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House Energy and Commerce Subcommittee on Health Holds Hearing on Implementing NIH Research
LIST OF SPEAKERS

BILIRAKIS:

As everyone here today is aware, we recently completed our effort to double the budget of the National Institutes of Health. I often say that while we're not famous for following through on our promises up here at Washington, this is one case where I think Congress really came through for the American people. However, it is our job to ensure that we get the most out of this massive investment of resources.

Today's hearing is another in a series of hearings that will examine different aspects of NIH, and we'll focus today on how private industry's partnership with the federal government helps move new discoveries from the bench to the bedside. After all, what good is the bench without it getting to the bedside?

As we will no doubt discuss today, the 1980 Bayh-Dole Act laid the foundation for our current system of technology transfer. Prior to Bayh-Dole, the federal government held the patent rights to new technologies that were developed using federal funds. This greatly discouraged private sector innovation and the translation of these discoveries into useful products.

Bayh-Dole changed all of that by permitting entities such as universities and small businesses that develop new technologies using federal funds to retain title to these technologies. In addition, Bayh-Dole allowed federal agencies to license inventions that are developed through intermural research.

While we will spend the majority of this hearing learning more about technology transfer and its role in speeding new therapies to patients, it's safe to say that Bayh-Dole created a highly successful model that helps fuel our research driven by technology and pharmaceutical industries.

As we will hear from our witnesses, the technology developed using federal resources is often far from any potential commercial uses. Considering the substantial investment needed to turn these discoveries into therapies, it just makes sense for the federal government to partner with private entities willing to incur the necessary risk to bring new products to market.

I'm glad that we have a variety of perspectives on this important issue before us. I think that after today every member of the subcommittee will have a much better understanding of the relationship between the federal government, the research community and the private sector.

And again, I'd like to thank our witnesses for being with us today.

And with that, I will now yield to the gentleman from Ohio for an opening statement.

And we might be able to go through two or three opening statements, and then, of course, we'll have to recess for the vote and then return.

Mr. Brown?

BROWN:

Thank you, Mr. Chairman.

I think Ms. Capps and Mr. Stupak both want to (inaudible) their opening statements so they can move on to questions (inaudible), perhaps we can get through that.

I want to welcome our witnesses and look forward to hearing their testimony, and thank the chair for calling this hearing on this really important issue.

Each year for the last five years, NIH has been allocated several billion dollars to support basic research in biomedical science. (inaudible) the federal government is investing taxpayer dollars in the future of health care, improving health care through promoting scientific curiosity and discovery.

Universities, hospitals, institutes from my own state of Ohio have accepted the challenge as they have elsewhere in using public dollars to promote discoveries that some day will improve the health of not just Ohioans, but people in nation after nation around the world.

Case Western Reserve University School of Medicine is among the 20 top recipients of NIH research funding among the nation's medical schools. Just yesterday, Ohio State was awarded a grant as part of the public-private partnership initiated by the Friends of Cancer Research.

Yet today, House Republicans are asking my Democratic colleagues on the floor to -- and asking all of us -- to vote on an appropriation bill for the Department of Health and Human Services that jeopardizes the progress we've made. This bill falls short of what is needed merely to keep up with inflation and research costs, which NIH estimates at 3.3 percent for fiscal year 2004.

As is everything else around here, all important public functions like that have been cut in order to make room for a tax cut that goes overwhelmingly to the most privileged people in our society.

I will vote against this bill on the floor, because federal funding in biomedical research is a worthy investment, but questions about Congress's commitment to NIH research underscore the importance of understanding in both qualitative and quantitative terms the government's return on its investment in biomedical research.

The reason for today's hearing -- as I said, I thank the chair for this -- is to talk about how basic research investments in (inaudible) are realized as a public health benefit. This process is a complex system with many parts, each critical, each contributing to the success of the whole.

For this process to work, we must never forget that this process has a face; the face of a patient who one day can benefit from cancer vaccines, or from stem cell research, or from a novel diagnostic technique.

Policy (inaudible) like patents, the Bayh-Dole Act, the (inaudible) Act and incentives for commercialization are important links in the bench-to-bedside chain, but they are ineffective if at the end of the day a patient cannot afford or does not have access to treatment. They are ineffective if they discourage, rather than nurture, research formerly in the domain of open scientific discourse.

Congress has long recognized that the value of an idea is in using it. Bayh-Dole allows universities to patent and license discoveries made in the course of government-sponsored research. But growing concerns about the prohibitive costs of prescription drugs and their effect on the health care system overall has renewed debate over the licensing of inventions.

There are also concerns that some of the incentives can hinder, rather

than accelerate, research. In this context, the witnesses' views on key issues are extremely important.

Among others that Chairman Bilirakis raised, those issues include whether American taxpayers should accept an ends-justifies-the-means approach to justify the outrageous cost of prescription drugs when they've already subsidized the research on those drugs on the front end and seen drug prices significantly lower in other nations, as well as whether and to what extent patents may actually be hindering what our Constitution explicitly states is the intention of patents: promoting science and the useful arts.

I look forward, Mr. Chairman, to the enlightening discussion.

I thank you for calling this hearing.

BILIRAKIS:

The chair was going to recognize Mr. Burr.

Mr. Stupak?

STUPAK:

I waive to the chair.

BILIRAKIS:

I thank you.

Ms. Capps?

CAPPS:

(OFF-MIKE)

BILIRAKIS:

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Lindberg.
Please proceed sir.

LINDBERG:
Thank you, Mr. Chairman, for this opportunity to brief you and your colleagues about the National Library of Medicine. The role of the library is important to the nation's health, and this is due in large part to the strong support we have received from the Congress historically.

Progress in health care is a cyclical process, much as the title of your hearings implies. It starts with a problem recognized by a medical practitioner. This leads to a experiments or experimental observations. Scientists describe the results in what we now call the peer-reviewed scientific literature. This informs the next cycle of experiments, which in turn are read by clinicians to use in patient care and by patients to inform their participation in treatments and cures.

The National Library of Medicine, NLM, collects about 27,000 scientific periodicals from across the world and includes about 5,000 of the very best in the printed Index Medicus and the online Medline file. The print version started in 1879, the computer version effectively in 1965. NLM is the biggest medical library in the world, again due to the encouragement and support of the U.S. Congress, plus gifts from many historical holdings by scholars. The library is a major scientific and medical resource in the U.S. and abroad.

Let me give a measure of the information available to physicians. Medline holds the descriptions of over 14 million scientific reports. Each year we add 500,000 new ones. Clearly, no doctor or scientist can possibly know all that is described in this library.

Consider the case of a conscientious medical practitioner. Let us imagine the doctor faithfully reads every night before going to bed two articles from the specialty journals to which he or she buys. May one imagine then that the doctor has by this method kept up with progress? Really, no. By the end of such a year, this good doctor will have fallen 648 years behind on reading the new publications.

So in reality, what good doctors do is search the NLM files, without charge and available night and day on Internet, and read the best one or two articles for the particular patient problem of the moment.

We can or could tell you countless examples of getting a tough diagnosis made through this system, of selecting the best new drug for treatment, and even of coming to understand new terms and ideas through reading the right paper at the right time.

Special files cover complementary and alternative medicine, space medicine, bioethics, AIDS and toxicology.

There is also a version of this knowledge that is aimed at patients' families and the public. We call this Medline Plus. This is organized into about 600 health topics, including genetics information for the public.

An additional important computer resource for linking laboratory discoveries to clinical practice is clinicaltrials.gov. Here one can find out about over 7,700 clinical trials in over 75,000 American communities, including the purpose of the trial, the enrollment requirements and the telephone number of the investigator who can take on new patients.

The system began in 1998. It was created by NLM with initially the participation and support of all NIH institutes and subsequently inclusion too of trials supported by the major pharmaceutical manufacturers. The stimulus for creation of this system was congressional, namely the 1997 FDA Modernization Act which required that FDA, NIH, and NLM make some such system

available for serious and life-threatening diseases.

Mr. Chairman and members, so far I have described three major NLM computer-based information systems that provide the fundamental infrastructure that connects doctors, scientists and patients with worthwhile writings and publications on human health. This has worked well for really about 160 years. But now, a new science challenges us, the Human Genome Project. This and similar genomic studies on literally thousands of animals, plants, and microorganisms make our traditional books to some extent inadequate.

The human genome alone contains billions of nucleotide bases, tens of thousands of genes, hundreds of thousands of biological proteins, to do the work of the genes. I'm sure my colleague Francis Collins discussed this with you in earlier hearings before the committee, and doubtless more skillfully than I.

The simple point I want to make now is the genomic information simply is not readable from printed books. It is accessible only through a computer system that can present the right portions of the data along with the desired relationships.

This is comparable to the child's looking at a drop of pond water, the life of the teeming protozoa and bacteria is visible to today's school child, just as it was to Leeuwenhoek centuries ago, only through the lens of a microscope. At NLM, that microscope to modern medicine is the National Center for Biotechnology Information, NCBI.

NCBI was authorized by the Congress in 1989. It has the responsibility to collect and update and provide creative access to all the human genome data from the U.S. and abroad, as well as much else.

The spectacular new anti-cancer drug Gleevec, for example, came directly from clever use of these data by scientists in academia and at Novartis labs.

Taking together all of the NLM computer knowledge sources I have mentioned, these are used online more than a million times a day, 500 million users per year.

I apologize for describing only the outline of these systems in order to stay within my time. I also made a more detailed description for the record, and of course if you wish, I'd be happy to go into more detail or do my best to answer any questions.

Thank you.

BILIRAKIS:

Thank you very much, Dr. Lindberg.

And, of course, there will be questions, and so you'll have that opportunity.

Dr. Rohrbaugh, please proceed, sir.

ROHRBAUGH:

Chairman Bilirakis and members of the subcommittee, I am pleased to present to you a synopsis of NIH technology transfer activities, both within the National Institutes of Health and at institutions receiving NIH funds.

First I would like to speak to the NIH mission, which is to uncover new knowledge that will lead to better health for everyone.

In furtherance of this mission, we conduct our technology transfer activities with the following goals in mind: to expand fundamental knowledge about the nature and behavior of living systems, to improve and develop strategies for the diagnosis, treatment and prevention of disease, and to communicate the results of research to the scientific community and the public at large with the goal of improving public health.

One of the greatest challenges to realizing the promise of the NIH mission is the ability to translate basic research findings into drugs and therapies for patients. Translating a new drug discovery from the laboratory to an initial clinical evaluation in patients requires navigation of a multi-step review process involving several critical implementation issues over the course of six to 10 years.

This bench-to-bedside pathway often begins with the transfer of an early-stage technology developed in the course of federally funded research to a private sector partner.

ROHRBAUGH:

While this is but one step in a lengthy and expensive process, it is often the step that jump-starts the development of a new therapeutic product.

The overwhelming majority of the NIH budget, over 80 percent, is devoted to the support of scientists at approximately 1,700 organizations. This is what is known as our extramural program.

A much smaller portion of our budget, slightly less than 10 percent, supports research and training conducted by the federal scientists at NIH facilities. This is known as our intramural research program.

I believe it is important to make this distinction while discussing technology transfer activity because these two areas are governed by different legislative authorities.

In its broadest sense, technology transfer is the movement of information and technology from research findings to practical application, whether for further research purposes or commercial products. At the NIH, we transfer technology through publications of research results, exchange of data, sharing materials, public-private partnerships, as well as the patenting and licensing of technologies.

The NIH Office of Technology Transfer administers over 1,500 active licenses and approximately 2,400 patents and patent applications. In fiscal year 2002, we received more than $51 million in royalties from licensees. This accounts for about two-thirds of the royalties collected by all federal laboratories combined.

About 200 products have reached the market that include technologies licensed from the NIH; 17 of these are vaccines and therapeutics. We view these products as the best and ultimate measure of our success in facilitating the transfer of technologies that the private sector develops into products that benefit the public health.

This leads me to a brief discussion of the Bayh-Dole Act of 1980, which applies to recipients of federal funds. As you mentioned, Mr. Chairman, the act provides incentives to move federally funded inventions to the private sector, where they benefit the public.

With a few exceptions, the legislation does not prescribe methods to be used in the licensing of these inventions, but the institutions must agree to pursue practical application of inventions and to provide the U.S. government with the royalty-free right to use the invention for government purposes.

That federal government right does not extend from the federally funded technology to the final product except in those rare cases where the technology is the final product.

Moreover, this government right applies only to the patents -- that is, the intellectual property -- not to the materials themselves that constitute the physical embodiment of the invention.

