Compiled Written Public Comments

NIH Workshop on *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*

June 28, 2023 – August 19, 2023

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44. Jennifer Burke, Partnership to Fight Chronic Disease

Submission Date: 6/29/2023

Name: Fred Reinhart

Name of Organization: Not Provided

Comment:

As a 38-year veteran of academic technology transfer and Past President of AUTM, I would like to comment on the upcoming workshop.

The role of NIH, including its internal research and funding of extramural research is at the heart of America's successful medical, biomedical and pharmaceutical sectors. Americans benefit from access to a wide range of leading-edge diagnostics, vaccines and therapeutics. It is no secret that the U.S. is the leading innovator in these fields. One factor that supports these outcomes is the model that draws public and private stakeholders into cooperative partnerships in which each can contribute based on their strengths and resources.

NIH is the world's leader in medical research and awards funding to both research institutions and companies. Academia performs basic and applied research, identifies, protects and licenses promising inventions to new and existing companies. Industry does developmental and applied research and supplies the majority of funding to carry new Dx, Rx , vaccine and other innovations through the developmental and regulatory phases and into the commercial realm.

With respect to inventions derived from research in academia and teaching hospitals, over 300 important vaccines and therapeutics have reached the public as a result of academic licenses to industry. It would be foolish and counterproductive to undermine such an effective model yet several groups (specifically KEI and UAEM) are trying to do just that. They are doing so by making one blatantly false claim: that drugs like Xtandi, a prostate cancer drug, were developed with government money. They weren't. The federal government provided several million dollars to UCLA which resulted in early results that two companies built upon and brought to market after investing over $900,000,000. Thus, to say Xtandi was developed by the government and its price should be regulated by the government is simply not true. Such claims conveniently ignore the realities of the U.S. drug development model in which industry invests the majority of time and money that creates a new therapeutic.

The critics mentioned and others also have chosen to creatively and deliberately misinterpret Bayh-Dole law to claim that its "march-in" provision can be used to set prices. It cannot and the reasons have been widely detailed already. Yes, we need to ensure affordability and wide access to all new Dx, Rx and vaccines. We need to find ways to do that without undoing the remarkably effective system already in place.

Fred Reinhart
Plymouth, MI

Additional Comment (attachment): None

Submission Date: 7/8/2023

Name: Josh Sarnoff

Name of Organization: DePaul University College of Law

Comment:

Request to comment at the 7/31 workshop on transforming discoveries into products. FWIW, some of what I will say is included in the attached, discussing the ability of NIH to compel trade secrecy sharing should it develop the political will to do so.

Thanks.

Josh Sarnoff

Joshua D. Sarnoff (he, him, his)
Professor of Law
DePaul University College of Law
Center for Intellectual Property Law and Information Technology

Additional Comment (attachment): Available at https://hastingslawjournal.org/wp-content/uploads/1-Levine-final.pdf

Submission Date: 7/15/2023

Name: John Fraser

Name of Organization: Burnside Development and Associates

Comment:

Written submission as I am unavailable during the scheduled time of the July Workshop.

regards

John A. Fraser, RTTP, CLP
President
Burnside Development and Associates
Past President, AUTM

Additional Comment (attachment):

One more example of Tax Payers' Dollars at work though the National Labs, the Stevenson Wydler Act and the Bayh-Dole Act.

My name is John Fraser, a former President and Chair of AUTM. I have headed 4 academic technology commercialization offices – 2 in the US, 2 in Canada of which 2 were for-profit, 2 were not-for-profit.

I am unavailable during the schedule Workshop time, so I want to point out one more example of a very high profile drug and how research at a National laboratory and an academic center lead to the new, now widely known drug (**Ozempic and Wegovy**).

This occurred in the environment supportive of innovation provided by both the Stevenson-Wydler Technology Innovation Act of 1980 and the Bayh-Dole Act of the same year.

The following is verbatim from an article in the Wall Street Journal June 23, 2023

Monster Diet Drugs Like Ozempic Started With Actual Monsters

By Rolfe Winkler and Ben Cohen June 23, 2023 7:53 am ET

Before there was Ozempic or Mounjaro, there were fish guts and Gila monsters.

The blockbuster diabetes drugs that have revolutionized obesity treatment seem to have come out of nowhere, turning the diet industry upside down in just the past year. But they didn't arrive suddenly. They are the unlikely result of two separate bodies of science that date back decades and began with the study of two unsightly creatures: a carnivorous fish and a poisonous lizard.

In 1980, researchers at **Massachusetts General Hospital** wanted to use new technology to find the gene that encodes a hormone called glucagon. The team decided to study Anglerfish, which have special organs that make the hormone, simplifying the task of gathering samples of pure tissue.

They hired a Cape Cod fisherman to find the slimy bottom-feeders known for their sharp teeth and lightbulb-like lure. The fisherman tossed his catch on the dock, where two young scientists dissected “the ugliest fish you could ever imagine,” said Dick Goodman, one of those postdocs.

After plucking out organs the size of Lima beans with scalpels, they dropped them into liquid nitrogen and drove back to Boston. Then they determined the genetic sequence of glucagon, which is how they learned that the same gene encodes related hormones known as peptides. One of them was a key discovery that would soon be found in humans, too.

It was called glucagon-like peptide-1 and its nickname was GLP-1.

After they found GLP-1, others would determine its significance. Scientists in Massachusetts and Europe learned that it encourages insulin release and lowers blood sugar. That held out hope that it could help treat diabetes. Later they discovered that GLP-1 makes people feel fuller faster and slows down emptying of food from the stomach.

But there was a problem: GLP-1 vanishes from the human body nearly as fast as it is secreted, chewed up by enzymes and washed away by the kidneys in minutes. That meant there was little chance of developing the magic peptide into a drug.

To investigate whether it helped diabetics, scientists had to infuse GLP-1 intravenously. Studies showed it worked, lowering blood sugar. But some also foreshadowed the main side effect that plagues today’s GLP-1-mimicking drugs: nausea.

The early research that led to GLP-1 drugs included an experiment on Anglerfish.

David Nathan, a **MassGen** physician scientist who led a 1991 study, still remembers what happened when they increased the dose: “One person leaned over the side of his chair and threw up on my shoes.”

The key to the first drug would come from a serendipitous discovery inside another odd-looking animal.

Around the time Goodman was cutting open fish, Jean-Pierre Raufman was studying insect and animal venoms to see if they stimulated digestive enzymes in mammals. “We got a tremendous response from Gila monster venom,” he recalled.

It was a small discovery that could have been forgotten, but for a lucky break nearly a decade later when Raufman gave a lecture on that work at the **Bronx Veterans Administration**. John Eng, an expert in identifying peptides, was intrigued. The pair had collaborated on unrelated work a few years before. Eng proposed they study Gila monsters.

Gila monsters are poisonous lizards with powerful jaws and beaded skin.

Native to the U.S. southwest, Gila monsters (pronounced: HEE-luh) are poisonous lizards measuring 20 inches with powerful jaws and black-and-orange beaded skin. Adults eat four

meals per year, and live most of their lives below ground, slowly digesting energy stored in their tails.

Eng and Raufman studied powdered Gila monster venom ordered from the Miami Serpentarium, whose owner survived 172 snake bites over the years as he produced venom for research.

Eng isolated a small peptide that he called Exendin-4, which they found was similar to human GLP-1.

