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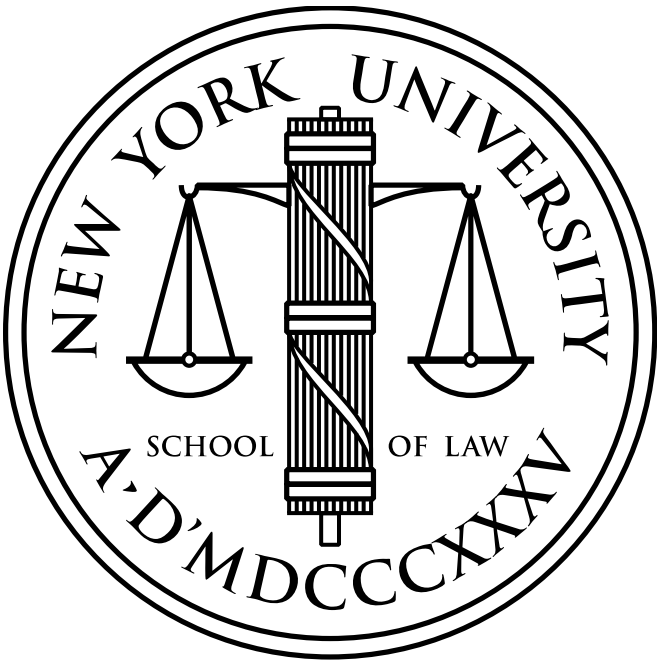

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WHAT ROLE SHOULD GOVERNMENTS PLAY IN SETTING REWARDS FOR MEDICAL INNOVATION?

MODERATOR: LISA OUELLETTE

PANELISTS: MICHAEL ABRAMOWICZ, DANIEL HEMEL, AND BHAVEN SAMPAT

On March 10, 2021, our journal partnered with the Engelberg Center on Innovation Law and Policy to host a symposium addressing the role and impact of U.S. innovation policy on access to medicine. Our 2021 Symposium Issue—Volume 11, Issue 1—captures that event.[*]

The following article represents the first of four panels. This panel considered what role governments should play in setting rewards for medical innovation. It was moderated by Professor Lisa Ouellette of Stanford Law School. The panelists included Professor Michael Abramowicz of George Washington University Law School, Professor Daniel Hemel of the University of Chicago Law School, and Professor Bhaven Sampat of the Columbia Mailman School of Public Health.

LISA OUELLETTE: As the first panel of the symposium, I think it is important to reiterate that everyone participating in this panel and in the symposium more broadly today cares deeply about access to medicines. So, even though there will be disagreements throughout about the best policies for achieving these goals, those disagreements come from a place of wanting to save lives and improve health outcomes.

[*] This transcript was modified for editorial purposes. A recording of the panel is available at NYU Journal of Intell. Property & Entertainment Law, *2021 JIPEL Symposium - Access to Medicine: The Role and Impact of U.S. Innovation Policy (Panel 1)*, YOUTUBE (Apr. 3, 2021), https://www.youtube.com/watch?v=g_KdHn3QkKw.

The original framing of this symposium was focused on the role of government patent rights in increasing access to medicine. As a preliminary note, it's important to recognize the value of pivoting away from government patent rights as the key policy lever here because the government has direct patent rights over only a very small percentage of drugs and whether the government has patent rights has little relevance for the system of allocating access to drugs. But the government does have a lot of control in setting both access and rewards without doing anything related to patents through programs like Medicare and Medicaid and the kind of bulk purchasing it's been doing throughout the pandemic and direct government provision. And in designing these institutions, policymakers should recognize that they have independent control over two elements of innovation policy: how access to those new technologies is allocated in terms of the out-of-pocket costs for patients and how those technologies are incentivized. Our panel is focused on improving the incentive side of innovation policy while facilitating access. The panels later in the day are focused more directly on access. I think it's important to remember throughout that, in many real healthcare systems, the choice of patents as part of the incentive side of innovation policy doesn't create a tradeoff with access—we really can think about these questions separately.

On the incentive side, there are a number of reasons that, for medical innovation, market signals are an imperfect signal of social value. Scholars have proposed a number of prize system alternatives—Michael's written a wonderful research handbook chapter on this.[1] Many of the specific prize schemes seem politically unlikely to happen anytime soon, but as scholars—such as Rachel Sachs and Ben Roin[2]—have noted, the current U.S. system actually is already somewhat like a prize system and could be even more so. Other countries are even more directly involved in shaping rewards through health technology assessment. So, the real question facing today's policymakers on the incentive side is how rewards for medical innovation should be set—both how much money should be spent on a given problem and what institutional mechanisms should be used for distributing those rewards. The plan for this panel is to focus on those two issues: first focusing on how the size of the rewards should be set and then turning to the institutional structures.

