ALLIANCE OF U.S. STARTUPS & INVENTORS FOR JOBS

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National Institutes of Health Workshop entitled
Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

My name is Robert P. Taylor, General Counsel for Alliance of U.S. Startups and Inventors for Jobs ("USIJ"). I am pleased with the invitation to appear as a public speaker during the subject workshop to present the views of USIJ and its constituencies, which comprise individual inventors, entrepreneurs, startups, and the investors that fund these entities. Many of USIJ's members and supporters are engaged in developing health care related products such as new drugs, medical devices and health care management tools. USIJ was founded nearly a decade ago to help inform government officials, members of Congress, and the Federal Judiciary regarding the role that patents play in promoting investments, development and technology transfers of these and other products that incorporate new technologies. By ameliorating some of the competitive risks associated with investments in startups and small companies, patents should play a key role in enticing venture capitalists and other investors to fund such activities, particularly in the area of pharmaceuticals, biotechnology and medical devices.

This USIJ cohort is currently responsible for the majority of new health care therapies and products, sometimes in collaboration with a larger company and other times on their own.[1] This is not to suggest that larger healthcare companies do not create new products on their own as well, but the inherent risks associated with investing in such products before they have full FDA approval often make it more attractive to wait until a smaller company has been successful in proving the science and scalability of making a product before committing funds for obtaining full FDA approval. Moreover, for a startup focused on a single technology, the risk of failure is far more likely to be existential than for a larger more diversified company. The key point from our perspective is that entrepreneurs, startups and small companies are an extremely important part of the healthcare ecosystem and present their own need for special consideration.

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[1] A study entitled "The US Ecosystem for Medicines: How new drug innovations get to patients," concludes that for the period 2011 to 2020, "55% of U.S. originated therapies were created by small biotech companies; 45% were created by large companies." https://vitaltransformation.com/2022/12/the-us-ecosystem-for-medicines-how-new-drug-innovations-get-to-patients.

Introduction.

NIH has long been at the forefront of American leadership in scientific research relating to the development of health-related products and services, and our citizens can be justifiably proud of the accomplishments of this agency. That is particularly so for the period since implementation of the bipartisan Bayh-Dole Act ("BDA") (35 U.S.C. §§ 200 – 209) in 1980, which unleashed a staggering amount of entrepreneurial zeal and creative energy. That outcome was entirely predictable because it is precisely the type of creative effort that – when properly incentivized – has driven American innovation since the founding of our republic. Prior to the implementation of the BDA, much of the scientific and technological research carried out by government agencies or developed pursuant to government grants to universities, research labs and others lay fallow in file drawers, notebooks and patents owned by either the government or the contractors that carried out the research. Although many if not most of the patents covering this government funded research were available for licensing, and a handful were in fact licensed, none of those licenses led to products that actually reached the market. This palpable lack of interest in commercializing products based on NIH research is informative – unless investors and private companies can actually own or control the technologies they bring to fruition, they are not likely to commit the time or money needed for this high risk undertaking. Simply put, what Congress learned after years of trying to interest private companies in using the inventions reflected by the patents on government funded research was that full ownership or exclusivity is an essential enticement without which there are far fewer takers, if any.

The BDA corrected this tragic waste of uncaptured value by allowing universities and research labs to own the patents that arise from their research efforts and to license those patents exclusively to private investors willing to provide the capital necessary to develop the manufacturing and delivery capabilities needed and to see the new products through the regulatory approval process.[2] As a result of these licensing relationships, the aftermath of the BDA has been the approval by FDA of hundreds of new drugs and medical devices, with many more in varying stages of completion.