In most cases, a federally funded technology is combined with other intellectual property or know-how, often proprietary to a company, to develop

the final product.

NIH-funded technology is usually at the earliest stage of development and requires much further investment to bring the technology to the marketplace. Thus technology transfer is a high- risk venture and few inventions ultimately result in products that reach the marketplace. Yet the NIH has been fortunate in having a number of its technologies licensed and incorporated into methods of making, administering or as components of new products.

In summary, the field of technology transfer facilitates the movement of research findings to promote further research or to develop them further into products of use to the public. It is through our statutory framework, unique institutions and public- private partnerships that the nation has created the most envied research enterprise in the world.

I can assure you, Mr. Chairman and members of the subcommittee, that the NIH is committed to its mission of improvement of public health and will utilize all the mechanisms it has to achieve this mission.

I thank you for the opportunity to come before you today, and I welcome any questions you may have.

BILIRAKIS:

Thank you very much, Doctor.

Dr. Barker?

BARKER:

Good morning. Thank you, Mr. Chairman and members for the opportunity to be here today to discuss a new task force that the NCI has established with the Food and Drug Administration. I have the privilege of co-chairing that task force, along with Dr. Mullin, who will speak after me.

Before highlighting the mission and work of this task force, I would like to focus just briefly on the stunning advances in biomedical research over the past few years that recently led our director at the National Cancer Institute, Andrew Von Eschenbach, to challenge the cancer community with a goal. And that goal is to eliminate suffering and death due to cancer and to do it by 2015. That is a daunting and challenging goal for all of us.

BARKER:

Why do we believe that that is a doable and feasible goal, even though it is a major challenge? The reason is that (inaudible) research over the past few years has led to unimagined advances across the entire research continuum of discovery, development and delivery.

As a result, we've reached an inflection point in research, meaning that projects from this point forward can be unprecedented and nearly unimagined.

The sequencing of the human genone, which you heard about from Francis Collins recently, and associated progress in new areas, such as genomics and proteomics, are allowing us to (inaudible) the genetics changes and mechanisms that actually produce cancer. (inaudible) cancer is a process, a process with multiple opportunities to develop (inaudible) effective interventions to detect, treat and prevent this disease.

The development of (inaudible) therapies and preventions for cancer is really within our grasp. For the first time in our national effort to conquer this devastating disease, we have (inaudible) concept. What do I mean by that?

We have (inaudible), such as (inaudible), that you just heard about from Dr. Lindberg. We're on the threshold, we believe, of a paradigm shift in the way we treat cancer. (inaudible) efficacious drugs with minimal toxicity.

(inaudible) detect cancer early, before it metastasizes (inaudible) approaches finally for preventing the disease.

To achieve (inaudible) the extraordinary advances in basic science, fueled in large measure by the doubling of the NIH over the last five years. We must also make progress in translating that research into patients and delivering those agents to people in need.

(inaudible) accelerate efforts to translate these advances from the laboratory into the clinic we have undertaken a range of new initiatives. Our new partnership with the FDA is one of those initiatives. There are others.

NCI has a long history of working with the FDA to deliver safe, more effective drugs to patients as soon as possible. For example, a current program ongoing at the NCI (inaudible) of proteomics is allowing our agencies to jointly (inaudible) of proteomic (inaudible) diagnostics technologies. (inaudible) and they can be detected. (inaudible) other areas, such as diagnostic imaging and molecular targeting.

(inaudible) the work of this task force, Dr. Mullin and I and our colleagues have just begun. (inaudible) continuing research, including the development of a formal interagency agreement, which will allow us to do several things. (inaudible) bioinformatics platforms; joint programs to further optimize the processes (inaudible); (inaudible) joint training programs and appointments for staff. (inaudible) to discuss each of these activities, we anticipate that each of these (inaudible) will be (inaudible) in our joint efforts. (inaudible) to leverage both of our capabilities.

(inaudible) that could enable the development of standard approaches (inaudible) potential biomarkers of clinical benefit. (inaudible) for the conventional measures that we usually use to measure (inaudible) in clinical trials.

Finally, all of these initiatives will benefit from staff training and joint appointments of staff and fellows who will have training rotation at both agencies. The task force is currently assessing existing programs that offer opportunities for joint training and appointments as well as determining (inaudible) efforts in areas such as new technologies.

In conclusion, the goal of this task force is to ensure that the NCI and the FDA work together more effectively than ever before for the benefit of cancer patients and their families. With over 1.4 million Americans expected to be diagnosed with cancer this year and (inaudible) people expected to die from this disease, (inaudible) people today, (inaudible) eliminating suffering and death from this tragic disease. (inaudible) this new alliance with the FDA (inaudible) development of a seamless continuum between discovery, development and delivery of new cancer drugs and devices that will be needed to achieve our goal.

Our director, Dr. Von Eschenbach actually on the cover of our plan for 2004 made the following statement: "When I look into the eyes of a patient losing the battle with cancer I say to myself it just doesn't have to be this way." We're committed to ensuring that it just doesn't have to be this way.

Thank you again for this opportunity to discuss this new initiative. We're excited about this new collaboration with the FDA. And I'd be happy to answer any questions when we get to the question period. Thank you very much.

BILIRAKIS:

Thank you very much, Dr. Barker.

Dr. Mullin?

MULLIN:

Good morning, Mr. Chairman, Ranking Member Brown and the members of the subcommittee. I am Theresa Mullin, the assistant commissioner for planning at the U.S. Food and Drug Administration. And since January of 2003, I've been directing FDA's development of a new strategic plan. I've played the lead role in coordinating the agency's new initiative to improve innovation in medical technology beyond 2002. And I'm co-chairing with Dr. Barker the Interagency Oncology Task Force.

And we appreciate the opportunity to testify with NCI about our collaborative efforts to facilitate drug development. Today I'd like to provide FDA's perspective on why we're entering into this collaboration and what we hope to achieve.

FDA's primary role is to ensure the safety and effectiveness of drug products through pre-market drug review and post-marketing safety. Today I'll focus on our role in the pre-market phase.

There are several phases to drug development, and FDA interacts with product sponsors all along the way. This enables the sponsor to focus research on studies of compounds that are likely to lead to approval. And after completing and analyzing their research, sponsors, including NCI-funded researchers, file an application with FDA. The application provides evidence from clinical trials to demonstrate that a product is safe and effective for its intended use.

By setting clear standards for the evidence that we need in order to approve a product, we can take the guesswork out of the process. Under the prescription drug user fee program, FDA's committed to goals for fast review and actions on submitted applications. For example, we're committed to completing the review and acting on 90 percent of submitted priority applications within six months. In 2002, FDA continued to meet those review goals, but the number of approvals for truly new drugs is now at the lowest level that we've seen in about 10 years. This is directly related to the decline in the number of applications submitted to FDA for new drugs, new molecular entities and biologic licensing applications. But this is a worldwide phenomena right now.

The chart you see over here with the bars shows you the trends in filed applications and those approved. The line shows the number of filed applications. And this is just looking at new molecular entities; that's the really new drug applications and biologic licensing applications. And the bars show the number of approvals for those kinds of products. And you can see that there really is a pattern that follows. What we get submitted to us is what we can work with for approvals.

But we think of this as temporary because at the same time that that's occurring, the government and industry are spending significantly increased amounts of funds on research and development, and there are a lot of complex and innovative new products in development, as Dr. Barker was describing and others have described. And so we see this as an opportunity for FDA and NCI to move more products to application.

In January of this year, FDA launched an initiate to improve innovation in medical technology, and that focuses on trying to maximize our efficiency in reviewing and communicating with sponsors and also trying to put out the best guidance possible for sponsors to speed development all along the pipeline.

My second chart shows the drug development pipeline, and the lettering in orange, it's too small for you to read, I think, from where you're sitting, but it describes some of the problems that sponsors may face in trying to develop products all along the way. And the (inaudible) that we have in green, which I'm afraid you also can't see, what FDA -- the kinds of actions that FDA

is trying to take all along the way to help products move as quickly as possible.

And as part of that initiative, we'll be clarifying regulatory pathways for some emerging technologies. For example, cell and gene therapies.

And we're developing guidance to help specify the clinical end points for clinical trial design, so that we can get the best quality applications possible submitted, and that allows us to avoid delays in approval and it helps reduce development costs.

Our collaboration with NCI in the interagency task force is really a great fit to what we're trying to do in this more general way and it'll allow us to expand and strengthen our work in trying to develop new cancer and helping with speeding drug development of cancer products.

The NCI-FDA collaboration will provide FDA reviewers with some exposure, additional exposure to state-of-the-art technologies and that will give them a better understanding of those technologies for products in development. By the same token, NCI researchers could benefit from hands-on experience with the FDA review process to understand better the kinds of evidence of safety and effectiveness that are looked for for quick approval of new products.

Although the interagency task force is at its early stages, we are considering several areas. I'll be brief here because Dr. Barker has described them. But joint training and fellowships. Development of markers of clinical benefit, including surrogate end points. Information technology infrastructure to better collect and share data. And improve the development process.

We look forward to collaborating with NCI in building on the institute's cancer bioinformatics infrastructure to streamline data collection, for example, integrating data analysis for (inaudible) clinical, pre-approval and post-approval research. This spans all the sectors in development and delivery of new cancer therapies, and we're hopeful that that collaboration will ultimately help reduce the reporting burden for clinical investigators and improve the quality of the data.

(inaudible) study of drug development has (inaudible) faster development times and quicker decisions to terminate unsuccessful compounds, and higher success rates provide industry with substantial savings in drug development. (inaudible) also benefit from those opportunities (inaudible) our task force will probably yield additional ideas for streamlining the process.

In conclusion, FDA safety and effectiveness standards are viewed by many as the gold standard, and FDA is recognized as the world leader in both quality and speed of regulatory review. We believe that FDA and NCI's new Interagency Oncology Task Force will further our goals in providing new drugs for patients who need them as swiftly and cost-effectively as possible. And I'm happy to answer any questions you have.

BILIRAKIS:

Thank you very much, Dr. Mullin.

I hear your testimony and all I can think of is wow. And yet, at the same time, think back, I lost my sole surviving brother this last April to lung cancer, and, you know, it makes me wonder, all these good things are taking place, but he wasn't helped.

Let me ask Drs. Barker and Mullin very quickly, has the task force been created -- and it sounds like gangbusters to me, so I commend you for it -- but was it created because the feeling was that there is just a lack of proper coordination among NCI and FDA? What would you say there?

MULLIN:

I speak first...

BILIRAKIS:
Yes, very quickly.

MULLIN:
I think we actually see that we have a lot of good success, it looks like a great opportunity to build on what we've got already. There are a number of collaborations going on, and we want to take it up to the next level, I think, and do it more broadly. We see a lot of synergy.

BILIRAKIS:
Should the same thing be done regarding other diseases, other institutes, et cetera?

MULLIN:
I think so, and I know our commissioner, Dr. McClellan, has been reaching out, and we're looking for opportunities to do this, yes.

BILIRAKIS:
OK. Dr. Barker, anything you wanted to add?

BARKER:
I would just add actually I think it's more opportunity than anything else. In the cancer arena especially we have a pipeline of 100, I think, maybe some days thousands of opportunities for new drugs and new diagnostics. And I think we want to do everything we can to help the FDA by bringing our science forward in ways that can inform these processes.
And it helps that, I think within 24 hours, actually, of Dr. McClellan's appointment, actually, Dr. Vonishnikoff (ph) was in his office, offering him the opportunity to actually -- and Dr. McClellan was actually so enthusiastic about this, and it just grew out of that almost immediately.

BARKER:
So it's -- I think we're all committed to this.

BILIRAKIS:
That's terrific.
And I do think it should be considered for other diseases.
Dr. Lindberg, are you aware of any research materials produced largely in part by federally funded projects that are not made publicly available? And if they are, if that is the case, why aren't they?

LINDBERG:
I don't.
But there are a variety of mechanisms involved.
NLM really deals with the public scientific literature, and generally speaking, there is not a great amount of delay in bringing forward those announcements.
In addition to the literature itself, of course, there sometimes involves materials, organisms or tissues or whatever, as an integral part of the search.
And NIH has taken the formal position of stating that it wants to encourage the ready availability of both kinds of results of research funded

by public funds as quickly as possible.

BILIRAKIS:
Well, you illustrate in your written testimony how the health care providers are able to access journal articles on MEDLINE in order to get up-to-the-minute information, et cetera. Obviously that's an undeniable benefit.

