The Benefits to Society of New Drugs: A Survey of the Econometric Evidence

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Many economists believe that "new goods are at the heart of economic progress" (Bresnahan and Gordon 1997) and that "innovative goods are better than older products simply because they provide more 'product services' in relation to their cost of production" (Grossman and Helpman 1991). An industry whose propensity to generate new goods is among the highest is the pharmaceutical industry. It is one of the most R&D-intensive industries in the economy. Moreover, due in part to extensive FDA regulation, we have unusually good data about the launch and diffusion of new pharmaceutical goods. I have used these data to perform a number of econometric studies to assess the health and economic impacts of new drug development and use.

I hypothesize that people may obtain several kinds of benefits from using newer, as opposed to older, pharmaceutical products: longer life, improved quality of life, and reduced total medical expenditure. My studies have been designed to estimate the magnitude and value of these benefits and compare them with the cost of using newer drugs.

I have used a number of complementary approaches and data sources to address these issues. One study uses aggregate U.S. data to determine the contribution of new drug approvals to longevity increase. Several others use disease-level data that I constructed to evaluate the effect of pharmaceutical innovation on hospitalization rates and quality of life indicators (activity limitations, disability days). And several other studies have used individual-level data—or even data *below* the individual level.

Virtually all of my research is based on large, publicly available data sets, most of which were produced by federal agencies. These include the Vital Statistics—Mortality Detail files, the National Ambulatory Medical Care Survey, the National Hospital Discharge Survey, the National Health Interview Survey, the Medical Expenditure Panel Survey (MEPS), and unpublished FDA data obtained

via the Freedom of Information Act. The mortality data are based on a complete census of deaths in the United States, and most other data sets are based on large, representative samples of health care providers and households.

My studies are based on data covering all medical conditions (diseases) and all drugs. They therefore provide evidence about the health and economic impacts of new drugs *in general*, not the impacts of specific drugs or on particular diseases. While the methods I use could, in principle, be applied to specific drug classes or diseases, the number of observations about particular drugs and diseases in publicly available data sets is generally too small to obtain statistically reliable results.

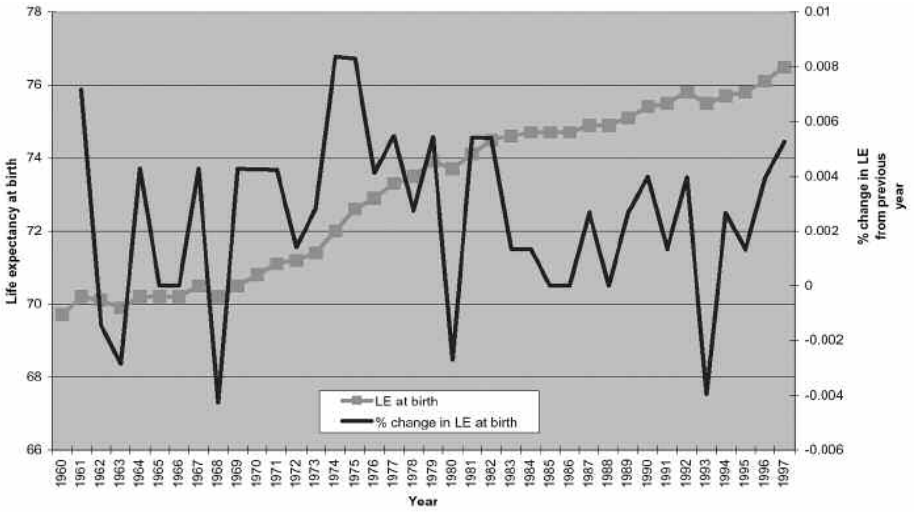
In the first section of this article I will describe some of my research about the impact of new drugs on longevity. In the next section, I will discuss quality-of-life effects, and in the third section, I will review my findings concerning the impact of new drugs on medical expenditure.

LONGEVITY

Between 1960 and 1997, life expectancy at birth increased approximately 10 percent, from 69.7 to 76.5 years. Nordhaus (2003) estimates that the value of life extension during this period nearly equaled the gains in tangible consumption.[1]

While life expectancy has tended to increase since 1960, as Figure 1 indicates, there have been substantial fluctuations in the rate of increase. Life

