# Medical Research

In 1980, federal funding paid for more than two-thirds of the medical research in this country. Today it pays for less than half. Although much of the money for medical research now comes from private sources, the federal government—and its policies—continue to influence the pace and direction of that investigation.

## *Fast* Facts

- *With $28 billion in funding from the federal government, the National Institutes of Health supports the bulk of basic science in the United States (as opposed to clinical research, which is primarily funded by private industry). Page 92.*
- *According to a 2003 study by the Tufts Center for the Study of Drug Development, it costs on average nearly $900 million to develop a new drug. In a 2006 study, the same research group estimated that it takes on average $1.2 billion to develop a biologic therapy. Page 97.*
- *Congress enacted the Prescription Drug User Fee Act (PDUFA) in 1992. This legislation allows the FDA to collect money from drug companies to help fund their review of new drug applications. Page 99.*

Consider the typical drug. In many cases, it takes up to 17 years for a promising compound to wend its way through a complex research-and-regulatory process to become an approved medication. During the time a drug takes to go from bench to bedside, federal policy impacts not only the potential for discovery, but how and when that product is made available to the public.

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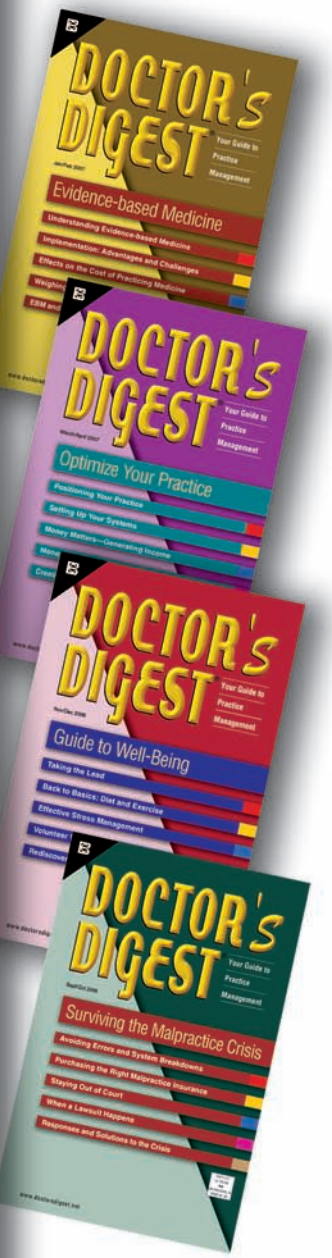


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That voyage often starts with the National Institutes of Health (NIH). With $28 billion in funding from the federal government, the NIH supports the bulk of basic science in the United States (as opposed to clinical research, which is primarily funded by private industry). Although there are 6,000 scientists directly employed by NIH, only a small proportion of the funding goes to support research within the Institutes. In fact, most of the research budget funds grants to medical schools, teaching hospitals, universities, and other research centers.

Within the past few years, NIH-funded studies have begun to venture more into the realm of clinical research in an effort to facilitate the translation of scientific discoveries to applied medicine. Still, most new discoveries are eventually turned over to private industry, which funds the remaining research and development on a speculative basis. Intellectual property laws, specifically the patent system, provide some guarantee that drug and biologic companies can not only recapture the more than $50 billion in research they fund each year, but make healthy profits as well.

The last stop in this process of getting new treatments to the public is the Food and Drug Administration's (FDA) approval process, which has been the subject of much debate in Congress lately. There has been a lot of open public discourse about what the agency has or has not done to ensure the safety of new medications. Not only have lawmakers stepped up their oversight of specific cases of approved drugs with problematic safety profiles, but many have also begun to question the very structure of FDA, which currently gets more than half its operating budget through user fees from industry.

## Turning on the Tap

The NIH has long been considered a jewel in the crown of the federal government. Increasingly, though, advocates in the medical community are voicing a concern that policies that have allowed funding for medical research to plateau will have a ripple effect that may not be felt for years.