Eng then tested his new peptide on diabetic mice and found something intriguing: It not only reduced blood glucose, it did so for hours. If the same effect were to be observed in humans, it could be the key to turning GLP-1 into a meaningful advance in diabetes treatment, not just a seasickness simulator in an IV bag. Hoping that he could sell it to a pharmaceutical company that would develop it into a drug, Eng filed for a patent in 1993.

Jens Juul Holst, a pioneering GLP-1 researcher, remembers standing in an exhibit hall at a European conference next to Eng. The two had put up posters that displayed their work, hoping top researchers would stop by to discuss it. But other scientists were skeptical that anything derived from a lizard would work in humans.

"He was extremely frustrated," recalled Holst. "Nobody was interested in his work. None of the important people. It was too strange for people to accept."

After three years, tens of thousands of dollars in patent-related fees and thousands of miles traveled, Eng found himself standing with his poster in San Francisco. This time, he caught the attention of Andrew Young, an executive from a small pharmaceutical company named **Amylin.**

"I saw the results in the mice and realized this could be druggable," Young said.

When an Eli Lilly executive leaned over his shoulder to look at Eng's work, Young worried he might miss his chance. Not long after, Amylin licensed the patent.

They worked to develop Exendin-4 into a drug by synthesizing the Gila monster peptide. They weren't sure what would happen in humans. "We couldn't predict weight loss or weight gain with these drugs," recalled Young. "They enhance insulin secretion. Usually that increases body weight." But the effect on slowing the stomach's processing of food was more pronounced and Young's team found as they tested their new drug that it caused weight loss.

To get a better understanding of Exendin-4, Young consulted with Mark Seward, a dentist raising more than 100 Gila monsters in his Colorado Springs, Colo., basement. The lizard enthusiast's task was to feed them and draw blood. One took exception to the needle in its tail, slipped its restraint and snapped its teeth on Seward's palm—the only time he's been bitten in the decades he's raised the animals. "It's like a wasp sting," he said, "but much worse."

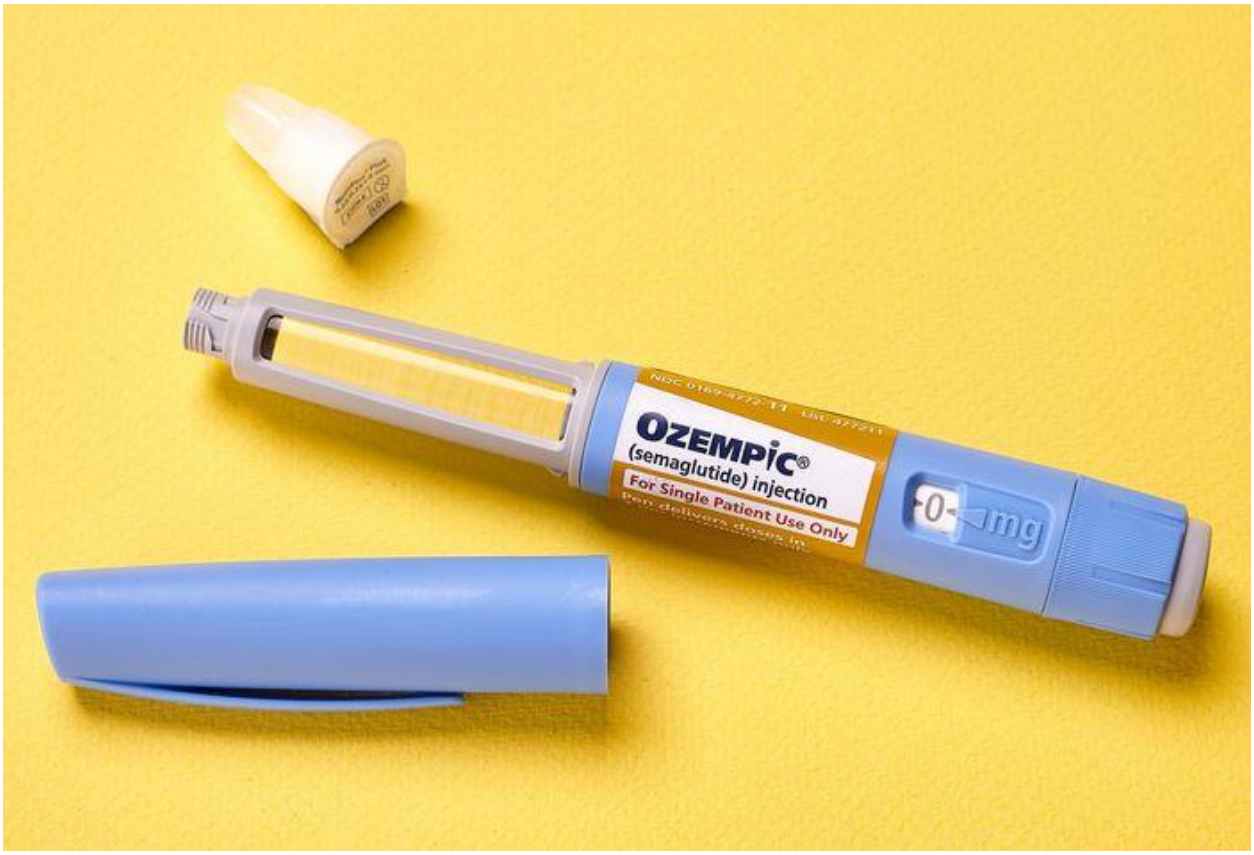
Nine years after the chance San Francisco meeting between Eng and Young, **the Food and Drug Administration approved the first GLP-1-based treatment in 2005.**

The twice-daily injection remained in the bloodstream for hours, helping patients manage Type 2 diabetes. Eng would be paid royalties as high as $6.7 million per year for the drug, according to federal government data available after 2015. “It was a long journey,” said Eng.

The proof of concept pushed other pharmaceutical companies to make more-effective and longer-lasting GLP-1 drugs.

At first, **Novo Nordisk** executives had little interest in GLP-1 drugs. They gave priority to Novo’s main business of selling insulin. “A lot of people didn’t believe in it,” says Jens Larsen, international medical director for the Danish company. He stopped his own mid-1990s study of IV-infused GLP-1 when patients on a higher dose started vomiting. The research was shelved until 2001.

The Gila monster-derived drug gave them a push, said Larsen: “It made companies more aware that this could be a serious competitor and we had to step up and put more people on it.”



An Ozempic pen by Novo Nordisk. PHOTO CREDIT: F. Martin Ramin/The Wall Street Journal
Photo: F. Martin Ramin/The Wall Street Journal

Novo kept at it, working on its own drug that more closely resembled the human peptide. With some clever chemistry it bumped up this drug’s time in the body to a day. Its first GLP-1 drug, the once-daily shot liraglutide, would receive FDA approval in 2010.

Seven years later came its longer-lasting diabetes drug, the once-weekly shot semaglutide. As it turned out, it was also the best of the drugs for weight loss, making it the first blockbuster in the category. A higher dose was approved in 2021 to treat obesity.

Those two approved doses are better known today by their brand names: Ozempic and Wegovy.

Submission Date: 7/24/2023

Name: Sarah Kaminer Bourland

Name of Organization: Patients for Affordable Drugs

Comment:

Hello,

Attached are comments from Patients for Affordable Drugs for the upcoming workshop on “Maximizing NIH’s Levers to Catalyze Technology Transfer.” We were unable to sign up in time to share oral comments, so please keep our organization in mind if any slots become available.