Figure 1
Life Expectancy at Birth, 1960–97: Trend and Fluctuations

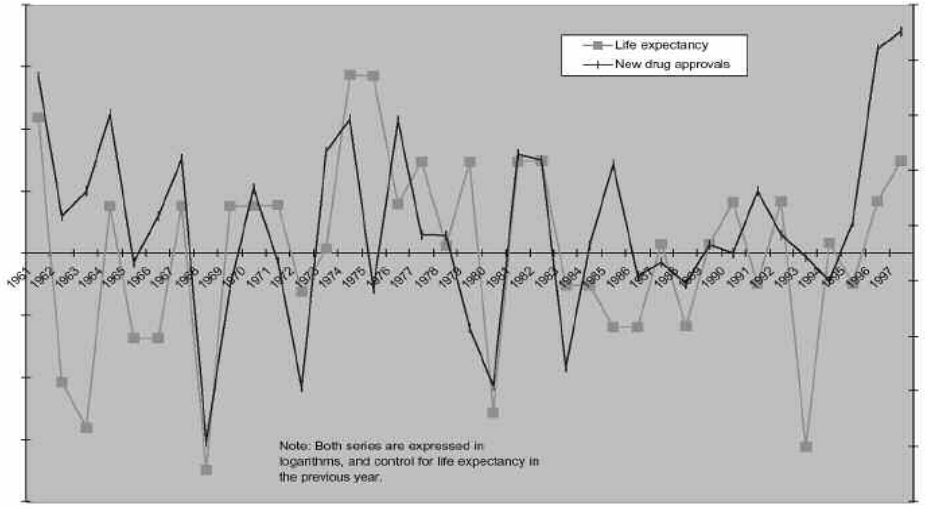


expectancy increased at an average annual rate of 0.25 percent; it increased more than 0.70 percent in 1961, 1974, and 1975, and declined more than 0.25 percent in 1963, 1968, 1980, and 1993. Measurement error is unlikely to account for much of the fluctuation in life expectancy. As noted in Anderson (1999, 34), "The annual life tables are based on a complete count of all reported deaths," and there are about 2 million deaths per year. Growth in real per capita income (GDP) also doesn't account for these fluctuations. The period in which life expectancy increased most rapidly (1973–75) was a period of dismal macroeconomic performance.

There is, however, a highly statistically significant relationship between the number of new molecular entities (NMEs) approved by the FDA and longevity increase: *The periods during which the most new drugs have been approved by the FDA tend to be the periods in which longevity grew most rapidly.*[2] This is consistent with the hypothesis that the greater the number of drugs that are available to physicians and consumers, the higher longevity will be.[3] The number of drugs available in a given year is not simply equal to the sum of the number of drugs approved in all previous years, since the introduction of new drugs may render older drugs obsolete. I estimate that the obsolescence rate of drugs is about 5 percent per year.

Figure 2 displays the relationship between life expectancy and the number of new drug approvals, holding constant life expectancy in the previous year, which, on theoretical grounds, it is appropriate to do. The estimates indicate that the average new drug approval increases the life expectancy of peo-

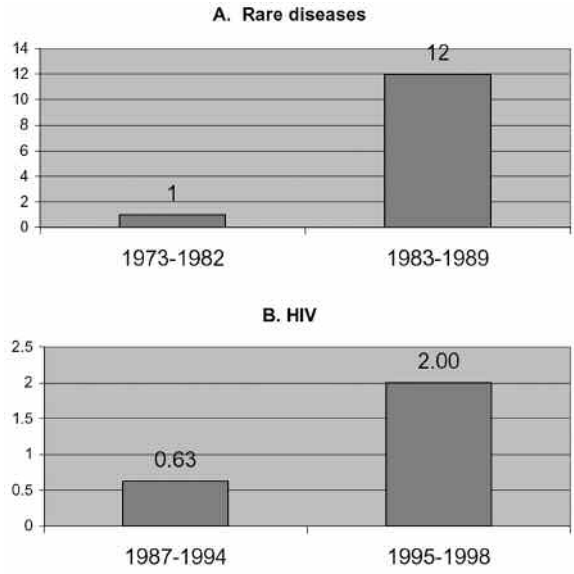
Figure 2
New Drug Approvals and Life Expectancy at Birth, 1961–97



ple born in the year that the drug is approved by 0.016 years (5.8 days). This may sound insignificant, but since there are approximately 4 million births per year in the United States, the average new drug approval increases the total expected life-years of the cohort by 63.7 thousand years (4 million births times .016 years/birth). New drug approvals in a given year also increase the life expectancy of people born in future years, but by a smaller amount (due to obsolescence of drugs).[4] I estimate that the average new drug approval increases the total expected life-years of current and future cohorts by 1.2 million. In other words, *current and future generations will live a total of 1.2 million life-years longer due to the average new drug approval.* The cost to the pharmaceutical industry of bringing a new drug to market is often estimated to be about $500 million. Hence cost per life-year gained is $424 ($500 million/1.2 million life-years). According to Murphy and Topel (2003), this is a small fraction of the economic value of a life-year, which they estimate to be on the order of $150,000.

Increased longevity, while desirable for its own sake, may also have positive implications for medical expenditure. A recent National Academy of Sciences study showed that costs in the final two years of life were lower for people who lived longer. "The older you are when you die, the less expensive the last two years are," said the study's principal author, Kenneth G. Manton, director of the Center for Demographic Studies at Duke University.[5]