The NIH budget doubled between 1998 and 2003, leading to an expanded research capacity. New laboratories were built, new faculty hired, and with the help of a completed map of the human genome, an explosion of new ideas was generated, says Dave

Moore, Director of Public Policy for the Association of American Medical Colleges (AAMC).

But that budget expansion came to an abrupt halt a few years ago—not even keeping pace with inflation. Tighter budgets are perhaps an understandable outcome of the real need to rein in the federal budget at a time when increased funds are going to the war on terrorism and the conflicts in Iraq and Afghanistan. However, observers say this budget tightening may leave research institutions at risk—and slow down the pace of important medical developments.

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"I don't think that there was any expectation on the part of the Congressional champions or on the part of the public that the 14-percent or 15-percent increases that occurred during the doubling were going to go on indefinitely," he adds. However, the research community didn't expect such a sudden pullback.

After taking into account a one-percent, across-the-board cut in funding, NIH's budget last year actually ended up being less than in 2005, making 2006 the first time in 36 years that federal funding for medical research dropped in real dollar value.

Many researchers complain that they are finding it more and more difficult to predict whether high-priority projects will get funded and ongoing grants will get renewed. Last year the National Cancer Institute (NCI) funded the top 11 percent of research grant applications. By comparison, in 2005, NCI funded the top 16 percent; and just a few years ago, the top 20 percent of research grants received NCI funds.

So, Mr. Moore says, just as the ramp-up of intellectual capacity hit its peak as a result of the budget increases of the past, NIH is funding a smaller proportion of grant applications. Without funding, research institutions have to cut back on staff and facilities. Mr. Moore believes that this will erode the country's hard-won research capacity and may slow down the development of important new therapies.

## FDA on Critical Path

In 2004, the FDA launched its Critical Path Initiative, an ambitious plan to improve the process of drug discovery and approval. However, despite vocal support in Congress for these goals, the effort has struggled along without funding.

"Today's revolution in biomedical science has raised new hope for the prevention, treatment, and cure of serious illnesses," Richard Pazdur, MD, director of the FDA's oncology drugs division, said during a 2004 House hearing shortly after the agency launched the Critical Path Initiative. "However, there is growing concern that many of the new basic science discoveries made in recent years may not quickly yield more effective, affordable, and safe medical products for patients. This is because the current medical product development path is becoming increasingly challenging, inefficient, and costly."

One basic concept of the Critical Path is to allow the FDA to step outside its role as regulatory agency so that officials can work with companies on developing industry-wide standards that will not only reduce the time it takes to move new drugs to market, but will help weed out unsafe ones sooner. The far-reaching goals of the initiative are to leverage new technologies in order to promote common goals in drug development, such as identifying safety signals early in development, targeting patient populations accurately, streamlining the approval process, and taking better advantage of post-market data collected within the clinical setting.

"For the current investment of $60 billion in science, last year we had only 18 new drugs. We believe a more efficient system that has a better process would be able to improve on that fivefold," says Raymond Woosley, MD, PhD, president of the Critical Path Institute in Tucson, Ariz. The Institute acts as a bridge between the FDA and industry, and has been able to act as a catalyst for projects proposed by the agency.

One of those projects is the Predictive Safety Testing Consortium, described in the FDA's news releases as an "unprecedented sharing of potential early indicators of clinical safety." The consortium includes 16 drug companies and more than 120 scientists who meet regularly to share their data and have it validated by the Institute's own experts.

The same scientists had been meeting with the agency for years, but individually their methods were of limited value to the FDA. In contrast, the Institute was able to come in as an impartial middleman to negotiate the terms under which the scientists could begin to talk to

each other as well as the agency.

"If you want to create a science-based agency, the key is to allow them to behave and work like scientists," says Robert Goldberg, PhD, vice president of the Center for Medicine in the Public Interest in New York City. "Scientists in America work on a collaborative basis."

Agency officials confirmed what Dr. Woosley and other Critical Path supporters have claimed, that despite industry support for Critical Path, the effort to move forward on the initiative's priorities has been hampered by inadequate funding and staff within the agency itself. Without a specific budget for Critical Path activities, FDA scientists have missed many of the meetings important to the initiative's goals or could attend only by using vacation or otherwise unpaid time off.

