

# Healing Medical Product Innovation



No matter how it's tallied—in total, per capita, or as a percentage of gross domestic product—U.S. spending on health care outstrips that of any other nation. Many experts identify costly new technology as the biggest driver of health care spending. Previous studies aimed at reining in spending on technology have focused on changing how existing medical technologies are used. But what about also encouraging the creation of technologies that could improve health and reduce spending, or that provide large-enough health benefits to warrant any extra spending? A recent RAND study focused on policies that could help change which medical products—drugs, devices, and health information technologies—get invented in the first place.

To spur inventors to create medical products that lower health care spending and promote health, policymakers need to address the perverse financial incentives that lead inventors and investors in the opposite direction. Currently, large profits are most often available from creating increasingly expensive products that boost spending, whether or not they also substantially improve health. In contrast, inventors face relatively weak incentives to create products that would help decrease spending.

The RAND research team developed ten high-priority policy options that could change the costs, rewards, and risks that inventors and investors face. We synthesized information from scientific, trade, and popular literature; conducted interviews with more than 50 national experts from a variety of fields; sought input from a panel of accomplished technical advisors; and developed illustrative case studies of eight medical products.

## Who are the key players along the medical product innovation pathway?

In its simplest form, the innovation pathway for medical products has three stages—*invention, regulatory approval, and adoption*. Figure 1 shows key actors at each stage—the individuals and entities that make the most important decisions—as well as individuals and entities that seek to influence them. For example, inventors and investors obviously play key roles in the invention stage. The U.S. Food and Drug Administration (FDA) is the dominant player in the approval stage, and the physicians and hospitals deciding which technologies to use for which patients largely determine how quickly and broadly a product is adopted, thus determining a product's success in the U.S. market.

Inventors and investors are strongly influenced by their expectations about the prospects and costs of gaining regulatory approval and the eventual



The Centers for Disease Control and Prevention designated vaccines universally recommended for children, including the *Haemophilus influenzae* Type b (Hib) vaccine, as one of the country's ten great public health achievements of the 20th century.

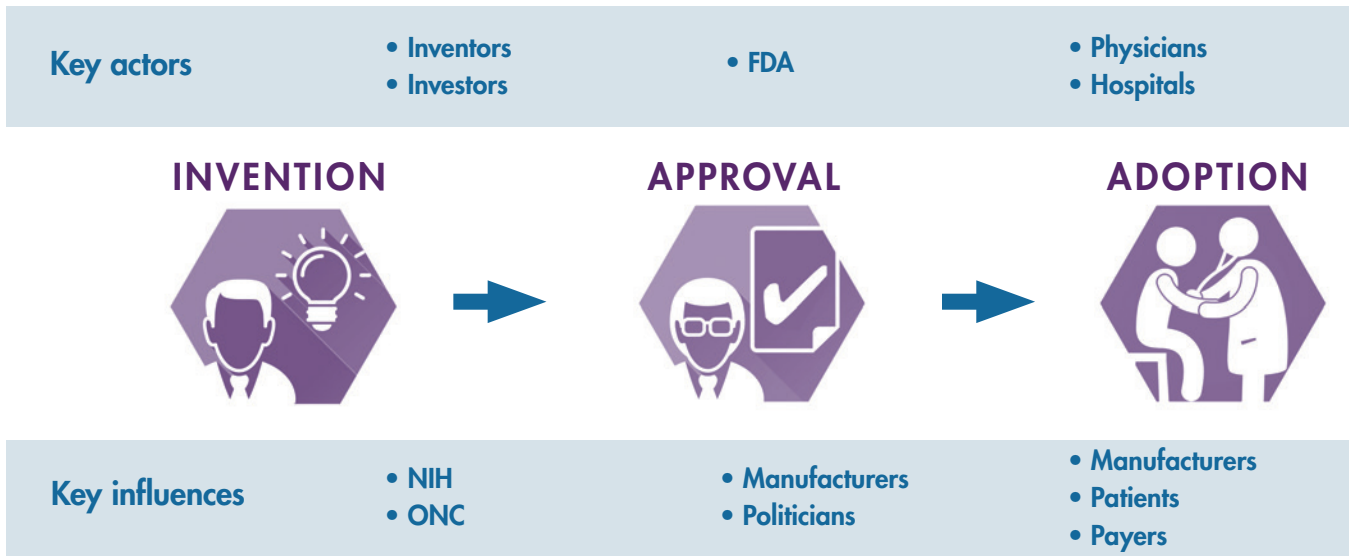
adoption and use of their products. In turn, these expectations determine the anticipated costs, risks, and market rewards of pursuing their ideas for creating new medical products.