Thank you,

Sarah Kaminer Bourland Legislative & Policy Director (she/her)
Patients For Affordable Drugs, Patients For Affordable Drugs NOW

Additional Comment (attachment):

Submission Date: 7/25/2023

Name: Andrew Schlafly

Name of Organization: Eagle Forum Education and Legal Defense Fund

Comment:

To whom it may concern:

Eagle Forum Education and Legal Defense Fund, a nonprofit organization founded by Phyllis Schlafly in 1981, is pleased to comment on the National Institutes of Health's (NIH) invitation to comment regarding the “Workshop on Transforming Discoveries into Products: Maximizing NIH’s Levers to Catalyze Technology Transfer.”

Please accept our comments, which are attached as a pdf file.

Thank you!

Andrew L. Schlafly
Counsel for Eagle Forum Education and Legal Defense Fund

Additional Comment (attachment):

Submission Date: 7/26/2023

Name: Frank Cullen

Name of Organization: Council for Innovation Promotion

Comment:

Dear Director Jorgenson,

I hope you're doing well. I've attached comments from the Council for Innovation Promotion -- a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere -- on the 7/31 Office of Science Policy technology transfer workshop.

The Council for Innovation Promotion appreciates your attention to these important issues, and also the opportunity to share our views. Please contact me should you have any questions or require additional information.

Sincerely,
Frank Cullen

--

Frank Cullen
Executive Director, Council for Innovation Promotion

Additional Comment (attachment):

Submission Date: 7/26/2023

Name: James Edwards

Name of Organization: Conservatives for Property Rights

Comment:

Attached please find comments from the coalition Conservatives for Property Rights (CPR) regarding the National Institutes of Health's (NIH) July 31 "Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer."

Kindest regards,

James Edwards

Additional Comment (attachment):

Submission Date: 7/26/2023

Name: Joseph P. Allen

Name of Organization: Bayh-Dole Coalition

Comment:

Dear Director Jorgenson,

My name is Joseph P. Allen, and I serve as executive director of the Bayh-Dole Coalition. The Bayh-Dole Coalition is a diverse group of research and innovation-oriented individuals and organizations committed to preserving the Bayh-Dole law, and informing policymakers and the public of its many benefits.

I am submitting the attached comments on behalf of the Bayh-Dole Coalition to the NIH ahead of their workshop: "Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer." Please let me know if you need any additional information and I look forward to the upcoming workshop.

Best,
Joseph P. Allen

--

Joseph P. Allen
Executive Director

Additional Comment (attachment):

Submission Date: 7/27/2023

Name: Walter Copan

Name of Organization: N/A

Comment:

Dear Director Jorgenson:

Thank you for the opportunity to submit comments regarding the National Institutes of Health's forthcoming workshop, Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

These are attached. Best wishes for a productive workshop. Please fee free to reach out if I can provide additional support.

Kind regards,
Walt

Walter G. Copan, PhD
Vice President for Research and Technology Transfer

COLORADOSCHOOLOFMINES | https://research.mines.edu/

Additional Comment (attachment):

Submission Date: 7/27/2023

Name: Stephen Heinig

Name of Organization: Association of American Medical Colleges

Comment:

Attached, please find written comments of the Association of American Medical Colleges for consideration at the NIH's July 31 workshop and for inclusion in the record.
Please let us know directly if further information would be helpful, or if there is any difficulty in transmission.
Thank you.

Stephen Heinig
Director, Science Policy
Association of American Medical Colleges

Additional Comment (attachment):

Submission Date: 7/27/2023

Name: Adam Mossoff

Name of Organization: George Mason University

Comment:

Dear Director Jorgenson,

Please find attached my written comment for consideration by the NIH in its Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

If you have any questions, please feel free to contact me via email or by telephone at (703) 993-9577.

Best regards,

Adam Mossoff

Adam Mossoff
Professor of Law
Antonin Scalia Law School
George Mason University

Additional Comment (attachment):

Submission Date: 7/27/2023

Name: Brian O'Shaughnessy

Name of Organization: Licensing Executives Society (USA & Canada), Inc.

Comment:

Dear Colleagues:

The Licensing Executives Society (USA & Canada), Inc. appreciates the opportunity to submit comments for NIH consideration in relation to its "Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer." Our comments are attached.

Please feel free to contact me with any questions.

Respectfully submitted,

--Brian

Dinsmore

Brian P. O'Shaughnessy
Partner
Chair, IP Transactions and Licensing Group

Dinsmore & Shohl LLP • Legal Counsel

Sr. V.P., Public Policy
Past President (2016-2017)

Additional Comment (attachment):

Submission Date: 7/27/2023

Name: Lizbet Boroughs

Name of Organization: Association for American Universities & COGR

Comment:

Dear Dr. Jorgenson,

On behalf of AAU and COGR, I am pleased to submit our joint comments for consideration during the NIH's upcoming workshop, "Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer. "

My best,

Lizbet Boroughs, MSPH
Associate Vice President for Federal Relations
Association for American Universities (AAU)

Additional Comment (attachment):

Submission Date: 7/27/2023

Name: Robert Taylor

Name of Organization: Alliance of US Startups and Inventors for Jobs

Comment:

Attached is my written statement for the NIH workshop entitled “Transforming Discoveries into Products: Maximizing NIH’s Levers to Catalyze Technology Transfer.”

I submitting this document as a signed version in PDF format, which includes a signature page and an Appendix. I also am submitting it in Word format without a signature or Appendix, should the agency need to alter the margins or pagination to incorporate into a larger document.

My contact information is below, if you have any questions.

Bob Taylor

PLEASE ACKNOWLEDGE RECIEPT

Robert P. Taylor
RPT Legal Strategies PC

Additional Comment (attachment):

Submission Date: 7/27/2023

Name: Cassidy Parshall

Name of Organization: Public Citizen

Comment:

Hello,

Please find attached comments from Public Citizen regarding the National Institutes of Health Office of Science Policy's July 31, 2023 workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

Thank you for the opportunity to provide written comments.

Sincerely,
Cassidy Parshall

Additional Comment (attachment):

Submission Date: 7/27/2023

Name: Stephen Susalka

Name of Organization: AUTM

Comment:

Dear Director Jorgenson,

Please find attached AUTM's written comments for the NIH's Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

Sincerely,
Steve

Stephen J. Susalka, PhD, CLP, RTTP (He/Him)
Chief Executive Officer

Additional Comment (attachment):

Submission Date: 7/27/2023

Name: Fred Ledley, Paula Chaves da Silva, & Edward Zhou

Name of Organization: Bentley University

Comment:

Please accept our written comments concerning the Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

We are looking forward to joining this workshop on Monday.

Fred Ledley
Paula Chaves da Silva
Edward Zhou

Fred Ledley, M.D.
Professor, Departments of Natural and Applied Sciences, Management
Director, Center for Integration of Science and Industry
Bentley University

Additional Comment (attachment):

Submission Date: 7/27/2023

Name: Alex Moss

Name of Organization: Public Interest Patent Law Institute

Comment:

Please find attached the comments of the Public Interest Patent Law Institute regarding the upcoming NIH Workshop. Please let me know if there are any problems with the transmission.