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[1] Michael B. Abramowicz, *Prize and Reward Alternatives to Intellectual Property*, *in* RESEARCH HANDBOOK ON THE ECONOMICS OF INTELLECTUAL PROPERTY LAW 350 (Ben Depoorter & Peter S. Menell eds., 2019).

[2] *See, e.g.*, Rachel Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 154 (2016); Benjamin N. Roin, *Intellectual Property versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999 (2014).

On this first question of the size for innovation rewards—whether that money is spent through direct government funding or ex post rewards or something else—I thought I'd start by turning things over to Daniel.

DANIEL HEMEL: Thanks, Lisa, and thanks to the organizers of the panel—really happy to be here.

My number one thought on the size of rewards is that they should be bigger. We don't spend all that much on pharma. About 12% of total health spending in the United States is on prescription drugs, so prescription drugs are not why healthcare is so expensive. We devote about 1.6% of GDP to prescription drugs. That seems surprisingly low to me—though it's high by international standards—given that these are the things that, in a lot of our cases, are going to save our lives. I would like to live in a world in which the top STEM students who want to make a lot of money go to biotech rather than to hedge funds. And I think we can do that. The tradeoff between innovation incentives and access to medicine is a policy choice, i.e., we are choosing to pit those into conflict, and we don't need to. A decade ago, that was a major theme of the literature in innovation policy and IP, and it still is to some extent, but I think it's largely a vestige of 1990s austerity politics that, as we are seeing now, the government can spend a lot more money than it does on really important things. And I think saving people's lives is a really important thing. Right now, we're seeing big rewards to Pfizer, Moderna, and Johnson & Johnson, combined with free access to vaccines. The government could just buy a lot more life-saving drugs and give them out to people for free.

We can look at the values that we use in the innovation context. The Institute for Clinical and Economic Review uses in its Remdesivir evaluation a quality-adjusted life year of $50,000. The Department of Transportation—in deciding how much car manufacturers should have to spend to make your roof more crush-resistant or to add a tire pressure monitoring system so that your car doesn't skid out of control—uses a value of a statistical life of $11 million. And those two numbers are only consistent if the average person has 220 more healthy years of life to live. We're using much lower values in the pharma context than we are in other contexts. I think size matters more than exactly how you do it, but ultimately I think rewards should be based on social value, rather than cost. I don't really see an alternative to social value—we want to incentivize researchers to focus on the most promising solutions to the most serious problems.

And the way to do that, it seems to me, is to give the largest rewards to the people who come up with the most life-saving solutions, and to try to (ex ante) funnel government investment into the most promising projects.

LISA OUELLETTE: Great. Thanks, Daniel. Michael, I know you've written about having the costs that we're spending on R&D play some role in rewarding innovators. What role do you think that should play compared to thinking about social value?

MICHAEL ABRAMOWICZ: Good question. Let me talk about that, and then I'll also talk a little bit about what Daniel said in terms of the total amount.

Daniel said, and I agree, that ultimately what we care about is social value. Whether it's patents, whether it's direct government spending, whether it's altering Medicaid or Medicare policy and so forth, we want to give bigger rewards for bigger contributions. I think the trickier question is whether we want to be entirely measuring welfare directly or whether we want to also look at inputs, like the cost that researchers spend on particular research projects. There are arguments on both sides. There's a danger to focusing too much on cost, which might encourage some wasteful spending. At the same time, we need to worry a little bit about the need to adjust for risk. We can't just say, "Well, we're going to reimburse your costs if you're successful and not reimburse you if you're not successful." I think there's wide agreement in the literature among people with a variety of views that, to the extent the government is reimbursing costs, we need to take into account risk. The problem is that this is not so easy to do. There's a danger of hindsight bias, and I think the more subtle difficulty is that a lot of the cost that we want to reimburse is not for the most immediate project that, let's say, a pharmaceutical company undertakes. It's for building the company and building the capacity to undertake that project. I certainly think we see that with COVID. We're really compensating Pfizer, Moderna, and so forth for building their companies in the first place—bringing people together with expertise who know how to work together. We're not compensating them so much for the direct outlays on the particular project—that, too, of course—but not just that.

So, those are some dangers of considering costs, but I also think there is a huge benefit in that cost can be a lot easier to measure than social value. I think that's why we see cost so much in government contracts—why we have cost-plus contracts, for example. We just think it tends to be easier to measure cost than social welfare. In the end, you might want to have some kind of hybrid system: costs less than 100% so we don't have wasteful spending, as well as some kind of assessment of social welfare.

