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Redirecting Innovation in U.S. Health Care

Options to Decrease Spending and Increase Value

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Short abstract

This article identifies promising policy options to spur the creation of new medical technologies that will reduce total U.S. health care spending or will provide health benefits that justify any increase in spending.

Abstract

New medical technologies are a leading driver of U.S. health care spending. This article identifies promising policy options to change which medical technologies are created, with two related policy goals: (1) Reduce total health care spending with the smallest possible loss of health benefits, and (2) ensure that new medical products that increase spending are accompanied by health benefits that are worth the spending increases. The analysis synthesized information from peer-reviewed and other literature, a panel of technical advisors convened for the project, and 50 one-on-one expert interviews. The authors also conducted case studies of eight medical products. The following features of the U.S. health care environment tend to increase spending without also conferring major health benefits: lack of basic scientific knowledge about some disease processes, costs and risks of U.S. Food and Drug Administration (FDA) approval, limited rewards for medical products that could lower spending, treatment creep, and the medical arms race.

The authors identified ten policy options that would help advance the two policy goals. Five would do so by reducing the costs and/or risks of invention and obtaining FDA approval: (1) Enable more creativity in funding basic science, (2) offer prizes for inventions, (3) buy out patents, (4) establish a public-interest investment fund, and (5) expedite FDA reviews and approvals. The other five options would do so by increasing market rewards for products: (1) Reform Medicare payment policies, (2) reform Medicare coverage policies, (3) coordinate FDA approval and Centers for Medicare & Medicaid Services coverage processes, (4) increase demand for technologies that decrease spending, and (5) produce more and more-timely technology assessments.

The United States spends more money on health care than any other nation—in total, per capita, and as a percentage of our gross domestic product. Public spending on health care—primarily through the

Medicare and Medicaid programs—is crowding out spending on other state and national priorities, including education, Social Security, national defense, and deficit reduction. Private spending on health care takes large bites out of the disposable incomes of U.S. families.

A leading cause of high and growing spending is new medical technologies. Previous studies aimed at reining in spending considered changing the ways in which existing technologies are used. Our work for this project focused on identifying promising policy options to change which medical technologies are created in the first place, with these two related policy goals:

1. Reduce total health care spending with the smallest possible loss of health benefits.
2. Ensure that new medical products that increase spending are accompanied by health benefits that are worth the spending increases.

These goals reflect our definition of the "value" of a medical technology, which compares the increase in population health from using it to the extra spending attributable to its use. A medical product can have large health benefits for some patients and little or no benefit for others. Thus, a key issue for increasing value is improving the alignment between products and patients who will benefit from them.

We define *medical technology* broadly to include all applications of knowledge to practical medical problems. However, in this study we focused more narrowly on *medical products*, specifically drugs, devices, and health information technology (HIT).

To identify promising policy options, we first

- explored how the current U.S. health care system rewards inventors and their private investors for creating and commercializing products that tend to increase health care spending even if they do not provide health benefits that are worth that extra spending
- determined why new medical products that could substantially reduce health care spending often fail to gain traction in U.S. markets.

We argue that the best way to further our twin policy goals is by altering the financial incentives of inventors, private investors, payers, providers, and patients.

Our analysis synthesized information from peer-reviewed and other literature, a panel of technical advisors that was convened for the project, and 50 one-on-one expert interviews. These 30- to 60-minute interviews drew on the experts' firsthand knowledge to gather information about the determinants of medical product invention and adoption. The interview subjects included health care industry experts, drug and device inventors, regulators, payers and insurers, venture capitalists, health policy experts, and researchers.

We also conducted case studies of eight medical products: three drugs (including one biologic), three devices (a diagnostic, an implantable, and a costly machine), and two types of HIT (electronic health records [EHRs] and telemedicine). We use information from the case studies solely for illustrative purposes.

The Context for Medical Product Innovation in the United States

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We conceptualize the health care innovation pathway as having three stages:

1. creation of new products, which we call "invention"

2. regulatory approval for sale in the United States
3. processes that determine how and for which patients medical products are used, which we call "adoption."

We highlight what appear to be the most important decisions that determine which products are invented and brought to the U.S. market; the prices charged for them; the coverage, payment, and utilization management policies governing them; which products are used for which patients; and how the new products affect health and spending.

Invention of Medical Products

Inventors include *drug, device, and HIT companies*, and private *investors* provide money to support their inventive efforts. Their decisions about what kinds of products to attempt to create are driven by two key considerations. First, can a potential new product be successfully brought to market? Second, are the expected market rewards large enough to justify the invention and approval costs and risks? Private investors are likely to fund product-invention efforts only if the required investment is likely to generate a healthy financial return, regardless of the product's potential health benefits.

