Corby Kummer: I'm Corby Kummer of the Aspen Institute and the Atlantic and the Tufts Friedman School of nutrition, um, science and policy. And I am very fortunate, very fortunate to be joined by the most distinguished panel that will appear at the entire festival. You are here to witness it today. Uh, and from my life we have Peggy Hamburg, a the current chair of the board of the American Academy for the advancement of Sciences and international ambassador for the National Academy Secretary, Foreign Secretary of the national academies of medicine. Um, we have Stacy Doucette, Zena who is a health services researcher at Vanderbilt. We have Ken Davis, president, CEO of the Mount Sinai health system and professor of psychiatry and Craig Garthwaite, an economist and a director of the program on health care at Kellogg School of management at Northwestern. Um, so we're going to be talking about drug prices, how they got so high, uh, and what we can do about that. What about the system encourages his kind of disparities and strange spikes in prices and then drugs that aren't being developed, uh, and what can be done to change that if anything should be done to change it.

Corby Kummer: Um, and we were having, um, shall we say a spirited live in this discussion before this panel. Uh, and Craig said, I don't know why you're so surprised this just beginning for economists and yelling at each other is what it is. It is how economists say hello. Okay. So, uh, we're, we're going to have, we're going to have a lively exchange here, but I was going to start with Stacy to give us something of a, a broad picture analysis of how, uh, we are now in a system in which, uh, some price, some prices are so much higher than others. They seem mysterious from the outside, but for those who are able to trace back the history, it ma kes its own sense. Yeah. So, um,

StacieDusetzina: can we talk about drug prices being high? I think there are two components. There are the prices of the drugs, the spending on drugs that we're doing as a society. And there's also the spending that people are doing at the pharmacy counter when they're purchasing a prescriptions. And I think, I would hope that everyone on this panel would agree that, you know, drug prices, what we spend on drugs right now are high and going up because that's what the market allows. Um, Pharma companies price their products aggressively based on what they think that they can get for them. And we allow them to do that. And in a lot of ways, therefore, profit companies, uh, they owe their shareholders a return. And so they're behaving in the interest of, uh, those individuals not necessarily behaving in an interest of public health and society at large.

StacieDusetzina: And then when we think about it from the counter point of view, I'd say over the last decade or so, we've seen some erosion and health insurance benefits. So we know that a higher proportion of people are paying deductibles where you pay 100% of the drugs, price and co-insurance, where you're paying a percentage of the drugs price. And that's become really problematic. It's why you heard, you know, news stories about epipen, you know, Epi pens, price was going up. What we were spending on it was going up. But what you were experiencing at the pharmacy counter was why it really came up in such a

salient way because you went from maybe paying a $20 Copay, a flat fee, every time you filled your prescription to a percentage or 100% of that drugs price. So it's become really salient for people because you're being exposed to those prices more directly.

Kenneth L Davis: Okay.

Corby Kummer: Right. We do have a lot more to say about that, but we're going to move to Ken to talk about your idea of how prices work for your hospital system, but also you have a very sense of knowledge of drug development for all timers. Um, and that has its own fascinating and very indicative, uh, story of what incentives are and aren't for companies to develop those drugs. So this is a case study that may take a little time. I'm sorry, Corby. It may take a little full

Kenneth L Davis: time. Um, um, I've been involved in Alzheimer's research for a long time. Before I became the CEO and um, from my lab there was proof of concept that produced or three of the four drugs that are approved today for Alzheimer's disease. The first time we uh, showed that a compound called a colon esterase inhibitor, that's the kind of group they are, would work was 1977. It was nearly 25 years later before the first one of those drugs went on the market. Part of the reason for that and including conversations that I would have with companies about, hey, this is an opportunity would be things like the market's too small. I'd say the market's too small for what? And they'd say, well, there's this drug out there called hydrogen and it does $35 million a year. And we would say with our estimates, we, you know, these could be billion dollar drugs.

