SUMMARY OF THE TESTIMONY OF ANDREW NEIGHBOUR

Over the past twenty years or so, the NIH and research universities throughout the United States who receive their funding support from extramural NIH grant programs have developed a collaborative and effective alliance that yields enormous benefit for our society and for mankind.

In this testimony, I will describe some of these benefits as well as some of the challenges and controversies that have the potential to impede this success.

The passage of the Bayh-Dole Act in 1980 was a bold and inspired move that shifted from the government to universities the responsibility for protecting and commercializing inventions made with federal funds. NIH has played a lead role in its implementation and in building a strong alliance with research universities.

Universities have built effective programs for managing the intellectual property generated from federal grants and contracts. They are committed to disseminating the results of their research through publication and technology transfer to the public and industry so that innovative products can improve the quality of life for our society.

Technology transfer is a complex and resource intensive activity. The University of California spends approximately $20 million per year to manage a portfolio of more than 5,000 inventions, and 1,000 active licenses. 1,000 new inventions are disclosed each year.

Major discoveries that resulted from NIH-funded research at the University of California 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 has formed a major platform of research that has fostered additional federal and private funding spawning a plethora of high value products.

Success has resulted in some criticism which, I believe, is founded mostly on three misunderstandings that are discussed in this testimony in greater detail:

- Technology transfer is not a linear process;
- Money is an incomplete measure of technology transfer performance; and
- Universities do not do technology transfer to make money.

The reality is that fundamental advances in life sciences and biomedicine have arisen from NIH funding, and the technology transfer laws and practices have aided their development into useful and valuable knowledge and products from which the public derive enormous benefit.

Disturbing this activity would impede the advantages and benefits that accrue from the alliance between the NIH, universities and industry that has emerged from passage of the Bayh-Dole Act.

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House of Representatives, Committee on Energy and Commerce
Subcommittee on Health
Michael Bilirakis, Chairman

National Institutes of Health: Moving Research from the Bench to the Bedside
Subcommittee on Health
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Chairman Bilirakis, Ranking Member Brown, Representative Waxman and Members of the Subcommittee:

On behalf of the University of California, I welcome this opportunity to testify before this subcommittee on the topic of "NIH: Moving Research from the Bench to the Bedside." As the Executive Director for the Office of Research Administration at UCLA, I am responsible for the management of both publicly and privately sponsored research for the campus, and for the transfer of its innovative technologies to the marketplace. I have enjoyed more than twenty years working in the realm of technology transfer in both academic and corporate sectors. I also serve as a Board Member of the Council on Governmental Relations (COGR), an association of more than 150 leading US research universities, and am the incoming chair of COGR's Committee of Contracts and Intellectual Property.

BACKGROUND

Over the past twenty years or so, the NIH and research universities throughout the United States who receive their funding support from extramural NIH grant programs have developed a

collaborative and effective alliance that yields enormous benefit for our society and for mankind. In my remarks today, while I will describe some of these benefits, I will also discuss the challenges and controversies that have the potential to impede this success.

The passage of the Bayh-Dole Act in 1980 was a bold and inspired move that shifted from the government to universities the responsibility for protecting and commercializing inventions made with federal funds. The Act applies to research funded by any federal agency. However, because most life sciences and biomedical research is supported through the NIH, and this segment tends to generate the most intellectual property, it is the NIH that plays perhaps the most visible role in Bayh-Dole implementation. Over the past twenty years or so, the guidance, oversight and coordination provided by NIH has served to build a collaborative alliance between academe and the government leading to more and more effective technology transfer.

In the University of California alone, more than 6,500 individual scientists have reported new inventions since the enactment of Bayh-Dole representing the creation of a vast research enterprise that has brought immeasurable and invaluable benefits to society.

