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Another day, another breakthrough.

A COLLECTION OF  
COMMENTARIES

by prominent Mount Sinai physicians and scientists  
appearing in *The New York Times*



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*Kenneth L. Davis, MD and Dennis S. Charney, MD*

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## FOREWORD

We are pleased to share with you this collection of commentaries that have appeared in *The New York Times*.

Launched in April 2009 and appearing on the lower right-hand corner of the op-ed page, these pieces demonstrate Mount Sinai's thought leadership on a range of timely topics in science, clinical care, medical education, and health care reform.

Each month, we consider current debates in the national health care arena and either add our position and insights to an ongoing discussion, or develop a topic that no one is talking about—but that we all should be. All commentaries are grounded in Mount Sinai's strengths, and in each author's expertise and prominence in his or her field nationally.

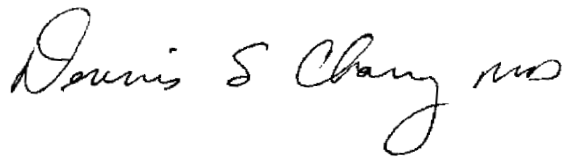
In 2011, we look forward to exploring new topics and expanding aspects of those we have previously covered in order to present readers of *The New York Times* with the full scope of our research, insight, and leadership.

We welcome any feedback and suggestions.



*Kenneth L. Davis, MD*

PRESIDENT AND CEO  
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DEAN, MOUNT SINAI SCHOOL OF MEDICINE  
EXECUTIVE VICE PRESIDENT FOR ACADEMIC AFFAIRS  
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# Promises Unfulfilled

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Kenneth Davis, M.D.

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NEW YORK—Advances in biomedical research have the potential to lead to unimaginable medical treatments. Our grandchildren should never experience many of the diseases that affected our grandparents. Yet in 2007 the FDA approved the fewest new drugs in nearly a quarter century. Last year was hardly better.

The problem lies in public policy and how it stifles innovation and risk taking. Academic medical centers around the country are patenting many potentially interesting drug targets and treatments, but these possibilities may never become reality due to a host of factors.

There is an enormous cost in discovering, testing, and gaining approval of novel drugs, and it is rapidly increasing. The drugs we would like to design, drugs that prevent disease, require many more years of testing, at far greater expense, than drugs of the past. Years of drug discovery and drug trials can leave inadequate remaining patent life and therefore provide no return on investment. Consequently, some great ideas that originate in our leading academic laboratories never find an industry partner to facilitate drug development.

To move from drugs that treat acute problems to drugs that prevent disease, we need changes in public policy that encourage innovation and provide adequate incentive. Current patent law discourages risk and innovation.

Simply put, we cannot treat all drugs as alike. The public good is not served by providing the

same period of marketing exclusivity to a drug that prevents the consequences of adult-onset diabetes and copycat drugs that treat seasonal allergies or erectile dysfunction. Generic substitution for drugs that offer little benefit over current treatments is to be encouraged, but a short period of market exclusivity for breakthrough medications is not in the public interest.

Congress must add flexibility to patent policy to take into account changing science as well as the public good. Breakthrough drugs with novel mechanisms aimed at diseases like diabetes and cancer that are especially burdensome to the health care system should receive longer protection. There should be disincentives for drugs that offer no benefit over existing pills.

The current growth in health care spending is not sustainable. However, often left out of the debate is the impact that truly

revolutionary therapeutics would have on the cost of health care. Imagine the cost of health care had there been no polio vaccine. Conversely, imagine the cost of health care if we could prevent diabetes.

We have the potential to leave our grandchildren with a great legacy of freedom from many of our most feared diseases and to harness the revolution in biomedical research. To do so will require wise, and even courageous, public leadership.

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*Kenneth L. Davis, M.D., is President and CEO of The Mount Sinai Medical Center in New York City. His wife, Bonnie Davis, M.D., is the inventor of galantamine for the treatment of Alzheimer's disease.*



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# BIOMEDICAL RESEARCH

## A Cure for Nation's Ills

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Dennis S. Charney, M.D.

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The United States will spend an estimated \$2.5 trillion on health care this year, yet millions of Americans still battle serious diseases that only more biomedical research can prevent or cure.

There is unequivocal evidence that investing in research can lead to dramatic improvements in our nation's health.

A recent analysis by the medical researcher and demographer Kenneth G. Manton, Ph.D., and colleagues found that increases in biomedical research funding by the National Institutes of Health (NIH) correlated with reduced mortality rates for four major chronic diseases: cardiovascular disease, stroke, cancer, and diabetes.

We have the potential to do much more. With the sequencing of the human genome and dramatic advances in technology, we are at the threshold of identifying the genetic susceptibilities or predispositions for many common diseases. It is within our reach to create drugs that could predict, diagnose, and treat some of the world's deadliest and most debilitating diseases. We need to effectively treat congestive heart failure. Stop the progression of diabetes. Predict and prevent Alzheimer's disease. Minimize cancer risk and maximize cancer cures.

Yet, over the past 30 years, the U.S. has allocated only \$44 per citizen per year—about 12 cents per day—for biomedical research. And since 2004, NIH funding, excluding stimulus grants, has been stagnant while inflation and costs have continued to climb. The result is a 13 percent decline in real purchasing power since 2003. Meanwhile, other nations have stepped up funding and assumed a larger portion of the world's research investment.

Biomedical research is an economic driver that can reduce

health care costs. Investment in basic biomedical research is necessary to spur medical and scientific innovation. The American biotech industry, one of the most important components of the nation's economy, depends on research funding and requires innovation to remain competitive. Not only is the biotech industry critically important for its own sake, but it is also tightly linked to many other growing fields. It creates good jobs in biotechnology, pharmaceutical, and scientific instrument industries and those, in turn, generate more jobs in other sectors.