But I'm curious about what type of doctors have been able to take most advantage of this service. Are the patterns of utilization different between doctors who practice in urban areas versus those who practice in rural or frontier communities?

And of course I would ask does the library LOM have the capability to track this type of information? Otherwise, you wouldn't be able to answer my question.

LINDBERG:
Right.

No, we're concerned about all of those things.

Historically, actually the library has taken the point of view that it would pay for the communication costs even before there was Internet. So there was exact parity whether you practice in a rural area or a metropolitan area, because the communication costs were absorbed in the -- earlier the charges for the surge.

We do, however, worry more about the availability of computers and Internet connections on the part of the public. We think probably only half of the people really have that access, and so we've initiated a string of experiments with public libraries, because they're more numerous and they're more likely to be at a community level, asking ourselves whether the public would bring medical questions to the library, what are the nature of the questions, how good are the answers, how can we help.

And in all cases we found that it's actually a very good strategy. People do bring questions to the library. In many cases, they get very, very good answers.

And the -- what worried me was how can we help, because I was afraid they were going to say that more likely to provide, you know, $10 in library loans to a 100 million people.

But in fact, the answer was that the public library people would like instructions from the medical people on how to do these sort of searches, and that, of course, is readily available.

So that's a somewhat long way to answer your good question.

BILIRAKIS:
Well, would -- you have indicated possible lack of computers, but could a country doctor, for instance, pick up the telephone and call the Library of Medicine...

LINDBERG:
Absolutely.

BILIRAKIS:
... and get the information that they might need?

LINDBERG:
Yes, sir.

It happens all the time.

BILIRAKIS:
It happens all the time?

LINDBERG:
Yes.

BILIRAKIS:
So my son who is an internist -- how long has he been out of medical school, now 10 years -- anyhow, he would know that the Library of Medicine is available for this type of information?

LINDBERG:
I'm pretty certain that he would.
We get about 1 million calls a day.

BILIRAKIS:
I guess I'll have to ask him that.
You do a million calls a day?

LINDBERG:
Yes.

BILIRAKIS:
Wow.

LINDBERG:
And of that, about 30 percent actually are non- doctors, non-scientists, ergo members of the public.
Of course, we know we can all wear more than one hat, but basically about a third of the use of the library is now the public, and we're very happy about that.

BILRAKIS:
Thank you very much, Doctor.
Mr. Brown?

BROWN:
Thank you, Mr. Chairman.
I would like to ask all four panelists one sort of central, at least central in my mind, question.
I start with the technology transfer of Taxol, which has been very successful for the public and successful for Bristol-Myers and successful for the government drug.
I think that the facts generally are well known, the GAO report of earlier this summer.
NIH invested $484 million on discovering developing Taxol, most of that from National Cancer Institute. Some of that money was to begin the clinical trials.
Bristol-Myers told GAO, although GAO seems to look at this number with a bit of skepticism, that once they were given the drug, to produce and market they spent somewhere in the vicinity of $1 billion, including their clinical trial costs. Bristol-Myers -- the government began the clinical trials,

Bristol-Myers during that period provided -- supplied the drug, $90 million or so worth of the drug it cost to them and then they said, Bristol-Myers has told GAO they spent about $1 billion total on the clinical trials.

Bristol-Myers made $9 billion in profits. For several years running, they made $1 billion dollars a year. But overall, from '93 to 2002 they made $9 billion. NIH negotiated a royalty rate of five- tenths of 1 percent, which resulted in the government getting back $35 million in royalty.

I would add also that of the $9 billion in profits in those 10 years, a significant amount of that came from the government, Medicare I assume, and hospital costs, because Medicare as we know doesn't have a drug benefit. But Medicare paid Bristol-Myers for Taxol $687 million over the period '94 to '99. I don't have the numbers for the entire 10 years.

So in other words we have a drug that taxpayers put basically half a billion dollars in, very quantifiable, very proven, that number of dollars. We have a drug that was almost given to a company, who has done a good job of developing it, further developing and marketing. They claim $1 billion. That number is probably high. But even if it were $1 billion, Medicare paid $600 million of that.

So of $600 million, it was $9 billion -- it made $9 billion in profits. Government gets a paltry $35 million.

My question is is that fair? Is that a good system that way?

And my more specific question is should we consider a larger but still modest return on royalty rate for the government, considering what the government put in and what Bristol-Myers has reaped?

Now, understanding this doesn't happen every time, but when it does, if Bristol-Myers or any biotech firm or drug company makes this kind of money, these kinds of huge profits off a blockbuster drug when the government has done almost all, if not all, the basic research and really discovered this product, is there something we should do differently from the way we do it now?

LINDBERG (?):

I don't think I can offer you any wisdom on that topic.

Sorry, just not an expert in it.

BROWN:

What about as a taxpayer?

LINDBERG (?):

Well, what I'm remembering is the people in the street claiming that we're going to strip the planet of yew trees because of Taxol, and I was grateful that the synthetic chemists were able to make it in a lab.

I think it's a great outcome. And I really don't know the answer to your question, what is a fair return. I simply don't.

BROWN:

Dr. Rohrbaugh?

ROHRBAUGH:

Well, the -- at the time that the National Cancer Institute started working with Bristol-Myers Squibb, they were looking for partners to move forward an important -- what they perceived as an important potentially therapeutic -- chemotherapeutic drug, and it's been quite a success with over 1 million people treated, primarily women, for ovarian and breast cancer, and

now lung cancer.

It's a generic compound that's being combined with a number of other therapies by many different companies in treating millions, now more than a million, people.

So from the perspective of our mission to benefit the public health, this has been a great success.

With respect to the return, the only mechanism we have to receive a return is to license inventions made by government scientists. And the only invention here that was made by a government scientists was a method of administering the drug. And this method was not required for FDA approval, it not in the packaging insert, it's not in the instructions.

It was only a small part of the total package, so to speak, of the drug that went forward. And we licensed that technology to Bristol-Myers-Squibb for a reasonable amount, considering the technology that we had licensed.

But ultimately, our mission is to benefit public health, and this has been a great success.

BROWN:

Dr. Barker, all right, very quickly, if you could just, Dr. Barker?

BARKER:

It's a complex question, and I'm not wise enough to answer it in terms of the return on investment issues. But I am able to tell you that Taxol was a revolutionary drug in terms of the treatment of ovarian and breast cancer, specifically, and now lung cancer. And I can even think back, I have a personal story in that regard actually. My mother, who was suffering from breast cancer at that point, was one of the first people on a clinical trial and actually probably gained an additional two years of life because of that drug. So from our standpoint in the cancer institute, this was an extremely successful venture in terms of this particular drug. So I think for us it was a success story.

Mr. Brown, I don't think I have a good answer to your question; it's a difficult one. I think prospectively, it's hard to know how things will work out often when you're developing a product. And in hindsight, things may look different as well.

BILIRAKIS:

Mr. Buyer for eight minutes?

BUYER:

I don't villainize drug companies, so the answer is not a difficult one. What is excluded, I think, out of the proposition that Mr. Brown has given to you in a question is that if we, as the government, i.e., are going to take public dollars and make this investment, we believe that in the end we're going to improve the quality of life of our society. And from that, there are tremendous benefits, both that are tangible and intangible, whether it's quality of life and productivity, and is it meaningful to have a mother for a child.

I mean, the list goes on and on and on. So get out the pen and paper, Mr. Brown, and try to calculate all those other things; that's what I would ask. But yet, it's a lot more fun in politics to villainize somebody or something out there. That's the politics of it. And that's what's unfortunate. And it just turns my stomach.

I applaud your answers.

I do have a question that's outside of the scope, perhaps, of the hearing. It was sort of stimulated as I was listening to testimonies. The more you want to collaborate, that's all wonderful; the access to the library, that's all wonderful. But what stimulated my thinking -- and I don't know the answer to this question that I'm about to ask -- is about your information technology enterprise architecture. So you can talk about how you want to collaborate and talk to each other, but if under HHS, and you've got NIH and CDC and HRQ (ph) and FDA, can you all talk to each other in an architect enterprise?

And then you've got institutes below each of them. Let me just ask the two doctors, here we've got the cancer institute and FDA. Can you all talk to each other? Can you send e-mail? Can everybody talk to everybody within...

BARKER:
Everybody's on the same network, yes. We can pull up names on our, you know, Outlook and...

BUYER:
So everyone within HHS is all on the same enterprise architecture? There are no little cultures out there that you can't access?

BARKER:
We certainly have a lot of things in common at this point (inaudible).

BUYER:
That's great.

BARKER:
I think the challenge for us in science, actually, is the explosion of data from genomics and proteomics and areas of science that has evolved very quickly, that's prompted us specifically at the cancer institute, to create a grid to connect our cancer researchers, physically, the physicians with the scientists. And so that's a challenge that we're actually rolling out this year, a new information grid. But it's totally connected to everything else we just talked about, so we're actually in pretty good shape I think.

BUYER:
So between your hardware, your storage and your servers and your software, it's all compatible and you all can talk to each other and there are no problems?

BARKER:
I think that that is a major initiative and goal for our department, and in probably the president's management agenda, but I know, that HHS is working very diligently to -- we have a lot of things in common, and we're working to have everything possible that makes sense to have common and interconnected.

BUYER:
Working toward that goal, so we're not there yet?

BARKER:
(inaudible)

BUYER:
Dr. Lindberg?

BARKER:
(inaudible)

BUYER:
Dr. Lindberg, do you have anything you can add to it?

LINDBERG:
Well, I think, just at the level of communicating, I don't think there's any problem whatsoever, but I would attribute that as much to the Internet as I would to our own department.

LINDBERG:
Now whether there's reason to communicate, that's of course an administrative matter. But I've been delighted -- and I've been in government only since '84 -- but I've been delighted to see how many good people there are in each of the agencies and how we easily they do work together. I think it's a myth to say that they don't work together, when there's reason to.

BUYER:
I'm not proposing there's even a myth. I just want to make sure if you want to corroborate you've got the architecture to actually do it. Because what I discover in other work with other departments and agencies, you'd be shocked to find out who's got what funding steam, and somebody goes out and buys whatever they want and find out that they can't talk to each other.
Thank you. I yield back.

BILIRAKIS:
The chair appreciates that.
Mr. Stupak for eight minutes.

STUPAK:
Thank you, Mr. Chairman.
Let me just follow up a little bit on what Mr. Brown was saying.
He used Paxil, but just on any of these drugs that the government helped to develop, a lot of us feel that the return we're getting is inadequate. Paxil, to use Mr. Brown's numbers, the government put $400 million to $500 million (inaudible) to date it's been $35 million. A lot of people believe that we should at least go a dollar for dollar, you know, return on the money. Do you think that would stifle research if we did that?
Does anyone care to answer that?

ROHRBAUGH:
In the early '90s -- late '80s, early '90s -- we had a reasonable pricing clause in our agreement, and there was concern by the mid-'90s that this was causing companies not to even consider collaborating with us.

STUPAK:
What's reasonable reimbursement? You said you had a reasonable reimbursement clause. Can you define that for me?

ROHRBAUGH:
That's part of the problem.

STUPAK:
You can't define it.

ROHRBAUGH:
It's difficult to define. But all we had was a clause that said that the price would be reasonable.

STUPAK:
So you moved from reasonable to what?

ROHRBAUGH:
And in 1994, we held two public hearings with members of the public constituency groups, et cetera, who determined that the clause inhibited the formation of potentially beneficial scientific collaboration without providing an offsetting benefit to the public. And some question whether we...

STUPAK:
I don't mean to rush you, but I want to get through a lot of questions. And I don't take eight minutes. I'm trying to get these four answers.
So what's the standard now? What's (inaudible) what is it now?

ROHRBAUGH:
There is no control in our license agreements over the pricing of...

STUPAK:
So each is negotiated.

ROHRBAUGH:
We negotiate a standard licensing agreement based on the technology we're licensing. And industry tells us if we have -- if the government has control over its costs they would not work with us and therefore these drugs would not reach the market.
So I think our choice is: Does the government...

STUPAK:
How would you have control of their costs when they spend $2 on advertising for every $1 on research? That's the problem some of us have: They spend twice as much on advertising they do on research and development, and government seems to be supplementing that, and we're getting 0.2 percent return?

ROHRBAUGH:
Our mission at the NIH is to bring new products -- to facilitate the development of new information and new products that are brought to the market by the private sector with a great deal of time and investment by the private sector.