Regulatory Approval of Medical Products

The U.S. Food and Drug Administration (FDA) ultimately decides which products will reach the U.S. market and with what approved uses ("indications"). Its mandate is to ensure that products sold in the United States are safe and effective; doing so can take years. FDA decisions involve major stakes for medical product companies—not only whether products are approved but also how long the review and approval processes take.

Adoption of Medical Products

Providers, such as *hospitals and physicians*, decide which drugs and devices to use and for which patients, as well as which EHR systems to purchase. Many entities try to influence their decisions. *Drug and device manufacturers* directly market their products to prescribers, facilities, and patients. EHR vendors market their products to hospitals and physicians. *Patients* try to influence physician decisions, with limited success. *Public and private payers* influence provider decisions by deciding which products and services will be covered for which patients, how much to pay for covered products and services, and how to promote compliance with their coverage and payment policies.

Thematic Analysis

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To help us develop policy options, we distilled five themes from the information we synthesized:

- lack of basic scientific knowledge
- costs and risks of FDA approval
- limited rewards for medical products that could lower spending
- treatment creep
- the medical arms race.

The themes are features of the U.S. health care environment that substantially affect the costs and risks of, and financial rewards for, medical product invention. The first two themes relate to whether a product can be brought to market and the costs and risks of doing so—that is, they relate to the

invention and regulatory approval stages of the innovation pathway. The last three themes relate to the adoption stage and describe features of medical product markets that either (1) limit the market rewards that inventors and investors expect from products that could lower spending or otherwise provide good value or (2) provide large market rewards for products that provide low value.

Lack of Basic Scientific Knowledge

Efforts to invent technologies to treat, cure, or prevent a disease are unlikely to progress unless the underlying disease processes are reasonably well understood. Many high-burden medical conditions lack effective treatments because scientific understanding falls short of what inventors and investors think is sufficient to justify investments. The probabilities of inventing products that are safe and effective figure prominently in the decisions of drug and device inventors and private investors.

Costs and Risks of FDA Approval

Some stakeholders say that FDA approval takes too long, costs too much, and discourages innovation. Others say that the time involved in FDA reviews and approvals is necessary to ensure product safety and effectiveness. Whether or not the regulatory process could be faster without compromising safety, inventors face the following facts: As the time required for approval increases, so do inventors' costs, and so does the time inventors have to wait to generate sales in the United States.

Limited Rewards for Medical Products That Lower Spending

In most U.S. industries, consumers benefit from competition because competitors vie for business by offering product improvements, lower prices, or both. Customers tend to buy from the sellers that provide the best value. Price competition in many U.S. health care markets is not as vigorous as in many other industries, and, as a result, it fails to adequately reward innovators that develop technologies with the potential to lower spending. This failure results from three phenomena:

1. Limited price sensitivity on the part of consumers and payers: Key sources of limited price sensitivity include fee-for-service (FFS) payment arrangements that reward providers for providing more care, generously insured patients, lack of price transparency, and limitations on Medicare's ability to consider cost in coverage and payment decisions. Several ongoing trends and developments appear to be increasing price sensitivity. These include increased use of payment methods that put providers at financial risk, increasing deductibles in many private insurance plans, declining prevalence (and generosity) of employer-sponsored health insurance, the excise tax instituted by the Affordable Care Act (ACA) on especially generous employer-sponsored insurance plans (sometimes called “Cadillac plans”), and high cost-sharing rates in the lower-premium plans offered on the health insurance exchanges instituted by the ACA.
2. The limited time horizon of providers when they decide which medical products to use for which patients: In many instances, the health benefits from using a drug, device, or HIT are not realized until years in the future, at which time the patient is likely to be covered by a different insurer, such as Medicare. When this is the case, only the later insurer will obtain the financial benefits associated with the (long-delayed) health benefits.
3. Fragmented decisionmaking: Many provider systems are siloed. When this is the case, most decisionmakers consider only the costs and benefits for their parts of their organizations, and few take into account savings that accrue outside of their silos.

Treatment Creep

The value of a treatment or diagnostic test depends on the health benefits it provides for the patients who use it. Undesirable treatment creep often occurs when a medical product that provides substantial benefits to some patients is used for other patients for whom the health benefits are much smaller or completely absent. Treatment creep is encouraged by FFS payment arrangements, and it is enabled by lack of knowledge about which patients would truly benefit from which products. Treatment creep often involves using products for indications not approved by the FDA. Such "off-label" use—which delivers good value in some instances—is widespread and difficult to control. Treatment creep may reward developers with additional profits for inventing products whose use can be expanded to groups of patients who will benefit little.