I want to echo a little bit of what Daniel said about the total amount of spending but with a different view. My view is that we've spent way too little during COVID on vaccines and that we probably could have been a lot further along if we

had spent more. I worry that if we switch too much to incentivizing pharmaceuticals based on the anticipation that the government is going to spend money, the government is going to spend too little. I mean, we spent billions on COVID, but not a huge number of billions. If that's the case, are we really going to trust the government to spend enough on other research projects with potential benefits years down the line?

I think overall we do see the government spend a lot of money on healthcare, but maybe less on research because the benefits are further down the line. That's a major problem with our kind of political economy—we don't have systems that will quite give incentives for political actors to value long-term benefits enough.

LISA OUELLETTE: Bhaven, do you want to weigh in here?

BHAVEN SAMPAT: Thanks, Lisa. To be frank, I've thought less about some of these issues, especially the ex post reward issues, than some of my comrades on this panel. So, hopefully my reflections here aren't naive. Let me just pick up on a couple of things that both Michael and Daniel said.

My sense—and maybe I'm wrong—is that when we're talking about both R&D costs and social value, we're talking about two constructs that are notoriously difficult to operationalize and measure. On the R&D cost side, from my reading of the accounting literature years ago, there's no great standards on how to think about capitalization, failures, spillovers across projects, and the kinds of infrastructural investments that Michael talked about. I think social value is even harder. If we took seriously proposals to reward drugs—individual drugs—based on social value, we would have to think through these things.

We would have to think through things like quality versus days—how much quality is worth, and how much do we value lives today versus 10 years from now? How much do we weigh the U.S. versus the global disease burden? And how do we measure the quality gains from a drug? You run into questions like: What kinds of studies count? What is the right comparator? Do you rely on clinical trial evidence? Clinical trials with surrogate endpoints? Real-world evidence? None of this is necessarily insurmountable, but it's hard.

The general point is that the system is broken, and we should do more, and we should spend more, but beyond the kind of theoretical prize discussion or ex post rewards discussion, it would be useful to think through the cost of administering whatever system we come up with in a principled way and the kind of political economy of different systems and how they might be subject to or immune from different kinds of disease group politics.

And one last thing. The perfect shouldn't be the enemy of the good. I think we can comfortably ballpark social value for certain things like a COVID vaccine, an effective Alzheimer's treatment, etc., and come up with some lower bounds for social value. I think it's worth agencies thinking about specific problems in that sort of way. Another useful thing to do might be to create broad proxies for social value and then meter our existing policy instruments—everything from FDA exclusivities to patents to insurance—to those in a more blunt sense that moves with our proxies for social value.

I think a really nice effect of this discussion is forcing us to step back and think about the outcomes we want—working backwards from those, rather than the science push or technology aspects that have characterized a lot of biomedical research policy for the last 75 years or so.

I'll leave it at that and look forward to the discussion.

LISA OUELLETTE: Great. Thanks, Bhaven. Daniel, do you want to weigh in on any of the thoughts Michael and Bhaven have shared?

DANIEL HEMEL: We probably agree on the panel that if, instead of spending 1.6% of GDP on prescription drugs, we spent 3.2% of GDP, we would likely have more life-saving treatments. And we do make some of these hard decisions about quality-adjusted life years versus disability-adjusted life years versus expected value of life years gained in other contexts in deciding how clean our air should be or how safe our cars should be. It is politically challenging but not politically impossible.

I think the Institute for Clinical and Economic Review is a good model of how to do this. We can imagine a world in which Medicare and Medicaid cover a larger portion of the population and more drug pricing is just set by the government based on a measure of social value. That won't be perfect, but I think Bhaven is entirely right that the perfect shouldn't be the enemy of the good. My one criticism of the way that NHS does it in the U.K. or that the Institute for Clinical and Economic Review does it here is that the numbers should be 5 times or 10 times larger than where they are now.

MICHAEL ABRAMOWICZ: I'll jump in, if I may. Daniel may have more confidence in our political system's ability to measure quality and so forth in a reasonable way. Maybe you could create some kind of very independent administrative agency and do it. But I think another thing we've seen during COVID is the need to ration vaccines—that is, we've needed some mechanism for scarce allocation.

I don't feel like any of the state governments have done a particularly commendable job of creating a coherent methodology. People may say, "Well, if you're 64, and you have a serious condition, then you should get your medicine before somebody who's 68 and doesn't have a condition." However you think the big picture looks in terms of which groups should get it first, it's certainly a very crude system that we have. I'm not convinced that you can eliminate that crudeness just through the magic of creating an administrative agency.