Regards,
Alex Moss

_____
Executive Director
Public Interest Patent Law Institute

Additional Comment (attachment):

Submission Date: 7/28/2023

Name: Jocelyn Ulrich

Name of Organization: Pharmaceutical Research and Manufacturers of America

Comment:

Dear Dr. Jorgenson,

Please find attached comments from PhRMA to inform the proceedings of NIH's Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

Sincerely,

Jocelyn

Jocelyn Ulrich, MPH
she/her/hers
P*h*RMA
Deputy Vice President
Policy, Research and Membership

Additional Comment (attachment):

Submission Date: 7/28/2023

Name: Hans Sauer

Name of Organization: Biotechnology Innovation Organization

Comment:

Please find attached BIO's comment in preparation for the NIH upcoming technology transfer workshop. Thank you in advance for considering our comments; we look forward to the workshop on Monday.

Sincerely,
Hans Sauer

Hans Sauer, Ph.D., J.D.
Deputy General Counsel,
Vice President, Intellectual Property
—
Biotechnology Innovation Organization (BIO)
www.bio.org

Additional Comment (attachment):

Submission Date: 7/30/2023

Name: Mark Emalfarb

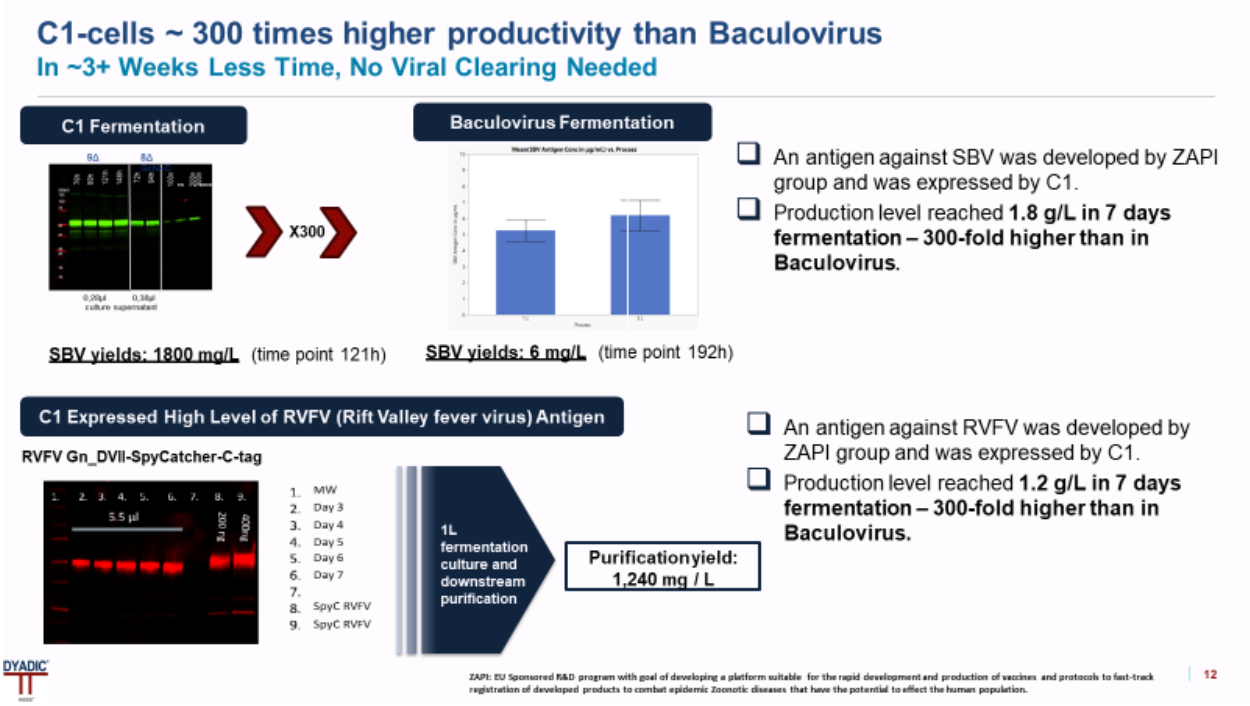
Name of Organization: Not Provided

Comment:

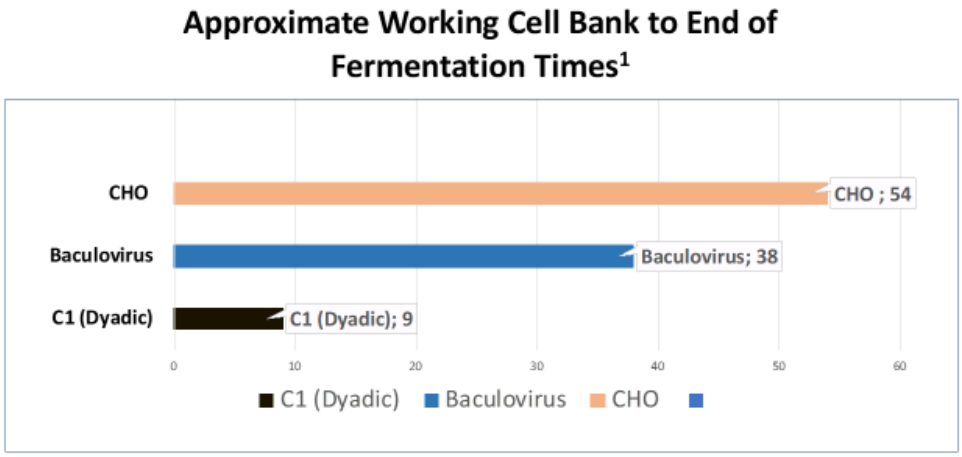
NIH and biotech/pharmaceutical companies need their scientists to utilize the most efficient cell lines in their discovery and development programs.

Too often this is overlooked by scientists early on, inefficiencies are locked in, and if a biologic makes it to commercialization the poor choice of inefficient cell lines at the beginning of the research and development stage ends up with less doses of a vaccine or a drug being available and the cost of manufacturing each dose is greater than it should be wasting tax payer's dollars and making the vaccine and/or drug less available for middle & lower income countries.

An example of this is as follows see two slides comparing yield (c1 cells are ~ 300 times more productive) and speed of manufacturing C1-cells vs Baculovirus and CHO cells (C1 production batches are much shorter).



Short Fermentation Timeline



[1]Ranges: C1 6-9 days; Baculovirus 28-38 days; CHO 41-54 days

Additional Comment (attachment): None

Submission Date: 8/11/2023

Name: James Love

Name of Organization: Knowledge Ecology International

Comment:

Attached is a comment on the shrinking time the public has to comment on NIH exclusive patent licenses.

Jamie

Additional Comment (attachment):

Submission Date: 8/15/2023

Name: Katharine Ku

Name of Organization: Wilson Sonsini Goodrich & Rosati

Comment:

Additional Comment (attachment):

Submission Date: 8/16/2023

Name: Peter Pitts

Name of Organization: Center for Medicine in the Public Interest

Comment:

Attached are my comments per the Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

Thank you,

Peter J. Pitts

Additional Comment (attachment):

Submission Date: 8/17/2023

Name: Robert Pavey

Name of Organization: Pavey Family Investments

Comment:

Attached is my statement s a Word document.