STUPAK:
I don't disagree, but if you have a reimbursement program, (inaudible) should be reasonable -- by that I mean at least a little bit more than 0.5 percent.
Let me move on to something else.
Dr. Mullin, you indicate in your testimony that FDA is there to make sure that we have safety and effectiveness of a drug is paramount in your mission

statement. We've done hearings on the enchrone (ph) and urbotex (ph). And while the drug was being developed in the initial application to see if it was going to be a beneficial cancer drug, there was a lot of hype in that drug through USA Today, Business News, even 60 Minutes. FDA testified they were appalled at the statements or (inaudible) being made.

Should not the FDA then step in when these drugs are being promoted and hyped, while they're still in the initial stages of development, and say wait a minute, folks. If you're concerned about safety and effectiveness of drugs, at the hype you just saw on USA Today or 60 Minutes, don't you have a responsibility to step up and say that's not true, that's not what the tests are showing?

MULLIN:

I'm afraid, Mr. Stupak, I can't -- I don't know the legal constraints on the agency with respect to what we can say when the product is still under IND.

(CROSSTALK)

STUPAK. Sure. But under IND, when they're making claims that can't possibly be true, to protect your mission, to continue to be the gold standard, as you like to be referred to, don't you have a responsibility as the FDA to say these claims are not going to the effectiveness or the safety of a drug -- it's an IND, as you call it -- don't you have the responsibility to let the public know that this isn't true? Because as we saw, we got all kinds of investor fraud and everything else associated with that.

MULLIN:

I'd like to be able to follow up with you, with the people who are most familiar with that drug and that issue so I can give you an accurate answer on that, if that's all right.

STUPAK. OK. And further on you testified that drugs are being approved now, 90 percent within the six months underneath PADUFA. During this six-month period, have you been able to get all the information requested from the drug companies?

MULLIN:

I think maybe I didn't say it clearly enough on what that meant. FDA won't approve a product until all of our questions are answered. But what we will commit to is a complete review and a letter and an action. And the action might be a letter that says, This is not approvable, or, It's approvable, but the following questions must be satisfactorily addressed.

So it doesn't mean an approval within six months, unless the application does answer all the questions and there's adequate demonstration of safety and effectiveness.

So I didn't mean to imply that we approved them and guarantee anything of that kind. We will approve a product when it's shown that it's safe and effective and we're satisfied that we have the evidence that's necessary.

STUPAK:

Well, if we're concerned about the safety and effectiveness, and consumers are concerned at how quickly some of these drugs are being approved, when we take a look at it, underneath this new system we've had in place, we've had more drugs withdrawn in the last few years than you did in the whole history of the FDA because they've been approved so quickly, they had to be later withdrawn.

And the answer we usually get with the FDA is, Well, if it's 3 or 4 percent that have to be withdrawn, that's what it was before. Even though we're approving more drugs quicker now, we're still withdrawing about 3 or 4 percent of more drugs, which has resulted in about 1,200 deaths. Is quickness the standard they're using? Or are you under a legislative time frame to do it in six months? Or is it really safety and effectiveness that should be the rule here?

MULLIN:
Well, the review process, there is a legislative time frame, which is 180 days. But we work with our committee trying to meet the PADUFA commitments that are not legislative, but that FDA has committed to.
And that's just for review.
We don't have a particular time frame for withdrawal and what -- those statistics that you're referring to means on average. And what we looked at in the 3 to 4 percent that you described is the average over a longer term, in terms of withdrawal rates for approved products.
And one of the things that we're seeing is a much greater uptake of new products once they're approved, and there is a much greater use of new products...
(CROSSTALK)

STUPAK:
... greater drugs are being approved, but a greater number of being withdrawn when you just look at the raw numbers, and later being withdrawn.

MULLIN:
Well, actually, and the rate of withdrawal has not gone up, and...

STUPAK:
Not gone up, but you've got more drugs, you're withdrawing more drugs. So how is that an improvement upon the safety factor, is what I'm asking?
Let me ask you this -- my time's almost up. You said on page 4, "Once a drug is approved for sale in the United States, our consumer protection mission continues to be monitored for the use of marketed drugs for unexpected health risks, and we take steps to inform the public."
Other than a public health advisory to doctors, which you (inaudible) through a MedWatch, how do you inform the public? And what mechanism is in place to do post-marketing review once a drug is approved for sale?

MULLIN:
Post-marketing review. Part of what prescription drug users (inaudible) authorization. Last year, we actually established enlarged personalizing safety and oversight and have additional funds now to do that activity.
One of the things FDA is currently doing (inaudible) strategic actions (inaudible) that we're developing is to try to get work with others who collect data to get the largest capability to the active surveillance that we can (inaudible) because we know that drugs are -- they're used according to labeling, and they're also used in the way that is not always according to labeling.
And it's very important that we get the earliest and best information that we can to understand what the problem is. If there's a problem on a product we need to analyze whether it's product or how it's being used...

STUPAK:
Right, realize all that but...
(CROSSTALK)

STUPAK:
(inaudible) in place, like, six months later or even a year later...

BILIRAKIS:
Mr. Stupak, your time has expired. Let her finish answering the question, please.

STUPAK:
Sure. I'm just trying to get to the meat of it.

BILIRAKIS:
I know. I understand.

MULLIN:
What we're -- one quick thing on that. We have this program in place now, so (inaudible) in the post-market period, the first two to three years when (inaudible) something unexpected that we wouldn't pick up on in clinical trial, we are doing a lot more active work. And over the next five years expect to spend about $70 million on post-market safety, which is so much better than we've been able to do in the past.
So I think we will be very vigilant in the first two years, because that's when a lot of the safety problems happen and we pick up on them.

STUPAK:
And then my other question was: How do you...

BILIRAKIS:
Mr. Stupak...

STUPAK:
... inform the...

BILIRAKIS:
... your time has expired.
(CROSSTALK)

STUPAK:
I have two questions.

BILIRAKIS:
... and it's expired a good bit.

STUPAK:
Other than MedWatch, do you do anything else to inform the public?

BILIRAKIS:
Ma'am, don't answer the question, please.
Your time is expired.
I want to remind myself that when the yellow light comes on, it means your time's almost up. When the red light comes on, it means your time is up, and

it gives all members an equal opportunity to question the witnesses.
Mr. Whitfield, you're now recognized for five minutes.

WHITFIELD:
Mr. Chairman, thank you very much.
I suppose this question would go to Dr. Mullin, but of the approvals that you give for new medicine, would you have any idea of what percent of those would be coming from what I would refer to as small maybe start-up companies, versus companies like Merck, Bristol- Myers, and the large, large drug companies?

MULLIN:
You know, I don't have that (inaudible) top of my head. But we do keep track of that information, and I can get that information to you.

WHITFIELD:
Do you have any idea at all?

MULLIN:
I'm going to -- and I'm going to hazard a guess that it's at least 20 percent, but I think higher than that from small companies.

WHITFIELD:
Twenty percent?

MULLIN:
And I suppose this would go to Dr. Barker or someone else, but are there funding mechanisms in the government that helps bridge this R&D phase of drug development and assist small companies to bring the drug through the FDA clinical trials for a new drug application.

BAKER:
The National Cancer Institute has several of these mechanisms, including, of course, the SBIR and STTR grants, which many small companies use actually to develop drugs. And that's probably one of the most I think effective mechanisms. Those are partnerships generally with universities and small companies.
We also have at the NCI two other programs that actually -- one called the unconventional innovation program, the second called, it's called the IMAT program. Both of those programs actually are good vehicles for small companies to actually bring their drug forward.
Small companies often don't know going into these kinds of development activities how much they're going to cost. So we're actually looking more closely at that at the NCI, because we do have a lot of interesting (inaudible) as you imagine, in the biotechnology companies. And many of these small companies just don't make it.
And we're looking for (inaudible) to capture some of that technology, or to win some different kinds of assistance maybe through some of our university relationships.
It's an issued we're very interested in.

WHITFIELD:
The very first two you mentioned, one was SBIR, and what was the other one?

BARKER:
STTR. It's one with more of a technology focus grant for diagnostics and other kinds of technology. The first one is actually more for therapeutics...

WHITFIELD:
And do you have any idea how many dollars are available for those programs each year?

BARKER:
In the case of the SBIR program, it's in proportion actually to the amount of dollars that you receive as a federal agency. And I don't have that number right at hand. I can certainly get it for you.

WHITFIELD:
Thank you.
I guess we'll be going back to FDA again, but I notice in your notice in your testimony you referred to, at some point, priority approval and standard approval. Would you explain to me how you determine what is a priority and what's a standard?

BARKER:
FDA determines whether an application will be a priority or a standard, and the priority applications are ones for treatment or therapies that represent a new approach to diagnostic treatment, and it just, so it's something that offers an approach or a therapy that hasn't, that doesn't already exist.
So, for example, the first of kind in an area for diagnostic or treatment.

WHITFIELD:
And you mentioned also new drug applications in biologic license applications.

BARKER:
Yes.

WHITFIELD:
Would that, would either one of those include, or would it be separate, a new drug delivery technique, for example?

BARKER:
A new drug delivery system, for example, might involve a device component in a biological, or a device and a drug combination, and those we refer to as combination products, and they may be classified as a device and deemed what is called PMA, that's a, it will be jointly reviewed by a device center and the center that would handle, say, the drug component of it, or the biologic component of it.
We actually have a new Office of Combination Products to facilitate and make sure those reviews occur in a very timely fashion.

WHITFIELD:
But if the drug delivery system consisted only of some new chemical mechanism, or, for example, a system that would disguise the drug being used

so that your own immune system would not attack it.
Would that be considered a device, or would that be a drug delivery system, or...

BARKER:
I don't think I can answer that, I'm sorry to say. And it actually can be kind of complex sometimes to figure out what the, where the home of it, where the review will be primarily done, and there are increasing numbers of products that are combination products that are very effective, very ...

WHITFIELD:
Thank you.

BILIRAKIS:
Thank you, Mr. Whitfield. Ms. Capps, you're now recognized for eight minutes.

CAPPS:
Thank you, Mr. Chairman. I thank you for your presence here today at this panel and for the committee for organizing it. I was not here when the goal of doubling the funding for NIH was started, but one of my proudest moments was to see that goal realized.
And we'll be (inaudible) to speak on the floor because of our funding appropriation that we're dealing with today, which includes NIH funding, and I'm dismayed that we've actually gone backward the very next year by flat-lining the budget.
I really so support what you all do, that umbrella of the NIH that includes each of your particular positions. I think the fact that the Congress took this on, to double the funding, speaks to the value that the American people place in what you do, and that is, well, for some folks, and me included, research is to be valued for its own sake. I was married to an academician for over 30 years, and that whole life means a lot to me, and I think when you get such wonderful unintended results sometimes from trips to the moon, or wherever people, what people decide to do with their intellect.
So I would value it for its own sake. But now we see clearly, and I have the experience of having a daughter in the battle of her life for a year with lung cancer, and I know what clinical trials are about.
And so, to the extent that we see close-up the impact of what you're about makes this a very significant arena for our deliberation as members of Congress, as well.
We are raw, some of us, from having gone through the Medicare modernization, including prescription medications debate, right here, a few weeks ago, and then two weeks ago on the floor, and so that's why there's feeling about the high cost.
And I want to use this little time to explore the relationship between what you do, valuable as it is in itself, and then the close relationship that exists in the private sector which allows, to the degree that that's an ingredient that is essential to having that really make a difference in people's lives.
And so I don't even know where I'm going address this, but I'm going to start with the fact that by Bayh-Dole we initiated with a relationship with universities, and I know our second panel is going to get us more there, and I'm not going to go so far as to say how can we get more of a return on some of these very lucrative byproducts, because I don't know that you can

anticipate that in advance, and you wouldn't want that to be the issue.

But I was taken with a comment, I think Dr. Rohrbaugh, you mentioned a method by which a standard agreement is negotiated, and maybe that's a good starting point to hear from you, in ways that perhaps with our leadership we should develop, or should we revisit Bayh-Dole, or should we, what advice can you give someone like me? Start with that. Very open, I'm sorry.

ROHRBAUGH:

Well, Bayh-Dole applies to the recipients of federal funds.

CAPPS:

Yes.

ROHRBAUGH:

There is the Stevenson-Widler (ph) amendments to the Federal Technology Transfer Act that applied to federal agencies, and directs our activities in technology transfer.

We license technologies at a very early stage. We often don't have much more, if we're fortunate to have a proof principle often before that point of time.

So industry takes on a great risk in having very early stage risky technology that may not prove to be of benefit, may fail, most of them fail in the process of development. That's just the way things work.

CAPPS:

Yes.

