



"American Science, American Lives"
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Medical research spending from all public and private sources in America totals about 60 cents a day per person--less than the price of this newspaper. Yet we know that the returns on investments in research are prodigious. An eye-opening study, "Exceptional Returns," by Funding First, an initiative of the Lasker Trust, concludes that "medical research surpasses every other source of rising living standards in our time." Congress implicitly recognized this when it approved large budget increases for federally sponsored research over the past several years. But overcoming disease requires more than extra dollars. After 30 years of involvement in supporting research, I'm convinced we can improve the process of medical discovery and treatment.

We've achieved great successes in fighting disease. Life expectancy in the U.S. increased 54% during the 20th century, from 50 to 77 years. One of every five babies born in 1900 did not live to celebrate a fifth birthday. But public health initiatives improved sanitation and reduced infant mortality, creating large gains in average life span during the century's first decades. Around mid-century, penicillin and the Salk vaccine played a role. In the last third of the century, lifespans increased because of better treatment and prevention of cardiovascular disease. While medical research had little to do with early public health improvements, research grew in importance over time and explains why fewer Americans die from heart attacks today.

Our success in treating heart disease and strokes is even more dramatic when the data on the nearby chart are adjusted for our aging population. Advances in molecular biology, genetics, immunology and neuroscience could produce similar gains against a range of diseases, which will come faster if we take the right steps now.

It isn't for lack of effort that mortality from other serious diseases hasn't matched the decline in cardiovascular deaths. Dedicated researchers seek better treatments and cures for diabetes, kidney disease, Alzheimer's and every form of cancer. But these scientists face an array of disincentives. We can do better.

The Food and Drug Administration, which has an essential regulatory mandate, has started to show very encouraging signs of a determination to improve the drug-approval process. An indication of how far it has to go can be seen in the comments of Gordon Binder, the former CEO of Amgen, the world's largest biotechnology company. "I thought we were doing God's work," he laments. "But it took a 100,000-

page application to get Epogen [an anemia drug] approved. Ten years later, the successor drug took 500,000 pages."

Excessive regulation is one reason that health care represents one of every seven dollars in the GDP. Businesses and individuals spent \$330 billion last year on treatments for heart disease and stroke. A person with diabetes incurs four times more than the average person in medical bills. Then there's cancer. Funding First reports that people who die from cancer would have lived an average of 15 years longer if they hadn't had the disease. For those of us who have lost loved ones in their prime--as I did when my father and other relatives succumbed--even one of those years would have been a precious gift.

It sounds cold-hearted to speak of "monetizing" a year of life. Yet economists have done just that, creating models to determine economic value at various ages. Their studies produce a surprisingly narrow range of estimates. University of Chicago economists Kevin Murphy and Robert Topel, whose work was supported in part by the Milken Institute, calculate that stopping cancer deaths would be worth more than \$800 billion every year. That's 200 times the federal investment in cancer research.

Obviously, we're not likely to eliminate every cancer and other disease in any foreseeable future. In many cases, simply transforming a terminal illness into a chronic condition would be a major advance. Even if we could reduce deaths from one disease, like ovarian cancer, the return on investment would be priceless. We can accelerate that progress by stepping back and analyzing the system of research and treatment from beginning to end. This will help determine the best tax policies to stimulate research, the most effective incentives to encourage participation in clinical trials of new treatments, the optimum length for patents, what regulatory shortcuts make sense, how best to modernize medical education and other steps that can lead to faster cures.

Among proponents of the systems approach in biomedicine is Leroy Hood. A pioneer in the mapping of the human genome, Dr. Hood is president of the Institute for Systems Biology. He says the complexity of the problems faced by medical researchers demands integrative approaches that are alien to much of the scientific establishment. He notes that "we know a lot about immunological responses--we've been studying them for 30 years." But we know a lot less than we should because we've been "studying them one protein at a time," losing insights that come with viewing the system as a whole.

Technology that didn't exist five years ago allows us to look at thousands of genes simultaneously. By understanding the differences among these genes, doctors may be able to treat patients effectively years before symptoms appear. According to Alan Robinson, vice provost for medical education at UCLA, "There's a major revolution coming in predictive medicine that's as important as the discovery of the germ theory." The cost of sequencing a single gene has dropped from millions of dollars a quarter-century ago to \$150 in 1998 and less than \$9 today. Dr. Hood believes that in 10 years we may be able to sequence an individual's entire genome--more than 20,000 genes--in 20 minutes for less than \$1,000.

Recently, I invited several physicians and scientists to propose ideas to help accelerate progress against a range of diseases. Among many possible initiatives, they suggested:

Train more "translational" researchers--physician/scientists who are as comfortable treating patients as they are in the laboratory. They have essential hands-on knowledge that spans the gap between basic research and clinical applications.

Give patients more information about the availability of clinical trials, make it easier to enroll, and provide incentives that encourage participation.

Establish a national database in which patients could make anonymous data about their cases available. As a cancer survivor, I've talked to many patients and the vast majority said they'd release their data if it could shorten the path to cures and better treatments.

Expand tissue banks where researchers compare healthy and diseased tissue and study the differences, a once-laborious process made relatively easy by new technologies. Sometimes, an old technology like television helps this process along. In 1995, when Dr. Hood joined Gen. Norman Schwarzkopf and me on national TV to discuss the need for families to provide data and tissue for a new prostate cancer gene study, more qualified families signed up in a week than academic institutions had been able to recruit in several years.

Extend patents for pioneering drugs--"new chemical entities"--longer than to marginally improved versions. When it takes as long as 14 years for approval to put a new drug on the market, there isn't much time left to recover R&D costs before the patent expires.

Re-examine the FDA's efficacy standard. Today, manufacturers must prove that new drugs are not only safe, but also that they work in most patients. That's a good standard when a drug is one of many treatment options, as it could be, say, in the case of high blood pressure. A different standard might be appropriate, however, for patients with untreatable terminal illnesses and no other options. Advances in genomics are expected to produce drugs that work for some patients but not others, or that are effective for some who are not at risk for side effects, even if other patients can't tolerate them.

These and other ideas led a prominent group of experts to join me in establishing the Center for Accelerating Medical Solutions, a nonprofit, publicly supported think tank. The Center will commission studies of the entire research and treatment process, publish concrete recommendations and provide leadership for their implementation. Our mission is urgent. More than a million Americans suffer heart attacks every year. Strokes hit 600,000. Cancer kills 550,000. Our children face a greater risk of dying from cancer than their grandparents faced. Even a single year's acceleration in medical solutions would make a big difference. For example, finding a breast-cancer cure just one year earlier could prevent hundreds of thousands of deaths worldwide among women whose disease is still at a curable stage, and save millions more from painful, disfiguring treatments.

The choice is ours: We can sit back and wait for more cures and better treatments, or we can marshal our resources to solve medical problems sooner and save more lives. Maybe yours.

Mr. Milken, chairman of the Milken Institute and the Center for Accelerating Medical Solutions, co-founded the Milken Family Foundation in 1982 and established the CaP CURE Prostate Cancer Foundation in 1993.