Prepared Statement of Robert D. Pavey

Partner, Morgenthaler Ventures and Manager, Pavey Family Investments
for
National Institutes of Health Workshop entitled
Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

Thank you for allowing me to submit this prepared statement.

Bob Pavey
Managing Member
Pavey Family Investmenrs

Additional Comment (attachment):

PAVEY FAMILY INVESTMENTS

August 18, 2023

Prepared Statement of Robert D. Pavey

Partner, Morgenthaler Ventures and Manager, Pavey Family Investments
for: National Institutes of Health Workshop
entitled
Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

Dr. Lyric Jorgenson
NIH Office of Science Policy
6705 Rockledge Dr #750
Bethesda, MD, 20817

VIA EMAIL: SciencePolicy@od.nih.gov

Dear Director Jorgenson,

My name is Bob Pavey. I have been a venture capitalist for more than 50 years, both as a partner in the firm Morgenthaler Ventures and currently on my own as Pavey Investments. I have invested in a number of companies pursuing breakthrough inventions in several different technologies, including both digital technology companies and biopharmaceutical companies. During the 1990s, I served as President of the National Venture Capital Association and in that role and subsequently have developed a broad perspective on the economic forces affecting investment in US early-stage technology. I am also currently a Trustee of Case Western Reserve University where my primary focus is on technology development and technology transfer.

I have reviewed a number of the written statements that were presented to the Office of Science Policy at the NIH workshop on "Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer," and I would like to add a few thoughts of my own for your consideration. In my opinion, transforming scientific discoveries and other novel ideas into products has been one of the greatest accomplishments of this country over the past fifty years and I would very much like to see the robust continuation of this great accomplishment. The remarkable growth we have enjoyed, particularly since 1980, can be attributed to a number of factors, chief among them the emergence of an investment community that was able to diversify the risks involved in investing in unproven technologies and, in many cases, unproven companies.

There always have been risk takers (known sometimes as angel investors) willing to back adventurous entrepreneurs on a one-off basis; the Spanish monarchy's willingness to provide funds to Christopher Columbus is a well-known example of "patron" style investments that have been with us throughout history. Many angel investors are still active worldwide, but what made the American venture capital experience different was the emergence of financial organizations that took a systematic approach to investing in multiple promising startups and small companies. When the risk is high that any given startup will fail, investments make more sense if a fund of investment dollars can be spread into multiple investments, in hopes that successful investments will more than offset the failures. At a

high level, this is the VC model today. And indeed when modern portfolio management theory became generally accepted about 40 years ago, institutional investors and university endowments began allocating a minority of their investment capital to private equity firms. This allowed firms such as mine to support many promising young companies while at the same time providing better returns of many non-profit institutional investors.

The American VC industry as we know it today began shortly after World War II. The industry progressed very slowly until about 1980, when the government agency responsible for regulating pension funds allowed pension funds to move to modern diversified portfolio management. At that point the entire venture capital industry exploded with growth and new investment capital. Several other forces converged about the same time that added to the growth – The reduction of capital gains taxes in 1978, the creation of the Court of Appeals for the Federal Circuit (rebuilding of a patent system that investors could rely on), and the passage of the Bayh-Dole Act that allowed the recipients of government research grants to own and license the patents that covered their work. As a result of these changes, thousands of new companies have been formed based on new and better technologies and more agile managements. Many of those small companies of the 1980s are the corporate giants of today.

Sadly, this growth cycle is showing signs of winding down. This is a key factor the agency should keep in mind as it pursues "Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer." For a variety of reasons, investors have become more risk averse, a trend that is not healthy for our future as a nation. To some extent, this increased aversion to risk is masked by the enormous influx of later stage investment capital. On closer look, however, we see that investment capital available at the seed stage is not growing. Put differently, much of private equity capital flowing into small companies over the last few years has gone into late-stage companies that no longer face startup risks. These trends become particularly important at the point where NIH is trying to maximize "technology transfer" to private companies that are willing to assume the extreme risks associated with drug development.

Much of the decline in risk taking is a direct result of government policies that increase the perceived risks facing the entrepreneur and the investor. For many investors, including myself, patents are no longer regarded as reliable protection for risky investments. My perception is based on personal experience trying to enforce a patent that is being infringed by a very large company. These large companies simply refuse to take a license and have told me that their policy is to fight every case as long as they can, because it deters other small companies from suing them. That experience is far from unique; it seems clear to me that few if any small companies can afford to enforce their patents, even strong patents. The cost is prohibitive and the time to win a patent battle can be a decade. Many venture capitalists today only invest in software, avoiding companies that depend on patents.

Perhaps an even greater threat to investors today comes from the demands by some people in Congress and the Biden Administration that they can make drugs cost less by exercising so-called "march-in rights" or by controlling the prices that private companies can charge for therapies. These ideas emanate largely from people with little or no knowledge of the return needed to justify the risk of new drug development. Such arguments are damaging the investing climate, which will only get worse unless NIH and other agencies firmly reject them.

Respectfully submitted Robert D. Pavey

Submission Date: 8/18/2023

Name: Karen Kerrigan

Name of Organization: Small Business & Entrepreneurship Council

Comment:

Thank you for the opportunity to submit comments regarding NIH's recent workshop: Transforming Discoveries Into Products - Maximizing NIH's Levers to Catalyze Technology Transfer.

I have attached comments regarding the role that small innovative firms and entrepreneurs play in innovation, and the incentives needed to continue to drive innovative discoveries and bring those to market for the betterment of consumers and our nation's health.

Please contact me if you have questions, or need additional information.

Thank you,
Karen Kerrigan

Karen Kerrigan
President & CEO
Small Business & Entrepreneurship Council
www.sbecouncil.org
@SBECouncil

Protecting small business, promoting entrepreneurship

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Gerard Scimeca

Name of Organization: Consumer Action for a Strong Economy

Comment:

Dear NIH:

Please see our attached comments to the Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

If feasible, please send confirmation of receipt, thank you.

_____

Gerard Scimeca
Chairman, CASE

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Patricia Kelmar

Name of Organization: U.S. Public Interest Research Group

Comment:

Please see attached our comments. Thank you very much.

Patricia Kelmar, JD
Senior Director, Health Care Campaigns
PIRG and PIRG EducationFund

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Jon Soderstrom

Name of Organization: Wilson Sonsini Goodrich & Rosati

Comment:

Please see my comments in the attached.

Jon Soderstrom, PhD | Chief Licensing Advisor | Wilson Sonsini Goodrich & Rosati

Additional Comment (attachment):

Lyric Jorgenson, PhD.
Office of Science Policy
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

Director Jorgenson,

My name is Jon Soderstrom, and I served as the managing director of Yale University's Office of Cooperative Research for 25 years. As someone with over three decades of experience in technology transfer, I appreciate the opportunity to submit comments regarding the National Institutes of Health's July 31 workshop, *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*.

My entire career has tracked the remarkable trajectory of American life sciences innovation since the passage of the Bayh-Dole Act in 1980.[1] Prior to then, when I was a student researching intellectual property, the federal government held title to roughly 28,000 patents. Less than 5% of those patents had been licensed or commercialized.[2] And with the government's approach of predominantly issuing non-exclusive licenses for federal innovations, companies were reluctant to invest the time and resources necessary to develop an invention for the market.

Bayh-Dole established certainty of title by providing for patent ownership by the inventors: the universities and scientists who made the discovery. The law has been instrumental in promoting collaboration between government, universities, and the private sector -- facilitating the transfer of technology from the lab to the market.