Kenneth L Davis: They come on. So nothing happened because it was a new mechanism, a new proof of concept. It took a long time. Now we're at another important moment, pivotal moment in Alzheimer's disease research despite the colon esterase inhibitors. We haven't had another drug in like 30 years. And we have an epidemic of Alzheimer's disease that isn't to say that we didn't have an idea about how we might be able to deal with this problem. We all thought early on that this was a problem with amyloid in the brain and all you have to do is clear the amyloid or stop it from happening. We've had nearly 35 trials that have now failed with that hypothesis and something else has happened along the way. And that is we've identified that the changes that lead to Alzheimer's Disease Happen 20 years earlier in your brain. So now instead of thinking, let's design a drug that we will give acutely to people who have Alzheimer's disease and may make them better or slow the progression.

Kenneth L Davis: Now the thought has to be, let's treat people before this symptomatic. Let's stop the progression. Let's slow. It may be 50% so that instead of getting it in 20 years, you get it in 40 years and instead of getting an average age 80 you get an average age. 100 will be okay by a hundred so, so now the studies become very, very different with 35 failures. And now the notion that we've got to give the drug to well people and study them maybe for five years and see how many convert to Alzheimer's and how many don't you suddenly look at this and you

say, oh my God, if you're a drug company that could be a billion dollar study. I mean, and then if it doesn't work, I gotta do another one. You know, cause I've got to get two approved so if it works, so I'm not going to do two in parallel, I'm going to do them sequentially. And you say how much patent life is left after that? It was like, Ooh, that's a big problem. Is this really going to be what I want to do or should my money go somewhere else? And my thought is that to incentivize companies to take the kind of risk that needs to be taken for what it will be, that real breakthrough generation and Alzheimer's drugs will require us to take a look at patent law and how we can incentivize them to have more periods of exclusivity

Corby Kummer: patents. Let's start with patents. Um, an orphan drugs. I mean I imagined it as economist, you're in favor of patent protection. You're in favor of giving companies incentives to spend lots of money to have longer life. How do you think the patent, uh, regulation is working now? And also talk a little bit about in the wake of the affordable care act,

CraigGarthwaite: cause I think we've mixed a couple of systems together here in terms of like market exclusivity and patents. But to take a step back, it's not the sort of economists like patents, everyone economists like is we like things to be sold at marginal costs, like the costs or production. That's the goal. Cause that's what that expands output. The most number of people get access to the product. And so we'd have antitrust authorities. We have an attempt to get competition. The goal is always to get prices closer to marginal cost so as many people can consume it as possible. The problem is for drugs though, is that if we sell things at marginal costs, that people who make the initial investment to develop the drug can never get paid back for that investment. That investment is going to be, you know, several hundred million, billion dollars and any up to $2 billion bank on the product, let's say.

CraigGarthwaite: And so it's just a trade off that we, that economists and that we all face actually economists describe, which is we either have high prices today and we get drugs in the future or we have marginal cost pricing or really low pricing today and we don't get drugs in the future. And that sort of the two ends, let me be clear that that's the two ends of a continuum. And what we're deciding is societies just sort of where we want to be between those two extremes. All right. And maybe we've, you know, as a society going a little bit more towards too much innovation. Right. And why we've gotten there is that we are unwilling to not pay for any new drugs. So every new drug that comes out, we pay for it. In the United States, we do not say no for some drugs like cancer, we mandate that Medicare can't say no.

CraigGarthwaite: You have to cover every product no matter how good it is, as long as it gets to the FDA. That's the part d yeah, it was under the something Medicare. What's part B to any cancer drug you do up a cancer drug, it gets to the FDA. It's getting paid for full stop and it's a paid for for a lot of money because you know that they have to pay for it. All right. And so in that sense we ended up spending a

lot, right? And that's a choice we're making us society, we can choose to spend less and we'll get less innovation. By innovation I mean an investment in r and d and that's fine. But I know people seem to misinterpret what I say will get less innovation. That's clearly a bad thing. It's not because the trade is, we'll get more access to that so people get more access to drugs and so on the end we're just trading those things off.

CraigGarthwaite: Where patents come in then is really, that's the patents and market exclusivity, which is granted by the FDA is the mechanism we use to govern that trade off. How long do you get to have no competition? Right. That's what it is. I would pause it that patent law is not very finely tuned for pharmaceuticals. Why do I know that? Because you get 20 years for a patent for pharmaceuticals and you get 20 years for a patent for semiconductors. It seems unlikely that the optimal patent length you would devise for those two products is exactly the same. Instead, it's just an ad hoc. Then we'd had forever. All right, and you get [inaudible] the FDA as well, and so we can think about changing that. I would hope that if we do it though, we change it beforehand or so. A lot of what's happening now in drug pricing is people are upset about prices and they want to come in and retroactively change the pattern.