Economic analysis also reveals that biomedical research saves money and reduces health care costs. It is estimated that improvements in health from 1970 to 2000 were worth \$95 trillion, while the U.S. invested \$200 billion in the NIH. If 10 percent of that overall health savings, or \$9.5 trillion, resulted from NIH-supported research, our investment in medical research then provided a 50-fold return to the economy.

We have already seen such economic benefits from the improved health of our elderly population. NIH-supported research has resulted in positive health effects on chronic disease that have helped preserve the U.S. elderly workforce. This is associated with increased tax revenues and reduced Medicare costs.

The U.S. emerged from World War II as the world's economic superpower, leading to its international preeminence in scientific research. However, history suggests that as a nation's economy declines, so does its support for scientific research.

This is the time to reassert our global leadership in biomedical research. This is the time to make robust and sustained investments in research by dramatically increasing funding of the National Institutes of Health.

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# No Stem Cell Left Behind

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Ihor R. Lemischka, Ph.D.

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President Obama's recent lifting of the eight-year ban on federal funding for the creation of new embryonic stem cell lines signals an exciting new era of encouragement and support. However, if we as a nation are to capitalize on the enormous potential of stem cells, we should broaden the range of allowable stem cell research even more.

Pluripotent stem cells can produce all types of cells in the body and hold tremendous promise for our understanding of complex diseases and for the development of novel therapies. To date, we can obtain pluripotent stem cells from embryos, and we can create them by "reprogramming," or inducing, adult cells to resemble embryonic stem cells.

The way forward lies in our ability to produce pluripotent stem cells from individual patients. Reliable patient-specific pluripotent stem cell lines will allow us to study complex diseases and produce genetically matched cells that could eventually be used in cell transplantation therapies without the fear of immune rejection. Patients with cardiovascular disease, liver and blood ailments, and spinal cord injuries could benefit greatly from stem cell-derived treatments.

Recent work has reported reprogramming of cells from patients with Lou Gehrig's syndrome, spinal muscular atrophy, Parkinson's disease, Type 1 diabetes, and others. Teasing these cells to mimic disease in the lab could provide enormous insights into how and why these disorders develop. This, in turn, could open up avenues for the development of novel diagnostics and the identification of new and more effective drugs.

While reprogramming adult cells from patients has

exciting potential, the exact properties of these cells are still unclear. Only rigorous comparative studies between these cells and pluripotent stem cells from the same patient that are derived by other means can clarify this issue.

Such methods include revolutionary areas such as somatic cell nuclear transfer, which involves placing genetic material from adult cells into eggs that have been cleared of their own genetic material. As yet, this has not been achieved with human cells and eggs, but this technology should be developed and could bring us to the forefront of new treatments. Currently, efforts to explore this technology are not eligible for federal funding.

To realize our goals, the scientific community needs to mobilize and educate the public and lawmakers about the benefits of stem cell research, with full sensitivity to

all moral and ethical points of view. Widespread understanding of all areas of stem cell research—embryonic and adult—would eliminate any fears of the unknown, encourage scientific freedom, and rally support.

Funding is essential to success. States might dial back their support believing that federal resources will increase. Instead, states should follow New York's example. New York State plans to spend \$600 million over 11 years on stem cell research—an initiative that is an investment in the health of our people, the health of our economy through job creation, and one that gives our state the competitive edge as others compete for federal dollars.

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# Fulfilling the Promise of Biomedical Research

Dennis S. Charney, M.D. & Kenneth L. Davis, M.D.

The signing of our nation's historic health care legislation should be just the beginning of a national discussion on how biomedical research can bend the cost curve of medical care through new therapeutics. Debates leading up to this landmark event were characterized by a paucity of discussion on the potential impact of biomedical research on the health of individuals, our nation, health care costs, and the economy.

There is clear evidence that increases in biomedical research funding by the National Institutes of Health (NIH) have led to reduced mortality rates for chronic diseases including cancer, cardiovascular disease, stroke, AIDS, and diabetes. Today, the average life expectancy at birth in the United States is 78; 80 years ago it was 57. A good part of that increase is related to advances in biomedical science.

Antibiotics, vaccines, cardiovascular drugs, anti-ulcer drugs, anti-inflammatory drugs, and bronchodilators have had major effects on mortality of common diseases. Most recently, anti-retroviral drugs have dramatically reduced deaths resulting from AIDS. Imagine the cost to our health care system if advances in AIDS treatment or cardiovascular disease had not been made. Even more to the point, imagine a health care system without a polio vaccine.

Today, human genetic studies have the potential to transform the way clinical medicine is practiced. Increased knowledge of the molecular pathways underlying disease may reveal novel drug targets, leading to personalized—rather than population-based—approaches to diagnosing, treating, and ultimately preventing human diseases. Robust investments in biomedical research now would bring promising results within the next decade.

We also need a drug-development infrastructure that can handle the acceleration in biomedical research. The pace of approval for new drugs by the U.S. Food and Drug Administration remains unacceptably low. From 1950 to 2008, the agency has approved 1,222 new drugs—with the per annum number remaining flat. Given the promise that biomedical research holds, it is a tragedy that in 2008 only 21 drugs of novel mechanism were approved for use in the United States. This is well below the level required to dramatically enhance human health—and far beneath the scientific community's capacity for drug discovery and development.

In addition to potentially changing the course of human health, the large-scale investments in biomedical research would also stimulate economic growth. A recent study demonstrated that in one year alone, NIH funding for New York State generated nearly 30,000 jobs and over \$4 billion in business

activity. At the national level, more than 1.2 million people are employed in the biosciences, and the Bureau of Labor Statistics projects that employment in biosciences will grow at an annual rate that is 13 percent higher than the overall rate of employment. Additional investments would lead to even greater growth.