Indeed, since I first joined Yale in 1996, over 15,000 new companies have been formed, and 200 drugs and vaccines, brought to market.[3] In New Haven, I was able to play a small role in this remarkable progress, overseeing the development of 74 new start-ups that have raised over $2 billion in venture capital backing and led to more than 50 different products -- all based on Yale intellectual property.[4]

Considering the extensive positive impacts of the Bayh-Dole Act, any changes should be approached with caution to avoid disruption of the entire innovation ecosystem.

Certain lawmakers, for instance, have called upon the NIH to impose so-called "reasonable pricing" clauses for all of the agency's grants, licenses, and Cooperative R&D Agreements

[1] https://www.academia.edu/86403600/Remarks
[2] https://www.gao.gov/assets/rced-98-126.pdf
[3] http://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-2021_1.pdf
[4] https://news.yale.edu/2021/06/28/soderstrom-longtime-director-ocr-honored-25-years-leadership

(CRADAs).[5] Such clauses would deter private-sector partners from engaging in collaborative research with the NIH, hindering the progress that Bayh-Dole has made possible.

The concept of reasonable pricing clauses is not novel. In 1989, the NIH briefly adopted the policy for its CRADAs, thereby setting pricing restrictions on any products that stemmed from discoveries arising from its CRADAs or exclusive licenses.[6] While well-intentioned, this did not yield favorable outcomes for anyone involved, including patients. Rather, the number of CRADAs fell from 42 in 1989 to an average of 32 annually, as both universities and companies hesitated to partner with the NIH.[7]

As a result, NIH Director Harold Varmus rescinded the policy just six years later, stating that "the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public."[8] Fortunately, collaborations between academia and the government soon recovered, with the number of CRADAs rebounding to more than 160 by 1997.[9]

This period well illustrates the deterrent effect that reasonable pricing clauses can exert on the technology commercialization process. Such requirements inject uncertainty into the ecosystem and weaken intellectual property rights -- stymying productive public-private collaborations and depriving patients of potentially life-changing medicines.

The NIH is at a pivotal juncture: the agency can either concentrate on propelling scientific advancements for patient benefits or upend its successful policies in an attempt to tackle broader healthcare challenges. These issues have dominated discussions recently – including during the July 31 workshop – and the NIH must be careful not to let them overshadow the agency's core mission.

Not disavowing the NIH's long-standing role in facilitating public-private partnerships allows basic scientific research to be more efficiently translated into tangible therapies. These fruitful collaborations not only offer a wealth of innovative medicine choices but naturally promote competitive prices. Straying from this course with restrictive rules or inappropriate interventions -- however well-intentioned -- would halt the progress patients so desperately need.

Consider that just four years after the passage of the Bayh-Dole Act -- at the height of the HIV/AIDS epidemic -- two Yale researchers began studying an antiviral therapy that had yet to be commercialized.[10] When their work suggested the drug had promise, they licensed it to Bristol

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[5] https://www.washingtonpost.com/health/2023/06/12/sanders-hold-nih-director-drug-prices/
[6] https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf
[7] https://bayhdolecoalition.org/wp-content/uploads/2023/06/CRADA-QA-Nov-2021-FINAL.pdf
[8] 1995 - 1989 = 6 https://bayhdolecoalition.org/wp-content/uploads/2023/06/CRADA-QA-Nov-2021-FINAL.pdf
[9] https://bayhdolecoalition.org/wp-content/uploads/2023/06/CRADA-QA-Nov-2021-FINAL.pdf
[10] 1984 – 1980 = 4 https://www.academia.edu/86403600/Remarks

Myers Squibb, which shepherded the treatment through clinical trials and got fast-track approval from the FDA. Zerit would become the first effective medicine for HIV-AIDS.[11]

Absent the Bayh-Dole Act and a technology transfer framework that leverages intellectual property rights, medicines like Zerit -- along with hundreds of other cutting-edge treatments -- might never have reached the market to benefit patients. Millions of lives could be lost.

As the NIH looks to the future, it is crucial to acknowledge the importance of protecting intellectual property rights, fostering public-private partnerships, and driving the development of medical breakthroughs. And the agency must be careful not to inadvertently stifle the very engine that has propelled U.S. leadership in the life sciences.

Thank you for your consideration on this important matter.

Respectfully,

Jon Soderstrom

[11] https://www.academia.edu/86403600/Remarks

Submission Date: 8/18/2023

Name: Justin Mendoza

Name of Organization: Universities Allied for Essential Medicines

Comment:

Hello,

Please find attached comments from Universities Allied for Essential Medicines.

Thank you,
Justin Mendoza

Justin Mendoza, MPH
Executive Director, North America
Universities Allied for Essential Medicines
UAEM.org | Twitter | Facebook | Instagram

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Kevin Walters

Name of Organization: Wisconsin Alumni Research Foundation

Comment:

Dear NIH Office of Science Policy,

Please find attached a letter from the Wisconsin Alumni Research Foundation to Acting Associate Director Jorgenson in regards to the invitation to comment on your Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer. As noted in the letter, we have also attached our recent letter to the Senate HELP Committee due to its relevance to this topic.

Thank you for the opportunity to contribute to this important conversastion. Please let us know if we can be of any further assistance.

Best,

Kevin Walters

Wisconsin Alumni Research Foundation (WARF)
Public Affairs Analyst
Pronouns: he, him, his
www.warf.org

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Tom Giovanetti

Name of Organization: Institute for Policy Innovation

Comment:

_____

Tom Giovanetti
President | Institute for Policy Innovation (IPI)

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Adam Mossoff

Name of Organization: Hudson Institute

Comment:

Dear Director Jorgenson,

Please find attached my second comment for consideration by the NIH in its report from the Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

If you have any questions, please feel free to contact me via email or by telephone at (703) 993-9577.

Best regards,

Adam Mossoff

Adam Mossoff
Senior Fellow
Chair, Forum for Intellectual Property
Hudson Institute

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Stephen Ezell

Name of Organization: The Information Technology & Innovation Foundation

Comment:

To NIH Colleagues:

The Information Technology and Innovation Foundation herewith submits these comments with regard to the NIH "Workshop on Transforming Discoveries Into Products: Maximizing NIH's Levers to Catalyze Technology Transfer."

Kind regards,

Stephen Ezell

Stephen Ezell
Vice President, Global Innovation Policy | The Information Technology & Innovation Foundation

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Michael Mohr-Ramirez

Name of Organization: Taxpayers Protection Alliance

Comment:

To Whom It May Concern,

Please find comments from the Taxpayers Protection Alliance attached. Let me know if you have any questions – thank you!

Best,
Michael

--
Michael Mohr-Ramirez
Federal Policy Manager
Taxpayers Protection Alliance

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Emily Michiko Morris

Name of Organization: The University of Akron School of Law

Comment:

Dear Director Jorgenson:

Please accept the attached cover letter and law review article for consideration in relation to the July 31, 2023 NIH Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

Please do not hesitate to contact me if you have any questions.

Thank you for your time and consideration.