Figure 3
Average Annual Number of Drugs Brought to Market



Case Studies of Orphan Diseases and HIV

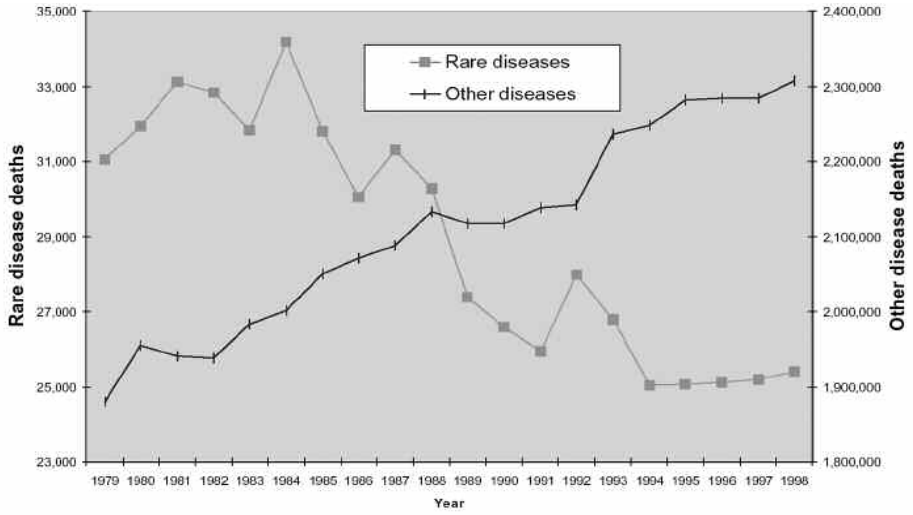
During the last two decades, there have been large, sudden increases in the number of drugs available to treat two kinds of diseases: "orphan" (rare) diseases and human immunodeficiency virus (HIV). As Figure 3 indicates, the average annual number of drugs for rare diseases brought to market during 1983–99 was twelve times as great as it was during 1973–82,[6] and the average annual number of HIV drugs brought to market during 1994–98 was three times as great as it was during 1987–93.

These increases occurred for different reasons and under different circumstances. The increase in drugs for rare diseases occurred because Congress passed the Orphan Drug Act in January 1983. The increase in drugs for HIV occurred because AIDS was first reported in 1981, was identified as being caused by HIV in 1984,[7] and (in the 1990s) the average length of time required to develop a drug was about 15 years.[8]

Both increases provide a good opportunity to investigate the effect of pharmaceutical innovation on mortality. In Lichtenberg (2001a, 2003a), I investigated the effect of increases in the number of drugs available to treat these diseases on mortality associated with them.

Before the Orphan Drug Act went into effect (between 1979 and 1984), mortality from rare diseases grew at the same rate as mortality from other diseases (*Figure 4*). In contrast, during the next five years, mortality from rare dis-

Figure 4
Number of Deaths from Rare Diseases and Other Diseases, 1979–98



eases grew more slowly than mortality from other diseases. I estimated that one additional orphan drug approval in year t prevents 211 deaths in year $t + 1$ and ultimately prevents 499 deaths, and that about 108,000 deaths from rare diseases will ultimately be prevented by all of the 216 orphan drugs that have been approved since 1983.

Consistent with previous patient-level studies of HIV, I find that new drugs played a key role in the post-1995 decline in HIV mortality (*Figure 5*). I estimate that one additional HIV drug approval in year t prevents about 6,000 HIV deaths in year $t + 1$ and ultimately prevents about 34,000 HIV deaths. HIV drug approvals have reduced mortality both directly and indirectly (via increased drug consumption). HIV mortality depends on both the quality and the quantity of medications consumed, and new drug approvals have a sizeable impact on drug consumption: One additional HIV drug approval in year t results in 1.2 million additional HIV drug units consumed in year $t + 1$ and ultimately results in 3.6 million additional HIV drug units consumed.

As summarized in Figure 6, mortality from both diseases declined dramatically following increases in drug approvals.

Effect of Increased Drug Use Associated with Medicare Eligibility

Most people become eligible for Medicare suddenly, the day they turn sixty-five. Although Medicare does not pay for most outpatient drugs, Medicare

Figure 5
HIV Drug Approvals and HIV Mortality Reduction

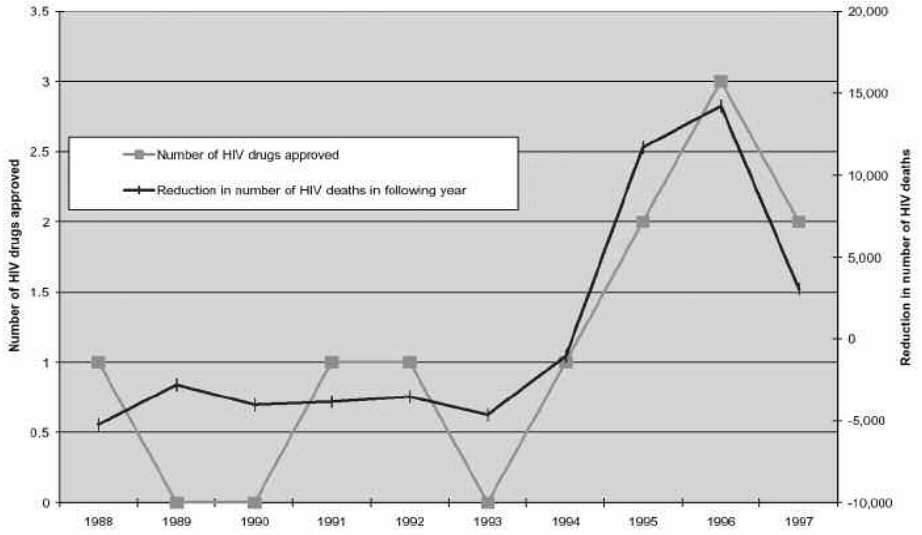
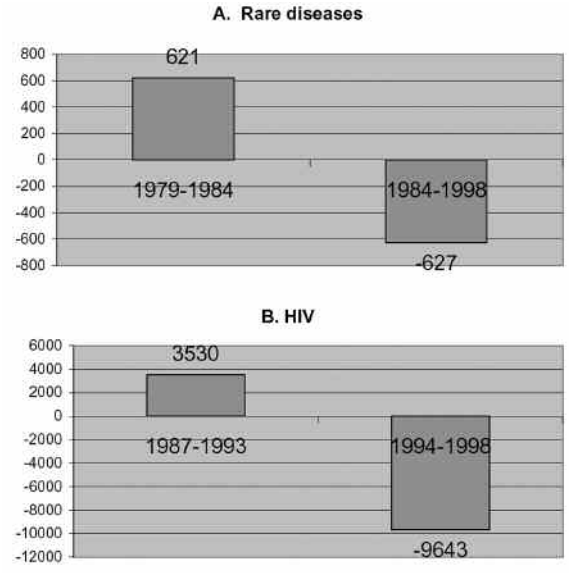