Last year the Bush administration proposed $6.7 million in funding for the Critical Path Initiative. While that request made it into the appropriations process, Congress never completed those bills, leaving the initiative once again in budgetary limbo.

Although $6.7 million would greatly improve the situation, that proposed funding level is small compared with the potential to save money through research into the effectiveness of treatments. Consider the example of bone marrow transplants, a procedure that costs more than $100,000 and had been performed on 3,000 to 4,000 women with breast cancer a year. With a federal grant of a couple of million dollars, just a fraction of what the nation was spending on the treatment, physicians established a comprehensive registry to track their outcomes. With the registry data, researchers found that the transplants were not only ineffective, they were actually harming women. This investment in effective research will end up saving millions of dollars—and will prevent unnecessary suffering.

Even without additional federal funding, the FDA has been undergoing an internal reorganization that will facilitate this effort. "Part of the goal is to make sure that FDA is right in the forefront of science, that we're not lagging behind or we will be a barrier to progress," said Janet Woodcock, MD, the agency's Chief Medical Officer.

That means modernizing the standards by which the agency judges investigation treatments, Dr. Woodcock says. "The point of the Critical Path Initiative is that these standards have to evolve. We can't just sit in 1970. We need to use up-to-date measurements, and we can't just have [drug or device] companies coming in and say, 'We want to use this [measure or biomarker],' which is what has been happening. There has to be a public and rigorous process," she says.

During the 1980s and early 1990s, there was a similar decline or slowing of the NIH budget. At that time, many institutions could make up for the decline with money from clinical services or other sources to help tide over investigators.

Unfortunately, due to reductions in reimbursement for clinical services, few institutions have that sort of flexibility anymore. They are being hit by cuts in funding from all angles.

**Dr. Loscalzo** also attributes attrition among the ranks of researchers to funding cutbacks: "As it becomes increasingly difficult for established investigators to renew their grants, their frustration is transmitted to trainees, who increasingly opt for alternative career paths, shrinking the pipeline of future investigators."

Joseph Loscalzo, MD, PhD, physician-in-chief and chair of medicine at Brigham and Women's Hospital in Boston, expressed concern in an editorial in *The New England Journal of Medicine* in April 2006: "Until approximately 20 years ago, clinical income often subsidized research; but managed care, increased scrutiny, efficiency in the management of clinical expenses, and reductions in federal support for teaching hospitals have rendered clinical margins insufficient to support the research mission," Dr. Loscalzo wrote.

Another factor is the long-term implications of tight funding that discourage new physicians from pursuing clinical research projects. Mr. Moore says this is causing some physicians to turn away from research projects and focus solely on their clinical practice. "And that would be unfortunate, because we need more physicians who are trained in research to do these translational and clinical applications," he says, referring to research that moves an idea from the basic science stage to an actual treatment for people.

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The impact is being felt across the country by academic centers and institutions, which receive about 85 percent of the federal research funding. NIH spends about 10 percent of its annual budget on intramural research (i.e., research conducted at NIH);

the remaining 5 percent goes to administrative expenses.

The AAMC has launched a project to inform Capitol Hill staffers about this mix based on the theory that all politics is local—cutbacks in the NIH budget directly affect constituents nationwide. "There are really two messages here," says Mr. Moore. "One is that the NIH budget is spent across the country, and two is that there is this critical relationship between medical research and improving people's health. What's at risk is beginning to sink in.

"Members of Congress are beginning to understand what we potentially are going to lose if the erosion continues," Mr. Moore goes on. "Unfortunately, the NIH budget operates in a larger fiscal environment, and that is a very tight environment," he says.

It is because of that larger fiscal reality that advocates for more medical research have agreed to make a modest request for a 6.7-percent annual increase over the next three years.

"That is a well-thought-through percentage increase based on trying to get back on track after a period of plateaus and cuts," says Mary Woolley, President and Chief Executive Officer for Research!America, a not-for-profit alliance based in Alexandria, Va. "What that will do is re-establish a base from which to significantly grow the enterprise. It also recognizes that we have other national priorities that we have to address for the next few years. It's not a time to ask for all that could be used well, because frankly much more money could be used," she says.