Emily Michiko Morris (she/her/hers)
David L. Brennan Endowed Chair and Associate Professor
The University of Akron School of Law
Support Akron Law

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Lori Pressman

Name of Organization: Not Provided

Comment:

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Ashlyn Roberts

Name of Organization: Incubate

Comment:

Good afternoon:

On behalf of Incubate, a coalition of early-stage life sciences venture capital firms representing the patient, corporate, and investment communities, please find the attached comment in response to the NIH's workshop, *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*.

Thank you for your consideration in these comments, please do not hesitate to contact myself or John@incubatecoalition.org for additional information.

Best Regards,
Ashlyn

Ashlyn Roberts
Coalition Director
@incub8coalition | incubatecoalition.org

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Drew Johnson

Name of Organization: Not Provided

Comment:

Good afternoon-

Thank you for allowing me the opportunity to comment on the NIH's July 31, 2023 workshop, focusing on the future of technology transfer in the context of biomedical innovation. Please find my comments attached and pasted below.

Respectfully,
Drew Johnson

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Claire Cassedy

Name of Organization: Knowledge Ecology International

Comment:

To Whom It May Concern:

On behalf of Knowledge Ecology International, please find attached the following written comments regarding the NIH "Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer":

- The Need for Increased Transparency and Public Safeguards in NIH Licenses. Claire Cassedy. August 18, 2023.
- The NIH does not enforce the statutory requirement to restrict the scope of exclusive rights in a patent license as set out in 35 USC § 209(a)(1-2). James Love. August 18, 2023. (Apologies if you have already received a copy of these comments).

Thank you for your consideration of these comments.

Best regards
Claire Cassedy

--
Claire Cassedy
Knowledge Ecology International
www.keionline.org

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: James Love

Name of Organization: Knowledge Ecology International

Comment:

Additional Comment (attachment):

Submission Date: 8/18/2023

Name: Charles Sauer

Name of Organization: Market Institute

Comment:

More innovation is fairly easy – create the right incentives

For good or bad – people, businesses, investors, and society react to incentives. Incentives help drive entrepreneurs to take risks, investors to put their money behind an idea, and inventors to develop new things. The US patent system is what has provided that incentive to US innovators, and with strong patents as the reward what has driven our economy forward – since our founding.

However, often when we talk about innovation – inventors end up being considered the villians. When they make money from something that we need. When they profit from something that makes our lives' better. But, we are often only looking at the winners. The ones that took the risk – and succeeded. Many inventors never develop the next life saving vaccine, quality of life changing technology, or even a best selling toy. It takes lots of different innovations to get the few that end up changing our world. And, most of the time – these innovations are funding by the individuals. They take on this risk because we have a strong patent – maybe not as strong as it once was, but we have a good patent system. That is the incentive that is needed.

Incentives work, for instance, when training a puppy – you give them treats when they do something that is good. Eventually, that puppy starts doing the things that you like more often. People and businesses are not that different. If you want them to do something you give them a reward – and eventually you start getting more of that thing. In the case of innovation – their "treat" is a property right.

A property right for inventions – a right that is limited in time and only granted with disclosure – gives innovators the knowledge that if they risk their resources and develop the next big thing, then they can defend their right and profit from their idea.

At the recent workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer – many of the ideas discussed and some of the comments submitted would lessen the value of this incentive. Not allowing exclusive licenses weakens the incentives, adding a pricing caveat to March-In would weaken the incentive, referenced based prices would weaken the incentive, and adding more control would weaken the incentive. These ideas would weaken the incentive to innovate and therefore lessen the amount of innovation. These ideas wouldn't catalyze technology transfer – they would neutralize technology transfer.

So, if the NIH is asking to speed more innovation in order to spur competition, then the answer is simple – give the inventors, the investors, the businesses even more rights. Make technology transfer easier, give the developers more rights, and focus on the things that bring more people to the table instead of less.

Unlike a puppy that has a warm bed and cozy blanket at night– entrepreneurs have to take risks and aren't guaranteed a soft landing at any point in the process. They depend on knowing that their innovations won't be stripped from them.

In order to catalyze innovation and technology transfer – give the inventors some treats instead of the stick.

Charles Sauer

President

Market Institute

--
Charles Sauer
President
Market Institute

Additional Comment (attachment): None

Submission Date: 8/19/2023

Name: Jennifer Burke

Name of Organization: Partnership to Fight Chronic Disease

Comment:

Dear Director Jorgenson:

On behalf of the Partnership to Fight Chronic Disease (PFCD), we appreciate the opportunity to submit comments to the NIH in response to the topics covered in the workshop titled *"Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer."* PFCD is a national coalition of patients, providers, community organizations, business and labor groups, and health policy experts committed to raising awareness of the number one cause of death, disability, and rising health care costs: chronic disease.

PFCD is deeply concerned about the ongoing push to misuse the Bayh-Dole Act as a policy backdoor towards sweeping drug price controls that will hinder innovation, especially in addressing chronic diseases. We urge the NIH to uphold more than two decades of precedent by once again rejecting calls to twist Bayh-Dole into a price control mechanism.

Four decades ago, a bipartisan group of lawmakers realized that federally-funded research with commercialization potential was languishing on laboratory shelves. In fact, less than 5% of more than 28,000 inventions under the federal government's ownership ever reached the market -- a significant waste of R&D funding and potential breakthroughs.

To alleviate this problem, Congress passed the Bayh-Dole Act in 1980. This legislation decentralized IP management of federally-funded research and innovation to universities and other nonprofits that received research grants. The rationale was thattech transfer professionals would be more adept at recognizingpotentially-valuable innovations.

This straightforward solution sparked a surge of innovation across the United States, as universities began licensing promising research to private entities equipped with the resources and expertise to bring life-changing products to market.

Today, technology transfer under the Bayh-Dole Act sustainsover 6.5 million American jobs and contributes a trillion dollars to our GDP. This

framework efficiently channels the efforts of university researchers, entrepreneurs, and investors towards promising new technologies with the potential to benefit patients and drive our innovation economy. As a result, more than 200 lifesaving drugs and vaccines have reached the market.

Yet, for the past two decades, activists have targeted the Bayh-Dole Act as a potential lever to enact harmful price controls on any drug that receives federal funding in its earliest stage of research and development. They claim that so-called "march-in" rights include price as a criterion for agencies like the NIH to unilaterally relicense IP.

The NIH has routinely rejected this call for backdoor price controls, most recently in March 2023. While the Bayh-Dole Act includes four specific criteria for IP relicensing, price is not mentioned once, and the authors of the law have explicitly stated that the law was never intended to permit price controls.

In addition, during the July 31 workshop -- and in broader contexts -- march-in advocates began calling for NIH to revive the "reasonable pricing clause" in its Cooperative Research and Development Agreements (CRADAs) and other collaboration, funding, and licensing agreements. However, there is instructive precedent that the NIH must take into account when evaluating this request.

Back in the early 1990s, the NIH instituted a reasonable pricerequirement on drugs that stemmed from early-stage research conducted with federal laboratories and private partners. This requirement resulted in industry partners walking away from CRADA-controlled research without any "offsetting benefit" to be found in cheaper drugs. In 1995, then-NIH Director Harold Varmus rescinded the policy, stating:

> "An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with [federal laboratories] without providing an offsetting benefit to the public. Eliminating the clause will promote research that can enhance the health of the American people."

There is no evidence to suggest that the same decline in research partnerships could be avoided in this revived proposal. NIH should resist calls to repeat the mistakes of the past and focus on conducting and funding the research that patients -- including those with chronic diseases -- count on to provide new treatments and cures.