ROHRBAUGH:

And we license our technologies that are invented by government employees under standard licensing agreements, with terms that are negotiated based on the value of the technology, the stage of the technology, and its overall value.

And so, and what we license ultimately is typically a small part, or only one part of the final product, even if we have a chemical entity that becomes ultimately a drug developed by a company, the company may usually provide an awful lot of other important proprietary technology in formulating it, in encapsulating it, in developing it, in finding ways to make it better and cheaper, in bringing it to market. So ours is only a small part of the final product, typically.

CAPPS:

I'm not saying that you don't need to defend the private sector, I'm just concerned that there, from some of your remarks that I heard earlier in seems like they're holding hostage to some degree, that they won't, if you go too far down the road they are not, and limits the amount that they can make or do any kind of things that impinge on that, that they won't have a relationship with you. What is that like?

ROHRBAUGH:

Industry and investors in industry are reluctant to, the investors are reluctant to invest and companies are reluctant to take on technologies at a very early stage, as our technologies are, if we have some control over the final price of the product.

It's too far downstream, they have to invest so much money into it, ours

is a small part of the final product, they just have, will not work with us under those conditions.

CAPPS:
I'll wait until the second panel to get into it more that the university might have a different relationship with you in terms of that partnership.
But I don't want to, I'm looking at the clock, and Dr. Barker, I do want to get in one question about the National Cancer Institute, and the mapping of clinical trials.
And maybe that isn't even what you came prepared to discuss, but that is certainly a very big interest to many people.

BARKER:
Could you clarify your question?

CAPPS:
To make it easier for, and it wouldn't just be cancer, but that's certainly an area where lifesaving can often be seen as getting into a trial, and how can we make that work more efficiently.

BARKER:
I know you're very familiar with this process. We, as you know, also we only have about 3 percent of patients go on clinical trials who have cancer, and that's a very complex, there's a whole series of complex reasons why that's true.
We've undertaken a lot of activities at the NCI, ranging from new communications tools to actually new bio and chromatic systems to ease the burden of actually putting people on clinical trials.
And if communities increases funding basically for the cooperative groups, actually make them more competitive in terms of actually really enhancing opportunities to put people on clinical trials.
And clinical trials actually is a major initiative across to National Institutes of Health, it's point one of Dr. Zerhouni's road maps this year.
So we have an enormous number of initiatives, especially in the Cancer Institute, to actually increase accrual and to make it simpler for patients to access, know about the trials and ultimately be enrolled, and for physicians to actually have enough resources to out patients on clinical trials.

CAPPS:
Because this is an area, and I know my time is up, this is an area that funding could really be useful, that would be a real impact on consumers.

BARKER:
Well, I think the doubling of the NIH budget has actually allowed us to do an enormous number of things, in clinical trials, and certainly going forward that would be beneficial to continue to improve this for cancer specifically, but I think for other diseases, as well.

CAPPS:
Thank you.

BILIRAKIS:
Dr. Norwood, five minutes.

NORWOOD:
Thank you very much, Mr. Chairman, I'm enjoying this immensely and having a lot of my questions answered buy others' questions, so I'd like to take my five minutes and yield it to Mr. Stupak and let him finish his line of questions.

STUPAK:
I thank the gentleman for yielding, and appreciate the courtesy, because I was trying to ask Dr. Mullin, in the information we that have, and I asked you about how do you notify the public, then, about the effectiveness of a drug or the safety of a drug, because they say you issued public health advisories to doctors, which are commonly called dear doctor letters, or else there's Med Watch.
How does the public know about the safety of a drug? If you have a question, how do you communicate that to the public, I guess I'm asking?

MULLIN:
Mr. Stupak, if FDA has a question, or ...

STUPAK:
When the FDA's found something wrong, so that's when you do a dear doctor, you have to notify the prescribing physicians that you have to watch for this, or do something like this?
How do you inform the public? As you said in your statement, again, on page four, "If new unanticipated risks are detected after approval, we take steps to inform the public and change how a drug is used or even remove it from the market.
So I'm asking, how do you inform the public?

MULLIN:
Actually, as part of this planning effort that I've described this year, we are identifying a number of partners through, both public and private, to try to both get the data, as I mentioned before we see information technology is one key to try and get a more complete picture as quickly as possible.
We're going to be partnering with Grant Hughs (ph) for the AHRQ, with CDC networks ...

STUPAK:
OK, but there's no mechanism, like launching some kind of program to inform the public? It's still being developed.

MULLIN:
Well, on the other part of that, yes, and we're trying to partner with, well, as you know, the list of Med Watch partners of various practitioner groups and specialties, and we're basically going to be disseminating information through as many conduits as we can to professionals, health care professionals.

STUPAK:
Health care professionals, but I'm asking about general public. So we, the patients, and eventually the victims when a drug goes wrong, how do we know to watch for this?

MULLIN:

Well, we're looking for ways to get better information to the media in better ways, which is a very effective way to reach patients and refer them to their physicians, and we actually have been pretty successful in that mode of having people become aware through media, and then people ask their doctor or can visit FDA's web site, or get more information at that point as they need to.

BILIRAKIS:
Has the gentleman, the advising of the provider, of the medical doctor, are you satisfied in terms of how that is done?

STUPAK:
Well, the question was for the public. Providing the medical doctor doesn't help the patient or the families if there's a problem.

BILIRAKIS:
Well, certainly a medical doctor ought to know, and...

STUPAK:
Sure, they should. Yes. The key word is "should."

BILIRAKIS:
Are you satisfied as to how that is done? I don't know where ...

STUPAK:
I'm satisfied that they notify their physicians, but how do you get it to the public, I'm just trying to say, how do we get it to the public?

MULLIN:
Well, and I think that's, we absolutely agree with that, and we have a Patient Safety Initiative going around the FDA to identify every mechanism possible to reach people, to do it through media.
We think every venue, every channel you can go to to try to reach people.

STUPAK:
Let me ask you this, in that you're going to have to change a label because of a safety concern on a drug you have, or that labeling that's on a drug product, does that have to be changed within so many days, or months or years, whatever it's going to be?

MULLIN:
I know there's a time frame for it, Mr. Stupak, but I don't know what it is. I can get that information for you.

STUPAK:
If you would, I'd appreciate it.

STUPAK:
I appreciate your courtesy, Dr. Lorewood (ph), so let me follow up on that question.
Thank you very much. Mr. Chairman, I'll just get in one quick one, since I've got a minute left. I am a big fan of NIH. I'm very pleased with the work that you do. And I presume that I understand it right when you do basic science, you do research, it comes out basically through the national library;

that's where people actually pick up on that. Do I understand that right?

LINDBERG:
I think that's right. I think I could add something to the question Mr. Stupak asked, actually, because there is a phenomenon we call Clinical Alerts. Now, when MEDLINE searches are done, and they're done a million times a day, we have a banner in certain cases that announces a piece of emergency information. So for example, when the Women's Health Trial, the estrogen-progesten trial, when it reached the point where they could conclude early that it should be stopped, I mean, beyond the combined drugs, that was a clinical alert that was announced, and the decision was made by the director of the relevant institute, in that case Heart & Lung.

In earlier cases -- now, that was an alarm, they said stop doing it, because you're endangering people. But in happier circumstances, a trial will be terminated early because of a very good result. For instance, the use of massive doses of corticosteroids for acute spinal cord injury. That was a 20-institute -- I mean, it was tested in 20 academic centers and NIH, and it ended early because it was so effective.

So that was a clinical alert that announced that we don't want anyone on the control side of that one anymore, we want everybody getting the treatment.

So we do have at least that mechanism, and it relates to drugs, but not directly. It more relates to clinical trials. We fought very hard to get it in, because in some of the better journals, New England Journal of Medicine, for instance, there had been a rule that if you're going to announce these results before it's published, we won't take your paper. And in order to put through this particular theme, we convened a meeting at National Library of Medicine in which the editors of New England Journal and JAMA and certain other major papers all agreed that this should happen; these clinical alerts should be permitted and it would not bother anybody's acceptance or non-acceptance of the paper.

So I'm just suggesting that this is yet one other mechanism which we do use.

BILIRAKIS:
Ms. Eshoo, for five minutes?

ESHOO:
I didn't make an opening statement, Mr. Chairman.

BILIRAKIS:
Under the rules, you have to be here in order to waive your opening statement.

ESHOO:
All right, I'm sorry.

Well, I'd like to welcome the panelists here, and repeat what I always say when anyone from the NIH comes before us, that it represents, I think to our country, the National Institutes of Hope. And I think really that's why you're here today, to talk about the undertakings that are a part of that mission of hope. And I salute you for the work that you do and what it is producing for the people of our country, and certainly for the world.

You are the gold standard, and we want to keep you that way.

I think the investments that have been made are amongst absolutely the

best that the Congress has ever made. Absolutely amongst the best.

And so, I want to start out with that, because I have enormous respect for each one of you and the work that you do and the work that has come out of our National Institutes.

I'd like to just say something about some of the conversation that took place earlier in the committee's hearing. I don't know how many members know that earlier this week, I think it was Monday, that a GAO report found that the federal government, while it has been licensing agreements for only four of the top 100 drugs dispensed by the DOD, that there are only four. I think that the case is not as large as maybe it was preferenced.

And I think that members should avail themselves to this GAO report, because even though it's being charged, this whole case that the federal government is paying X number of dollars, getting very little out of it, I would say that it's important to read the report, because there are only four out of 100 that are actually dispensed by the DOD.

The federal government contributes 1.6 percent in terms of bio- research. So while we are a player, and a very important one, and I think that we should be doing more, most frankly, but because, again, I think this is amongst the most important and the greatest impact return for the investment dollars. It is 1.6 percent.

It reminds me of constituents at town hall meetings that believe that 25 percent of the federal budget represents foreign aid. And it's widely exaggerated. There are those that don't support any dollars for foreign aid, but I don't think that we should lose sight of the context here.

And as we don't lost sight of the context, we will, I think, more fully appreciate what 1.6 percent is bringing back to us.

To any of the witnesses, how often has the NIH turned over fully completed drug products to a drug or biotechnology company? Has that every happened?

(UNKNOWN)

I'm not aware of any.

ESHOO:

Anyone on the panel aware of any?

That's what I thought, but I think that it's a question that's worth asking.

Dr. Rohrbaugh, you mentioned that the reasonable pricing clause had a detrimental effect on public-private partnerships. Can you elaborate on that? And do you have statistics showing that?

ROHRBAUGH:

Those conclusions were made based on public hearings that were held in 1994. I don't have all the statistics, but the report that I would be happy to refer to you is on the Web site from those committees. And they did conclude that it was having a chilling effect on the interests of industry to work with the National Institutes of Health collaboratively and in licensing technology.

ESHOO:

And it's now a decade later since that report. Do you believe that...

ROHRBAUGH:

Yes. It's had a positive effect. And since from the standpoint of our statistics, our licenses, our royalty income, all of the measures of our tech

transfer activities are higher, much higher than they were at that time, and new and better drugs are being developed from our partners, who invest their time and money in these early stage technologies.

ESHOO:
I thank you all again, and I think that you are really a great source of pride to our country in terms of what you do. I'm so impressed with what the library is doing. I thought that the national do-not-call list had a lot of hits, but I think that you're right up there. And that speaks, excuse the expression, volumes about what you have and what you do.
Thank you very, very much.

BILIRAKIS:
The chair thanks the gentlelady. And you certainly made a point that I tried to make. And that is, (inaudible) bringing this thing to me, that they do so much and what is available, if only to people, the patients and particularly the medical providers, are aware of all that is available to them, and that's something that concerns me. I don't know whether it should or shouldn't.
Mr. Burr, recognized for five minutes.

BURR:
Mr. Chairman, I won't take five minutes. I would like to pose two questions, probably to Dr. Rohrbaugh and Dr. Barker.
The first one is what do you see the future of combination products playing in the delivery of health care in this country?
And the second question would be, as we look at the plus-up that Congress has made in the NIH budget over the last several years, and hopefully a plus-up that will continue, how much of those extra dollars have been used for extramural research?