## Next Stop: R&D

Research conducted at the NIH is just the first step in the development of new treatments, says Lila Feisee, Managing Director for Intellectual Property for the Biotechnology Industry Organization, a trade group that represents makers of biopharmaceuticals. "Basic research in and of itself is interesting. But you're not going to develop anything out of basic research unless something in it adds some commercial value or is something that will attract someone to develop it," says Ms. Feisee.

According to a 2003 study by the Tufts Center for the Study of Drug Development, it costs on average nearly $900 million to develop a new drug. In a 2006 study, the same research group estimated that it takes on average $1.2 billion to develop a bio-

logic therapy.

Recognizing a need to ensure return on investment despite the high cost of development, Congress passed the Drug Price and Patent Term Restoration Act in 1984. Also referred to as the Hatch-Waxman Act, the law gave makers of drugs and biologics the option to extend their market exclusivity up to five years, resulting often in millions of dollars in additional revenue.

"**Members of Congress** are beginning to understand what we potentially are going to lose if the erosion continues," Mr. Moore says. "We're not going to have new people coming into science, we're not going to be able to sustain ongoing initiatives, and the pace of research discoveries that are going to help people's lives, that's going to slow down. Unfortunately, the NIH budget operates in a larger fiscal environment, and that is a very tight environment," he says.

However, recently that law has come under fire due to a loophole that allows makers of brand-name medications to challenge, and therefore delay, the entry of generic versions to the market. Because generic drugs are often priced well below the brand-name agents, some lawmakers are arguing that this tactic is causing added cost for patients.

Lawmakers are discussing ways to tweak the patent laws that apply to drugs and biologics with the aim of balancing the need to encourage innovation against increasing pressure to allow lower-priced generic medications on the market sooner.

After a drug or biologic therapy has been researched at NIH and developed through private R&D, the final step is marketing approval, which is the purview of the FDA. For a drug to receive marketing approval, it must meet three criteria:

- The drug has to be safe and effective in its proposed use(s), and the benefits of the drug must outweigh the risks.
- The drug's proposed labeling is appropriate and contains all necessary information.
- The methods the pharmaceutical maker will use to make the drug are adequate to preserve the drug's identity, strength, quality, and purity.

Gaining approval used to be a long process, usually taking more than a year. Now the approval process rarely delays the introduction of a new drug by more than 6 months for acceler-

ated approval or more than 10 months for other drugs.

"Back in the late 1980s and the very early 90s, the FDA had so few resources that applications would come into the FDA, they would sit around, nobody would even look at them," says Janet Woodcock, MD, the agency's Deputy Director and Chief Medical Officer.

To help address this problem, Congress enacted the Prescription Drug User Fee Act (PDUFA) in 1992. This legislation allows the FDA to collect money from drug companies to help fund their review of new drug applications. Next year, the agency hopes to receive close to $400 million in user fees. The user fee program has helped the FDA bring in more review staff to conduct application reviews. With those new staff members, FDA has cut review time in half.

"The review times are very controversial; and although I think there is pretty scant evidence of this, many people believe that the speeded-up reviews are causing more mistakes. When [drugs are] approved, there is always a fair amount of uncertainty about how they are going to perform on the market, because the conditions are quite different from the pre-market condition," Dr. Woodcock says.

Review of an application does not mean that the agency has to give a thumbs up or down within the prescribed period, but it is expected to respond in some fashion within that window—whether that means approving the drug or requesting more information. And while the FDA tries to deal with all applications expeditiously, the six-month review period is not mandatory.

"If there is the occasional application where we can't get finished in that time, we just don't get finished," says Dr. Woodcock. However, about 90 percent of applications are processed within that window, she says.

These days the FDA is confronting new challenges. Increasingly, companies are coming to the agency earlier in their research-and-development stage to help ensure that the approval process goes smoothly. Those early conversations are soaking up a lot of staff time, says Dr. Woodcock.