To implement the objective of this workshop – "Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer" – I urge the agency to focus on those aspects of these public/private partnerships created under BDA that are most important in enticing companies to pour money and effort into moving beyond the science to create useful

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[2] The BDA, in Section 202, provides for contractor ownership of patents developed using government research grants. Exclusive licenses, depending on their specific terms, can be tantamount to full ownership. The primary feature of such licenses is that the patent owner is not allowed to license other entities to practice the patent, either within a designated field of use or at all.

products. Most everyone understands that startups, small companies, entrepreneurs and their investors make a major contribution to our nation's development of new products based on research funded by NIH (and other agencies as well). As noted above, more than half of all new drugs come from this cohort. What are not as widely understood are the motivating factors that incentivize and disincentive these entities to start down the lengthy and risky path that leads to the new products. I encourage NIH to examine these factors from the perspective of the entrepreneurs and scientists who will devote the time and energy needed to create a marketable product from a partially proven idea, and the venture capitalists and other investors who must provide the funds necessary to make this process work.

Risk of Failure.

An overarching consideration in the mind of any startup entrepreneur or investor is the high probability at the outset that the enterprise will fail, usually ending in the complete loss of invested time and money by the founders. There are many types of risk that all startups and their investors must contend with – *e.g.*, the technology that works in the lab may not work at a scale feasible for commercial production; the executive team may fail to execute on the business plan; funding may be discontinued before the process is completed as some investors reassess the prospects for success; a newer and better technology may come along that nullifies some or all of the business assumptions; the ultimate cost of production may exceed the achievable selling price; etc.

A particularly daunting risk facing the developers of any new drug or medical device is the enormous and unpredictable cost associated with the need for regulatory approval. It is not unusual for any new drug to require years of experimentation and research before it can be proven to be both effective as a treatment and safe for humans and animals, during which time the developer receives little or no revenue from the product. Although overall costs can vary widely, a new drug can easily require ten or fifteen years of development work and $2B or more from inception to final FDA approval.[3] Even for those drugs that turn out to be successful, the time value of money makes this type of investment even more expensive, particularly for venture capital firms that must show returns on their investments to remain in business. It is also the case that only about 10% of the drugs on which work is initially commenced ever reach the point of market approval, meaning that close to 90% of the initial efforts at drug development fail for

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[3] A report entitled "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," published in the Journal of Health Economics 47 (2016) describes a study of 106 new drugs developed by 10 different companies. The study estimates the average cost per drug at $1.4B without considering the time-value of the out-of-pocket investments. If a reasonable cost of funds is added, the total average cost is $2.8B per drug. https://pubmed.ncbi.nlm.nih.gov/26928437.

one of more of a variety of reasons, even after the science itself is proven and promising, because in clinical trials the product is either not safe or not effective or both.[4] Simply put, this is not an undertaking for the risk averse.

Price Controls Pose an Ongoing Existential Risk to Investing in Drug Development.

A foundational principle for investing in new drug development is that assumption of all the foregoing risks makes sense, if at all, only if the profitability of a successful venture is sufficiently attractive to cover the cost of the inevitable failures. Some critics of drug manufacturers are prone to look only at the product that successfully reaches the market and argue that the operating margin for the product is too high, leading to an uninformed insistence that NIH demand that products stemming from NIH funded research be sold at "reasonable prices." These arguments are wrong for a variety of reasons, most pointedly that bureaucrats have no idea as to what a reasonable price might be, because the actual cost of the risks assumed are not calculable. There are **theories** as to what might be a reasonable price for a specific drug, of course, but these calculations are not made by the people that, years earlier and during the development process, were willing to put up their own capital for funding the enterprise. The imposition of price controls after the fact is particularly damaging to investor confidence, because ownership or exclusive license rights to inventions are the primary basis for making the investments in the first place.[5] That is precisely why only a market-based system that allows the seller to price its product at a level of its own choosing can work effectively. Many startups go bankrupt trying to develop new products in areas dominated by established incumbents, and those that succeed must cover the cost of the failures or the investments will never be made in the first place.[6]

NIH's experience with the BDA actually confirms the difficulty in a governmental agency's efforts to inject itself into the arms-length bargaining that takes place in the real world.[7] NIH's

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[4] The study referred to in the previous footnote puts the success rate for the drugs studied at 11.83%. *Id.* at p.23.

[5] Indeed, the seemingly perpetual demands for price controls is, in itself, a risk factor that must be accounted for in an investor's assessment of whether to accept a license from NIH or a government contractor to develop a new drug.

