

The Economic and Human Impact of New Drugs

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The benefits of new drugs to society exceed their cost by a substantial margin. These benefits include net decrease in overall medical expenditures, reduced limitations on work and other activities contributing to quality of life, and increased longevity. Further, new drugs contribute to health and economic growth in the United States. Formularies, to the extent that they restrict drug choices, restrict access to new drugs.
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New drugs contribute to health and economic growth in the United States. Formularies, to the extent that they restrict access to new drugs, restrict access to important benefits. The benefits of new drugs to society—reduced total medical expenditures, improved quality of life, and increased longevity—exceed their cost by a substantial margin. Formulary policies and other such public policies affect both the development of new drugs and their subsequent utilization, thereby indirectly affecting the achievement of these societal benefits.

ECONOMIC PROGRESS

Economists, in general, believe that new products are essential to economic progress. Innovative goods are better than older products simply because they provide more services in relation to their cost of production.^{1,2} People are economically better off today than they were a century ago, not because they have more “stuff,” but because they have newer stuff. They have new products, including new drugs.

The pharmaceutical industry is one of the most research-intensive industries in the economy; therefore, it has a greater propensity to generate new goods than just about any other industry. Data from the National Science Foundation show that research and development (R&D) spending in the pharmaceutical industry tripled between 1985 and 1995,³ and the pharmaceutical industry devotes more than 10% of its revenue to R&D expenditure.⁴

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R&D is a major source of economic growth, and pharmaceuticals are the locus of much R&D spending.

The importance of medical research, in general, should not be underestimated. Economists agree that although the United States spends more on medical research than any other country (\$18.4 billion in 2000 compared with \$3.7 billion for all of Europe), it may be spending too little.⁵ Conservative estimates indicate that a one-time expenditure for R&D of \$15 billion will save 1.6 million life years per year—an annual value of \$27 billion. Further, economists estimate that medical advances that reduce mortality from cancer and heart disease by as little as 10% would add approximately \$10 trillion to national wealth.⁵ Considering the extraordinary value of improved health, the benefits are substantial.

NEW DRUG UTILIZATION

The quality of a person’s health is dependent on the vintage (or year approved for sale) of the drugs he or she consumes. In the case of pharmaceuticals, the U.S. Food and Drug Administration (FDA) regulates approval of the active ingredient of a drug. Some older drugs may be very effective, but in general, the drugs that were more recently approved by the FDA are of higher quality.

Some of the data I use to analyze the benefits and costs of new drugs are from the Medical Expenditure Panel Survey (MEPS),⁶ a large, nationally representative probability survey of health care use and spending in the United States. MEPS data contain information on drug utilization, mortality, and medical expenditure for the entire U.S. population or representative samples over several decades.⁷ Information is available at the patient level, providing data similar to those described by Horn elsewhere in this supplement,⁸ and can be aggregated to the disease level. On the basis of these data from a patient base of more than 23,000 in 1996, I was able to quantify dollars saved by replacing old drugs with new drugs for various diseases. Additionally, these data allowed comparisons between total medical expenditures of people using new

Table 1. Frequency of and Spending for 1996 MEPS Events (N = 23,230)^a

Event Type	No. of Events	Mean Expenditure (US \$)	Total Expenditure (US \$)	Total Expenditure (%)
Inpatient visit	2207	7587.60	16,745,833	41.5
Office-based visit	100,320	81.45	8,170,815	20.2
Prescribed medicine	171,587	32.77	5,623,511	13.9
Outpatient visit	9957	412.55	4,107,802	10.2
Dental visit	22,165	142.92	3,167,747	7.8
Emergency room visit	3899	345.34	1,346,490	3.3
Other medical expenditure	6402	189.70	1,214,484	3.0
All	316,537	127.56	40,376,682	100.0

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Abbreviation: MEPS = Medical Expenditure Panel Survey.

drugs and those of people using old drugs while controlling for age, sex, race, education, income, diagnosis, insurance status, disease duration, and number of comorbidities. Expenditures included office and hospital visits, home health care, and prescription drugs. The MEPS event file for prescribed medications contains 171,587 observations (Table 1), with 90% of these linked to only 1 medical condition.⁷

Results from these analyses, described below, show that newer drugs are superior to older drugs because they reduce total medical expenditures, increase longevity, and improve overall quality of life.

Reduced Total Medical Expenditures

Using data from the 1996 MEPS and controlling for variables listed above, I compared the benefits and costs of replacing older drugs with newer drugs for given diseases.⁵ For example, suppose that two 70-year-old, male, white, high school graduates with incomes of \$40,000/year, who are both covered by Medicare and private insurance, are both taking an antiarrhythmic medication for a condition they each have had for 12 years. One of these individuals is taking a drug approved by the FDA in 1950, and the other is taking a drug approved by the FDA in 1995. In comparing their overall utilization of medical care, the individual using the newer drug has lower total medical costs and fewer lost workdays, as well as a higher probability of survival, than the patient using the older drug. The reduction in nondrug medical expenditures from using a newer drug was almost 4 times greater than the increased cost of the drug.⁵

Further analyses of data from the 1996 MEPS tie the health and cost benefits of newer drugs to the date of FDA approvals. If a drug approved by the FDA in 1987 is replaced with one approved in 1997, the direct cost of the newer drug would be about \$18 per prescription higher than the older one. The switch to the newer drug, however, would reduce the use and cost of other medical services,

such as hospital stays, office visits, home health care, and outpatient visits. Reduced utilization of these nondrug medical services would save approximately \$71 per year, which is about 4 times as much as the increase in drug cost. Switching from an old drug to a newer drug reduces the expected number of hospital admissions by 6 per 1000 people. In other words, if there were 1000 people taking the new drug and 1000 people taking the old drug, there would be 6 fewer hospital admissions among the people taking the new drug compared with those taking the older drug ($p < .006$).