We certainly haven't done that well on equity in our allocation decisions either. There was a debate early in the pandemic about the fact that African Americans and Native Americans had a greater burden from COVID, so there was a hope that maybe we could get vaccines to those communities first. And there was a debate as to whether we should consider race directly or zip codes. And, of course, the answer is that we've done more or less neither. There's been some attempt to get the vaccine into underprivileged communities, but there's a lot of fear of creating an allocation system that seems to privilege anyone above anybody else; the result is that any attempt to create more equity will not work.

I think the broader problem is that considering lots of potentially relevant variables doesn't seem to be possible during COVID. I worry that it won't really be possible to have a serious model-based allocation in anything.

LISA OUELLETTE: I think you're right on the inequities in the allocation that we've seen during COVID, but I think these questions of how we are allocating are, as I said at the beginning, separate from the questions of how we are incentivizing. Still, the questions of how we are incentivizing raise similar challenges.

I think that is part of the reason that the U.S. government has largely punted many of these questions to the private sector: it enables the government to avoid making those hard choices of which disease is more important than another, that kind of explicitly valuing lives in this context. It's not obvious to me why, in other contexts like Daniel mentioned, across many other portions of the administrative state, there seems to be more political feasibility in making these kinds of calculations.

DANIEL HEMEL: I want to pipe in and defend the allegations that are going on right now.

We basically have a healthcare rationing system that popped up all of a sudden, and some of us had frustrating evenings trying to get vaccine appointments for older relatives. But most of the people I know who are over 65 have had their

first shot. And most of the people I know who are in their 30s have not had their first shot. I'm in a privileged position—most of the people I know are top few percenters and predominantly white. But still I think if I compare the allocation of vaccines based on risk done by this kind of pop-up-federalist-disjointed-government effort versus allocations that happen in a market process—and when I'm comparing outcomes over the last few weeks to whether the market really allocates medications to the people who need them the most—I'm more confident in socialized medicine as an access allocation scheme than I would've been before. I think we're doing a better job than just the free market. Michael, those were fighting words.

[Laughter.]

LISA OUELLETTE: We have a question from Brook Baker[3] about directing funding toward wasteful and inefficient R&D. All three of you have said that we spend too little on many healthcare innovations and that we would have, if we spent greater rewards, more life-saving innovations. Brook Baker's question refers to evergreening exclusivities and "me too" drugs. Are there cases where there is wasteful spending in that direction? Do you think there are places where the current system provides too much, such that using social value as the lodestar would lower the rewards? Go ahead, Bhaven, you're nodding.

BHAVEN SAMPAT: Oh yeah, absolutely. I think that with a number of things that might come up this afternoon—including evergreening and product hopping—a good technology assessment enterprise could help obviate some of those problems.

As Daniel brought it up, we could also spend more on more valuable stuff. Now, of course, if the consumer faces that cost, then we run into the Sovaldi problem where you have a very valuable, but very costly drug. You'd want to couple that cost with some sort of insurance coverage to decouple the innovation incentives and the price. I agree that we could actually reduce expenditures considerably as well through a reasonable HTA apparatus, imperfect as it may be.

MICHAEL ABRAMOWICZ: I think it's pretty clear that the evergreening probably distorts research in one direction rather than another. I think it's a lot harder to say that the marginal research that's been spent on evergreening is actually not cost justified. I think that would be a very hard thing to measure. Some of the benefits—from some of the improvements to drugs—might be cost justified.

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[3] *See* Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303 (2008).

BHAVEN SAMPAT: Why would it be hard to measure, Michael?

MICHAEL ABRAMOWICZ: Well, there's a lot of different drugs, a lot of different kinds of innovations. And I think a lot of the concern on evergreening comes from the access side rather than the incentive side—that is, we're evergreening so that we can keep the prices high. I haven't heard so much the idea that the research expenditures on the improvements are themselves not worthwhile. I've certainly heard the argument that those research expenditures on improvements might be better allocated to other kinds of problems if you could magically move those to other kinds of problems.

I wanted to very quickly respond to Daniel's "fighting words." You know, I don't disagree with him altogether, but I think the danger is that we end up with the worst of both worlds—both incentives and access. On the free market side, if we anticipated a free market in which companies are fully able to exploit their patents and have an option for the first however many thousand people who get the vaccines, we probably would have gotten results a lot earlier. And I think that would have been a plus. The downside is that there was a sense among pharmaceutical companies that they weren't going to be able to do that—certainly if they wanted emergency use authorizations—so I think that depressed incentives to produce quickly.

We obviously still did better than we've done in the past, but this was one of the worst public health crises we've had in quite a while, and I think we could have done considerably better. Even after all that, we didn't do so great in terms of actual allocation, which makes me worry that our institutions—not only for allocation, but also for incentives—just aren't very well calibrated. At the very least, we need to have some better institutions if we're going to be relying on government decision making on these issues.