Perhaps the prototypical example of the benefit of federal/university collaboration is the 1973 discovery by Cohen and Boyer of recombinant DNA technology, otherwise known as “gene splicing.” In research funded by the American Cancer Society, National Science Foundation and NIH, these two scientists at Stanford and the University of California discovered the means to insert genetic material artificially into native DNA. This technique launched an entire new industry called “biotechnology.” As you will note, this invention predated Bayh-Dole. However, because of a special “patent agreement” with NIH, Stanford and the University of California were allowed to elect title to the patent and, in so doing, assumed the responsibility for licensing

the invention. During the life of the patent, Stanford's technology transfer office executed and managed more than 300 non-exclusive licenses with this growing biotechnology industry.

With this experience in view, many individuals and organizations believed that the task was well beyond the means and capabilities of the government. Consequently, they encouraged the Congress to consider moving the responsibility for commercializing federally funded inventions from the government agencies to the University receiving the federal grants. Passage of Bayh-Dole conferred not only the right to take title to inventions arising from government-funded research, but also an obligation to commercialize these inventions diligently for the benefit of the public. With this mandate, Universities began the difficult task of developing technology transfer programs equipped to steward their newly acquired intellectual property assets.

TECHNOLOGY TRANSFER AT THE UNIVERSITY OF CALIFORNIA

With the largest academic research enterprise in the US and perhaps the world, the University of California system has built a technology transfer program that many consider to be among the most effective yet developed. Initially, the program was centered in the Office of the President as a central Office of Technology Transfer. As experience grew, the University realized the merits of moving some of the activities to the local campuses, particularly those with large research programs. Presently, the larger campuses (and the federal laboratories managed by the University) perform most of the technology activities at the local campus. The system OTT provides coordination, oversight, policy review, legal support and some licensing support. The individual campuses that have their own technology transfer offices manage the licensing of their portfolios locally. The system as a whole expends approximately $10-12 million per year in operating expenses and the same amount in "out-of-pocket" patenting costs to manage almost 1,000 new inventions received each year. The University has accumulated a total portfolio of more than 5,000 active inventions in its system wide portfolio and monitors

almost 1,000 patent licenses with industry. In FY02, the University executed 125 new patent licenses and 55 plant licenses. In summary, the process involves the evaluation of inventions, protection of the intellectual property through patent or copyright, marketing to industry, negotiating and executing licenses, and monitoring the licensees' diligence in commercializing inventions.

Since the Cohen-Boyer invention, major discoveries that resulted from NIH-funded research at the University of California 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 has formed a major platform of research that has fostered additional federal and private funding spawning a plethora of high value products. UCLA alone has brought to the public many valuable advances in healthcare including devices to correct brain aneurisms, the nicotine patch to control tobacco addiction, positron emission tomography (PET scanning), and new diagnostics for breast and prostate cancer. All of these examples were either directly or indirectly supported by NIH and the technology transfer process.

Unfortunately, however, these very successes have turned a spotlight onto the process which, in turn, has caused some to ask just how successful are we? Are we getting too rich from tax-payer supported research? Or perhaps we are wasting this resource and not realizing adequate return on investment.

While oversight and monitoring of federally supported programs is clearly appropriate and desirable, some of the criticisms appear to be founded on misunderstandings of the process and the drivers that motivate its participants.

In my view, there are three myths that underlie most of the criticism of the technology transfer process. They can be briefly summarized as:

(i) Technology transfer is a simple linear activity from “bench to bedside;”

(ii) Money is a sound measure of performance and value; and

(iii) Universities commercialize their inventions to create wealth for themselves.

I will now amplify each of these myths.

MYTH #1: TECHNOLOGY TRANSFER IS A LINEAR ACTIVITY

Previous speakers have provided definitions of the term “technology transfer.” Many people who are not familiar with technology transfer conjure in their minds a somewhat linear activity, whereby federally funded research in the university results in a new discovery. Then driven by the Bayh-Dole Act, the university technology transfer office: reviews the invention for commercial viability; elects title; files a patent; markets it to industry; negotiates a license; and the product, perhaps a new therapy for a major disease, goes to market. In other words, an academic researcher discovers a new drug and soon afterwards it shows up in the pharmacy.