[6] This should not be controversial. Investing in drug development is somewhat akin to wildcat drilling for crude oil, which has been a common way of locating potential subterranean pools of oil since the early 20th century. The profit from a successful well has to cover the cost of all the dry ones or the entire business model makes no economic sense. Current figures put the success rate at about 10% for on shore drilling, which is roughly on a par with success rates for drug development. https://knowledge.energyinst.org/search/record?id=115186

[7] The provisions in the recently enacted Inflation Reduction Act that give CMS the power to dictate prices have yet to take effect. It seems clear enough already, however, that to whatever extent CMS engages in these "negotiations," it is likely to reduce the number of new drugs that are available for Medicare patients and cause a

effort in 1989 to add a "reasonable price" provision to the licenses that were offered under the BDA had the effect of reducing the number of private enterprises that were willing to assume the risks of developing products under these licenses. In 1995, the agency removed the pricing requirement, acknowledging that the effort had been a mistake.[8] Investor interest thereafter rebounded, but no one will ever know what possible drugs might have been missed for lack of funding during the decline. Nevertheless, the siren song of price controls continues to waft through governmental circles periodically, as it seems to be doing currently, and must be rejected as the bad idea it has always been.

Governmental Contributions to Drug Research Are Grossly Overstated by Proponents of Price Controls.

Because the research for many new drugs is often initiated, in part, through basic scientific research funded by NIH or other governmental agency, we often hear arguments that this contribution gives the government the right to control the price or access to the drug once it is proven. This bogus argument reflects either pure ignorance or ideological foolishness – in either case it is preposterous in light the actual reality. Of course, a seminal research contribution by NIH may be an important contributor, but its principal value is to assist the recipient in attracting the private capital necessary to perform the vast majority of developmental work, assume virtually all of the risk, and bear the bulk (or all) of the cost. The fact is that the NIH contribution is but a tiny fraction of the total investment required to bring a new drug to market, with the remainder coming from investors with a large appetite for risky investments.

A study published in September 2022, entitled "The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals,"[9] showed that upwards of 95% of the total cost of developing a new drug to the point of clinical trials market is born by private investors, with the NIH contribution less than 5%. Moreover, for drugs that actually received FDA approval, the disparity is even more striking, with 98.5% of the total coming from private funding. For oncology drugs, the private contribution to cost is almost 99%. The study was based on NIH records covering the period between 1984 and 2021, during which NIH made 23,230 extramural grants for drug research, which in turn led to a total of 8126 patents that could be linked to discoveries funded by these grants. The study identified 41 therapies traceable to

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significant loss of jobs in the biopharma industry. https://vitaltransformation.com/2023/06/the-impact-of-ira-policy-expansion-proposals-on-the-us-biopharma-ecosystem

[8] https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf and https://ipwatchdog.com/2019/03/12/new-study-shows-bayh-dole-working-intended/id=107225

[9] Journal of Therapeutic Innovation & Regulatory Science (2023) Vol. 57:160 – 169. TIRS publishes peer-reviewed original research, review articles, commentaries, and letters to the editor on medical product discovery, development, regulation, access, and policy. https://www.springer.com/journal/43441

some portion of this universe of patents that reached the clinical trial stage successfully, and determined that 18 of the 41 received FDA approval. For the 41 therapies that underwent clinical trials, the aggregate contribution of NIH grants totaled $2.4B while the private contribution was $50.7B, or 95.5% of the total. This number did not include any post-approval contributions which make the disparity even greater. For drugs that actually received FDA approval, NIH funding accounted for $670M of the total cost while private sector investment totaled $44.3B or 98.5% of the total. Appendix A replicates Table 1 of the study listing all 41 therapies individually and showing the private versus public funding ratio for each.