LISA OUELLETTE: That's a great chance to pivot to our second dimension of innovation policy: the institutions. However much we are spending on innovation problems, there are a lot of different institutional mechanisms that we could use to distribute funding. So, if we decide that more money should be spent on a problem—like a vaccine for a disease with pandemic potential—that money could be spent through direct ex ante funding on grants and national labs, or it could be spent on ex post rewards through subsidies or purchases, etc. To kick off this discussion, I'll start with Bhaven, who has suggested that the public sector should be more directly involved in late-stage pharmaceutical development.

BHAVEN SAMPAT: The idea here is that, under the current system, we have a sort of division of labor going back to World War II where the government focuses on so-called basic research—since there are market failures there—and the private

sector—incentivized by patents and high prices—does the applied work, including clinical trials. There are some exceptions, but this is a high-level overview.

It's my observation, which is not unique to me, that this division of labor is not really God-given; it's actually given by Vannevar Bush, who is the architect of postwar innovation policy.[4] He had fairly strong and conservative views about the appropriate roles of government in the economy, including research. It was his idea that applied research should be left to industry, and we built an infrastructure around that.

But there were critics at the time, including New Dealer Harley Kilgore and the economist Paul Samuelson, who argued that there are pretty high social returns from government funding of applied research.[5] Indeed, they were writing in the wake of World War II, which showed that, as does the pandemic. Kilgore was explicit that government funding should be aimed at fixing market failures on the applied side as well, looking at areas where the market itself doesn't provide the desired outcomes.

How does that work in pharma and how does that relate? One of the counterarguments to the use of government rights to promote lower prices and broader access in pharma is that, even where the government owns a key patent, it's still typically the drug industry financing the costly clinical trials and additional development, consistent with this broad division of labor. But it's not clear that this needs to be the case. The government could go soup-to-nuts or end-to-end, at least in some cases, and support some of the applied work or contract with industry to do so, and then essentially price it at cost.

The idea is similar to those that Lisa and Dan have put forth that maybe the government should be funding trials.[6] But the argument is to start off by doing so in cases where the government already owns a key upstream patent and fully develops it as an experiment for thinking about how that might work going forward. It could give us some data on things like R&D costs and risks that would help us with policy design. Right now, we're flying without a parachute. That's the general proposal in terms of institutional mechanisms. I think some place like HHS would administer something like that.

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[4] VANNEVAR BUSH, SCIENCE—THE ENDLESS FRONTIER (Nat'l Sci. Found. 2020) (1945), https://www.nsf.gov/about/history/EndlessFrontier_w.pdf.

[5] *See generally*, Daniel J. Kevles, *The National Science Foundation and the Debate Over Postware Research Policy, 1942-1945: A Political Interpretation of* Science—The Endless Frontier, 68 ISIS 4 (1977).

[6] *E.g.*, Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Institutions and the Opioid Crisis*, 7 J. L. & BIOSCIENCES 1 (2020).

LISA OUELLETTE: Michael, do you want to weigh in here? I know you've written and focused more on ex post rewards and prizes. What do you think of shifting the institutional mechanisms towards government funding?

MICHAEL ABRAMOWICZ: I think there's a very strong case for that. It brings up this question about ex ante versus ex post. I agree that—to the extent that we can have the government funding more clinical trials, for example—that would be very beneficial. I don't see it necessarily as an alternative to the patent system, but potentially as a compliment.

We know Ben Roin, for example, has written about how the patent system can distort the decisions of which kinds of innovations to work on early on.[7] For example, if you think that a drug has a large danger of being found obvious, then the pharmaceutical company is less likely to actually take it through all the clinical trials, which really shows a distortion in what we're rewarding. What we're really rewarding is not the initial idea; it's the work going through clinical trials. Maybe we can fix that in the patent system, but if we can't, maybe something along the lines of what Bhaven was talking about would be very useful.

If we have a government role, then the question is ex ante versus ex post. I've tended to be an advocate of an ex-post-type reward for a couple of reasons.[8] First, with ex ante, there are a lot of familiar worries about the kind of grants—people may be less likely to find moon shots, for example. You might argue that that's just an institutional detail, but I think that ex ante grants are more likely to be susceptible to political pressures. There may be political pressure to work on A or B and to stay away from ideas out of the mainstream. The benefit of ex post is that it's easier to measure past social welfare than it is to project future social welfare. Also, especially if we can push the decision off in time such that we don't know who the decision-makers will be, then even if we think maybe they won't get the models right and they'll make mistakes, to the extent that that cancels out in expectation, we may get better allocations.