If the United States does not increase its investment in biomedical research, the world's center for medical innovation and discovery will shift. In the context of a struggling economy, growing federal deficits, and the challenge of our intractable disease burden, the United States should consider the opportunities that could be generated by a major investment in biomedical research.

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# Protecting Urban Academic Medical Centers: An Endangered Species

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Kenneth L. Davis, M.D. & Dennis S. Charney, M.D.

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Every day millions of Americans turn to academic medical centers – hospitals that are affiliated with a medical school – as destinations for the most complex, comprehensive, and life-saving care. Our most vulnerable populations also turn to urban academic medical centers, which often double as safety-net hospitals. These critical community facilities care for people with limited or no access to treatment. This is also where the sickest and poorest patients, and a disproportionate number of people who are uninsured, receive health care and emergency services.

Less appreciated is the fact that these institutions are centers for pioneering research and biomedical innovation, finding the treatments of tomorrow. Over half of the Nobel Prize winners in medicine over the past 30 years were affiliated with these institutions. Academic medical centers are also the lifelines to tomorrow's medicine, playing an essential role in educating and training physicians.

The dual roles of leading scientific innovation and providing clinical care for complex diseases and for our nation's most impoverished populations puts a demand on these institutions that is reaching a breaking point. This is especially true for our nation's best hospitals, whose affiliated medical schools also rank in the top 20 for National Institutes of Health (NIH) funding.

For 13 of these hospitals, 55 percent of the patients they serve are Medicaid or Medicare enrollees. Medicare pays hospitals on average just 91 cents on the dollar, and Medicaid only 88 cents per dollar; supplemental payments do not cover this gap. Revenues for Medicare and Medicaid, in a good year, rise by 1 to 2

percent, while health care expenses can rise by some 4 to 6 percent. The costs are driven by increased expenses in labor, medical-device technology, pharmaceuticals, and the infrastructure needed to provide primary care and emergency room services, which are in high demand in urban settings. These institutions' expenses are further aggravated by limited alternative care options such as sub-acute facilities and nursing homes, which require patients to remain in the hospital longer.

This is an equation that does not equate. The financial losses in clinical care jeopardize the foundation of the U.S. biomedical research establishment. This puts at risk our government's investments in the future of medicine, as made by huge NIH grants to the scientists and laboratories of these medical centers.

The advances that we see in our labs open up extraordinary possibilities for new therapeutics and diagnostics. This is a time in which medicine has the potential to revolutionize humanity, but there is also a real possibility that our generation will lose this window because our leading academic medical centers lack a sustainable business model that rests on a stable foundation.

The nation needs a comprehensive urban academic medical center survival act that protects these national, indeed international, resources. As a nation we need to protect the institutions that protect so many of us, rich and poor – institutions that can transform the lives of our children and grandchildren through the world-class research they conduct.

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# The Myth of Geographical Variation

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Ira S. Nash, M.D.

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The debate that preceded the passage of the Patient Protection and Affordable Care Act – popularly known as the “health care reform bill” – shed a harsh light on the enormous and growing expenditure on health care services in the United States, estimated to be about \$2.5 trillion last year, or about 17 percent of our gross domestic product.

Assessing whether that money is well spent should be a matter of serious discussion. Unfortunately, those talks have been distorted by the influential Dartmouth Atlas of Health Care, which claims that patients who go to urban medical centers get care that is more expensive and does not improve their health outcomes. This leads many to conclude that big-city hospitals are the cause of our nation’s outsized medical bill.

Using Medicare billing data, Dartmouth researchers focused on health care spending at the hospital where a patient was admitted most frequently – though not necessarily exclusively – in the last six to 24 months of his or her life. Hospitals in areas with lower population density tended to spend less per patient during this timeframe, and therefore were credited with offering a better value per health care dollar.

But determining the value of health care services is no simple matter, and rarely does it come down to price alone. Any credible analysis of value should include the number of patients whose lives were saved, not just how much was spent on those who died. It should also consider the severity of illness when a patient first enters the hospital, and how much health is restored. However, the report’s limited research parameters left out these and other important hallmarks of health care

quality. In addition, one hospital, even the one most frequently visited, cannot be held accountable for care provided at another institution.

The Dartmouth analysis also overlooked the relative disease burden in a given geographic region, which is higher in many urban areas than in most less-populous sectors. When the Medicare Payment Advisory Council adjusted for such factors, it determined that there was much less geographic variation in spending than the Dartmouth Atlas analysis had found.

The Institute of Medicine (IOM), a neutral body, now has two years to investigate this matter and recommend ways to reward quality and value that are sensitive to geographic realities. The IOM’s changes will take effect in May 2012, unless Congress objects.

As passed, health care reform includes provisions that call for various value-based programs

to be rolled out over the next few years, some to include incentives for hospitals that lower costs. Reducing waste and saving money are worthwhile goals, but in health care, such provisions need to be structured wisely to account for an institution’s patient demographics, severity of illness, complexity of care delivered, and overall operating expenses. Urban hospitals, for example, face higher labor costs and provide unreimbursed care to a larger population of patients who cannot pay themselves.

Anything less nuanced could put us at risk of creating a system that effectively rewards institutions for delivering poorer care, and punishes those providing excellent care in more challenging environments. The net result would be illusory savings, and poorer care for all.

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# What Patients Really Want

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Diane E. Meier, M.D.

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Much has been said recently about advance medical directives, including living wills and health care proxies. Opponents of health care reform have used inflammatory rhetoric—death panels, care rationing, euthanasia—as a political maneuver to frighten people, particularly Medicare beneficiaries, by misrepresenting the facts. But in all the raucous town hall debates and incendiary statements circulated on the Internet, one critical fact is overlooked: Not getting enough time to talk with the doctor is the number-one concern of patients with advanced illness, and their families.