Figure 6
Average Annual Change in Number of Deaths



subsidizes a service that people must use in order to obtain prescription drugs: physician care. In Lichtenberg (2002), I show that utilization of ambulatory care increases suddenly and significantly at age sixty-five, presumably due to Medicare eligibility. The evidence points to a structural change in the frequency of physician visits precisely at age sixty-five.[9] Attainment of age sixty-five marks not only an upward shift but also the beginning of a rapid upward trend (up until age seventy-five) of about 2.8 percent per year in annual physician visits per capita.

The number of physician visits in which at least one drug is prescribed also jumps up at age sixty-five (*Figure 7*). Data from the 1996 Medical Expenditure Panel Survey indicate that people between the ages of sixty-six and seventy-five consume about 66 percent more medicines per person than people between the ages of fifty-six and sixty-five (*Figure 8*).

I examined whether this increase in utilization leads to an improvement in outcomes—a reduction in mortality—relative to what one would expect given the trends in outcomes prior to age sixty-five. The estimates were consistent with the hypothesis that the Medicare-induced increase in health care utilization leads to slower growth in the probability of death after age sixty-five (*Figure 9*). Physician visits (which are highly correlated with prescription drug utilization—physicians prescribe drugs in over 60 percent of office visits) are estimated to

Figure 7
Number of Physician Visits in Which at Least One Drug Was Prescribed, 1985 and 1989–98