The decisions of key actors are influenced by others—for example, the National Institutes of Health (NIH), as the nation's principal funder of basic biomedical research, provides fuel for invention by virtue of its investments in creating basic scientific knowledge. Manufacturers, patients, and payers all try to influence a product's use for different reasons and with varying degrees of success.

## What drives the costs, risks, and rewards of medical product invention?

The decisions of inventors and investors are largely driven by two considerations. The first is a technical assessment of whether the new product can be successfully brought to market and, if so, how much

## The Medical Product Innovation Pathway (Figure 1)

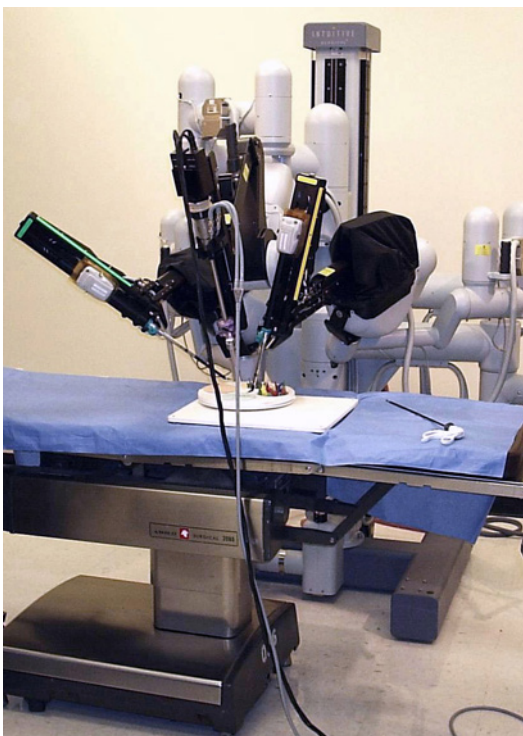


NOTE: ONC=Office of the National Coordinator for Health Information Technology.

money and time it will take. The probability of success is influenced by perceptions of risks: *scientific risk* (will the technology work?) and *regulatory risk* (will the FDA approve it for use?).

The second consideration is financial: Are the anticipated rewards of bringing the product to market big enough to justify the associated costs and risks at all three stages?

We identified five features of the U.S. health care environment that substantially affect the costs, risks, and rewards of medical product invention for inventors and investors. The five are set forth on the following page; to amplify the descriptions, we include paraphrases of comments from our expert interviews. The policy options that we developed were designed to address these features.



About 80 percent of all radical prostatectomies in the United States today are performed with robotic assistance, but there is no good evidence that robotically assisted radical prostatectomies produce better outcomes or have fewer serious side effects than manual radical prostatectomies.

# Roadblocks to High-Value Medical Product Innovation

## Lack of Basic Scientific Knowledge

Knowledge gaps increase the risk of failure, the likely costs, and the time required to bring to market products that could help decrease spending.

## *From the Experts*

When making decisions about where to invest R&D resources, developers consider the state of the basic science.

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## Costs and Risks of FDA Approval

The FDA approval process takes time and money; until FDA approval is granted, inventors and investors may receive no returns from the U.S. market to help recoup their investments.

The biggest impediment to high-value innovation—one that pushed developers to go in safer directions—is the difficult regulatory pathway.

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## Inadequate Rewards for Medical Products That Decrease Spending

Innovators who develop products that could reduce spending often cannot expect adequate market rewards for their efforts. Reasons include the facts that insured consumers do not pay the full price once they have exceeded their deductibles; many patients assume that newer, more expensive products must be better; and providers making decisions to use—or not use—a particular product often reap larger financial rewards from using a costlier alternative.