Research shows that people with serious illness want to talk to their doctors to ensure that their goals, values, and hopes will be primary considerations when difficult decisions must be made, when or if they are no longer able to speak for themselves. Research also shows that patients expect doctors to initiate these discussions, and as such, they are reluctant to raise these issues themselves, worrying that their doctor would not have time to respond—especially to their emotional needs.

Doctors indeed face immense time pressures, and operate in a system that does not reimburse or reward discussions with patients. Medicare and other insurers pay doctors well for procedures such as X-rays, chemotherapy, and surgery, but little or no compensation is provided for talking with patients.

Despite these obstacles, many medical professionals consider advance care planning to be as routine as annual flu shots and regular cholesterol checks. Doctors and patients dedicate time to share information and translate medical facts and patient wishes into a care

plan that can, and does, change over time as doctors and their patients reconsider the options.

It is most important to document whom the patient would trust to help make medical decisions if the patient were no longer able to make his or her own decisions. It is also helpful to decide what kind of treatment a patient would want if he or she were facing a serious illness that could result in permanent communication loss.

In contemplating such situations, some patients say they would want care focused strictly on their comfort, but others want everything possible done to prolong life, no matter what its quality. Desires like these are recorded in the medical chart to guide designated family decision makers and doctors, if and when the need arises.

Discussions about advance care directives should be revisited periodically throughout a long-term illness because in truth, doctors

generally cannot accurately predict prognosis until only a few weeks before death. Patients also change their minds, and new treatments become available. This is why regular conversations about hopes, worries, questions, and goals for medical care should be central to all doctor-patient relationships, no matter the patient's age, medical condition, or prognosis. Such discussions are never mandatory, but the vast majority of patients welcome them and are relieved to have an opportunity to air concerns and goals with their doctor.

Conversations about treatment options and patients' goals and wishes are a small but important step toward restoring power and control over medical decisions to their rightful owners: patients and their families.

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# Prevention: A Heart Health Imperative

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Valentin Fuster, M.D., Ph.D.

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Cardiovascular disease (CVD) is the number-one killer and major cause of permanent disability worldwide.

In the United States alone, one in three American adults – 80 million people – live with some form of this deadly disease. In 2009, an estimated \$475 billion will be spent on CVD treatment and related lost productivity. Treatment alone is not the answer as the cost of care is steadily increasing as a result of insufficient preventive action.

In the US, the trends tell the story. Since the 1980s, the prevalence of overweight and obesity among our nation's children and adolescents has more than doubled, to about one-third today. Nearly one-quarter of our high school students smoke, and two-thirds do not exercise at recommended levels. Initiatives are urgently needed to reverse this tide and tackle the growing burden of CVD.

In fact, CVD can start quietly in children as young as age three and progress slowly into adulthood. Smoking, high blood pressure, blood sugar and cholesterol, and being overweight put people at risk. However, these behaviors can be managed.

The mandate for patient care must be expanded to include prevention. Policy makers and health care communities play a major role in changing public attitudes through implementation of health-promoting measures, including diet, physical activity and tobacco control. The Food and Drug Administration's long-overdue authority to regulate tobacco products is a victory for CVD prevention. We need equally strong, pervasive protections against the other risk factors – and for all age groups.

Cost-effective screening and treatment programs,

including education for CVD risk reduction, are critical both in the US and abroad. In Rwanda, for example, the Millennium Villages Project Cardiovascular Disease Initiative is developing a protocol to screen all patients at local health clinics for six risk factors: smoking, blood pressure, blood sugar, cholesterol, abdominal circumference, and physical activity.

Children between the ages of three and eight are especially receptive to learning lifelong heart-healthy habits. In Bogota, Colombia, we have teamed up with Sesame Workshop to create culturally specific Muppet segments that focus on nutrition, fitness, and health education. After only one year, children involved demonstrated increased awareness of health-promoting behaviors.

A program like this could benefit high-risk populations in metropolitan areas such as New York City where two of five children

are overweight or obese, including nearly a quarter of kindergarteners.

For those with a history of heart attacks, the polypill is a three-in-one drug in development that will increase patient compliance and might reduce medication cost to as little as \$2 per month.

Other measures to advance heart health include the use of electronic health records that are programmed to assess every patient's cardiovascular risk profile in all primary care settings.

Currently, the vast majority of dollars are spent treating rather than preventing CVD. Instead, through simple, low-cost efforts, we could significantly reduce the prevalence and burden of this debilitating disease and save money and lives.

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# Recalculating Cancer

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Steven J. Burakoff, M.D.

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This year, 562,340 people – more than 1,500 each day – will die from cancer in the United States, and 1.5 million will be diagnosed.

Cancer is often described by very large numbers like these. But such figures obscure a fundamental shift in thinking that has taken place in cancer research, one that needs wider understanding by the public and policymakers.

There is no one denominator for cancer; it is hundreds of different diseases and each must be evaluated – and treated – on its own. One early example of this was our success in treating childhood leukemia. This condition represents a small fraction of all cancer patients – only 3,540 cases were diagnosed in the U.S. in 2008 – but within this, the cure rate is 90 percent, up from 40 percent 25 years earlier. When the denominator includes all cancers, however, the cure rate amounts to less than a quarter of one percent.

Much of this gain against childhood leukemia came from aggressive chemotherapy, a treatment that galvanized a new beginning in cancer treatment when it was first developed 60 years ago. We are now at another watershed moment in cancer research. Combination therapies and new enzyme-targeting treatments have turned many deadly cancers – certain adult leukemias and gastrointestinal stromal cell tumors among them – into chronic diseases.