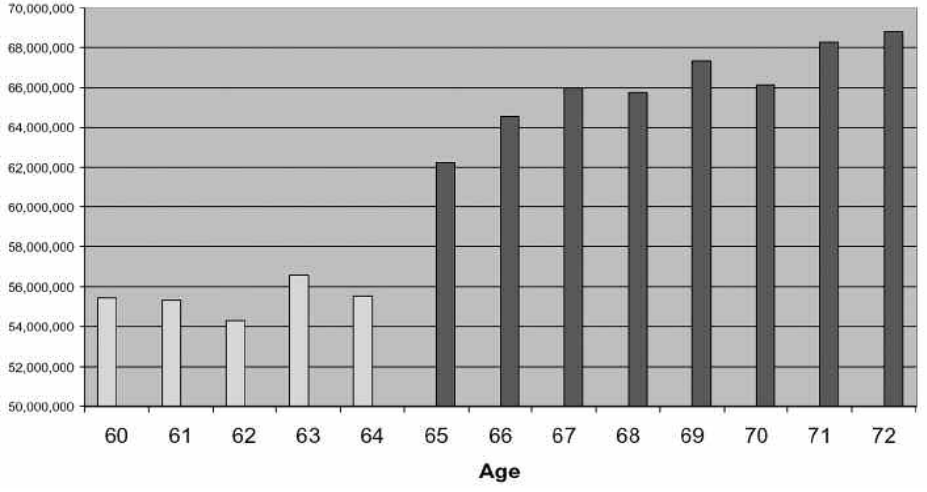


Figure 8
Median Number of Prescriptions, by Age, 1996

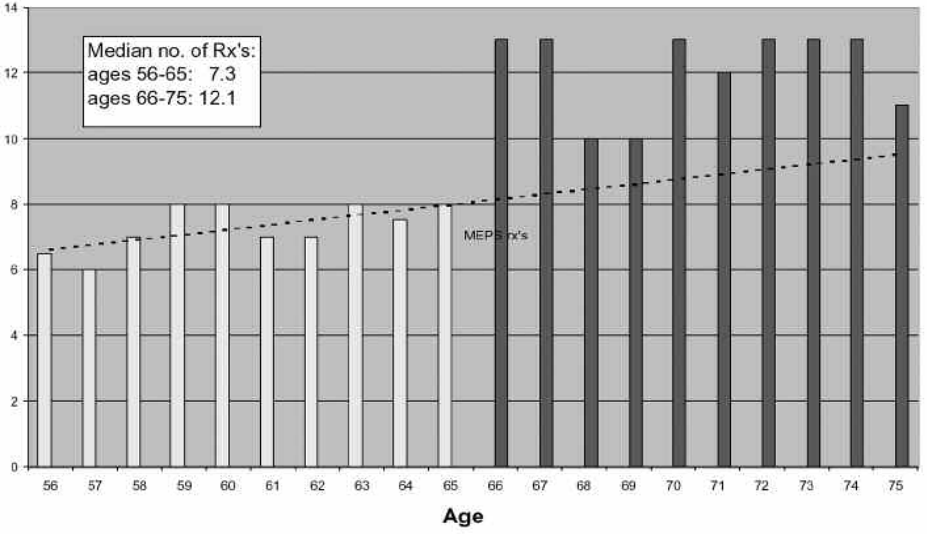
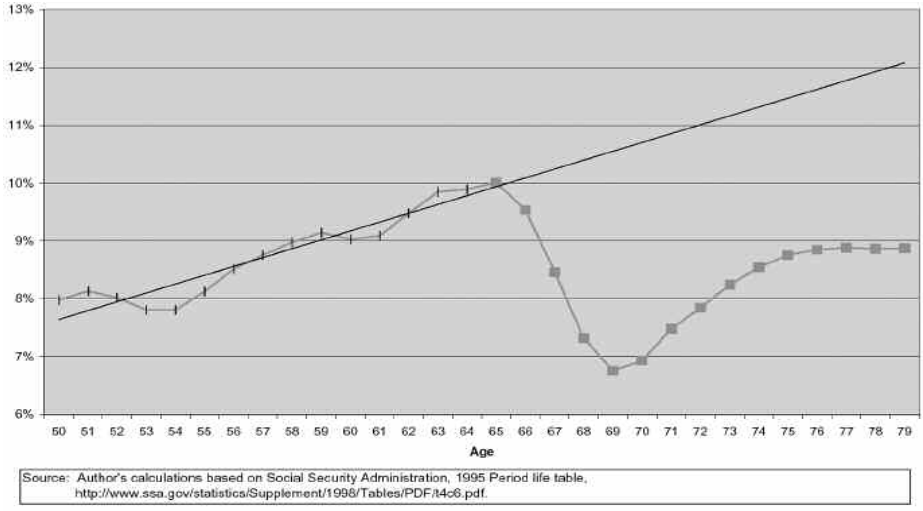


Figure 9
Percentage Increase from Previous Year in Probability of Death: Men



Source: Author's calculations based on Social Security Administration, 1995 Period life table, http://www.ssa.gov/statistics/Supplement/1998/Tables/PDF/t4c6.pdf.

have a negative effect on the male death rate, conditional on age and the death rate in the previous year: A permanent or sustained 10 percent increase in the number of visits ultimately leads to a 5 percent reduction in the death rate.

Data on age-specific death probabilities every ten years back to 1900—i.e., before as well as after Medicare—were enacted to provide an alternative way to test for the effect of Medicare on longevity and provide strong support for the hypothesis that Medicare increased the survival rate of the elderly, by about 13 percent.

QUALITY OF LIFE

In this section I present some new evidence about the impact of new drugs on quality of life ("health"), as measured by ability to work, activity limitations, and disability days. The analysis was performed using a combination of individual-level and medical-condition-level data. Most of the analysis is based on samples of over 300,000 observations spanning more than a decade (1985–96). I examined the following health indicators:

- Whether a person is *limited* in work, and a given condition is the main or secondary cause of the limitation
- Whether a person is *unable* to work, and a given condition is the main or secondary cause of the limitation

- Whether the person has *activity limitation*, and a given condition is the main cause of the limitation
- The total number of *restricted activity days* in the last two weeks for a given condition
- The number of *work-loss days* in the last two weeks for a given condition (for currently employed workers ages eighteen to sixty-nine)

I investigated the effect of drug *vintage*—defined as the year in which the FDA first approved a drug—on health. In particular, I tested the hypothesis that a person's health is an increasing function of the (mean) vintage of the drugs he consumes, *ceteris paribus*. If the hypothesis stated above is true, then the average health of a group of people is an increasing function of the average vintage of the drugs they consume, and the *change* in average health is an increasing function of the *change* in average drug vintage.

The estimates indicate that changes in mean drug vintage have highly statistically and economically significant effects on activity limitations and disability days. The magnitudes of these effects can be illustrated by calculating the costs and health benefits that a ten-year increase in mean drug vintage would have. Suppose that the average FDA approval year of the drugs consumed by a person in 1996 increased from 1970 to 1980. Newer drugs generally cost more than older drugs, and this switch to newer drugs would increase the person's drug expenditure by 27 percent, or $71, on average. However, the estimates imply that the switch to newer drugs would yield a number of benefits, whose value would exceed the increase in drug cost:

For employed people:

- The mean number of work-loss days per person per year would decline by 21.3 percent, or 1.02 days. Average daily employee compensation is about $140, so the value of this reduction is about $143.