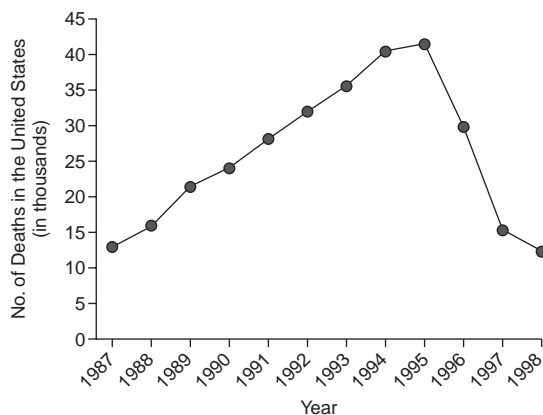
The mean cost of a hospital admission in 1996 was about \$8000. By reducing the expected number of hospital admissions by 6 per 1000, the savings would be about \$48,000 per 1000 people, or \$48 per person per year, on the basis of changing 1 prescription. Further, the savings come from reduced number of hospital admissions as well as savings from reduced length of hospital stay.

MEPS data for 1997 and 1998 confirm the original estimates and suggest that the effect may now be even larger.⁹ The cost of newer drugs continued to average about \$18 more per prescription than older drugs, but other medical costs were reduced by about \$129 per person per year. The nondrug cost savings are substantial, especially for providers that carry a large portion of the total hospital expenses in the United States, such as Medicare.

Increased Longevity

Pharmacologic innovation has played an important role in the long-term increase in life expectancy of Americans. The average person born in 1995 can expect to live 22 years longer than the average person born in 1920.¹⁰ Although the most widely used measure of economic growth is growth in annual per capita gross domestic product (GDP) income, this measure does not reflect increased life expectancy. A better method might be to calculate *expected* lifetime GDP (growth in annual income + the growth in life expectancy).

With mean age of death as an indicator of longevity, people who died in 1979 were about 69.5 years old. Those who died in 1998 were 73.5 years old. Therefore, over a period of 20 years, the mean age of death went up 4 years.¹¹ Recent data from the U.S. Department of Health and Human Services indicate that life expectancy rose in 2001 to a record high of 77.2 years.¹⁰ Data across diseases, however, show that longevity gains have varied quite a bit. The Orphan Drug Act of 1983,¹² for example, caused an explosion of drugs for rare diseases. More than 200 drugs and biological products for rare diseases have been brought to market since 1983 as a direct result of this legislation. In contrast, in the decade prior to 1983, only 10 such products came to market. These new drugs led to increased longevity for people who had those diseases, and in a few diseases, the mean age of death increased by about 18 years between 1979 and 1998. Across all diseases, however, the median increase in longevity was 4 to 6 years.

Figure 1. HIV Mortality Rate^a

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Abbreviation: HIV = human immunodeficiency virus.

Econometric investigations of the effect of technological changes are generally hampered by lack of reliable data. With pharmaceuticals, however, it is possible to identify, date, and classify every major and minor innovation since 1939, when the industry became strictly regulated by the FDA. In addition, beginning in 1980, data were collected regarding the use of approximately 1800 drugs.⁵ Using information provided in the FDA's list of New Drug Approvals since 1939, the 1980 and 1991 National Ambulatory Medical Care Surveys (which surveyed doctor-office visits), and the 1980 and 1991 Vital Statistics Mortality Detail files, I estimated the relationship across diseases between pharmacologic innovation and changes in mortality.⁵

The increase in R&D spending noted earlier reflects the high cost of research directed at the discovery of cures and treatments for diseases like acquired human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), other viruses, and drug-resistant bacteria.³ A good example of the potential impact of newer drugs on longevity is the course of treatment for HIV/AIDS. The development, FDA approval, and use of new HIV drugs played an important role in the dramatic reduction in HIV mortality between 1987, when the Centers for Disease Control first listed HIV as a cause of death, and 1998 (Figure 1).¹³ An abrupt reversal in HIV mortality occurred after 1995, and a two thirds reduction was seen in the number of HIV deaths in the United States in the 3 years that followed. Data from the FDA on exactly when different drugs for HIV were first approved indicate a new disease pathway that led to the introduction of antiretroviral drugs, and within 4 years, 9 new HIV drugs were available.