Genetic research has also put us on the path to targeted therapies that could have significant success. Consider that DNA decoding has identified a certain gene mutation in 10 percent of people with lung cancer, which accounts for a third of all cancer deaths. Nearly 100

percent of these patients respond to a small-molecule drug that focuses on the mutation. This is a clear victory over one disease, but a smaller achievement when the denominator expands to all lung cancers, and all cancers.

Developing vaccines to prevent cancers is another attainable goal that requires more emphasis. Cancer cells evade detection by the immune system – and the most sensitive diagnostic tools – in many insidious ways. We are working on ways to engage the patient's immune defenses to recognize and withstand these stealthy cells. Early data indicates that vaccines could have considerable impact on renal cancer and melanoma, which is on the rise.

There is great need to build an arsenal of targeted approaches. Certain diseases, such as ovarian and lung cancers, are rarely detected early. And our nation's increase

in life expectancy – 79 years for people born today, up from 63 in 1940 – further expands the pool of vulnerable populations since cancer risk increases with age.

Even as the nation faces other health challenges – from H1N1 flu virus to health care reform – we must strengthen our commitment to cancer research. The pledge to increase federal funding for cancer research is encouraging, but of the \$10 billion in stimulus money allocated for health care, only \$1.3 billion will go to cancer, and this must be spent in two years. Already, the number of grant applications has far outstripped the available funding. To capitalize on the promise of targeted treatments, we must recalculate budgets for the hundreds of diseases we call cancer.

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# Fighting Round Two: Recurrent Prostate Cancer

William K. Oh, M.D.

David B. Samadi, M.D.

Richard G. Stock, M.D.

Simon J. Hall, M.D.

In recent years, Americans have heard conflicting messages about prostate cancer. On the one hand, routine PSA screening may result in over-diagnosis and excessive treatment of the disease. On the other, prostate cancer remains the second-leading cause of cancer death for men in the United States. Both of these facts are true; how do we reconcile this?

Of the nearly 200,000 men diagnosed with prostate cancer each year, roughly one in three will develop recurrent disease and one in seven will die from it, often with great suffering. This is despite prostate surgery or radiation therapy, which are both treatments that usually cure the disease. How best to treat patients in the "second round" of their cancer fight is a topic in need of rigorous research, as there is no clear consensus on the optimal treatment approaches – or the most favorable time to begin them.

Most men with recurrent disease – a condition that can develop many years later and is usually heralded by a rising PSA – are candidates for additional treatment. Surgery or radiation for recurrent disease should be considered, but the results are often inadequate in this setting and can be associated with significant side effects.

Many patients will, therefore, receive hormonal therapy, which reduces the male hormones that feed prostate cancer and, in turn, can lower the PSA. Most patients and physicians are greatly relieved when the PSA goes back down, but so far there are no studies showing that hormonal therapy is effective in slowing the spread of cancer and ultimately extending life. Indeed, men with a rising PSA will live on average 15 years – even if hormonal therapy is delayed until the cancer has spread to bone or

other sites. The use of hormonal therapy must therefore be balanced against the known side effects, including impotence, weight gain, and bone thinning.

To effectively meet the myriad challenges of recurrent prostate cancer, we need a pool of competitive grants designated for research into the rising PSA population, including studies that investigate the timing and efficacy of hormonal therapy. At the scientific level, we need to sharpen our focus on identifying molecular-based diagnostics and therapeutics that better characterize the key differences in patients whose cancer has recurred. We must also develop more targeted and less toxic treatments. In the clinical arena, we need to expand databases that can track patient outcomes so we can determine which patients need aggressive care and which could be monitored without treatment.

Most important, all patients should have access to a multidisciplinary care team. Within a center for prostate health, urologists, radiation oncologists, and medical oncologists would meet with each patient and share their unique expertise to develop a treatment plan. This team approach would best serve individual patients as well as our national research efforts by fostering the interdisciplinary discussion needed to generate novel approaches to treatment.

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# Opt Out of the Black Market for Organ Transplantation

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Sander S. Florman, M.D.

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The system for organ transplantation in the United States is in drastic need of reform, and not just because the disparity between supply and demand continues to increase at an alarming rate. More than 105,000 men, women, and children await organ transplantation in the United States, and nearly 20 of them die every day without the opportunity for transplant.

More alarming is that a black market for human organs exists – right here and worldwide. While buying and selling organs is illegal in almost all countries, enforcement of the laws has been weak. In some nations, prisoners are executed and organs are procured for transplantation. In others, impoverished, illiterate, and desperate people sell their organs for a pittance.

The 1984 National Organ Transplant Act established a framework for a national system of transplantation and prohibited the buying and selling of human organs. Before being approved for transplant, living donor candidates must undergo rigorous medical evaluations, and their case must be reviewed by a multidisciplinary committee. Despite the law and the intense approval process, a black market for live-donor organs operates in the United States, undermining the very basis and sanctity of the doctor-patient relationship: honesty and trust. Since donor compensation is illegal, patients must lie to the very medical teams responsible for their lives by denying any financial arrangements.

It is easy to pass judgment on the practice of commercializing body parts, but it is not hard to understand

what is behind it. For example, the harsh reality is that of the 83,000 people in the United States awaiting kidney transplantation, most will never get one. For those who do, the benefits are well established. Compared with dialysis patients, transplant recipients enjoy a longer lifespan and a dramatically improved quality of life.

To save and improve many more lives, we need to increase our nation's supply of organs for transplant. Changing our deceased-donor system is one way to do so. Many countries have adopted a "presumed consent" model that considers all citizens to be donors upon death unless they specifically register to "opt out" of donation. In contrast, our current "informed consent" system encourages donation through awareness, primarily by inviting people to "opt in" when they sign their driver's license.