The reason that developers are deterred or discouraged from creating high-value technology that lowers overall spending revolves around reimbursement. . . . There's no market incentive.

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## Treatment Creep

Medical technologies that provide substantial health benefits to particular kinds of patients are often used for other kinds of patients, including many for whom there are small, or no, health benefits.

Companies will sometimes focus on one population to get over regulatory hurdles and then shift the focus for longer-term marketing.

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## Medical Arms Race

Health care providers such as hospitals often compete for business by offering the latest high-tech equipment or service rather than by offering greater value through larger health benefits and/or lower prices.

Marketing robotic surgery to hospitals for use in prostate surgery was “genius,” but there was no evidence that using the robot improved health outcomes.

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**In short, the medical innovation system is broken.**





A major limitation of today's electronic health records is the lack of interoperability between systems.

## How can we redirect invention of medical products?

Our analysis led us to ten high-priority policy options that could alter the financial incentives driving medical-product innovation. Some options would *directly* affect inventor and investor decisions by lowering invention or approval costs and risks. Other options would *indirectly* influence inventor and investor incentives by altering the expected market rewards of an invention. Figure 1 on page 3 highlights the stage of the innovation pathway at which each option operates. Policy options are described briefly on the pages that follow.

These options, individually or in combination, could redirect inventive efforts toward products that would help reduce health care spending and/or ensure that new products will provide health benefits that warrant any spending increases.

### Illustrative Case Studies of Health Care Technology

- Avastin for Metastatic Breast Cancer
- A Cardiovascular Polypill
- Electronic Health Records
- *Haemophilus influenzae* Type b (Hib) Vaccine
- Implantable Cardioverter-Defibrillator
- Prostate-Specific Antigen
- Robotic Surgery
- Telemedicine

Full case studies available at [www.rand.org/t/RR308-casestudies](http://www.rand.org/t/RR308-casestudies)

The FDA approved the use of Avastin for metastatic breast cancer patients, but later withdrew that approval. Nonetheless, by law, Medicare continues to pay for Avastin used for those patients because this use is listed in major drug compendia.



# Ten Policy Options for Healing Medical Product Innovation

## Enable More Creativity in Funding Basic Science

1

NIH's method for selecting which research to fund typically favors low-risk projects; if investigators fail to achieve their project goals, prospects for future NIH funding are greatly reduced.

A different model is used by the Howard Hughes Medical Institute. It funds scientists rather than projects, encourages risk-taking, and seems more willing than NIH is to continue funding promising scientists whose past risky endeavors did not pan out.

## Offer Prizes for Inventions

2

Substantial prizes could be awarded to the first individual or group that invents a drug or device that satisfies pre-specified criteria. Prizes could be offered by public entities such as the Centers for Medicare

& Medicaid Services (CMS) or NIH, by private health care systems, by philanthropists or charitable foundations, or by public-private partnerships. An alternative to an immediate cash prize is to offer a percentage of future savings to the Medicare program attributed to the invention.

## Buy Out Patents

3

Purchasing the patents of products that have already been invented could ensure that a product is commercialized at a lower price, increasing the immediate reward for inventing products that

decrease spending. Public agencies, private philanthropists, or public-private partnerships might be purchasers. A purchaser could put the patent in the public domain, generating price competition, or license the technology selectively, specifying the highest price that licensees could charge. The best approach might be to offer patent sellers a share of the savings to the Medicare program attributed to the invention.

## Establish a Public-Interest Investment Fund

4

Private investors often find the likely market rewards for inventing products that reduce spending too low to be attractive. When this is the case, a public-interest investment fund could provide the required

investment capital. A private-public partnership could tap the expertise of private-sector investors who are most capable of assessing the promise of technical concepts and inventors. They could be motivated to participate by being allowed to invest in projects supported by the fund, with their financial returns coming from a share of Medicare savings attributed to the inventions.

## Expedite FDA Reviews and Approvals for Technologies That Decrease Spending

5

The FDA could offer expedited—but not watered-down—review and approval processes for medical products with clear potential to substantially reduce health care spending. Creating such mechanisms

could lower inventors' regulatory costs and speed entry to market.