For all people:

- The mean number of restricted-activity days per person per year would decline by 12.0 percent, or 1.74 days.[10]
- The probability of having an activity limitation would decline by 9 percent.
- The probability of being completely unable to work would decline by 10.8 percent. Average annual employee compensation is about $40,000, so the value of this reduction could be as high as $300.

I am currently engaged in another study of the impact of drug vintage on quality of life. This study, which is restricted to the Medicare population, is based on the Medicare Current Beneficiary Survey for the years 1992–96, conducted by the Health Care Financing Administration. That survey contains a number of questions concerning the ability of respondents to engage in various

activities of daily living (ADLs), such as walking two to three blocks, lifting ten pounds, stooping/kneeling, reaching over head, and writing. I have examined the relationship between the vintage of the drugs consumed by an individual and his or her ADL limitations, controlling for the person's age, sex, race, education, income, insurance status, total medical expenditure,[11] medical history, the therapeutic class of the drug, and other attributes. Preliminary findings indicate that *Medicare beneficiaries consuming newer drugs have significantly fewer ADL limitations than people consuming older drugs.*

TOTAL MEDICAL EXPENDITURE

Case studies of a number of specific drugs have shown that these drugs reduced the demand for hospital care. For example, according to the Boston Consulting Group (1993), operations for peptic ulcers decreased from 97,000 in 1977, when H2 antagonists were introduced, to 19,000 in 1987; this is estimated to have saved $224 million in annual medical costs. The Scandinavian Simvastatin Survival Study indicated that "giving the drug simvastatin to heart patients reduced their hospital admissions by a third during five years of treatment. It also reduced the number of days that they had to spend in the hospital when they were admitted, and reduced the need for bypass surgery and angioplasty." But treatment with the $2/day pill that lowered cholesterol did not actually save money: Hospital costs were $8 million lower among the 2,221 volunteers who got the drug, but the medicine itself cost $11 million (*The New York Times* 1995a). On the other hand, the clot-dissolving drug TPA "costs $2,000 to administer to each stroke victim, but has the potential to save much more in long-term care for those who are helped" (*The New York Times* 1995b).

Other case studies have indicated that government-imposed rationing of pharmaceuticals led to increased use of hospital care. Soumerai et al. (1991) analyzed the effect of limits imposed by the New Hampshire Medicaid program on the number of reimbursable medications that a patient can receive on rates of admission to nursing homes and hospitals. Imposition of the reimbursement cap resulted in an approximate doubling of the rate of nursing home admissions among chronically ill elderly patients.

While these studies are valuable, the extent to which their findings apply to pharmaceutical use in general is unclear. Moreover, these studies have yielded mixed results about (or have not addressed) the issue of whether the reduction in hospital cost was outweighed by the increase in pharmaceutical cost. I have performed several studies to assess the impact of pharmaceutical use in general on the demand for inpatient hospital care and overall medical expenditure.

My first study on this issue was based on disease-level data: I constructed a database containing information about utilization of pharmaceuticals, ambulatory care and hospital care, by disease, at two points in time (1980 and 1991 or

1992). I controlled for the presence of "fixed (diagnosis) effects" by analyzing relationships among growth rates of the variables. The main findings of this study were as follows:

- The number of hospital bed-days declined most rapidly for those diagnoses with the greatest increase in the total number of drugs prescribed and the greatest change in the distribution of drugs.
- An increase of 100 prescriptions is associated with 16.3 fewer hospital days.
- A $1 increase in pharmaceutical expenditure is associated with a $3.65 reduction in hospital care expenditure (ignoring any indirect cost of hospitalization), but it may also be associated with a $1.54 increase in expenditure on ambulatory care.
- Diagnoses subject to higher rates of surgical innovation exhibited larger increases (or smaller declines) in hospitalization.

My second study on this issue was based on individual-level data, most of which were obtained from the 1996 Medical Expenditure Panel Survey, a nationally representative survey of health care use and expenditures for the U.S. civilian noninstitutionalized population. This survey collected extremely detailed data from 23,230 people on use and expenditures for office and hospital-based care, home health care, and prescribed medicines. MEPS contains data at three different levels of aggregation: the person level, the condition level (77,000 conditions), and the event level. A person may have several conditions (e.g., hypertension, diabetes, and glaucoma); a given condition may be associated with a number of events.

The unit of observation in my analysis was a prescribed-medicine event. I had data on over 171,000 prescriptions. Over 90 percent of the prescriptions are linked to exactly one medical condition, and the 1996 Medical Conditions file contains summary information about these medical conditions, including the number of hospital events, emergency room events, outpatient events, office-based events, dental events, and home health events associated with the condition. Expenditure (and charges) associated with each condition, by event type, can be computed from the records contained in the respective medical event files. For example, one can compute total hospital expenditure associated with individual x's hypertension. In addition to calculating expenditure, by event type, we calculated total nondrug expenditure—i.e., the sum of expenditures on the six event types listed above. The MEPS data enable us to control for many important attributes, including sex, age, education, race, income, insurance status (whether the person is covered by private insurance, Medicare, or Medicaid), who paid for the drug, the condition for which the drug was prescribed, how long the person has had the condition, and the number of medical conditions reported by the person.