BARKER:
As you know, the majority of our work at the NIH is in the extramural community, and certainly that's true at the National Cancer Institute, so most of those dollars have gone to the extramural community.
And part of that first question that's intriguing, that you I think everybody's beginning to say that the future of medicine actually is going to be in genetics, and we'll learn more about genetics, we're beginning to understand that these (OFF-MIKE) actually it's sort of more and more not going to be a single defect; it's going to be multiple defects. So they're a challenge, actually to drugs that issue and (OFF-MIKE) are looking at other kinds of ways to do that, all the way from computational biology and systems biology, to be able to (OFF-MIKE) to predict what that should look like, to very specific kinds of models in animals to actually effectively predict that before we can go into humans (OFF-MIKE)

UNKNOWN:
Well, my hope is that you devote to spend not only with FDA but possibly with CNS as it relates to understanding the world of combination products. My greatest fear is that we make tremendous progress at NIH, improve national programs and then we get this permanent red light that deals with the approval process that we improve and we have improved.
But the combination product decisions are much tougher down the road than what we've had up until this point. And I believe it's been even tougher to

try to determine the reimbursement scheme as it relates to those products.
And then many times, our great work is only for naught, in fact, we can't get it to the patient.

(UNKNOWN)
I would agree with that.

(UNKNOWN)
Thank you, Mr. Chairman.
Anything to add?

(UNKNOWN)
No, I don't

(UNKNOWN)
Thank you, Mr. Chairman. I yield back.

(UNKNOWN)
Sure. Thanks to the gentleman.
Mr. Allen (ph) to enquire.

(UNKNOWN)
Thank you, Mr. Chairman. And thank you, in particular, for allowing me to participate in this hearing today.
Though a member of the committee, I'm not a member of this particular subcommittee. And a lot of good work is done on this subcommittee.
I want to thank all of the panelists for being here today. This was a very helpful and informative hearing.
Dr. Mullin, I'd like to being with you. I've introduced a bill in June called the Prescription Drug Comparative Effectiveness Act of 2003. It's a bipartisan bill. It would fund studies of comparative effectiveness and cost effectiveness of prescription drugs that are used to treat particular diseases or conditions, specifically those which involve high amounts of expenditures from Medicare and Medicaid.
The bill authorizes $50 million for NIH and $25 million for the Agency for Health Care Research and Quality to carry out the studies in comparative effectiveness and cost effectiveness.
And Mr. Chairman, with your approval, I would like to offer for inclusion in the record, an editorial in the July issue of Clinical Therapeutics, which explains...

BILIRAKIS (?):
Without objection, that would be...

UNKNOWN:
The FDA, it is assumed under the legislation that the FDA would cooperate with NIH and ARC in dealing with this issue.
I assume you haven't had a chance to review the bill. But I wondered if you could comment briefly on the value of having better information on how drugs that treat a particular disease or condition should be compared to other drugs that treat the same disease or condition, and ultimately, of course, the question of relative cost effectiveness. You're probably familiar with what Oregon has done along these lines.

UNKNOWN:
(OFF-MIKE). I'm not a reviewer, but I know very well that they make those decisions about approval of the new products with all the other options in mind (OFF-MIKE).
And FDA have a trove of information and experience. And because of this process, we see everything. We see all the detailed, clinical data.

BARKER:
And we will be, I'm sure, collaborating. I know we have publications with AHRQ already underway. We want to share what we know more and there is a summary that's always provided at the end of the review process and it does (inaudible) that talks about that product in the clinical and (inaudible) of what's available to treat patients with the condition.
So, I think we see that as an opportunity.

BURR:
OK. Thank you for that. Of course, this goes beyond FDA's traditional mission of safety and efficacy, but it is an important area.
Dr. Rohrbaugh, you were talking earlier about the conversations you have with industry when something that's been developed at NIH is ready to go out and be further developed for the market. We have a staff memorandum here that says that in July 2001 NIH submitted to Congress a plan to assure taxpayers interests are protected and it talked about greater transparency. And it said you would modify your existing extramural policy manuals to assure that grantees and contractors report to the agency the name, trademark or other appropriate identifiers of a therapeutic drug that embodies technology used by NIH that you'd make that information available on a web-based database that...anyway, I just wondered if you could clarify just where that process is.
Is that kind of information now being developed and is it available on a database that could be used by the public?

ROHRBAUGH:
It is. What we've done for the intramural program, that program that I oversee is listed on our Web site, all 17 FDA approved technologies, drugs, therapeutic, vaccines that included at least in part, technologies licensed from the NIH.
With respect to our recipient for federal funds, that was handled by the office of extramural research and they have implemented that program and on their Web site, I believe there was only one reported drug last year. I don't know if any have been reported this year.

BURR:
But there should be more as we go forward?

ROHRBAUGH:
Yes.

BURR:
Yes. Well, it's important I think just because if we're going to understand this process, we need to know how much of the value or how much of the research went into a particular drug was publicly funded then we can discuss the policy implications of that. Thank you.
Thank you very much, Mr. Chairman.

BILIRAKIS:

And I thank the gentleman.

We're going to go into our second panel now, but I want to thank you all. You were just tremendous as usual. We will have questions in writing to you as per the way it's usually done. We would appreciate a timely response to them.

And you know the second panel has sat through the audience and listened to you and then of course, you're all busy people, so you'll probably leave and that's why I told the staff that I wanted one panel for everybody to be here to be able to hear each other and what not. But, I would hope that if you can't stay for the second panel, you would maybe ask someone from your particular office to stay in your place and take notes, because I know you're concerned and you're certainly interested in the comments that will be made by the second panel. Thank you so very much.

The second panel consists of Dr. Phyllis Gardner, Senior Associate Dean for Education and Student Affairs, Stanford University; Dr. Andrew Neighbour, Associate Vice Chancellor for Research, University of California, Los Angeles; Dr. Jonathan Soderstrom, Managing Director of the Office of Cooperative Research, Yale University; and Dr. Ellen V. Sigal, Chairperson, Friends of Cancer Research, located here in Washington, D.C. If you'll take your seats please.

Again, you're written statement is part of the record and we would hope that you would compliment and supplement it orally. We'll set the clock at five minutes and I'd appreciate it if you could stay as close to that as you can, but certainly I won't cut you off if you're on a roll regarding a particular point. OK. Let's start of with Dr. Gardner. Thank you all for being here and for your patience and waiting and having to wait while we have votes and that sort of thing.

Dr. Gardner, please proceed.

GARDNER:

Chairman Bilirakis and members of the committee, I'm pleased to testify before you today regarding technology transfer issues as they relate to the biotechnology industry. Thank you for your continued leadership in the area of health care.

I'm here today representing biotechnology industry organization or BIO. BIO represents more than 1,000 biotechnology companies, academic institutions and state biotechnology centers. BIO members develop medial and pharmaceutical products as well as agricultural, industrial and environmental products.

My testimony is based on my own experience in both the academic and private sector. I have been a tenure associate professor in the departments of meleckier (ph) pharmacology and medicine since 1984 at Stanford University. I'm a former Senior Associate Dean for education and student affairs. In addition, in the past ten years, I was associated with ALZA (ph) Corporation, a pharmaceutical company acquired by Johnson and Johnson as the vice president and head of their technology institute. I've been on biotechnology company boards. I've served on the boards of private and public biotechnology companies. I have founded companies and I have advised venture capital firms as a partner and adviser.

I want to emphasize three important points today and ask that my written testimony be submitted to the record. Point one; biotechnology industry differs significantly from large pharmaceuticals companies. There are over 1,400 biotechnology companies in the U.S. In contrast to large pharmaceutical companies, many biotech companies are small, not publicly traded and have not

achieved profitability yet. While large pharmaceutical companies tend to pursue blockbuster drugs, with market potentials of a billion dollars or more, many biotechnology companies pursue products with much lower market potentials, including orphan drug.

The biotechnology industry is the most research and development industry in the world. In 2002 the industry spent $20.5 on R&D focusing on new targets and highly innovative therapy. No industry spends more on R&D per employee. No industry faces a lengthier or more complex regulatory process to bring products to market. And you all know the statement; a biotech company typically spends 15 years and hundreds of millions of dollars to complete testing and secure products' approval.

Point two; the federal government funding plays a small but important role in biotech R&D. As Congresswoman Eshoo pointed out, only 1.6 percent of the industry's R&D funding in 2002 originated from the federal government. Thus, public support for biotechnology and the far greater dollars is key to the success of the industry. Federal R&D programs must be flexible enough not to cipher the private sector investment that's so critical to bringing products to market.

Point three; partnerships within the federal government and private sector foster innovations and improve health. Passage of the By-Dole Act (ph), which has been discussed much today and the federal Technology Transfer Act established vehicles, including licensing and the cooperative research and development agreement or CRADA protect transfer from the public to the private sector. Prior to these laws, federal agencies rarely relinquished ownership of totally funded inventions and valuable technology was left languishing in the shelves of research institutions.

In addition to CRADA and licensing, biotechnology companies also rely on direct financial support from the government through small business innovation research programs, the SBIRs and advanced technology programs or the ATP. The SBIR program is a competitive three-phase government funded program. It's used overwhelmingly by (inaudible) companies for start-up and early development stages of product development.

The advanced technology programs, by contrast supporting product development, it supports enabling technologies essential to the development of new products, processes and services across the first application areas. Both of these vehicles support (inaudible) companies in critical early stages. This early support is critical to support the large investments, the subsequent development in commercialization. They are particularly important in down markets and (inaudible) and other sorts of the private funding diverted to later stage less than (inaudible) company.

BIO does suggest one change in SBIR or one change through the Small Business Administration. That is that they redefine the definition of the size of small business and equity ownership so that it will not be preclude venture capital backed companies from being funded.

In conclusion, BIO supports the various vehicles that Congress has authorized for transferring valuable technology from the public to the private sector, giving it significant technological breakthroughs achieved in medical and health fields BIO believes that federal dollars invested biotechnology research has yielded a significant benefit generally for the health of a nation and specifically to the federal treasury.

Thank you again for your support of biotechnology's efforts to contribute and advance to help the United States. I would be please to respond to questions from the Committee. Thank you.

BILIRAKIS:
Thank you very much, Dr. Gardner. Again, thank you for coming such a long way to be here to help us out.
Dr. Neighbour, please proceed.

NEIGHBOUR:
Thank you. Chairman Bilirakis, members of the subcommittee, on behalf of the University of California, I welcome and thank you for this opportunity to testify before this subcommittee. As Executive Director of Research Administration at UCLA, I'm responsible for managing publicly and privately sponsored research at our campus and for the transfer of its innovative technologies to the marketplace.
I hope to demonstrate today that there exists an effective collaboration between American Universities, the life science industry and NIH that yields enormous benefit for our society and for mankind.
I will briefly describe some of these benefits as well as several challenges and controversies that have the potential to impede this success. I would ask that you refer to my written testimony for greater detail.
As you have heard already today, University Tech Transfer began approximately 22 years ago with the passage of the By-Dole (ph) Act. A fine example of successful technology transfer occurred in 1973 however, well before the Act was compensated or enacted, with the invention by Carron and Boya (ph) of the common DNA technology known as gene splicing. Funded in part by NIH, these two scientists at Stanford and the University of California discovered how to insert genetic material into native DNA. This technique launched a new industry called biotechnology.
At that time, only (inaudible) of NIH funded inventions vested with the government, however, because of a special patent agreement with NIH, the two universities were allowed to own the patent and assume the responsibility for its commercialization. There are Stanford's Technology Transfer Office license to patent in more than 300 emerging companies. Recognizing that effective licensing was beyond the government's resources, Congress, in a bold and inspired moved, passed the By-Dole (ph) Act and the universities took over the responsibility.
And since 1980, NIH has played a lead role in implementing the Act and universities have built effective programs for managing their intellectual property while maintaining their commitment to provide public access to the results of their research.
Major NIH funded discoveries at the University of California or UC, have included new technologies for improving radiographic imaging, improved methods to develop and deliver therapeutic drugs and novel diagnostics for people and animals. In addition, NIH funding is one of the major platforms for research that has fostered additional federal and private funding, scorning a flatware of high value products.
Unfortunately, success has led to criticisms, which I believe is founded mostly on three misunderstandings. These are, firstly, many think that transfer is a simple linear process that speeds inventions from the bench to the bedside. In reality, it is a rather complex slow and resource intensive activity, often spanning many years. UC, for example, spends almost $20 million per year in managing a portfolio of more than 5,000 inventions and 1,000 active licenses. Almost 1,000 new inventions are disclosed to us each year. And that's with less than five percent of those ever being commercialized.
The process is more of circle with nautical inputs and outputs in

something linear. Federal funds encourage support from industry and other sources. Academic research produces early stage scientific knowledge and that in turn stimulates the development of commercial products. Partnership with industry is invariably essential to convert the results of NIH funded endeavors to products that can directly aid the public.