"FDA is in charge of just everything you can think of, practically, almost all the food you eat, your toothpaste, medical devices, radiation-emitting devices, pet food, vaccines, repro-

ductive tissues, tissue transplants, biologics, and so forth. So the agency is really, really overextended in its realm of responsibilities," says Dr. Woodcock.

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While Congress has made efforts to authorize significant increases in funding through user fees, lawmakers have not substantially raised the money they appropriate for the agency—despite legislation that will increase the FDA's responsibilities for tracking potential problems with drugs on the market.

There are those who believe the user fees are the cause of the problems, rather than the solution. In March a group of 22 scientists wrote an open letter to members of the Senate Health, Education, Labor and Pensions Committee and the House Energy and Commerce Committee. In the letter, the scientists argued that problems in the FDA structure are contributing to the "serious problems in the nation's capacity to determine drug safety" identified by the Institute of Medicine (IOM). The scientists opposed reauthorization of PDUFA and instead called for "direct appropriations for the FDA," which would allow the FDA leadership to determine how the agency allocates its funding to fulfill all aspects of its mission, including post-approval surveillance and risk management.

## Changes to Come

Now in its fourth iteration, new PDUFA legislation would allow the FDA to collect nearly $400 million in fees from the industry starting in 2008. At press time, final legislation was still being negotiated.

"The resources and additional staffing made possible by the fees charged by the FDA have enabled the agency to review new medicines more efficiently, while maintaining its stringent safety and efficacy standards," says Billy Tauzin, president of Pharmaceutical Research and Manufacturers of America, a drug industry trade group. "The significant increases in user fees will

provide the FDA the resources necessary to improve and modernize its already strong drug safety monitoring system."

According to FDA recommendations to Congress, higher user fees will enable the agency to hire an additional 82 employees devoted to post-approval safety efforts. In addition to the raise in user fees, the reauthorization legislation requires the FDA to modernize its post-marketing surveillance procedures.

"This is going to be the biggest set of changes in post-market drug regulation since at least 1962," Mark McClellan, MD, former director of the FDA and now at the American Enterprise Institute, said at a recent drug safety forum. "FDA will be doing no less than entering a new era of post-market drug regulation."

Many of these reforms have come about in light of high-profile safety problems, such as those with COX2 inhibitors, wherein certain heart risks were not identified until after the drugs had been widely prescribed. The current system relies on physicians or patients to report adverse events to drug companies, which in turn report them to the FDA.

"This [information] goes into a database that collects several hundred thousand and growing adverse event reports per year …It's very important for helping the FDA identify problems, but it is not population based. It is not systematic. It doesn't capture anywhere near all of the adverse events out there," says Dr. McClellan.

The legislation would give the FDA the resources to modernize its electronic systems and software. In addition, for the first time, the agency would have access to both public and private databases that would help it build a more complete picture of possible safety problems. According to one analysis, if the FDA had had such a surveillance system in place when rofecoxib went on the market, it would have taken months instead of years to pick up on potential safety problems, said Dr. McClellan.

Moving forward, the FDA will also have more authority over approved drugs if problems are identified during post-marketing surveillance. Unfortunately, there are no guarantees that the FDA will use that authority effectively, says Curt Furberg, MD, a professor at Wake Forest University School of Medicine and a member of the FDA Drug Safety and Risk Management Advisory Committee. "The FDA does not have a good track record.

## Stem Cells Debate Continues

It's a debate that swells emotions on all sides: Stem cells hold great promise to cure disease and heal the injured, but research into this arena requires the use of human embryos. Trying to walk the thin line between promoting important science and stepping into uncharted moral territory, President George Bush in August 2001 signed an executive order restricting the use of federal funds for research involving embryonic stem cells to existing lines.

At the time there were believed to be as many as 78 eligible stem cell lines. As of March 2007, the number of stem cell lines available for federally funded research was 21, according to the NIH Human Embryonic Stem Cell Registry. Research!America, a coalition promoting medical research, says as many as 400 cell lines have been developed since President Bush's executive order. These additional cell lines are not eligible for federally funded research.