By controlling for condition, we are in effect comparing individuals only with other individuals with the same condition. We do not control for drug class, however, since we do not want to rule out comparisons between people consuming drugs in one class (e.g., SSRI antidepressants) and people consuming drugs in another class (e.g., tricyclic antidepressants) for the same condition.

My objective was to determine the effect of drug age—the number of years since the FDA first approved the drug's active ingredient(s)—on outcomes and expenditure, controlling, in a very nonrestrictive fashion, all of these factors cited above. But in addition to those observed individual differences, there may be other, unmeasured determinants, such as the physician's "practice style": Physicians prescribing older drugs might be less well trained, less likely to keep up with advances in medicine, and more likely to practice in substandard facilities. Fortunately, the fact that many individuals in the sample have both multiple medical conditions and multiple prescriptions means that we can control for *all* individual characteristics—both observed and unobserved—by pursuing a second approach. This involved estimating a model that includes "individual effects."

Table 1 shows the number of 1996 MEPS events, by type, and their associated average expenditures. Figure 10 depicts the frequency distribution of MEPS prescriptions, by the date the active ingredient was first approved by the FDA. About one-quarter of prescriptions consumed in 1996 were for drugs approved before 1950; more than half of the drugs consumed were approved before 1980.

First I analyzed the relationship between the age of the drug and the amount paid for the prescription. Not surprisingly, I found that new drugs are, on average, more expensive than old drugs prescribed for the same condition. For example, if a fifteen-year-old drug were replaced by a 5.5-year-old drug, the cost of the prescription would increase by about $18.

Then I examined the relationship between the age of the drug and the number and cost of nondrug medical events associated with the condition. Hospital

Table 1
Frequency of and Expenditure on MEPS Events

Event type	No. of events	Avge. Expenditure	Total expenditure	% of total expenditure
Inpatient visit events	2,207	$7,587.60	$16,745,833	41.5%
Office-based visit events	100,320	$81.45	$8,170,815	20.2%
Prescribed medicine events	171,587	$32.77	$5,623,511	13.9%
Outpatient visit events	9,957	$412.55	$4,107,802	10.2%
Dental visit events	22,165	$142.92	$3,167,747	7.8%
Emergency room visit events	3,899	$345.34	$1,346,490	3.3%
Other medical expenditure events	6,402	$189.70	$1,214,484	3.0%
All	316,537		$40,376,682	100.0%

stays are the most important of these, since they account for almost 42 percent of total medical expenditure. The estimates revealed that *people consuming newer drugs had significantly fewer hospital stays than people consuming older drugs*. Replacing an older prescription with a newer drug as in the previous examples would reduce the expected number of hospital stays by 0.0059—i.e., about six fewer stays per thousand prescriptions. Since the average expenditure on a hospital stay in MEPS is $7,588, one might expect a reduction in hospital expenditure of $44 (0.0059 × $7,588), compared with an increase in drug cost of $18. However, the reduction in hospital expenditure from the use of newer drugs is even larger than this—$56—because newer drugs are associated with shorter, as well as fewer, hospital stays.

The estimates indicate that reductions in drug age tend to reduce *all* types of nondrug medical expenditure, although the reduction in inpatient expenditure is by far the largest. This reduction of $71.09 in nondrug expenditure is much greater than the increase in prescription cost ($18), so *reducing the age of the drug results in a substantial net reduction in the total cost of treating the condition*.

I estimated the nondrug medical expenditure model separately, for those under and over sixty-five years of age. Nondrug medical expenditure is positively related to drug age for both groups, and drug age appears to have similar effects, in percentage terms, on nondrug expenditures of the elderly and the nonelderly.

It is sometimes suggested that because generic drugs tend to be less expensive than branded drugs, allowing people to use only generic drugs might

Figure 10
Frequency Distribution of MEPS Prescriptions, by Date Active Ingredient Was Approved by the FDA