NIH is facing significant pressure to sacrifice innovation and investment in favor of short-term wins for price controls. However, NIH must not forget its core mission to seek "the application of…knowledge to enhance health, lengthen life, and reduce illness and disability." PFCD urges the agency to reject calls to misuse Bayh-Dole and NIH policies for ill-advised and undefined price restrictions that subvert legislative intent and hamper innovation.

PFCD appreciates the opportunity to provide comments to NIH for the purpose of strengthening our nation's technology transfer ecosystem. We stand ready to assist and answer any questions.

Sincerely,
Ken Thorpe on behalf of the Partnership to Fight Chronic Disease (PFCD)

***

Jennifer Burke
Communications Director
Partnership to Fight Chronic Disease
www.fightchronicdisease.org
@pfcd

Additional Comment (attachment):

August [XX], 2023

Lyric Jorgenson, Ph.D.
Acting Associate Director for Science Policy
National Institutes of Health Office of Science Policy
6705 Rockledge Dr #750
Bethesda, MD 20817

Dear Director Jorgenson:

On behalf of the Partnership to Fight Chronic Disease (PFCD), we appreciate the opportunity to submit comments to the NIH in response to the topics covered in the workshop titled *"Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer."*[12] PFCD is a national coalition of patients, providers, community organizations, business and labor groups, and health policy experts committed to raising awareness of the number one cause of death, disability, and rising health care costs: chronic disease.[13]

PFCD is deeply concerned about the ongoing push to misuse the Bayh-Dole Act as a policy backdoor towards sweeping drug price controls that will hinder innovation, especially in addressing chronic diseases. We urge the NIH to uphold more than two decades of precedent by once again rejecting calls to twist Bayh-Dole into a price control mechanism.

Four decades ago, a bipartisan group of lawmakers realized that federally-funded research with commercialization potential was languishing on laboratory shelves. In fact, less than 5% of more than 28,000 inventions under the federal government's ownership ever reached the market -- a significant waste of R&D funding and potential breakthroughs.[14]

To alleviate this problem, Congress passed the Bayh-Dole Act in 1980.[15] This legislation decentralized IP management of federally-funded research and innovation to universities and other nonprofits that received research grants. The rationale was that tech transfer professionals would be more adept at recognizing potentially-valuable innovations.[16]

This straightforward solution sparked a surge of innovation across the United States, as universities began licensing promising research to private entities equipped with the resources and expertise to bring life-changing products to market.

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[12] https://osp.od.nih.gov/nih-to-host-workshop-on-transforming-discoveries-into-products-maximizing-nihs-levers-to-catalyze-technology-transfer/
[13] https://www.fightchronicdisease.org/public-policy-platform
[14] https://www.gao.gov/assets/rced-98-126.pdf pg 4
[15] https://drexel.edu/research/innovation/technology-commercialization/bayh-dole-act/#:~:text=The%20Bayh%2DDole%20Act%2C%20formerly,research%20programs%20within%20their%20organizations.
[16] https://www.law.cornell.edu/uscode/text/35/part-II/chapter-18

Today, technology transfer under the Bayh-Dole Act sustains over 6.5 million American jobs and contributes a trillion dollars to our GDP.[17] This framework efficiently channels the efforts of university researchers, entrepreneurs, and investors towards promising new technologies with the potential to benefit patients and drive our innovation economy. As a result, more than 200 lifesaving drugs and vaccines have reached the market.[18]

Yet, for the past two decades, activists have targeted the Bayh-Dole Act as a potential lever to enact harmful price controls on any drug that receives federal funding in its earliest stage of research and development.[19] They claim that so-called "march-in" rights include price as a criterion for agencies like the NIH to unilaterally relicense IP.[20]

The NIH has routinely rejected this call for backdoor price controls, most recently in March 2023.[21] [22] [23] While the Bayh-Dole Act includes four specific criteria for IP relicensing, price is not mentioned once, and the authors of the law have explicitly stated that the law was never intended to permit price controls. [24] [25]

In addition, during the July 31 workshop -- and in broader contexts -- march-in advocates began calling for NIH to revive the "reasonable pricing clause" in its Cooperative Research and Development Agreements (CRADAs) and other collaboration, funding, and licensing agreements.[26] [27] However, there is instructive precedent that the NIH must take into account when evaluating this request.

Back in the early 1990s, the NIH instituted a reasonable price requirement on drugs that stemmed from early-stage research conducted with federal laboratories and private partners.[28] This requirement resulted in industry partners walking away from CRADA-controlled research without any "offsetting benefit" to be found in cheaper drugs.[29] In 1995, then-NIH Director Harold Varmus rescinded the policy, stating:

> "An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with

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[17] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf
[18] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf
[19]https://www.researchgate.net/publication/228173125_Why_Don't_We_Enforce_Existing_Drug_Price_Controls_The_Unrecognized_and_Unenforced_Reasonable_Pricing_Requirements_Imposed_Upon_Patents_Deriving_in_Whole_or_in_Part_From_Federally-Funded_Research
[20] https://www.washingtonpost.com/politics/2021/09/08/claim-that-us-government-already-has-power-lower-drug-prices/
[21] https://www.keionline.org/bayh-dole/bayh-dole-timeline
[22] https://www.washingtonpost.com/politics/2021/09/08/claim-that-us-government-already-has-power-lower-drug-prices/
[23] https://bayhdolecoalition.org/bayh-dole-coalition-statement-on-nih-rejection-of-xtandi-march-in-petition/
[24] https://www.law.cornell.edu/uscode/text/35/part-II/chapter-18
[25] https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/
[26] https://www.statnews.com/pharmalot/2023/06/13/sanders-biden-nih-drugs-medicine/
[27] https://www.sanders.senate.gov/in-the-news/sanders-vows-to-oppose-nih-nominee-until-biden-produces-drug-pricing-plan/
[28] https://bayhdolecoalition.org/wp-content/uploads/2023/06/CRADA-QA-Nov-2021-FINAL.pdf pg 4
[29] https://bayhdolecoalition.org/wp-content/uploads/2023/06/CRADA-QA-Nov-2021-FINAL.pdf pg 4

> [federal laboratories] without providing an offsetting benefit to the public. Eliminating the clause will promote research that can enhance the health of the American people."[30]

There is no evidence to suggest that the same decline in research partnerships could be avoided in this revived proposal. NIH should resist calls to repeat the mistakes of the past and focus on conducting and funding the research that patients -- including those with chronic diseases -- count on to provide new treatments and cures.

NIH is facing significant pressure to sacrifice innovation and investment in favor of short-term wins for price controls. However, NIH must not forget its core mission to seek "the application of…knowledge to enhance health, lengthen life, and reduce illness and disability."[31] PFCD urges the agency to reject calls to misuse Bayh-Dole and NIH policies for ill-advised and undefined price restrictions that subvert legislative intent and hamper innovation.

PFCD appreciates the opportunity to provide comments to NIH for the purpose of strengthening our nation's technology transfer ecosystem. We stand ready to assist and answer any questions.

Sincerely,

/s/

Partnership to Fight Chronic Disease

[30] https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf
[31] https://www.nih.gov/about-nih/what-we-do/nih-almanac/about-nih#:~:text=NIH%20is%20the%20steward%20of,and%20reduce%20illness%20and%20disability.