A distinct relationship exists between the number of HIV drugs approved and the reduction in the number of HIV deaths in the following years.¹³ Using regression analysis, I estimated that the annual number of HIV deaths

is reduced by about 6100 on average by 1 additional HIV drug approval. Consequently, each time a new HIV drug enters the market and expands the portfolio of drugs available, there is a reduction in HIV mortality.

The rate of pharmaceutical innovation varies across diseases. Consider the contrast between diseases or disorders of the thyroid gland and disorders of other endocrine glands (including diabetes). Between 1979 and 1984, there was a 30% increase in the number of drugs available to treat thyroid disorders,¹⁴ but research stalled and no additional drugs for the treatment of thyroid disorders were developed until 1998. In contrast, for disorders of other endocrine glands, there has been a continued increase in drug development over time, and there were 50% more drugs available to treat those disorders than there were in 1979.

Cost of increased longevity. To get a more complete picture of the cost of drug development and to compare the costs of drug development with the longevity benefits, I analyzed data from the Office of Technology Assessment (OTA) and, again, the FDA. During the period 1979 to 1998, the FDA approved about 500 new molecular entities—about 25 new drugs per year. According to a 1993 OTA study,¹⁵ the mean cost of a new molecular entity approval in the 1980s and perhaps early 1990s was about \$360 million (in 2000 dollars, DiMasi et al.¹⁶ estimate the average out-of-pocket cost per new drug to be \$403 million; total approval cost estimate is \$802 million). Using the OTA figure of almost \$360 million for development and estimating the development of about 500 new drugs, the total cost of drug development from 1979 to 1998 was about \$182 billion.

Value of longevity. I estimate that the increase in the stock of priority-review drugs increased the mean age of death by about 5 months. Approximately 2.4 million people die in the United States annually,¹⁰ so the total number of life years gained per year is about 800,000.

Murphy and Topel⁵ estimate that the value of a life year—in the sense of willingness of people to pay to live an additional year—is \$150,000. This value is determined by wage differences between safe and higher-risk jobs. The more dangerous the job, the higher the compensation. On the basis of these data, one can make inferences about how much people are willing to pay to live an extra year. Assuming a life year is valued at \$150,000 and the annual gain in life years is 800,000, the total benefit is \$120 billion.

DiMasi and colleagues¹⁶ estimate that in the last 2 decades, drug development has taken about 14 years per drug. Suppose that the \$182 billion in R&D expense calculated above were evenly distributed over an initial 14-year period (i.e., \$13 billion/year for 14 years), and then in the 15th and all future years, the population would experience a gain in life years with an annual value of \$120 billion. The internal rate of return to that series of

cash flow is 18%, which is very high compared with the historical mean rate of interest on government bonds. Moreover, this rate of return reflects the value of increased longevity in the United States alone.

Improved Ability to Work and Quality of Life

New-drug utilization improves an individual's ability to work. Economic prosperity depends on output per hour of work, hours worked per employed person, and the employment rate. To the extent that medical innovations can increase labor supply and enable people to work who otherwise would be unable to work or increase hours worked because of improved health, medical innovations also increase prosperity or output per person.

The inability to work is not a trivial problem in the United States. Data from the National Health Interview Survey¹⁷ show that nearly 20% of persons aged 65 to 69 years and about 15% in the 55 to 64 age group report that they are unable to work due to illness or disability. I have conducted studies to evaluate the impact of new drugs on ability to work using data at the disease or condition level. These studies correlate the increase in the number of drugs available to treat a given condition between 1983 and 1996 with the change in the percentage of people who are unable to work owing to that condition. I found that an increase in the number of drugs available is associated with a decrease in inability to work. I estimated that the new drugs that were approved between 1983 and 1996 reduced the number of people who were unable to work in 1996 by about 1.4 million. In other words, if there had been no new drugs introduced after 1983, then there would have been 1.4 million more people unable to work in 1996 than actually were unable to work. With the average wage at about \$30,000 a year, the value of the reduction in the number of people unable to work is about \$43 billion a year. Work-loss days per year of currently employed persons are also reduced because some people are able to work more days.

Health status. People who consumed newer drugs were more likely to survive than those who consumed older drugs.¹⁸ Self-reports of health status were also positively associated with the vintage of drugs. People, particularly the elderly, were less likely to experience activity or social limitations if they had consumed newer drugs. Moreover, people who consumed newer drugs tended to experience greater increases (or smaller declines) in physical ability, such as the ability to walk up a flight of stairs or to walk 3 blocks, than people who consumed older drugs.

People in poor initial health tend to benefit the most from pharmaceutical innovation. While many other kinds of technical progress, such as computers and information technology, tend to benefit the most fortunate people the most, new drugs, tend to benefit the least fortunate people who are in poorest initial health the most. Pharmaceutical innovation, then, may reduce inequality as well as promote economic growth.

CONCLUSION

New drugs, in addition to contributing to economic growth, have important health benefits. The average new drug approved by the FDA yields benefits many times greater than the costs of development. Total medical expenditures are reduced, quality of life improves, and patients experience increased longevity because of the effects of new drugs. Formularies, to the extent that they limit access to newer drugs, may have a negative effect on health and economic growth in the United States.

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