The arguments favoring price controls – whether they come in the form of requests for the unlawful exercise of "march-in rights" that would distort the statutory language of 35 U.S.C. §203 or a request that NIH revert to the inclusion of a "reasonable price" requirement in its basic licenses to universities and other government contractors, as it did in 1989, are bereft of any proper basis in law or fact. Neither NIH nor any other government agency has any way of knowing or calculating what a "reasonable" risk-adjusted return should be, and the history of governmental efforts to control prices for the benefit of the public works out to have the opposite effect.[10] There is no more justification for NIH to try and control the price of drugs made under the BDA than there is for NIH or other government agency to argue that use of the federally funded interstate highway system entitles it to impose price restrictions on goods hauled to their destination that way; the suggestion is preposterous. This particularly so in light of the cost and risk factors discussed above and the need to attract new capital in order to have them at all.

Conclusion.

Apart from the brief (and unsuccessful) experiment in the early 1990s, NIH has successfully resisted numerous invitations to reinterpret the intent of Congress as to "march-in rights" or to impose unmanageable price restrictions on the universities and research labs that develop new therapies. Contrary to the false premise that this will lower drug prices for the benefit of the American public, we do not believe that to be the case. Were either of those efforts to succeed, the most likely outcome is that investment in new drug development will decline, as it did in the early 1990s, to the detriment of those that might need the drugs that never are discovered or developed.

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[10] The basic economic fallacy in attempts to control the price of goods or services is deftly explained by Robert L. Schuettinger in "Forty Centuries of Wage and Price Controls: How Not to Fight Inflation," published by Heritage Foundation (1979). https://cdn.mises.org/Forty%20Centuries%20of%20Wage%20and%20Price%20Controls%20How%20Not%20to%20Fight%20Inflation_2.pdf. The book recounts numerous historical examples of such efforts, dating back to the Code of Hammurabi, the Egyptian Pharaohs and continuing today, all notable failures.

Respectfully submitted,

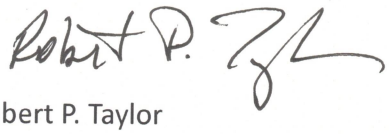

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Table 1 Total Public (NIH) and Private Funding for Cohort of Forty-One Therapies.

Therapy	Total Public Funding ($ Mil)	Total Private Funding[a] ($ Mil)	Year Approved
IMMU-132 /(Trodelvy)	$0.850	$22,519.457	2020
Tysabri	$7.575	$8756.691	2004
Myalept	$8.332	$3179.600	2014
Nexavar	$5.305	$1384.030	2005
Stivarga	$5.072	$1384.030	2012
Bexxar	$6.616	$1093.400	2003
Zelboraf	$7.144	$1047.950	2011
Spinraza	$1.604	$965.400	2016
Emtriva/Genvoya	$6.407	$951.000	2003
RTA-408	$71.746	$850.000	–
Diamyd	$5.799	$639.000	–
Zarnestra	$16.380	$628.000	–
RcoPro	$104.354	$625.000	1995
CMX001	$4.151	$613.500	–
Surfaxin	$38.388	$558.140	2012
Ixinity	$3.598	$508.300	2015
DTX301	$124.321	$481.733	–
Obizur	$7.014	$400.000	2014
haNK	$5.143	$350.460	–
Neuradiab	$313.768	$326.600	–
Increlex	$1.172	$326.270	2005
Treg	$1.804	$325.000	–
Prochymal	$4.959	$279.250	–
Amdoxovir	$19.124	$245.000	–
Horizant	$453.074	$219.990	2011
PA-457	$10.773	$218.830	–
TNFerade	$197.250	$205.900	–
Daytrana	$4.151	$200.000	2006
V2006	$11.215	$184.270	–
Gencaro	$2.377	$174.955	–
ThermoDox	$79.250	$170.000	–
SR9025	$36.127	$160.000	–
Rintega	$314.546	$145.100	–
GI-5005	$2.788	$122.600	–
Tolsura	$5.401	$96.700	2018
RiVax	$1.717	$93.000	–
Levovir	$41.201	$73.500	–
AEOL 10,150	$64.835	$69.460	–
Combipatch/Vivelle-dot	$4.150	$65.000	1998
Oncoprex	$404.693	$34.120	–
MBX-400	$10.934	$0.000	–
Total	$2,415.108	$50,671.236	
Total (approved only)	$670.208	$44,280.958	

Private funding excludes post-FDA approval funding