The majority of Americans do support donation, but despite aggressive national appeals, actual donation rates remain low. Whether presumed consent would eliminate a black market is debatable. That such a system increases organ availability has been overwhelmingly proven true: in nations with presumed consent, fewer than 5 percent of citizens register to opt out.

It is clear that our efforts to increase organ availability have not worked. We need innovative ideas and strong legislation that will allow us to save lives, protect donors, and end illegal black market practices. Choosing an "opt out" system for organ donation is a much better solution than allowing ourselves to opt into the black market.

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# What's Getting Into Our Children?

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Philip Landrigan, M.D.

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In the past century, the threats to our children's health have shifted radically. Life-threatening infectious diseases – smallpox, polio, and cholera – have largely been conquered. Babies born in the United States today are expected to live two decades longer than their ancestors were 100 years ago.

But our children are growing up in a world in which environmental toxins are ubiquitous. Measurable levels of hundreds of manmade chemicals are routinely found in the bodies of all Americans, including newborns. Infants are exposed to polychlorinated biphenyls, lead, and mercury in the womb and through breast milk. Baby bottles and toys have been found to contain phthalates, bisphenol A, and lead, all toxins that have been linked to reproductive and developmental disorders.

As harmful elements detected in everyday household items increase, rates of chronic disease have also risen sharply – and these conditions are now the leading causes of childhood illness and death.

Air pollution and cigarette smoke contribute to asthma, the most common chronic disease of childhood, which has increased 160 percent in the past 15 years for children under age 5.

Chemicals called endocrine disruptors – found in pesticides, herbicides, some plastics, and air and water – can interfere with the body's hormone signaling system, potentially causing reproductive disorders, neurologic impairments, and immune dysfunction. Cancer, which kills more children under age 15 than any other disease, is linked to solvents and pesticides.

Early exposure to lead, mercury, and certain pesticides are suspected to contribute to autism, attention deficit/hyperactivity disorder, and other developmental conditions, which affect 5 to 10 percent of babies born each year.

A contaminated environment takes an economic toll,

costing \$55 billion in medical treatment and lost productivity each year. Health care reform can be successful only if it is tied to strong environmental policies.

Historically, this has paid off. In the 1970s, landmark studies on childhood lead poisoning resulted in its removal from paint and gasoline, producing a 90 percent decline in lead poisoning. Children's average intelligence subsequently rose by 5 to 6 IQ points, and the economic productivity in the United States increased by \$100 billion to \$300 billion annually.

And in the 1980s, two major pesticides were banned after being shown to have detrimental effects on childhood development.

Long overdue is the National Children's Study (NCS), which was appropriated in 2009 for two-thirds of its \$300 million budget. The largest study of children's health in U.S. history, NCS will track 100,000 children from before birth through age 21 to determine the environmental and genetic factors that influence health and development. The data we collect

will allow us to develop a national blueprint for prevention.

The Child Safe Chemical Act (CSCA) is another measure that deserves support. During the past 50 years, more than 80,000 synthetic chemicals have been invented, and each year hundreds more are added to consumer goods, including cosmetics, motor fuels, and food packaging. Most are not tested for toxicity.

Introduced into Congress in 2005 and 2008, CSCA would mandate that all new chemicals be tested and found safe for children before being brought to market. It would require that 62,000 untested chemicals currently in use be proven safe or be banned. Similar legislation exists in Europe.

Our children are 30 percent of our population, but they are 100 percent of our future. They deserve our protection.

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# Sugar Tax May Sour New York's Thirst for Soda

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Derek LeRoith, M.D., Ph.D.

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Few medical trends in the United States are as alarming as our growing obesity rate. Over the past 20 years, the prevalence of obesity among adults has increased from 12 percent to 34 percent, and among children and adolescents, the rate has nearly tripled, from 7 percent to 19 percent.

This growth tracks with our nation's increased consumption of sugar, much of it in the form of sweetened sodas, juices, sports drinks, flavored waters, and ready-to-go teas and coffees. Research shows that sugary beverages are the only dietary element to be strongly linked to increased rates of obesity among children and adults. Whether the sweetener is sugar or its ubiquitous substitute, high-fructose corn syrup, excessive intake equates with empty calories and reduced consumption of healthy beverages, such as milk.

It is well documented that overweight and obesity set the stage for cardiovascular disease, some cancers, and type 2 diabetes. For children, whose soda intake has increased 75 percent in the past 30 years, this is particularly ominous: each additional 12-ounce soft drink consumed per day more than doubles a child's risk of becoming obese. Alone or together, obesity-related conditions can have great impact on quality of life and life expectancy. A diagnosis of diabetes in middle age can cost an individual about 20 quality-adjusted life years, and obese men with diabetes have a greater than 90 percent risk of developing coronary artery disease over 30 years.

Obesity affects us all. In New York State, obesity-related health problems cost an estimated \$7.6 billion per year, and nationally, annual Medicare disbursements for diabetes and related illnesses top

\$80 billion. Reversing such an entrenched and expensive trend cannot be handled on an individual basis; it must be approached by state and national policies designed to encourage changes in consumption patterns.

A "sugar tax" on all high-sugar foods—including those with high-fructose corn syrup—would be a bold and wise start. The possible impact on overall consumption rates and associated revenues varies across tax models, but it is estimated that in New York State, even a minimal penny-per-ounce tax on sugary beverages alone could exceed \$900 million in one year.

In addition to the potential population health benefits of reduced sugar consumption—an area that requires more rigorous studies—sugar-tax revenues should be channeled into health-promoting initiatives in neighborhoods that need them. Many areas with high rates of obesity have correspondingly low availability of vegetables and fruits. East and Central Harlem, for example, have among the highest rates of obesity in New York

City. In these neighborhoods, leafy green vegetables are available in only 3 percent of bodegas—with bodegas accounting for two-thirds of food stores. Tax funds could be used to support green markets, such as one established by The Mount Sinai Medical Center, and other distribution plans to increase availability of produce in areas that lack them.