The second misunderstanding is that money is often used to measure technology transfer success. It's metric ignores the many additional benefits that derive from technology transfer. The education of students that go on to fuel the workforce, new companies and jobs that aid regional economies and the products themselves that safe lives and improve the quality of life.

NEIGHBOUR:

And finally, many people believe that the universities do tech transfer to make money or to get rich. After all expenses are paid, even those universities with gross revenues from licensing in excess of $20 million to $50 million, only retain $5 million to $10 million of that. And this is reinvested back into the research enterprise.

While these funds are of great value to the university, few institutions would view this as an effective way to increase their capital assets. Imagine a world without knowledge of the human genetic code, recombinant DNA tools to splice and correct genes, ways to map and fingerprint DNA to convict the guilty and free the innocent. All of these technologies, together with vaccines and new drugs began in universities that were financed in whole or in part by NIH.

It is my fervent belief that this alliance between the NIH, the universities and the industrial sector is working well. And we must preserve it. But, we must also continue to strive to enhance its effectiveness and to ensure that arbitrary impediments are removed for the health of the public and of this nation. With a greater knowledge and understanding of the tech transfer process and the accomplishments of NIH and their academic progress, you on this committee, I believe, will play a key role in protecting these beneficial outcomes.

Thank you very much for the opportunity to testify before you today.

BILIRAKIS:

Thank you, doctor. And I will say to you all when we finish up that we would very much welcome suggestions from you in terms of how we can improve the overall process. Please, be thinking of that. Help us to help you so to speak.

Dr. Soderstrom?

SODERSTROM:

Thank you, Mr. Chairman. And I echo my comments of my colleagues here in welcoming the opportunity to address what we think is a very important topic for this government to face.

In my role as managing director of the Office of Cooperative Research, I have exactly the same responsibilities that my colleague Andrew Neighbour has. So, I won't bother to repeat those.

What I would like to underscore, however, is that in the course of fulfilling our research and educational missions, universities scientists often create intellectual assets that have the potential to benefit society and further the universities' educational goals.

Some of these assets, but, by no means all, maybe it will result in patentable inventions. As they initially emerge from the universities

laboratories, however, these inventions are not and I underscore are not commercial products. Rather, they require substantial investment of time, energy and financial resources to unlock their potential. That is not the role of the university. That is the role of the private sector.

This process is best realized in the significant commercial sector involvement. Under the protection of a license agreement that we negotiate with companies they can confidently invest in transforming these intangible assets into tangible products.

Prior to the enactment of the Bayh-Dole Act, companies faced a significant hurdles in negotiating such agreements with the universities because the government lacked the resources and links with industry needed to develop and market these inventions, hundreds of valuable patents and many new chemical entities were sitting unused on the shelves of laboratories throughout the United States.

In addition, the U.S. industry was not inclined to brave the government bureaucracy to license these patents. Thus, technology transfer from the universities was primarily accomplished by publishing the research results, training students for the workforce and, in some cases, with land grant universities, agricultural extension services.

The ability, however, to retain title and thus license the inventions has been a healthy incentive for universities to become much more involved in the technology transfer process. And such incentive was needed. We have ample evidence of that since participation prior to that was so under utilized.

Since then, we have seen that patent and licensing activities has encouraged faculty and the universities to get involved in a rather time consuming activity which has to be done in addition to our primary missions of research and education. University patenting and licensing efforts under Bayh-Dole has fostered the commercialization of many new technological advances that impact the lives of millions of people across this nation.

Numerous pharmaceutical and medical products, environmentally friendly or manufacturing technology, inventions which improve public safety and information technology services has resulted from the transfer of federally sponsored research results from academic laboratories to the business community and ultimately to consumers.

In many instances, these products and processes would not have reached the public without the incentives that are afforded by this act. Indeed, the British News Weekly, the economists recently concluded that the Bayh-Dole Act was possibly the most inspired piece of legislation ever to be enacted by the American Congress in the past half century. I agree.

If you look at the results, I think you will as well. Over the last 23 years, nearly 23,000 license agreements have been enacted and are currently active. In the last five years over 1,500 new products have been introduced to the marketplace. Last year, 494 new companies were formed based on licenses from academic institutions and since 1980 3,800 new ventures have been created. I think those are astounding results. And if I just look at my own institution, Yale University, which happens to be a substantial recipient of NIH funds, I see the same effect.

The result of the support of NIH funding has been a wealth of new knowledge that has led to discoveries that are transforming our understanding of human disease. Translating this knowledge into new means of diagnosis, prevention and treatment has yielded new inventions with the potential for profound and positive effect on the welfare and health and safety of human kind.

But, if I look, in particular, at one issue that hasn't been mentioned yet

today, but I want to draw attention to, which is the transformation of the local economy based on this. And based on just on Yale's strength in the biomedical sciences, we have been able to help build the biotechnology industry in and around an economically depressed area of New Haven, Connecticut. The results from the formation -- have resulted in the formation of 25 new biotechnology companies in the greater New Haven area. In the last two years alone, those companies have attracted $1.5 billion in private sector investment, all of which is going into the further development of NIH funded research.

More importantly, those companies now employ 1,300 people and they have begun the transformation of more of the areas.

Mr. Chairman, I want to bring to your attention something that I think exemplifies the heart of my testimony. I recently had a conversation with the vice chairman of the NASDAQ stock market. In the course of that conversation he related to me that he believed that based on his estimate 30 percent of the companies that are currently listed on the NASDAQ exchange owe their value to the results of government sponsored research and development. Technologies licensed from academia have been instrumental in spawning an entirely new industry, improving the productivity and competitiveness of those companies and creating new companies and jobs. The Bayh-Dole Act continues to be a national success story, representing the foundation of a successful union among government, universities and industry. And the success of this three-way partnership cannot be overstated.

Thank you, Mr. Chairman.

BILIRAKIS:

Thank you, doctor. You know, we've talked about the Bayh-Dole Act and its accomplishments and think back how much medicine might have progressed if that act had taken place earlier. And I'm told by staff and I guess some of you all could verify this, it took about 20 years of discussions before we could get to that particular point. So, (inaudible).

SODERSTROM:

That's absolutely correct, sir.

BILIRAKIS:

Well, Dr. Sigal, please proceed?

SIGAL:

Mr. Chairman, members of the committee, I'm very happy to be here today. I'm here in two capacities, one is personally and one is as the chairman of the Friends of Cancer Research. As a personal study, I think you should know that everyone in my family has died of cancer, everyone. My mother just recently died of pancreatic cancer. My sister died at 40-years old leaving a four-year old child and my father died of prostate cancer. So, I have devoted my life to making a difference in this matter.

Friends is a coalition of all the major groups in cancer research. It has the professional organizations, the American Cancer Society, ASCO, AACR (ph), as involved patient groups, Lymphoma, breast cancer, prostrate cancer and many individuals who care and make a difference.

The investment in the NIH and the results and what we have gotten out of this has been staggering to the patients in an enormous and well-spent money. And it will has made a difference and in the future it will make an enormous difference. Patients gain when scientific knowledge and understanding grows is

rapidly disseminated. Patients benefit when they have improved access and meaningful information about their diseases and conditions and their options to treatment or participation in clinical trials.

Patients benefit from the discoveries of the NIH scientists and those who research and support it by the NIH or transfer to the private sector with complex, risky and expensive process of development into commercial product.

The United States technology transfer policies are the envy of the world because the NIH, under the direction of Congress, has made the creation of new products essential goals of the American biomedical research. The most important benefit is that it benefits the patients and the people.

Since Bayh-Dole Congress has implemented a policy structure that recognizes and builds upon the fact that the marketplace can be a powerful tool in promoting innovation. It is the private sector firms that produce overwhelming percentage of goods and services that underlie the dynamic American economy in the United States. However, the government in this case the NIH plays an important role in expanding the basic understanding of science. It is the knowledge explosion that has been facilitated by dramatic increases in federal funding for biomedical research.

But if Congress after Congress has recognized the faster more easily technology can get into the hands of the private sector, the greater the likelihood that a product will be developed and marketed. As a patient representative and advocate, I want to discuss one concern that arises in discussions of technology transfer. Some well- intended policy makers have urged the government to impose price controls as a pre-condition to private sector licensing or government discoveries.

This has been urged in explicit ways and through policies that have a similar net effect. I can tell you from experience that seeking to guarantee access to a fair price achieved products using the mechanisms is troubling and will not work and will not help the patient who is the most important part of this equation. First, reasonable pricing process of the NIH have not worked in the past. The number and quality of discoveries that were licensed declined during a five-year period when such a policy was in effect. Companies who can undertake the risky and expensive process of drug development estimated of over $800 million product do not want the agreements that have disadvantage terms when they can invest those resources to consumer product without strings attached.

Second, companies cannot bear the risk of not knowing what price will be considered reasonable. Government discoveries or license that are building the product development that the stage very little knowledge is known about the potential product, therefore, it is impossible to define what a reasonable price will be.

Any steps to assure fair prices should be applied uniformly to all products, rather than penalize products created from the NIH. Second, narrowly crafted measures in Medicaid and certain other special federal programs now are assuring fair prices. Finally, the Congress should recognize that drug price competition is simulated by policies that advance the development of new products. It is in the interest of the patients to have more than one therapy on the market. This is critical. This is how we gain knowledge and this is how we get better products.

Recently, yesterday, the Friends of Cancer Research announced a public private partnership with the five pharmaceutical companies of the National Cancer Institute to really work on clinical trials for early stage trials in the communities for underserved patients and geriatric patients. It is a model of the way a partnership should work between the government and the private

sector. (Inaudible) companies came together for this knowledge to help the government, and we at the National Cancer Institute work with them for the benefit of patients and community. That is a positive model of a public private partnerships.

This kind of partnership celebrated yesterday was symbolic of the kinds of relationships that government and the Congress should be fostering. We cannot expect the government to do everything, but neither can we expect the private sector to fund every bit of fundamental research. We need to support and grow partnerships between the government and the private sector so that patients can be assured that both are pursuing the common good of expanding access to clinical trials by patients, and the developments of new products to treat and cure serious unmet medical needs.

As the Committee on Energy and Commerce continues these hearings on the National Institutes of Health of behalf of patients and patient advocacy groups, I urge you to keep the following principles in mind. First, do no harm. The current system of knowledge and management, information, dissemination and technology transfer at the NIH work remarkably well. Please, do not be tempted to undertake actions that would fundamentally jeopardize the record of success and the patients.

Second, as you contemplate the NIH, please keep in mind the necessity of positive partnerships and collaborations between government and the private sector. Patients can ill afford a public (inaudible) that demonizes either the pharmaceutical companies or biotechnology companies and the industry and the outstanding scientists and researchers at the NIH.

Thank you very much for the opportunity to participate and I'm happy to take questions.

BILIRAKIS:

Thank you, doctor Sigal. Thank you for being here, for sharing that with us, and for your courage and your dedication.

Well, I frankly, virtually every question has been answered already by your testimony. I would ask in terms of university research partnerships, how do -- is there a difference in how and what is the difference between working with the federal government versus the private sector?

NEIGHBOUR:

A complex question, but I think an interesting one. With funding from the federal government, we're obviously very concerned about basic knowledge and we're a lot freer to push the boundaries of knowledge to explore new areas that we think may have one day a potential of being a platform for the development of product. We typically focus on mechanisms, on systems and understanding diseases, not specifically on creating little white powders that will become drugs to be injected or given to patients.

So, the nature of the research from the outset is quite different. The second, probably the most fundamental issue that consumes a lot of my time are the intellectual property issues. As soon as we begin to work with a company, the company has to protect its business. And, consequently, significant concerns about ownership with inventions, access by that company to that intellectual property become a fundamental part of the negotiation between us and the company. And we need to maintain certain basic academic tenants, which are important to the university, particularly freedom to publish, protection of our institution and an opportunity to use the results of our research to support other researchers and other activities in the future. The company, tends, of course, to want to establish a monopoly position and take that

knowledge forward, invest in it and develop the project.

So, there are some fundamental difference but I think we've learned since the emergence of Bayh-Dole how to manage those differences and create partnerships that serve everyone's needs quite well.

BILIRAKIS:

Thank you, doctor.

Dr. Soderstrom, Dr. Gardner, whatever?

SODERSTROM:

I would just like to add one thing to my colleague and his comments because I was actually going to ask -- the answer I was going to give you was going to be fairly (inaudible). I was going to say quite well, thank you. In part, because over the last 20 years, as Andrew was pointing out, we have begun to develop norms of behavior and activities which are mutually supportive. I want to use one example from Yale that I think illustrates this point and I actually mentioned it in my written testimony, so I'll refer back to that.