Medical Arms Race

The "medical arms race" refers to hospitals and other facilities competing for business by making themselves attractive to physicians, who may care more about using new high-tech services than they care about lower prices. Many patients also prefer the latest, high-tech treatments. Because hospitals want to keep equipment operating near capacity in order to recoup its costs—and physicians make money by helping them do so—providers often use expensive technologies for patients for whom the health benefits are small. Robotic surgery for prostate cancer and proton beam radiation therapy provide striking examples of undesirable treatment creep: Although there is little or no evidence that they are superior to traditional treatments, these high-cost technologies have been successfully marketed directly to patients, hospitals, and physicians. High market rewards for such expensive technologies encourage inventors and investors to develop more of them—regardless of how much they improve health.

Options to Reduce Costs and Risks of Invention and Approval

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Using perspectives suggested by the innovation pathway, literature, our interviewees, and a panel of experts convened for the project, we developed ten high-priority policy options. These are the options that we think are most promising in terms of advancing our two policy goals, based on all of our sources of information and our judgment about which of the many options that we considered are most likely to have major impact. We first present five options for encouraging the invention of drugs and devices that would further our policy goals by reducing the costs and/or risks of invention and obtaining FDA approval:

1. Enable more creativity in funding basic science.
2. Offer prizes for inventions.
3. Buy out patents.
4. Establish a public-interest investment fund.
5. Expedite FDA reviews and approvals.

Enable More Creativity in Funding Basic Science

Invention of new medical technologies typically builds on a base of basic biomedical science. Major breakthroughs in medical product development often require earlier breakthroughs in basic science, which likely require many scientists to pursue innovative and risky research programs. For the most part, however, the National Institutes of Health (NIH), the largest federal investor in biomedical research, relies on methods for choosing and funding research that favor low-risk projects, and if

investigators fail to achieve their project goals, future NIH funding becomes less likely. A different model is used by the Howard Hughes Medical Institute, which funds scientists rather than projects, encourages risk-taking, and seems more willing than NIH is to provide additional funding to scientists whose past risky endeavors did not pan out.

Offer Prizes for Inventions

Substantial "prizes" could be awarded to the first individuals or groups that invent drugs or devices that satisfy prespecified criteria relating to their performance. Prizes could be offered by such public entities as the Centers for Medicare & Medicaid Services (CMS) or NIH, by private health care systems, by philanthropists and charitable foundations, or by public-private partnerships. An intriguing alternative to an immediate cash payment is a share of future savings to the Medicare program that could be attributed to an invention.

Buy Out Patents

Purchasing patents on products that have already been invented could increase rewards for inventing products that could decrease spending but are financially unattractive to inventors and investors. Public agencies, private philanthropists, or public-private partnerships might purchase patents. The purpose would be to ensure that a product is commercialized and offered at low prices. A purchaser could (1) put the patent in the public domain, and offerings by several manufacturers could then generate price competition, or (2) license the technology selectively, specifying the highest price that licensees could charge for the product. Realistically, only a small number of patents could be purchased if purchasing required full payment up front, so purchasers would need to be very selective. As with prizes, however, the best approach might be to offer patent holders a share of the savings to the Medicare program that could be attributed to the patented inventions.

Establish a Public-Interest Investment Fund

The market rewards for inventing products that reduce spending are often too low to be attractive to private investors. A public-interest investment fund (PIIF) could finance such inventive efforts. Such a fund would require both initial and ongoing investment capital.

Rather than relying on government officials to "pick winners," it would be very desirable to tap the expertise of experienced private-sector investors. A private-public partnership might be the best approach for doing so. For example, private investors could be motivated to help make the investment decisions by being allowed to invest in projects supported by the fund, with a share of Medicare savings offered to make potential returns attractive to them.

Expedite FDA Reviews and Approvals for Technologies That Decrease Spending

Review and approval processes could be speeded up, but not watered down, for medical products that are expected to substantially reduce spending. Four mechanisms already exist to speed FDA review and approval. However, criteria for which drugs and devices can use these mechanisms involve only health effects—e.g., a product will fill an unmet need for a serious condition. Creating a mechanism to expedite reviews for products expected to reduce spending could lower inventors' regulatory costs for such products. Creating the mechanism would require new legislation to expand the FDA's mission to include spending.

We also present five options for encouraging the invention of drugs and devices that would further our two policy goals by increasing market rewards.

1. Reform Medicare payment policies.
2. Reform Medicare coverage policies.
3. Coordinate FDA approval and CMS coverage processes.
4. Increase demand for technologies that decrease spending.
5. Produce more and more-timely technology assessments.

Reform Medicare Payment Policies

If CMS were allowed to consider cost in determining payment rates—which would require new legislation—the agency could set Medicare rates to save money in the short run and improve inventors' incentives over the long run.