Especially if you think there are some potential investments that might make a huge difference in the future, those are not likely to be fully funded ex ante. Consider the things that we should still be worried about, like antibiotic resistance. It's quite possible that, ex post, people will understand that developing a new antibiotic was really great once all the other ones turned out to have problems of

[7] Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672 (2014).

[8] *E.g.*, Abramowicz, *supra* note 1.

resistance. I think we're more likely to get funding on that from ex post rewards than from ex ante rewards.

LISA OUELLETTE: Daniel, do you want to share your thoughts?

DANIEL HEMEL: I definitely agree with Bhaven that we should be spending more on pharmaceutical development within the Federal Government.

In our first article together, Lisa and I said it's kind of weird that the process of getting a drug through FDA review is something that we have allocated to the private sector, that dealing with a federal agency is something that the Federal Government can't do; only pharma can.[9] The amount that we spend on the NIH is really low. We spend $30 billion a year on the NIH, and we spend something like $705 billion a year on the Defense department. I think I'm much more likely to be killed by cancer than by a Russian invasion, so I think we should have more ex ante government spending.

In order for that to be maximally effective, we'll have to get comfortable with paying government employees more. At the NIH, the salary tops off at about $418,000 a year, which is what Anthony Fauci makes. If you are really good at drug development and you want to make money, you'll leave the NIH and go to the private sector. But there's no reason why that needs to be the case. We could pay people who work for the NIH more or create a new agency within HHS that focuses on end-stage development. I think it's also important to remember with the ex ante versus ex post distinction that, to the Pfizer employees, the rewards are really ex ante; a Pfizer employee's career advancement might depend upon whether a particular drug development effort works, but she or he is a W2 employee who probably has some incentive compensation feature to her contract, but she doesn't own the rewards. We could have incentive compensation within the government, too; we just have to get comfortable with the idea that there will be people on the government payroll who will be making more than a half million dollars a year.

As a final point, one reason why we spend so much on Defense is because we've created a military industrial complex. We have companies like Lockheed Martin and Boeing who are essentially created by the Federal Government to then lobby more for Defense spending. Maybe we need, and we kind of already have, a pharmaceutical industrial complex where we give some rents to pharmaceutical companies so that they lobby for more government spending on pharmaceutical research. That's in no way an optimal structure, but sloughing off some rewards to

[9] *See* Hemel & Ouellette, *supra* note 6.

the private sector is maybe a necessary ingredient for getting the public sector to spend more.

LISA OUELLETTE: I'd like to get out of this institutional question and go back to a question brought up in the chat about funding for things like vaccine development versus state or local public health departments. Primarily we have been focused on new drugs, vaccines, and specific, concrete products. But we probably would all agree that there is an even bigger problem with funding for things that are less tied to a tangible product like public health measures. Are there ways to improve the institutional mechanisms for those kinds of innovations?

BHAVEN SAMPAT: It's a hard question, both on the public and private sector side, because there are no lobbies for prevention. So, in terms of thinking about that kind of stuff, it's hard on the public-sector-research-funding side to generate much momentum, which is probably why prevention and things like that have been relatively underfunded.

Another thing to point out is that there's a market failure on the diffusion side as well. So, going back to this idea that we have a kind of science-and-technology-push strategy, we assume that diffusion will just happen. One unique thing that we've learned from this pandemic is that that part of the process is not automatic. Some investments in government responses or government responsibility for those kinds of activities might yield high social returns.

MICHAEL ABRAMOWICZ: One thing that is challenging is that it's very hard for the government to figure out what the returns are going to be from different investments and whether there will be returns at all. One nice thing about an ex post system that's reliant on the private sector to produce innovations and diffusion is that the private sector then has the incentive to think, "Well, how fast can we do things?"

In the comments, Amy says that she doesn't think we necessarily could have had the vaccines much faster, and there's some empirical uncertainty there. I think we probably could have. There is evidence that some factories were new factories, and new buildings were opened, and yet I wonder, "Why weren't more open?" If we were producing more vaccines per day, we'd be able to get through this a lot faster.

The deeper point is that it's going to be hard for the government to make those projections. The private sector will make a lot of errors, too, but when you move the rewards ex post and make those rewards proportional to the contributions—if you make it such that the government gives you billions of dollars for getting us out of the pandemic months earlier—we can find out how fast we can go. That's the more

general lesson. I think people are not going to like the idea of people making more than half a million dollars on the government payroll. That's more than the President of the United States. I just don't think people will get comfortable. And the broader point is that those decisions are political rather than economic. I think if you can push more towards ex post rewards, we can target social welfare while still giving incentives for production.