Health care reform, no matter how comprehensive, is not enough to fix our nation's obesity epidemic and its related health problems. Greater access to health insurance should help many people receive the care they need to manage conditions that are caused or exacerbated by obesity. But even better would be to slow—and reverse—our nation's weight gain in the first place.

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# Why Are We Subsidizing Childhood Obesity?

Philip J. Landrigan, M.D., M.Sc.

Lisa M. Satlin, M.D.

Paolo Boffetta, M.D., M.P.H.

Obesity is epidemic in America's children. The potential health consequences for the next generation are grave, and the impact on the nation's health care costs — an estimated \$14 billion per year — is substantial and growing. We need urgent realignment of the health and farm policies that have contributed to this crisis.

Since 1980, obesity rates in children have tripled. Today, 13 million children are obese, including 14 percent of all 6- to 11-year-olds, and 17 percent of adolescents. Over 70 percent of these children will be obese adults, with increased risks of diabetes, heart disease, and certain cancers. Today's children may be the first U.S. generation in a century to have a shorter lifespan than their parents.

Insufficient physical activity is a major driver of childhood obesity. Structural features of the modern environment — too few sidewalks, unsafe playgrounds, and insufficient physical education programs — contribute, as do reliance on cars and a sedentary lifestyle. Poverty is a major risk factor. Chemical obesogens — synthetic chemicals that alter the body's metabolism — are coming under scrutiny.

But an especially powerful driver is the abundance of cheap, unwholesome food sweetened by the synthetic sugar substitute high-fructose corn syrup (HFCS). Consumption of HFCS has increased tenfold since 1974. The obesity epidemic in America's children precisely tracks this trend.

HFCS was invented in the 1960s. Production increased dramatically in the 1970s, after the U.S. Department of Agriculture (USDA) ended controls on corn, wheat, and soy production and replaced them with a policy that encouraged — and paid — farmers to grow as much of these commodity crops as possible. Today, these subsidies total \$19 billion per year. They have led to enormous increases in production of cheap corn starch. No subsidies are paid to fruit or vegetable farmers despite the clear health benefits of eating fresh fruits and vegetables.

High-fructose corn syrup now represents 40 percent of the non-calorie-free sweeteners added to U.S. foods. It is virtually the only sweetener used in soft drinks. Because of subsidies, the cost of soft drinks containing HFCS has decreased by 24 percent since 1985, while the price of fruits and vegetables has gone up by 39 percent. By 2006, the average American child drank 132 calories of HFCS per day from sweetened beverages, and the 8-ounce soft drink of a generation ago was replaced by the even cheaper 20-ounce super-size drink.

Due to these and other factors, it is estimated that overall caloric intake in the U.S. has increased an alarming 600 calories per person per day since 1970. Burning these extra calories would require, on average, an additional hour of physical activity per day.

As with tobacco, commodity subsidies need to be reexamined. It is incongruous and wasteful for health agencies to spend millions of dollars countering obesity while the USDA spends billions in farm subsidies that indirectly promote it. Fruit and vegetable farmers need more support: calories from vegetables are 100 times more expensive than those from HFCS, making it financially challenging for many consumers to make healthy food choices.

Curbing the obesity epidemic requires a multifaceted approach: education, increased physical activity, healthy school food, promotion of unprocessed foods — and a change in agricultural policy. Coordinated national leadership is essential.

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# Primary Care Parity

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Paul Klotman, M.D.

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In the national health care debate, access to care is frequently equated with insurance coverage. But coverage alone is not the cure. Patients need good primary care physicians to rely on, and as a nation, we need many more of them.

Numerous studies show that the availability of primary care physicians correlates with better health outcomes and lower health care costs. It is also well documented that in the United States, the supply of primary care physicians is far below that of nations with better health care outcomes and lower costs.

To promote primary care as a career choice, more action is needed from government as well as the institutions and regulatory bodies responsible for medical training.

Congress needs to retain provisions in proposed bills that would reduce the income disparity between primary care physicians and specialists.

Reimbursement should be aligned to the time spent with, and quality of care provided to, patients—rather than to the number of procedures and tests performed.

To make the field immediately more attractive, Congress should expand currently limited debt-relief programs to include all graduates pursuing careers in primary care.

As President Obama has emphasized, health care reform needs to include incentives that encourage use of electronic medical records and creation of medical homes focused on coordinated, quality care with care teams that include nurses, physician assistants, and others. Such improvements would reduce the administrative burden on primary care physicians while providing them greater job satisfaction and more time for patients.

To further foster growth, physician training must be

reevaluated. Medical schools and residency programs need to highlight primary care as a valued and respected career choice and provide the knowledge and experience contemporary primary care medicine demands.

The current medical resident training structure was developed a century ago, when patients received most of their care as inpatients. Today, all but the most acutely ill are treated in the outpatient setting.

New curricula focused on the divergent demands of inpatient and outpatient medicine are required. Attractive outpatient curricula would enhance primary care training in team leadership skills, cost-effective care, preventive medicine, and chronic disease management. This would also establish parity between primary care and other areas including specialty practices and academic pursuits. To achieve this, legislators need to create more residency spots by lifting restrictive caps, making access to internal medicine residency less intense and thus more attractive.

At all stages of training, future primary care doctors spend far more time learning treatment techniques than they do mastering prevention strategies—those proven to improve outcomes and reduce costs. Curricula that help all aspiring physicians master preventive medicine are needed.