But, one of the things that the National Cancer Institute has done is funded a number of laboratories around the country that are specializing in certain types of biological assays which can then be used to test different compounds for activity against a particular disease state. In the case of Yale, the laboratory of Dr. Yung-Chi Cheng is world famous for screening against things like Hepatitis B. Also, he was one of the original for setting up -- original investigators of setting up assays against HIV as well.

In the context of that, we've received many compounds from small biotech companies and major pharmaceutical companies which we then test against these assays which the NIH funded the development of. Out of that, we are able to concern things like which ones will have the lower levels of toxicity, less side effects et cetera and we are able to give that information back to the companies. That type of partnership, I think is particularly effective if we look at just one drug, 3TC, which we all recognize as Epivir. Epivir, the original formulation of 3TC had many different analogues, but using the techniques that Dr. Cheng and his colleagues at Emery University had developed, we were able to identify the specific version of the compound that would have the lowest profile of toxicity and the most efficacy, particularly when combined with AZT. I think that is an exciting partnership, which was afforded by the abilities that we have under Bayh-Dole.

BILIRAKIS:

Dr. Gardner?

GARDNER:

I'd just like to add that the vast majority of funding at most research intensive universities comes from the federal government and that is the kind of funding that fits more with the core values of a university endeavor. The core values of a university endeavor are to pursue fundamental knowledge and disseminate information freely. In the course of that educating the next generation of scientists.

I have worked in both sectors. The core values in industry are product development and in that context, intellectual property and confidentiality are extremely important. So, you can see there is a diversion in the core values. The partnership of the NIH and universities is profoundly successful and very good because they have similar core values. And this isn't to say that to

knock either set. They're both important. But, it does go to the question of how valuable is the license that comes from NIH, our federally funded research through a university or from NIH to a pharmaceutical company? By nature of the core value of this kind of research, fundamental knowledge, early knowledge dissemination, they're very early stage ideas, (inaudible) ideas. They've not gone through formulations or any of the stages of product development that are so expensive. So, it's understanding that should help to divert away arguments of high royalty bids or price controls on drugs that have a very early stage, a small part from the NIH, as important as it is.

BILIRAKIS:

Well, thank you.

Dr. Lindberg is still in the room and I don't know whether any of the people are here, but I know they're certainly represented here at my request. And I know that they all feel good about what they've heard you say. I didn't hear any criticisms from you or bureaucratic things that can be cleared up. So, hopefully, if there are, you might furnish them to us in writing later on or possibly even mention them during further questioning.

But, the chair now recognizes the gentlelady from California, Ms. Eshoo, for an inquiry.

ESHOO:

Thank you, Mr. Chairman.

I want to thank the panelists and welcome you here today. I think it was President Kennedy that said that -- when he made the remarks about the Nobel prize winners that were gathered in the White House that only one other time had there'd been such great intellect, I'm paraphrasing of course, is gathered there, other than the time that Thomas Jefferson dined alone. So, I'm reminded of that today because you are a very distinguished panel and I think that you informed the committee very well about your work.

I want to extend a special welcome to Dr. Phyllis Gardner, who, Mr. Chairman, is my constituent, and serves with great distinction as the senior associate dean for education and student affairs at Stanford University. But, the background that she just spoke of, I think is very important because there is an enormous linkage and really a symbiotic relationship between the universities, both public and private in our countries and then what flows out to the private sector. Dr. Gardner was the president of research at Alta Company, Alto, of course, has been acquired now by Johnson and Johnson. But, that speaks to a part of it and so how we fund this research and how it works through our universities, both public and private, is one of the great stories of America. This is a unique American story. And I think that if there's anything that -- and I said this to some of the panelist before we began, that we somehow have come to a place of such happily full appreciation or near full appreciation of this. But, I think that we have this pettiness about that we will always have this. That somehow this is always going to remain.

We have a very full and serious obligation to protect this, to keep the investments in it going. And to do everything that we can relative to the technology transfer that does take place, to Dr. Sigal and her courage and she says that everyone in her family has died of cancer, that's our challenge. That's our selective challenge. And I think that a society obviously is measured by how it takes care of its people and that's what you're here to talk about today.

Dr. Gardner, what do you think Stanford's technology transfer program has done for the bay area, of course, that's a softball to you? But, I think that

it's an important story and how are the technology transfers helping regions outside of the obviously benefits to health care? And, then my second question to you is that a number of my colleagues have asked by the federal government doesn't recoup more of its investment in research that leads to products. Why do you think more royalties on products should not be returned to the government?

And then to the full panel, what do you think an appropriate return on investment is for the government? Now, I ask that, I have a little different take on this than some of my colleagues on the committee, but I think that it's still these are still worthwhile questions.

BILIRAKIS:

Very worthwhile questions. I wish you had given the panel five minutes in order to answer those questions.

Go ahead, Dr. Gardner.

GARDNER:

First of all, the bay area is a thriving economy, both in the high tech and the biotech sectors. The high tech sector, starting with Fred Turman (ph) and funding (inaudible) and Hewlett Packard et cetera through some government funds and then proceeding thereon. And then with the Bayh-Dole Act, also the Cohen-Boyer (ph) patents, which brought in a quarter of a billion dollars total for the university at a royalty rate of a tenth of a percent. That puts forth this thriving economy in the Silicon Valley area. That is the envy of the growth that brings people from all over the world to try to imitate it. It's even the envy of many parts of the nation. And there are other centers that are important, certainly San Diego, the research triangle in North Carolina. Certainly, Ohio State is trying to get there. I am on the board of a company where they're pushing hard. But, we have been at the forefront and the numbers of jobs created, the uxorious (ph) created in the local economy, it's profound. And that's one of the reason why I would -- not only do we recoup investments from savings of the better health care that people have, which is a profound savings and the estimates are in trillions of dollars because of better health of workers.

And, not only do we get that, but we also have the centers of the economy to the knowledge based economy that the rest of the world is trying to imitate. And I just don't -- hope that we do not rock that boat because I believe it comes back to the federal government and stays through those two mechanisms.

NEIGHBOUR:

Mr. Chairman, if I could add that one return that's not being mentioned and is often not measured or talked about critics of drug pricing is taxes. It seems to me that at the end of the cycle the successful drug company that has to cover its manufacturing costs, its development costs, the winners and the losers, ends up with a profit that generates taxes that come back into the economy and support NIH appropriations.

They also sustain a (inaudible) for the employees, a large number of employees, who like you and I are taxpayers. And so that measurable benefit is a very real one and is the basis on which this society is built. So, I think return on investment, if ones focusing on dollars, if you do the math will actually come out ahead.

But, I think the more important thing is to not do the math. I think the most important thing is to think about the quality of life and what we would

not have if companies and the universities and NIH and the other federal agencies were not sustaining this incredible research enterprise, which, as has been stated, is the envy of the world. There is hardly a day or a week in my office that I'm not hosting a visitor from Chile, Korea, Japan, Italy, Germany, Great Britain, (inaudible), that wants to know how it's done. And we know how it's done and we've done it right. And I think anything that would interfere with that process, other than create an improvement would be a deficit for this nation.

BILIRAKIS:
I just wish the entire subcommittee were here to...

ESHOO:
I do too.

BILIRAKIS:
... listen to these comments.
Dr. Soderstrom?

SODERSTROM:
I'm going to add one more to that which is the list, and I alluded to it earlier, which is increased productivity, which we all know that Chairman Greenspan has pointed to as being the engine of the economy right now. Anyone who read the Wall Street Journal yesterday knows what happens if we don't have healthy workers in our businesses driving our economy. We can only look at Africa where President Bush is today and see what happens. We don't face that today. We don't face that because of many of the discoveries that were made with NIH funds that have been translated from the academic research into the biotech and biopharmaceutical industry. And I think that that's one of the costs, I'm not an economists, but I would add, has to be factored in.

BILIRAKIS:
I don't know whether you have anything to add to that, Dr. Sigal, but...

SIGAL:
Just very briefly, I think it's very clear that the mission of the NIH must be innovation discovery and knowledge for the public good. Once we start getting (inaudible) in terms of the investment, we are really going to be in trouble. But, the return on investment is the public health of these people all over the world.

BILIRAKIS:
Amen to that. Thank you.

ESHOO:
Thank you, Mr. Chairman.
Thank you, distinguished panelists.

BILIRAKIS:
Mr. (Inaudible) you would like to (inaudible)?

(UNKNOWN)
Thank you, Mr. Chairman. I very much appreciate the comments of the panel today and though I have been a frequent critic of pharmaceutical industry drug

pricing, I agree with much of what you have to say. But, because I'm a little concerned that what you say may be taken in the broader context then what you actually said, I want to make a couple of comments.

The passion that drives Dr. Sigal, the cancer in her family, is something we feel in many of our constituents because there are parts to this equation about the availability of prescription drugs. One part is innovation and I don't believe there's a single person in the Congress who wants to shut down that innovation. And then that, since you have all of our support, it's been -- but, the other half of the problem is distribution. And in Maine I can't tell there are thousands and thousands of my constituents who can't possibly afford to take the drugs that their doctors tell them they have to take. And they are next to Canada.

Women who are fighting for their lives with breast cancer in Maine have finally learned that Tomoxifin (ph) costs one-tenth as much in Canada as it does in the United States. And I assure you the industry's still making a profit up there. And, so what we try to do is figure out how to deal with this particular problem. And many of you talked about the disadvantages and I agree with this, of trying to price a product somehow while it's not -- while it's still within the NIH framework or in that sort of early research framework. And I don't think we buy that at all.

But, we do have a serious problem with Medicare. And it seems to many of us who are on Medicare, beneficiaries should pay the highest prices in the world. They are in the biggest health care plan in the country. If they were organized, that plan would provide them as ETNA beneficiaries and SIGNA beneficiaries and the United beneficiaries with some discount in the price that they pay. But, they don't get that because essentially they have to pay whatever the industry would charge.

And, so, just to kind of set this in kind of that's the issue that I think many of us are struggling with. We don't quarrel with the importance of innovation. We believe in Bayh-Dole. We think that this partnership between the universities and the NIH is extraordinarily valuable. But, we have to figure out how to make sure the people who need pharmaceutical products can actually get them.

I think it was Dr. Soderstrom mentioned a couple of other comments. I think you mentioned Africa and diseases in Africa. To always seem to me that we ought to expect the private sector to do what the private sector, with the assistance of the universities does best, that is develop innovative new products. It's not so good at producing products that don't yield a return, whether it's sleeping sickness or malaria or whatever, many of the diseases other than AIDS that are afflicting Africa are not getting the attention they deserve.

And, Dr. Sigal, one quick comment, because in your written testimony you had a reference to this study done at Tufts I simply can't resist making a couple comments about that study. The $800 million that the industry has repeated over and over again as the total cost to bring a new drug to market is based on the study at Tufts. I view that study as flawed. First of all, half of that $800 million, half of that $800 million, according to the study is opportunity costs. That is what the money could have earned by being invested somewhere else. But, there's no more profitable industry in the country than the pharmaceutical industry. So, there are reasons why the investment is so heavy in R&D in the pharmaceutical industry.

And the second thing I would say is I think they looked at about 66 different drugs, none of which, none of which were funded initially by NIH. And so the drugs that they took for a sample are -- is wildly different from

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the way most drugs come to the market. That is most drugs come with some, at least, initial research that is government funded through the NIH. And, so for those reasons, many of us quarrel with that study a good deal. But, we are with you completely on the need to keep this industry going. We respect, Dr. Gardner, the differences between biotech and pharma. And we simply have to find a way to deal responsibly with the other half of the problem, which is how we get the drugs to people who need them.

I've taken all my time and haven't given you time to respond and I must apologize.

BILIRAKIS:

Yes, the time is up.

You know, I've been hoping that this hearing would focus on bench to bedside, which is certainly very, very significant, and for the most part it has. I thank you so very much. I know it makes me feel an awful lot better from the standpoint of research and what it accomplishes and so many things that are byproducts of research that you all went into, which is just terrific, in addition to the health and the quality of health care the products economically.

I thank you very much for being here. We will have questions to you in writing. We would appreciate your responses. And, again, please feel free to let us know. If there are things that you suggest that NIH should do, or the FDA or the National Institute of Cancer or whatever the Cancer Institute or whatever that you think that maybe we should address or take a look at or ask or raise questions about or whatever, please let us know.

Dr. Sigal, you're shacking your head, so please feel free to do that. You've got an open invitation.

Thank you so very much for a great hearing. Hearing adjourned.

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