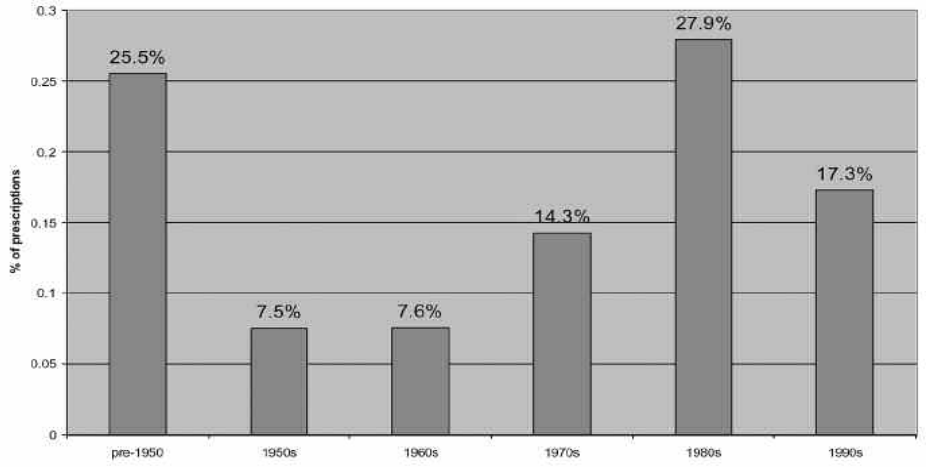
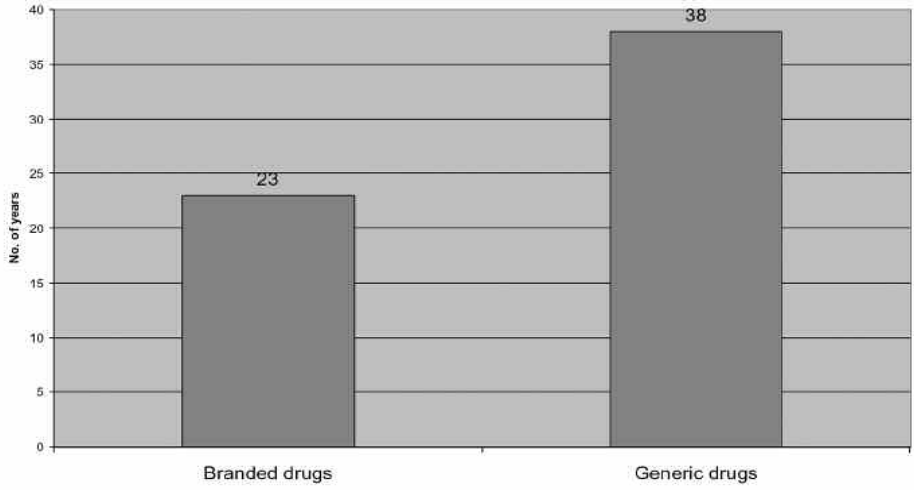


Figure 11
Mean Age (in Years) of Drugs Consumed in 1996



be an effective means of reducing health expenditure. As Figure 11 shows, generic drugs tend to be much older than branded drugs. Suppose that instead of consuming the actual mix of 60 percent branded and 40 percent generic drugs, people had to consume only generic drugs. This would increase the mean age of drugs consumed by 31 percent, from twenty-nine years to thirty-eight years. My estimates indicate that *denying people access to branded drugs would increase total treatment costs, not reduce them, and would lead to worse outcomes.*

Drug costs (and changes in drug costs) are visible to the naked eye; identification of drug benefits requires careful analysis of good data. People making drug policy decisions need to consider the full range of effects, not just the costs, of newer drugs.

NOTES

[1] Nordhaus (2003), along with Murphy and Topel (2003), offers parallel estimates of the value of recent increases in longevity. To the casual observer, it hardly seems possible—and may seem morally offensive—to put a dollar value on human life. But modern economics has devised a credible way around these imponderables, inferring the value people put on life from what they must be "bribed" in everyday settings to incur small but predictable increases in the risk of death. Let's say that moving from a factory line to outdoor construction increases a worker's chance of a fatal accident by one in 10,000 each year. In other words, if 10,000 workers made

the shift, expected on-the-job fatalities would rise by one per year. Suppose further that to induce 10,000 workers to play this death lottery voluntarily, an employer would have to pay an extra $500 annually to each worker, for a total of $5 million. One of these new construction workers is likely to die in return for the group gaining $5 million. Thus the value of one life in this example is said to be $5 million.

Estimates from the dozen or so work-related studies since the mid-1970s put the value of a statistical life in the relatively narrow $3 million to $7 million range. Using the relatively conservative estimate of $3 million for the average value of avoiding one death to calculate the value of extending life, Nordhaus estimates that in the 1975–95 period, the value of life extension nearly equaled the gains in tangible consumption.

[2] The rate of introduction of new drugs fluctuates considerably from year to year. Part of this is due to the inherent randomness of the drug development and approval process. But major changes in government policy have also clearly influenced the number of new drugs approved.

[3] Analysis of individual-level data (Lichtenberg 2001b) also indicates that people consuming new drugs are significantly less likely to die within a given period than people consuming older drugs.

[4] It takes about 18.5 years for half of the longevity effect of a new drug approval to occur.

[5] "Decrease in Chronic Illness Bodes Well for Medicare Costs," *New York Times*, May 8, 2001.

[6] "More than 200 drugs and biological products for rare diseases have been brought to market since 1983. In contrast, the decade prior to 1983 saw fewer than ten such products come to market." (Source: www.fda.gov/orphan/History.htm.)

[7] www.fda.gov/oashi/aids/miles81.html.

[8] DiMasi, J. A., "New Drug Development: Cost, Risk, and Complexity," *Drug Information Journal*, May 1995, cited in *PhRMA Industry Profile 2000*, Chapter 2, www.phrma.org/publications/publications/profile00/index.phtml.

[9] Reaching age sixty-five has a strong positive impact on the consumption of hospital services, but most of this impact appears to be the result of postponement of hospitalization in the prior two years.

[10] My study of the impact of Medicare, described in the previous section, indicated that average bed-days are lower after age sixty-five than one would expect from the pre-sixty-five trend. Increased use of drugs after age sixty-five may contribute to this.

[11] Total medical expenditure can serve as an indicator of the person's (pretreatment) medical condition or severity.

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