Like many other things, this process is not as simple as that. In observing that gravity could bend light waves, Einstein showed nearly a century ago that the shortest distance between two points is not a straight line but a curve. Thus, we too should imagine a technology transfer process that is not linear, but rather one whose beginnings and endings merge to form a circle. For example, while public funding supports discovery, the early stage inventions made in the basic science laboratory of a university frequently attract support from the private sector. Collaborations with industry that follow may then lead to the building of new products on the knowledge and platform technologies made by the university scientist. Industry turns these

through lengthy development cycles over many years into products. Most product candidates wither along the way; few make it through development and testing to the market. Product sales generate profits and wealth, some of which is returned through taxation to restore the federal coffers. In addition, through sponsored research and philanthropy, industry reinvests some of this wealth into new research. Sometimes new discoveries become the platform for the creation of new companies that bring new jobs to our communities and sustain economic development through taxes. Royalties paid to the university are shared with the inventor and the university portion is used to sustain the technology transfer process, build new research infrastructure, and support new discovery programs.

Iin fiscal year 2002, 973 new inventions were reported to University of California technology transfer offices adding to a total invention portfolio of more than 5,000 active cases. On receipt of a new invention disclosure, the first task for the technology transfer office (TTO) is to determine what funding sources were used to support the research yielding the new discovery. This is done to establish whether prior rights may be attached to the invention based on commitments to the funding source. If supported with any NIH grants or contracts (or any other federal agency), the invention will fall under the conditions of the Bayh-Dole Act requiring that we report the invention and decide whether or not to elect title and file for intellectual property protection through the US Patent and Trademark Office. To arrive at this decision, the TTO must exercise professional judgment based on a scientific, technical and business assessment to determine the commercial viability of the invention. Is it a profound scientific breakthrough with no commercial utility? Is it perhaps, simply a better mousetrap for which there is no market need? Or perhaps it is so new, that there are no comparable products in the market. The point being that technology transfer is not a straightforward process in which research by NIH always generates inventions with an obvious value in the marketplace. A certain medical school dean once asked me why we didn't only patent "the good ones." Because many University inventions

are so unrefined and untested, it is difficult to determine with certainty the future path for the majority of the inventions that faculty researchers disclose. Illustrative of the process is the oft used axiom of the princess kissing frogs in search of a prince.

Once the patent application is filed, the TTO sets about marketing the invention to appropriate industry partners in the hope of finding one willing to develop the invention into a product under a suitable contract or license. Frequently, the inventions themselves are valuable not as an actual saleable product, but as a technology that will assist the corporate partner in developing their own products. A common example arising from NIH-funded research might be the discovery of a new cellular component that is responsible for triggering cancer growth. It may be possible to gain a patent on the discovery of this protein and on its use as a target for drugs that might inhibit its function and stop cancer cells from spreading. The drug, in this example, would be developed exclusively by the company. However, they might need a license to the original invention and access to the knowledge and skill of the university inventor in order to develop their commercial product effectively.

Having found a company interested in licensing the invention, the TTO negotiates a license that establishes the obligations of the licensee to develop the invention diligently at its expense and to pay fees and royalties against future product sales in return for the license to make, use and/or sell the invention.

The “frog-prince analogy” is a good one as there is an enormous winnowing effect with very few discoveries getting through this process and reaching the marketplace. On average, the University of California files new patent applications on 45-50% of the new inventions disclosed each year. Approximately 30% of these will issue as US patents, and less than half of those will

ever be licensed. To recap, of the 973 new discoveries received in 2002, only 5% will be licensed. Many of these will fail to reach the market.

To close the loop on this circular process, however, it should be stressed that the discovery is often the beginning of a new process. Exposure to the researcher and his or her invention by the company frequently generates a new interest that results in the company becoming a private sponsor of a new research program in the inventor's laboratory. In addition, under those rare circumstances where a highly commercial invention does yield a successful product in the marketplace, income earned from royalties by the University is reinvested into research, and the companies tax obligations result in sources of revenue to fund future agency research appropriations, thereby completing the circle.

From this discussion, the Subcommittee will I hope appreciate the complexity of technology transfer and the relative difficulty of moving inventions from bench to bedside.