DANIEL HEMEL: I'll add two points. One, I think Amy is right in the chat that we would not have had an emergency use authorization approval a day earlier if we had put more money into vaccines. I think there is a question whether we would have more vaccines on the market today if there were 20 BioNTechs and Modernas rather than two. But the rate limiting factor was the clinical trial process—not that it took Moderna and BioNTech so long to develop their vaccine. Moderna had an effective mRNA vaccine for COVID-19 probably before most of us knew what COVID-19 was.

Michael is right that the government can give huge rewards ex post. We currently are in a political environment in which we feel comfortable having the government give large ex post rewards to pharma and less comfortable with publicly-funded efforts in the health space that don't pan out. But I don't think that is necessarily a political constant. In the Defense context, we tolerate a lot of spending on threats that don't materialize, and we're okay with that. If we could shift to a world in which we thought of public health threats the way we think of national security threats, then we could do a lot more of this in-house. My understanding is that we pay some weapon-scientists a lot of money, either within the federal government or nominally working for contractors, but reward them essentially ex ante. If we could do that for pharma too, then I think we could have more on the ex ante side.

MICHAEL ABRAMOWICZ: One quick response on the issue of "could we have done better?" I thought it was striking that we didn't see the pharma companies pushing for challenge trials. There were plenty of papers written by our bioethicists saying, "Maybe this is the time that it's actually ethical to do challenge trials."[10] It's not like the government convened all the ethicists, and they said, "Oh, we can't do it." There wasn't really a decision; it was just sort of a default.

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[10] *E.g.*, Athmeya Jayaram, Jacob Sparks & Daniel Callies, *Justifying the Risks of COVID-19 Challenge Trials: The Analogy with Organ Donation*, BIOETHICS (June 27, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8444865; *see also*, Seema K. Shah et al., *Ethics of Controlled Human Infection to Address COVID-19*, 368 SCI. 832 (2020), https://doi.org/10.1126/science.abc1076.

I think that's because the pharma companies had little interest in getting everything done faster. It didn't matter from their perspective whether they used challenge trials, which could be a lot faster, or the long trials, because either way they'd get paid eventually. It's just six months to a year difference. If anything, they might be better off having the pandemic go a little longer as long as their competitors don't beat them to the punch. But the problem with something like this is that if one company gets it, then everybody's going to do it, and so nobody pushes for it.

Now, maybe that's the right decision on ethical grounds, or maybe not, but I certainly don't think you see incentives for outside-of-the-box thinking that will really move things forward. I think that's more broadly a danger. Maybe we want to have the pharmaceutical industrial complex, but we need to think about the incentives that the complex actually has, and it's not always to advance public health.

BHAVEN SAMPAT: I just want to push back a little bit against the idea that it's difficult for the public sector to take risks. We spend, I think, $40 billion on the NIH, which primarily funds basic biomedical research under the guise of producing health outcomes. I'd say 90-95% of it doesn't actually result in anything that links to any health outcomes. Still, the NIH has perennially been a fairly popular agency with bipartisan support.

But you might argue that, within that bureaucracy, you want to change incentives to take on more risk-taking behavior. There are serious proposals—from adopting parts of the HHMI model to Pioneer Awards. There might be ways that you can tweak the incentives facing not internal NIH scientists, which are a small part of the game, but external researchers funded by the NIH on the basic research side. I think the applied research side is probably a different set of issues; we don't really know much about that, partly because there haven't been that many experiments in terms of government funding of applied research and medicine.

LISA OUELLETTE: I think this discussion is highlighting some of the error costs in relying on all of the different institutional mechanisms. One broader challenge in these discussions about innovation policy is that they often are focused on pointing out the flaws in a particular mechanism while assuming an idealized version of the other one. For the same reasons that we have underinvestment in preventatives by the private sector, it's very similar flaws that lead to underinvestment preventatives by the public sector.

I don't know what the right way is to move beyond that. I like Daniel's point that we spend lots on the military preventing things that never happen. If we could somehow shift the public debate to thinking about threats in the health system in the same way, then that would be useful, but I don't know how.

BHAVEN SAMPAT: Well, this might be a good moment to do that, right?

[Laughter.]

MICHAEL ABRAMOWICZ: There's one other dimension to defense versus medical, which is that medical spending helps everybody in the world. It is, of course, even better. But, on the other hand, it suggests that the optimal locus of organization is global rather than national. To the extent that, over time, the U.S. GDP becomes smaller relative to the world GDP, that's going to be more of an issue. There may be more political pressures. People say our direct benefit from that spending gets to be a relatively low percentage. There have been discussions about international institutions that might fund medical research, and maybe that's a little bit beyond our scope, but it's certainly an important thing for people to be thinking about.