One widely discussed possibility is for Medicare to move more quickly away from FFS payment approaches and toward approaches that reduce financial rewards to providers when spending is higher than needed to deliver quality care. Such approaches include *bundled payment* for episodes of care and *capitated* arrangements that provide fixed payments per person to provide all covered care. Expanding the use of such payment approaches—CMS already uses prospective payment approaches for hospital stays outpatient procedures—would put providers at financial risk for low-value care in additional circumstances and thereby increase their demand for less costly approaches to care. In turn, this could increase demand for medical products that would decrease spending.

Reform Medicare Coverage Policies

CMS could change its coverage determination policies in ways that would increase the health benefits per dollar of Medicare spending. We suggest several potential reforms, some of which would require new legislation. For example, CMS could expand use of its existing “coverage with evidence” process. Medicare could also stop paying for tests, procedures, and technologies that clinical experts have deemed inappropriate or ineffective; many of these have already been identified by the Choosing Wisely initiative. Medicare could also stop covering off-label use of some very expensive cancer and other specialty drugs in circumstances in which there is little or no evidence of effectiveness—a reform that would require new legislation.

Coordinate FDA Approval and CMS Coverage Processes

Another potential way to stimulate invention of products that decrease spending is to coordinate CMS coverage and payment determination processes with FDA review and approval processes. This could involve, for example, concurrent reviews, with CMS specifying early in the FDA review process what evidence CMS requires in addition to that required by the FDA. NIH scientists might also be involved as experts.

Coordination could reduce the time required to move a product to market. This option could be viewed as an extension of the FDA's Innovation Pathway 2.0 initiative. Identifying the best approach might be informed, for example, by what is learned from existing efforts involving parallel review by FDA and CMS. The Office of the Secretary of the U.S. Department of Health and Human Services would be an appropriate venue for considering the potential for coordination, the pros and cons of different

approaches, and specifying new requirements and rules.

Increase Demand for Technologies That Decrease Spending

Changing payer, provider, and patient incentives could increase demand for products that seem likely to help reduce spending. An across-the-board increase in cost-sharing or increasing use of high-deductible health plans could lead patients to request low-cost services or reject physician recommendations for high-cost ones. However, across-the-board increases in cost-sharing are undesirable because they undermine the financial risk–pooling function of insurance, and patients are likely to cut back on both low- and high-value care in response.

A more promising alternative is expanding use of value-based insurance designs (VBIDs), which require patients to pay more out of pocket to receive low-value services than for high-value ones. A key challenge for VBID, as for other policy options we have mentioned, is determining whether a service has high or low value for individual patients. This leads to our last policy option.

Produce More and More-Timely Technology Assessments

Health technology assessments (HTAs)—comparative effectiveness and cost-effectiveness analyses, for example—provide systematic evidence about the safety, efficacy, effectiveness, and cost of drugs, devices, and procedures. Such evidence can help payers and providers predict which patients are likely to benefit substantially from a technology's use. HTAs are conducted by both public entities and private organizations. Some of the latter share their assessments at no charge, while others do not. Medical technology evolves quickly, and thus HTAs are more useful when they are more current. Much more will be learned in the coming years about the comparative effectiveness of many medical interventions through research supported by the Patient Centered Outcomes Research Institute (PCORI). A provision of the Affordable Care Act, however, greatly limits consideration of costs in research supported by PCORI.

There is an emerging commercial model for producing more-timely HTAs. Specifically, rather than spending years to produce an HTA and updating it only years later if at all, a commercial entity called UpToDate keeps abreast of the literature via frequent literature searches and revises its HTAs whenever new findings warrant.

Concluding Thoughts

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The rate of growth of U.S. spending on health care appears to have declined in recent years, and some ongoing trends will help reduce spending. The facts remain, however, that spending on health care in the United States constrains our opportunities to make progress on major public and private priorities other than health, and there is substantial room for reducing spending in ways requiring only fairly small sacrifices in population health.

Because the stakes in reining in health care spending and getting more health benefits from the money we do spend are so high, we believe that all promising options should be considered—*and the sooner the better*. However, as helpful as it may be to change the nature of future drugs and devices, we cannot reasonably expect our two policy goals to be adequately addressed only by changing the incentives of inventors. For example, much of our health care spending does not involve drugs or devices.

Various stakeholders can be expected to resist many of these policy options. Fundamentally reforming Medicare would likely meet the most powerful resistance. Much of the resistance will decry

"rationing" and invoke "rights" of access to health care. Indeed, implementing some or all of our policy options would deny some U.S. residents medical care that would benefit them. However, because it is often the case that people other than the patient are paying the bills, it might be appropriate to conceive of consumer "rights" as pertaining not to all desired health care—effective or not, shockingly expensive or not—but rather only to effective and high-value care.

The longer we wait to institute fundamental reforms, the more money we will spend on health care offering little or no health benefit—and the harder it will be to achieve other major social priorities.

Footnotes

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