CraigGarthwaite: So we had a promise to a company that you do something and you get a certain amount of intellectual property if we come in and take that away after. I'm very concerned about what that does about trust in government. Right? It's the same problem I had when the, when the Trump administration and Republicans in general ended the risk quarters in the ACA, right? They violated an implicit contract between firms and government. It would be the same thing here. So if we're gonna change patent law and then kind of some good ideas about exclusivity, we can think about for that, we just sorta change it now going forward, not be like, oh, well you've already sunk $2 billion. That's nice. We're going to appropriate all of your IP that we can't do, but we can make changes going forward if you want to change that, that, that trade off we have between access and innovation.

Corby Kummer: Thank you. Because you've set up [inaudible] very well. Uh, which is to think about the comparison between semiconductors in Pharma. The idea should

MargaretHamburg: pharmacol ceuticals companies be considered on the same plane as a car manufacturer or a semiconductor manufacturer? And, uh, what should we think about the current system in terms of research and development costs and incentives? Uh, or maybe should we think differently? Well, I think one make a couple of points. You know, one is first of all that we really do need to recognize that the research and development process for medical products, not just drugs but drugs, vaccines, diagnostics and medical devices, um, is intrinsically, I think quite different than the development of many other products. And that, um, it really does require an integrated ecosystem. Ken has heard me use that term before, but where we think about all the different components and how they fit

together into a coherent hole that the end of the day produces drugs that are safe and effective, high quality and accessible by the people who need them.

MargaretHamburg: And that there's an alignment of what's being developed and what is actually needed for health care and, and public health. And I think everybody recognizes that, that no one pharmaceutical company can actually do everything from start to finish. It is an ecosystem, basic science research, you know, really is fundamentally undertaken by government funders as some philanthropy in some private industry. Promising discoveries that emerge from that then are embraced by a Pharma company or a smaller biotech company and developed further with the target of actually creating, uh, a drug or other medical products that can actually be demonstrated to be safe and effective for a given condition, can be manufactured in a reliable way and hopefully can be affordable so that people can, can use it for their medical needs. Um, so it requires thinking about investments in research, incentives like patents in market exclusivity. It depends on the right economic policies and conditions for, for companies to do their work.

MargaretHamburg: The regulatory process is a piece of it. Reimbursement, not everything gets reimbursed. I suspect that many people in this room have had something not paid for by their, um, insurance company. Um, but government, medicare does reimburse, but reimbursement is a big piece of that. So, so we need to be, you know, recognize that this is exactly like every other industry out there. Um, number one, and number two, that we all have a, a real investment as individuals and in society to make sure that drugs are developed that meet real world needs. And that some of those clearly are going to be big markets where companies are going to want to get in, make a product and make a profit. But other things that the world needs, um, may not actually create the right market. Incentives. Antibiotics is one example. And in a world where increasingly we're seeing, um, resistance of drugs to certain pathogens and microbes, uh, we want to make sure that we have the antibiotics that we need when one of us gets sick, um, or a loved one gets sick.

MargaretHamburg: Similarly, there are diseases happening in places that can't afford to pay for drugs, but they're serious diseases. And not only are they serious for individuals and communities in those other parts of the world, but potentially some of those diseases will have an impact on us in richer nations as well, whether because they produce, um, instability in those countries that destabilize other systems or because those diseases can be in one country one day and be in our backyard the next, because of the nature of the disease, so that we really have to figure out a way to, to fix some of these problems so that we can have an alignment between what's in the development pipeline and what are the unmet medical and public health

Corby Kummer: you've just set up beautifully and clearly the main dilemma we're facing in this panel. Um, I thank you very much. I'd like to come back to Stacey wish I'd said it shorter. I know no one could've said it better, so, uh, impossible tuition.