Over the past few years, the NIH has spent a little more than $600 million on all forms of stem cell research. However, less than $40 million of that money has funded research on human embryonic stem cells, while nearly half has been spent on non-human, non-embryonic research.

Within the past two years, Congress has passed two bills that would have expanded the availability of federal funding to new stem cell lines derived from excess embryos donated by fertility clinic patients. However, President Bush has stood fast, vetoing both measures.

The White House maintains that it is possible to pursue stem cell research without destroying human embryos. In a statement in June 2007 when he vetoed the latest legislation, the President pointed to the potential to "reprogram" adult cells to make them act like stem cells and to recent discoveries that indicate that amniotic fluid and placental tissue may also yield stem cells that may be capable of flexibility similar to embryonic cells.

According to a survey by Research!America, stem cell research has broad public support. That organization recently found that a majority of voters (56 percent) support expanded federal funding and (58 percent) opposed President Bush's decision to veto it.

The ban on federal funding does not mean that the research itself is banned. Currently, embryonic stem cell research on new cell lines may be funded either through a growing number of state efforts or with the help of the money donated by foundations and individuals.

"There has been more private support for embryonic stem cell research," says Mary Woolley, president and chief executive officer for Research!America. But, she adds, "It is nothing like what is needed."

She says that private funding may not reach as far as increased federal funding because dollars must first go to setting up the infrastructure for the research—which already exists in the public sector and at institutions funded by the government. "They are recreating the infrastructure, including literally the buildings for that research to be conducted, at huge expense," she says. "It's money that could be going to the research itself."

Some scientists studying embryonic stem lines with federal funding have set up two separate labs, one facility to handle the federally approved lines and another to work with unapproved lines.

Internationally, stem cell research has taken off, raising concerns that the United States will get left behind. "Many, if not all, researchers in this field believe that more interesting work is being done elsewhere and that if NIH had a different regulatory posture, [more] could be done with NIH money," says Ms. Woolley.

At the same time, others are concerned that in their rush to establish their own research protocols and requirements for stem cell research, the states may be treading into difficult ethical territory. For example, some contend that states have set up laws that could pave the way for therapeutic cloning, which involves somatic cell nuclear transfer using unfertilized human eggs. While researchers are usually barred from offering financial incentives to women to obtain the embryos from which the stem cells are derived, state laws may not include the same protections for unfertilized eggs. In theory, women could still be encouraged to sell their eggs despite the health risks of the procedure for harvesting them, opponents say.

A breakthrough in privately funded research may significantly change the tenor of this debate. Advocates point out that there was initially a lot of resistance to in vitro fertilization on ethical grounds. However, once a number of grateful new parents spoke out, much of that opposition backed down.

"It would be pretty hard to argue against embryonic stem cell research if indeed we find a cure for diabetes using stems, or we find a way to help people with paralytic injuries walk again or move their limbs or something that reverses the symptoms of Parkinson's disease," Ms. Woolley says.

But it won't likely be that simple. "This is an issue that is not going away," Ms. Woolley admits. "It will continue to be debated in Congress. It will continue to be a bone of contention between the majority in the Congress and the administration. It is by no means a simple, partisan issue, but the Congress does not have enough votes to override a veto."

I'm not optimistic," he admits. "The FDA loses interest in a drug after it is approved. The just don't pay much attention to it."

In a survey of staff scientists in the agency's Center for Drug Evaluation and Research, 66 percent said that they were less than wholly confident that the FDA adequately monitors the safety of drugs after they hit the market. Across the agency, 50 percent of respondents said they did not believe that the FDA was headed in the right direction.

Many of the scientists commented that increasingly politics was trumping the science, according to the Union of Concerned Scientists, a nonprofit group based in Cambridge, Mass., which conducted the survey.

Studies conducted by both the Government Accountability Office (GAO) and the Institute of Medicine, including discussions with agency rank and file, have concluded that the FDA is suffering from chronic organizational problems that have promoted interagency conflicts between different offices. There has also been a revolving door for top leadership that has made fixing the organizational problems that much more unlikely, the GAO reported to Congress.