As we continue to debate health care reform, it is essential to voice the fact that access to care relies on more than insurance. Ensuring that our most promising physicians-in-training are attracted to, and properly trained in, primary care medicine will give patients the access they need to doctors capable of delivering the highest-quality care.

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# Science and Medicine in the Service of Society

John H. Morrison, Ph.D. & David Muller, M.D.

Biomedical science matters most when it is translated into tangible benefits for patients. Every day, scientists expand our understanding of the genetic basis and molecular pathways underlying disease. This knowledge should ultimately be translated into highly personalized approaches to diagnosis, treatment, and prevention of disease for individual patients and communities.

As leaders in the education of tomorrow's physicians and scientists, how are we to respond to the expanding scope of twenty-first-century research? At every level of our educational mission, we must seamlessly integrate clinical relevance into scientific research, and scientific principles into clinical training.

Historically, medical schools emerged within universities primarily to educate physicians, yet Master's and Ph.D. programs centered at medical schools now produce the vast majority of the scientists trained in biological arenas relevant to medicine.

All too often, these programs simply co-exist, isolated by different curricula and cultures. If we are to maximize our capacity to impact clinical practice through scientific discovery, we need to produce leaders in biomedicine and health care who see themselves as members of large, interactive teams committed to clinically relevant breakthrough science. Clinically oriented medical school courses should become part of the graduate school curriculum and translational scientists should be part of bedside rounds for teaching physicians-in-training.

But we can take this one step further. For over a century, the defining missions of medical schools have

been to care and advocate for the underserved and to push the envelope of biomedical research. Because of increasing specialization, technological advances, and the competitive nature of research funding, most medical schools in the country have had to commit to one primary goal: they are either research oriented, or community and public-service oriented.

Teaching tomorrow's physicians and scientists this "hidden curriculum" — that science, service, and advocacy are unrelated — is an injustice to both our students and society. They can no longer exist as separate entities if we are to achieve our potential for applied innovation, such as preventing a patient from developing dementia and protecting a community from the environmental risks that will lead to cancer.

Science and service, innovation and advocacy: The National Institutes of Health (NIH) has already embraced the need to

bridge the chasm between the researcher's laboratory bench, the patient's bedside, and the community by setting the expectation for translational research that moves us toward the ultimate goal of better and more accessible care for all.

Medical schools must acknowledge the equal importance of these missions if we are to produce leaders who will be agents for change, translating the bounty of scientific discovery into improved quality of life in our communities and across the globe.

Science is the underpinning of everything we do, but in the absence of service, there is no context for understanding why our scientific breakthroughs matter.

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# WE'VE BEEN DONATING

## OUR BRAINS TO SCIENCE FOR 150 YEARS.

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First to describe *Streptococcus Enteritis*, [Lahman] which causes infection of the intestine.

First description of Tay-Sachs disease.

First non-surgical method to test patency of fallopian tubes.

First operation performed under intratracheal anesthesia.

First to define a direct role of androgens in inducing the morphologic changes of the polycystic syndrome in the ovary.

First description of pulmonary hypertension.

First to describe condition of behavior change at the outset of menses (PMS, premenstrual syndrome).

First cystoscope for children.

First successful pulmonary lobectomy for suppurative disease.

First to perform pulmonary lobectomy for inflammatory disease.

The first safe method of storing blood.

Isolated *Rickettsia prowazekii* in the blood.

Discovered the cause of Epstein's disease of kidney and developed therapy to treat it.

First pediatric service in a New York City general hospital.

First successful treatment of tumors of the bladder by transurethral electrocoagulation.

Discovered that human blood groups are inherited according to Mendel's law.

The first textbook on thoracic surgery in the United States.

First published description of a brain tumor called "spongioblastoma."

Performed the first gastrectomy for peptic ulcer in the United States.

First successful liver transplant in New York State.

The first to demonstrate how asbestos can cause cancerous changes in the DNA of cells.

Developed first cardiac stress test.

Developed ultrasound-guided technique to insert radioactive seeds into the prostate to treat prostate cancer.

First independent otology service in any New York hospital.

Discovered that in using insulin, physicians were treating only the symptoms of diabetes and not the cause.

First intratracheal insufflation of anesthesia in humans.

First description of Crohn's disease.

Developed intensive short-term medical treatment of syphilis with arsenicals.

Developed the concept of sub-cellular pathology (the "organelle").

First successful resection of a middle third esophageal carcinoma.

Developed uroselectan, an injectable compound that allows clear visualization of kidneys, ureters and bladders.

Identified a marker (fetal fibronectin) for preterm birth.

Identified glycine solution as best choice for bladder irrigation during transurethral resection (TUR).

Discovered evidence that an enzyme could inhibit acid secretion.

First to recognize eosinophilic granuloma of the bone.

Demonstrated that efficiency of IVF could be greatly increased if the sperm were assisted in reaching the surface of the egg.

First to describe postperfusion syndrome following open heart surgery.

Developed black blood MRI for diagnosing cardiovascular diseases.

The first blood bank in New York City.

Created an influenza vaccine, the first genetically engineered vaccine.

First to reverse the gene defect in Fabry's disease.

The first use of platinum in the United States for the treatment of ovarian cancer.

First academic department of geriatrics.

Pioneered current treatments for Alzheimer's disease.

First U.S. surgeon to successfully perform an abdominal colectomy for colitis.

First to classify transient circulatory disturbance of the brain known as transient global ischemia.

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Apparently, breakthroughs can be contagious: more than a hundred were made possible by the generous contributions of doctors at Mount Sinai Medical Center. And they make a powerful argument for



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placing yourself in our care. After all, who wouldn't want to be treated by the hospital that pioneered the treatment? 1-800-MD-SINAI • [www.mountsinai.org](http://www.mountsinai.org). **Another day, another breakthrough.**

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