiate rebates with HHS for drugs given to state Medicaid patients by safety net providers and sell drugs to comparable outpatient clinics at discounted prices.⁹

The development and FDA approval costs for a new drug run upwards of a billion dollars. Thus, given the government's Medicare and Medicaid market and pricing policies, we should not be surprised that drug companies did not focus their efforts at innovation on drugs targeting the afflictions of the elderly or the poor—who suffer, for example, high rates of mental health problems such as bipolar disorder.¹⁰ Manufacturers evidently counted the prospective payoffs inadequate to warrant the investment; they looked for their principal profits to the general and open pharmaceutical market, where they could charge whatever prices the market or private insurance companies would bear for products under patent.

II. A GAME CHANGER: THE MEDICARE DRUG BENEFIT

Circumstances changed dramatically with the passage of the Prescription Drug Act, or PDA, in December 2003.¹¹ The act was a response to the increasing dependence of senior outpatients on a long list of costly medications, including those for heart disease, cancer, osteoporosis, hypertension, arthritis, diabetes,

7. Margaret Blume-Kohout & Neeraj Sood, *The Impact of Medicare Part D on Pharmaceutical R&D*, (Nat'l Bureau of Econ. Research, Working Paper No. 13857, 2008).

8. PHARMACEUTICAL R&D, *supra* note 1, at 28.

9. 340B DRUG PRICING PROGRAM, <http://www.hrsa.gov/opa> (last visited Dec. 14, 2014).

10. Milt Freudenheim, *A Windfall from Shifts to Medicare*, N.Y. TIMES, July 18, 2006, <http://www.nytimes.com/2006/07/18/business/18place.html>.

11. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat 2066.

gastrointestinal disease, and Alzheimer's disease.¹² It provided them assistance in paying for prescription drugs through a combination of tax breaks and subsidies. It went into effect in 2006 through Medicare Part D.

The PDA, which passed by a hair-thin margin, had been highly contested, not least over the key issue of pricing. The pharmaceutical industry lobbied hard against any arrangements that, like those governing drug prices under Medicaid after 1990/1992, would subject prescriptions to prices negotiated by Washington. The industry won its battle.¹³ The PDA prohibited the federal government from negotiating discounts with drug companies for Medicare and Medicaid patients and from establishing a formulary—that is, a list of acceptable prescription drugs for particular conditions. Both functions were left to private providers such as insurance companies and HMOs.

The PDA also turned 6.5 million Medicaid patients who were eligible for Medicare into so-called “dual eligibles,” people whose medical services remained in Medicaid but who, for their prescription drugs, were moved out of the Medicaid class of regulated drug prices into Medicare Part D. The migration significantly enlarged the market for drugs sold at uncontrolled prices.¹⁴

In response to the PDA's enormous expansion in the prescription drug market for seniors and the free-for-all pricing it allowed, the pharmaceutical industry increased its research-and-development expenditures sharply beginning in 2004. And the increase went heavily for drugs used by Medicare beneficiaries.¹⁵

All the while, the PDA produced a windfall for the drug industry. In 2006, when the PDA went into effect, Medicare Part D enrolled about 22.5 million people, 29% of them the dual-eligibles (total enrollment reached 30 million by 2013). The price of brand-name drugs had climbed about three times faster than the rate of inflation and pharmaceutical revenues had skyrocketed.¹⁶

III. INNOVATION—BUT AT THE RIGHT COST AND FOR THE RIGHT PURPOSES?

The pharmaceutical industry defended its high prices, revenues, and profits by insisting that all were necessary for its investment in the research and development that would produce new prescription drugs. The industry deployed multiple arguments: such drugs saved considerable money in other health-care costs and improved quality of life. A vibrant and innovative drug industry also helped grow

12. Blume-Kohout & Sood, *supra* note 7, at 16.

13. Morgan Cook, *Medicare Part D: Profit Trumps Public Interest*, ORANGE COUNTY REG., Dec. 30, 2013, <http://www.ocregister.com/articles/beneficiaries-594505-drug-drugs.html>.

14. Another 45 million people remained eligible for prescription drugs in rebate-covered state Medicaid programs. Freudenheim, *supra* note 10.

15. Blume-Kohout & Sood, *supra* note 7, at 12, 15-16.

16. *Id.* See also Cook, *supra* note 13; Freudenheim, *supra* note 10.

the American economy and make the nation more globally competitive. According to a study by the Congressional Budget Office, imposing price controls on Medicare Part D would reduce pharmaceutical investment in R&D, risking costs to the economy and to the availability of new, life-saving drugs.¹⁷

But from a public-interest point of view, the price of innovation has been remarkably high, perhaps indefensibly so. The Department of Veterans Affairs is legally permitted to negotiate drug prices and establish a formulary for allowable medications. It pays on average between 56% and 63% of the prices charged for drugs under Medicare Part D.¹⁸

Costs aside, much of the pharmaceutical industry's increased investment in R&D appears to have been concentrated in medical areas where effective medications already existed. Companies aimed to gain market share by producing me-too drugs rather than by seeking new drugs with consequential benefits for the treatment of disease.¹⁹

In 2013, nineteen Senators introduced a measure—the Medicare Drug Savings Act—that would curb the price increases by at least returning the dual-eligibles to the Medicaid rebate arrangement, but it has stalled in the face of assiduous lobbying by the drug industry. Senator Jay Rockefeller of West Virginia, one of the cosponsors, noted that even with the restoration of rebates, the economic and policy environment for drug innovation would remain highly encouraging. He says that the drug industry could well afford R&D, noting it spends far more on advertising and marketing than it does on drug innovation.²⁰

Drug-cost savings would of course be all to the good, helping to curb the mounting fiscal threat to Medicare and Medicaid, but forcing pharmaceutical companies to pay their fair share of the health system would not address the question of how to encourage the development of new, medically consequential drugs. Dealing with that conundrum might well require rethinking our approach to drug innovation. Guidance might be found in how the military obtains the technologies it needs. It does not rely solely on the initiatives of defense firms. It provides incentives in the form of grants and contracts targeted at the innovation

17. Lechleiter, *supra* note 5.

18. Austin Frakt et al., *Should Medicare Adopt the Veterans Health Administration Formulary?*, 21 HEALTH ECON. 485, 487 (2012).

19. David Dranove et al., *Pharmaceutical Profits and the Social Value of Innovation* (Nat'l Bureau of Econ. Research, Working Paper No. 20212, 2012).

20. Press Release, Jay Rockefeller for West Virginia, Rockefeller and 18 Other Senators Introduce Legislation to Protect Seniors & Reduce Deficit By \$141.2 Billion (Apr. 16, 2003), <http://www.rockefeller.senate.gov/public/index.cfm/2013/4/rockefeller-and-18-other-senators-introduce-legislation-to-protect-seniors-reduce-deficit-by-141-2-billion>; WV-Sen: Join Jay Rockefeller's (D) Call to Stop Medicare Price Gouging, DAILY KOS, July 19, 2013, <http://www.dailykos.com/story/2013/07/19/1224995/-WV-Sen-Join-Jay-Rockefeller-s-D-Call-To-Stop-Medicare-Price-Gouging#>.

of specific weapons systems and their components. The United States might consider a similar strategy in the ongoing war against disease, introducing public-interest considerations into the dominantly private, market-oriented system of drug innovation that now prevails.