Such problems may have allowed a number of potentially unsafe drugs to slip through the system and created a "crisis in public confidence," according to Steven Nissen, MD, who until last year chaired the FDA's Cardiovascular and Renal Drugs Advisory Committee.

"We have to work a lot harder now…to keep the politicians out of the science as much as possible and to keep the commercialization of science from coloring everything we see and hear of scientific value," he says.

Congress has done a lot over the past decade to speed the approval process, says Merrill Goozner, director of the Integrity of Science Project at the Center for Science in the Public Interest and author of *The $800 Million Pill: The Truth Behind the Cost of New Drugs* (University of California Press, 2004). "Every law passed since the 1992 Prescription Drug User Fee Act has been designed to expedite the consideration and approval of new drugs," he says. "The introduction of surrogate markers, the creation of an accelerated approval track, and guarantees in the user fee law that new drug applications will be con-

sidered within a specific time period have all worked to expedite the process and make it easier to develop new drugs."

It's clear now that both Congress and the FDA need to focus more attention on ensuring that drugs are safe after they are approved, says Mr. Goozner. The agency should monitor drugs for the first few years after approval before drug companies are allowed to begin aggressively marketing them, he says.

"Of course, I'd exempt truly lifesaving or unique therapies from these requirements," Mr. Goozner adds, "but when it comes to the next blood pressure, cholesterol-lowering, or diabetes management drugs—where there are already plenty of alternatives on the market—prudence in the rollout would be the wiser course in terms of protecting the public from potentially unsafe products."

## Back to NIH

While the role of NIH remains largely one of funding basic research and fueling new discoveries, in recent years the Institutes have begun to delve into clinical research, with support from lawmakers.

"Congress has not dictated in great detail how NIH spends its money, but there has been an expectation, particularly since the doubling of the budget, that has been expressed by certain members of Congress that NIH should be doing more on the clinical side, that NIH should be doing more to get products out to the public, although that has never been articulated in legislation or an appropriation bill," says AAMC's Mr. Moore.

So far, much of this clinical research has focused on the area of rare diseases—conditions or illnesses that affect only a small population of patients. NIH has also started some research on treatments for which there may be no clear commercial applicability. This has allowed NIH researchers to take advantage of expanded knowledge within the basic sciences.

Congress passed a reauthorizing measure last year, signed into law at the beginning of this year, that gave the NIH director more discretion to fund research that crosses institutional boundaries—for example, research into stroke rehabilitation that brings together scientists from the biological, behavioral, computational, and engineering sciences.

"To a certain extent, that was Congress responding to the way science is now being conducted. It's not simply disease-focused types of research, but it's research that cuts across areas of science," says Mr. Moore.

But, according to Mr. Moore, this approach has set up a potential conflict among advocacy groups. "You really have these two forces at work," Mr. Moore explains. "On the one hand, science is being done in a more interdisciplinary nature, in a more trans-institute way. At the same time, you have a lot of folks wanting to focus on a specific or individual disease."

**"One thing that has occurred** over the past 20 years is that anytime the budget gets tight, people try to look after their own individual disease interests," says Mr. Moore. "We have seen a lot of that over the past couple of years."

For politicians, that means having to answer questions from their constituents about how much is being spent on Alzheimer's disease, diabetes, or cancer. "One thing that has occurred over the past 20 years is that anytime the budget gets tight, people try to look after their own individual disease interests," says Mr. Moore. "We have seen a lot of that over the past couple of years."

While the role of NIH in studying the application of research findings will likely be debated, the government does have an important part to play in ensuring that knowledge is turned into application, says Research!America's Ms. Woolley. In addition, funding for health services research is needed to ensure that the medical care being delivered today is evidence based and up to date. "Unfortunately, quite a bit of [today's health care] is neither of those right now," she says.

Americans expect high-quality care, but there is a lot we know about improving people's health that we don't necessarily know how to apply, she adds.

For example, "If we knew more about how to help people make appropriate nutritional choices, we could make a huge difference for health in this country. If we knew how to get that last 25 percent of the population that's still smoking to stop, we could make an enormous difference for their health and for everybody around them," she says.

Research could help answer those questions.