MYTH #2: MONEY IS A SOUND MEASURE OF PERFORMANCE AND VALUE

For the external observer, it is tempting and easy to measure technology transfer by the amount of money it yields. For any given University, this would mean examining the annual gross revenues derived from licensing its inventions. The technology transfer circle is like a catherine wheel, a firework (popular in Great Britain) consisting of a disk with rockets equally spaced around its perimeter. When lit, it spins at high speed and showers energy and light in a broad circumference. Indeed, some licenses generate income, but the research enterprise yields so much more. In reality technology transfer includes the training and graduation of students who move into the world as trained scientists and professionals. Knowledge is created and shared through publication and presentation. Faculty scientists serve as consultants and advisors to

the public and private sectors. While some inventions must be patented to ensure commercial interest and value, not all discoveries benefit society through licensing and commercialization. Counting dollars to quantify technology transfer ignores these other sometimes more valuable benefits that accrue from federally supported research activities in the University.

A letter from Carl Feldbaum, President of the Biotechnology Industry Organization, dated June 11, 2001 to Dr. Maria Friere, then Director of Technology Transfer at NIH, succinctly and thoroughly lists the varied and significant returns on investment that accrue to the public from NIH-sponsored research. These include basic science knowledge and understanding; the development of new therapeutics and diagnostics; scientific training that provides employees for a rapidly growing new biotechnology industry; research tools to advance scientific research; and the licensing of new inventions from both intramural and extramurally-funded research.

Furthermore, a quantitative performance assessment is predicated on the assumption that more money means greater societal value. Is a University that makes many millions of dollars from an improvement in cell phone technology necessarily more successful at technology transfer than one that develops a cure for a rare disease that may yield less than one hundred thousand dollars?

Critics of academic technology transfer who focus on the revenue streams derived from licensing often erroneously contend that universities should not get rich from exploiting tax payer's funds. Simply put, universities do not "get rich" from their technology transfer activities. The University of California, widely held to be one of the most successful university systems in the field of technology transfer averages an annual gross income from licensing of approximately $80 million. After payment of legal expenses, the cost of providing technology transfer services, and the inventor's share, $20-25 million is returned to the system to support

ongoing research. This amount represents less than one percent of the total research expenditures of the UC system. The annual survey published by the Association of University Technology Managers (AUTM) shows that fewer than ten universities generated more than $20 million in gross revenues in FY2002. In virtually all cases, this was because each had a single invention that yielded the majority of the income. At the University of California, 25 inventions from its total active portfolio of 5,000 produced 68% of its annual income.

Similarly, few individual inventors receive significant funds from their inventions. Since most inventions yield less than $10,000 in gross royalties per year, few faculty inventors realize any significant gains from the 35% revenue share that must be split with their co-inventors.

It has also been argued by some that royalty bearing licenses of federally funded discoveries contribute to unreasonable pricing of “blockbuster” drugs. While it has been clearly documented that few if any of these drugs arose directly from federally funded research, it has been unequivocally demonstrated that drug pricing is determined by the high cost of development and testing required before a drug can be sold, and that royalty obligations have negligible effect on market price of these treatments.

Paradoxically, NIH was recently criticized for not charging a high enough royalty for technology it developed that was part of a major drug now marketed by Bristol-Myers Squibb.

Therefore, measuring technology transfer accomplishments by the amount of money an invention generates for the university or the inventors fails to capture the broader benefits to the public that accrue from NIH-funded research and the larger research enterprise.