## Reform Medicare Payment Policies

6

Currently, CMS is not allowed to consider cost in determining payment rates—if it were, 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 swiftly to adopt approaches—such as bundled and capitated payment arrangements—that put providers at financial risk for costs not required to deliver high-quality care. Expanding the numbers of providers facing and circumstances involving such risks should boost demand for cost-saving drugs, devices, and other health care technologies.

## Reform Medicare Coverage Policies

7

CMS could change its coverage determination policies in ways that would increase the health benefits per dollar of Medicare spending. For example, CMS could expand use of its existing "coverage

with evidence" process. Medicare could also stop paying for tests, procedures, and products that clinical experts have deemed inappropriate or ineffective; many of these have already been identi-

fied by the American Board of Internal Medicine Foundation's *Choosing Wisely* initiative. Medicare could also stop covering off-label use of some very expensive cancer and other specialty drugs in circumstances for which there is little or no evidence of effectiveness. Some of these policy changes would require new legislation.

### Coordinate FDA and CMS Processes

8

For products that are likely to help reduce spending, CMS coverage and payment determination processes could be coordinated with FDA review and approval processes. Coordination could reduce the

time required to obtain revenues from the Medicare market. Identifying the best approach might be informed by what is learned from current efforts involving parallel review by FDA and CMS.

### Increase Demand for Technologies That Decrease Spending

9

Changing payer, provider, and patient incentives could increase demand for products that decrease spending. One promising approach is expanding use of value-based insurance designs (VBIDs),

which require individual patients to pay more out of pocket to receive services that are less likely to benefit them. A major challenge in implementing VBIDs is determining which services are more and less likely to substantially benefit individual patients.

### Produce More and More Timely Technology Assessments

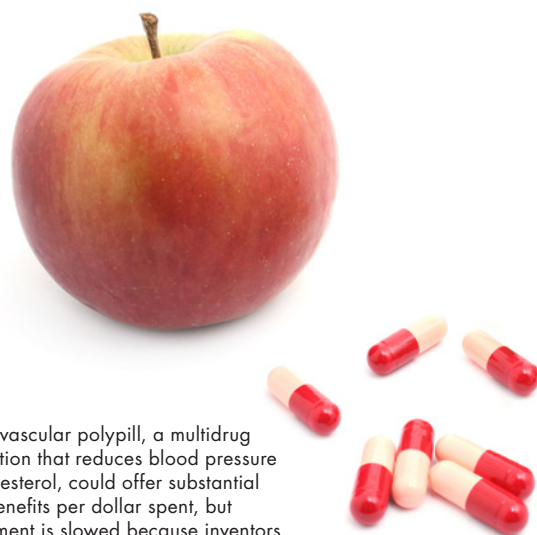
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Health technology assessments (HTAs) provide systematic evidence about the safety, efficacy, effectiveness, and cost of drugs, devices, and procedures. Because medical technology evolves quickly, HTAs

are more useful when they are more current. An emerging commercial model may suggest a good way to produce more timely HTAs—namely, by keeping abreast of the literature through fairly frequent literature searches and revising HTAs when new findings warrant.

Several of these options are novel; thus, there are few precedents or existing analyses to help policymakers design and successfully implement them. Others have already been proposed but not implemented. In our view, the potential benefits of implementing specific policies could dwarf the costs of doing so. For example, the potential savings to the Medicare program alone that could result from implementing several of the options would generate a large pool of money that could be used to spur invention of products that reduce spending or provide substantial health benefits.

Because the stakes in reining in health care spending are so high, and the need to get more health benefits from the money we spend is so great, we believe all of these options should be considered—the sooner the better. ■



A cardiovascular polypill, a multidrug combination that reduces blood pressure and cholesterol, could offer substantial health benefits per dollar spent, but development is slowed because inventors cannot justify the cost required to seek regulatory approval.

## Technical Advisers

To help us achieve our project goals, we convened a panel of national experts to review our ideas and weigh the promise of various policy options suggested by our findings. The panel offered comments on our draft analytical framework, weighed the pros and cons of different case study topics, and suggested several policy options. However, the panel members do not necessarily endorse the study findings.

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