DANIEL HEMPEL: Well, I was just going to say, I think the defense analogy is a great one in that we did decide that we would be the world's policemen; we would defend Western Europe and not really make them pay for it. Now, it may be that, in retrospect, American hegemony benefited the rest of the world less than we thought it did at the time, but in that context, we allowed the rest of the world to free ride off of our efforts. So, why not do the same in pharma?

MICHAEL ABRAMOWICZ: That might not be as politically popular now. I mean, just my sense, and I suspect that may be true in pharma, too. I'm making a political prediction. I'm certainly in favor of increasing spending to the NIH; I just don't know if it's as politically viable as it might be.

BHAVEN SAMPAT: I think a more prosaic difference between DoD and NIH is that DoD explicitly acts like a mission-oriented agency: it has some specific goals, and it funds research to achieve those goals. The different parts of HHS don't really talk to one another. I mean, this is like Burt Weisbrod's old healthcare quadrilemma article in some sense.[11] Medicare is not going back to NIH and saying, "These are the specific priorities." It just doesn't function in that sort of way. Those are two different arms, and it seems like some sort of integration might be useful.

LISA OUELLETTE: One question in the Q&A that we haven't gotten to is asking about who should be rewarded: the scientist at the firm who is doing the research versus the shareholders of that firm. We've been thinking about these

[11] Burton A. Weisbrod, *The Health Care Quadrilemma: An Essay on Technological Change, Insurance, Quality of Care, and Cost Containment*, J. OF ECON. LITERATURE 29, no. 2, 523-52 (1991).

institutional mechanisms at a bigger picture level. Do any of you have thoughts on that issue of the rewards for the actual scientists and what policymakers should be doing in that regard?

MICHAEL ABRAMOWICZ: A lot of times, individual scientists can benefit from *awards* rather than *rewards*. I think it's probably the kind of prizes you put on your wall that might be a better way to recognize individuals. There are certainly lots of institutions, like open source software, that work more on the basis of recognition of individual contributions. Still, I'm skeptical at how well that can be scaled into the pharmaceutical space.

DANIEL HEMEL: It might be helpful to distinguish between the Pfizers of the world and the BioNTechs of the world or the Modernas of the world. There are some companies where the vast majority of equity is held by shareholders; the scientists who are doing the work are not the ones who are getting the rewards. But there are a lot of companies that are involved in COVID-19-related R&D, particularly on the vaccine front, where it is particular scientists who are becoming multimillionaires or billionaires because of this.

There's still a superstar economy, but it's the people with MDs and PhDs who are getting rich. I think that exacerbates the problem of how we get the best R&D minds to stay within NIH or within a new kind of applied pharma agency within HHS. They're the people like Anthony Fauci, who are willing to live a top-1% but not top-0.001% lifestyle because they're public servants. Unless we increase rewards for government scientists, we're going to be relying a lot on the good graces of the future Anthony Faucis for that.

LISA OUELLETTE: We have three minutes left in the panel. I thought we could conclude by giving each of you a minute to wrap up with any concluding thoughts, including if you had to give a Twitter-sized version of—for people who haven't been thinking about rewards for medical innovation—what you hope they take away from this panel. Michael, do you want to go first?

MICHAEL ABRAMOWICZ: Sure. I don't have a Tweet prepared and ready with 140 characters, but one thing I would say, just as a closing, is that it's important to find ways of funding all stages of research, including developing the idea for drugs, clinical trials, and manufacturing. That's where I think they've fallen the shortest during COVID. If the government is going to be focusing on Medicaid or other kinds of programs, they should probably be thinking about where we fall the shortest and try to add incentives on that.

DANIEL HEMEL: I guess my concluding thought would be something like, "More spending on innovation need not come at the expense of access, but will require political will." That's about 280 characters, so I'll stop there.

BHAVEN SAMPAT: It's quite an exercise. "Start from the outcomes we want and work backwards." I think the pandemic taught us that that's a useful way to approach biomedical innovation policy. Start from the outcomes and work backwards to the types of investments and institutions you need.

LISA OUELLETTE: Great! Thank you so much to all of you for having this discussion. There's a lot more we could say, but we are out of time. I will turn things back over to Zach.

ZACH BASS: Thank you, Lisa. Unfortunately, I have to be the villain throughout this event and tell people to stop talking when I could keep listening to all of you talk for the rest of the evening.

I think your panel did an excellent job at really hitting the core of the issue, which is governmental spending as an expression of priorities. It's an expression of our national values. After this pandemic, is there going to be a rethinking of national priorities? I thought Daniel's point of "am I more likely to be killed by cancer or invading Russians" stood out. That's a pretty compelling question after this pandemic. Thank you all. I thought that was masterfully done.