MYTH #3: UNIVERSITIES COMMERCIALIZE THEIR INVENTIONS TO CREATE WEALTH FOR THEMSELVES

Focusing on the income derived from licensing for one moment, an experienced businessman would conclude that based upon return on investment ratios, University technology transfer is largely unsuccessful. A quick search of the Patent Office database shows that the Regents of the University of California have been awarded 4,313 US patents since 1975. That's more than Pfizer, Inc., (2,774) and less than Merck (6,346). While the University may thus be in the same league as certain Fortune 100 companies, there are fundamental difference in its commercialization strategies. For profit companies focus their research in market segments in which they do business. Typically, they support internal research and development for the purpose of expanding their targeted strategic business interests. Universities not only attempt to broaden their research enterprise across all disciplines, they do not direct the research objectives of their faculty. Another particularly critical point is that the university relies on their own faculty to decide whether or not to publish their findings or to seek a proprietary position on their discoveries before they are more broadly disseminated. Protecting the right of its faculty to select topics on which they conduct their research and to publish whatever and whenever they see fit are among the basic tenets of academic freedom. Consequently, university inventions that may have great potential value do sometimes find their way in to the public domain for all to use without the exclusionary protection of a patent. If universities were to run technology transfer as a business, we would behave very differently.

The mission of the research university is education, the pursuit of knowledge, and public service. Basic academic studies of bacteria in hot springs in far away places may seem eclectic to some. But imagine how a drug for cancer would have been discovered by a major multinational pharmaceutical company had it not been for laboratory processes that use

enzymes isolated from these very bacteria to manipulate genes to produce the drugs that now treat patients.

The primary purpose of technology transfer in a research university is to provide a supportive and sustained environment for the researcher to flourish. Licensing generates corporate collaborations building partnerships with industry. Companies have resources that Universities cannot afford that academic scientists need access to for their research. Some inventions will stall without corporate involvement. Many potential life science-based discoveries need the formulation, manufacturing, testing and marketing skills of corporations to turn them from an academic discovery to one that can be dispensed from the pharmacy. As indicated above, revenues from technology licensing represent less than one percent of our total research budget and a fraction of a percentage point of total operations. Given the cost of technology transfer and the relatively low cash returns, this is an ineffective source of operating capital and the University does not view its purpose to be one of budget supplementation.

Universities measure their success by their contribution to the spinning catherine wheel. Not only how many inventions has it yielded, and how many have made it into the market to provide benefit to the public, but also how many graduates has it prepared for the world. State universities support and contribute to local economic development. Growth of its research enterprise creates jobs in the university itself. Sometimes it generates new ventures that grow in to new companies. The leading biotech companies like Amgen and Genentech all grew from academic origins. At the University of California alone, more than 200 new companies have been spun out based on new technologies invented by its faculty in recent years.

CONCLUSION

In supporting the Bayh-Dole Act and our role in technology transfer, universities are faced with a conundrum. On one-hand, some believe that we are getting rich using tax payers' support through federal grants from NIH and other agencies. Conversely, some argue that we should derive a greater financial return on investment and criticize us for being incompetent and wasting federal or public funds.

The reality, however, is revealed when one measures the broader value and benefits that emanate from the university academic enterprise – namely the fundamental advances in knowledge and technology arising directly and indirectly from the creative efforts of hundreds of thousands of expert academic scientists and their students. The enablement of new products that have changed our world, especially in the form of improved understanding of disease, of accurate diagnostics, and effective therapeutics that allow the dying to live and improve the quality of life of so many.

What would the world be like today without our 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 let the innocent free? All of these technologies together with vaccines and new drugs began in universities that were financed in whole or in part with federal funds through the NIH. Imagine a world where our collective expertise that has been built over the past 20 years to bring these and other innovations forward is eroded and impeded by changing the law because a minority feel it's not working – a feeling founded on a lack of knowledge and understanding of the complexity of the task.

The alliance with NIH is working. Guidelines developed and promulgated by the agency encourage the broad dissemination of research tools developed in universities that can facilitate

new research discoveries. Giving Universities the opportunity and the right to manage their inventions assures that they will be transferred diligently and effectively in a manner beyond the capabilities and resources of the agency if it were to carry this responsibility alone.

Mr. Chairman, Subcommittee Members, it is my fervent belief that this alliance between the NIH, the universities and the industrial sector is working well. 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 sake of the public and this Nation. With a greater knowledge and understanding of the technology transfer process and the accomplishments of NIH and their academic partners, you will play a key role in protecting these beneficial outcomes.

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