Anything else, Stacy? Um, can you talk a bit about, um, we've been talking about party, about the idea that, um, uh, certain drugs just get protected. They're tremendously expensive, but that distorts the reimbursement for a lot of other kinds of drugs. Um, and tell us something about how formularies, how many people here could define formulary. If we took you outside and asked you to write it down on a pad of paper. Um, think could some of you, could you define what a formulary is and then talk a bit about how they're approached here versus in Europe and go governments negotiating for prices. Sure. So does everybody know what Medicare part D is? We'll start there. So medicare part D, assuming you're all medicare part d literate here, protease prescription drug benefits that you get most people age into it at the age of 65. Um, and it covers your outpatient prescription drugs. So,

StacieDusetzina: um, one of the really tricky things about Medicare part D is, um, and thinking about this, what we're spending and what people are paying are related to the protected class status for some drugs. And there are some good reasons we have protected class status. It basically mandates that you cover all of the drugs within a class. Um, and there are things like antidepressants and antipsychotics and cancer medications, um, and a lot of very expensive drugs. Um, we basically say to drug manufacturers and that, you know, we, we will allow you to price as high as you want and we'll accept that price because we don't really have any ability to walk away. We have to cover all of the drugs. Now, um, usually what happens is a formulary would be used to try to distinguish between uh, for the patient for the prices of drugs that have competition.

StacieDusetzina: So you would have formulary placement that says if you are in tier one, you as a patient would have lower costs if you pick a drug on tier one versus one that is on a different tier. So it's a way to kind of align your cost sharing with sort of the relative value of the drug that the health plan has decided. Now with protected classes it gets complicated because with all the drugs being covered, I studied cancer drugs. What that results in is everything has to be covered. Everything has a high price regardless of the benefit that it provides. And all of the benefits are kind of uniformly bad. So you could take a cancer drug. That cure basically is nearly curative or you can take one that does nothing but provide toxicity and we have both types of drugs on the benefit. They cost the same a main amount to medicare and they cost the same amount to you as a patient.

StacieDusetzina: So there's no distinguishing between them. And the way that we think about this, I guess in other countries, um, what we see how they get better prices is they do some, uh, value assessments. Cost effectiveness analysis is one of the ways that they can do this, where they look at the drugs benefits and they look at the drugs cost and they sort of figure out, you know, what's the right price for a drug, what's the right price based on the amount of innovation you're getting. So if you applied something like that, if we are able to apply something like that here, and if we were able to walk away from a drug rather than paying for everything, you could see that we would probably do a better job getting our prices down and we may be able to improve people's benefits so that if you

need to take the lifesaving cancer drug that's affordable for you, and maybe the one that doesn't really have any proven benefits is not affordable or is not on the formulary. Thank you. Great. Can you, um, do where, but he had including a formulary

Kenneth L Davis: decider. So, uh, because so many, uh, healthcare systems and states have different formulary assessments and processes, can you tell us what is possible to reveal publicly or semi-public [inaudible] about determining this kind of value trade off in determining your formula? And then I'm going to ask you about how rational or irrational this seems. Okay. Um, so we're self insured. We have 42,000 employees. Some are in a union and a lot of them are non-unionized, but we're self insured. So we have a group of people who uh, work on our benefit package and some of that is around formulary management, making the decision, are we gonna pay for this drug when this drug comes out? So we don't approve every drug because there may be already generic drugs that are just as efficacious or we don't need another more expensive branded drug does in the same class of compounds.

Kenneth L Davis: So we simply say no, let me give you some examples of drugs. We would have said no to. Um, everybody remembers the purple pill. Nexium, the purple pill. Well Nexium, the purple pill is just really the very same drug as was private sick and this a little complicated chemistry. But there are things called received mud mixtures because molecules come in like mirror images of each other and what's called the deform. The other forms in l form. Well humans only respond to the l form. So Palace that comes out, it's the DL form patent. He runs out, company says make the l form patent law lets you do it. Now I would've said not on my formulary, where now prescribing generic private sec. And you did of course. Um, but it doesn't always work that something so sensible as the generic, which is just the same as the reformulated drug.

Kenneth L Davis: Uh, you're right. For instance, we talked about any psychotics being a protected class. This is something I know a lot about having treated lots of schizophrenia patients. The first major antipsychotic drug was thorazine happened in the 1950s. It's mechanism of action is it blocks up the goal of the dopamine receptor. There have been, I don't know, I've lost count 30, 40 anti-psychotics since then. Everyone blocks the dopamine receptor. Okay. There isn't a new mechanism of action. There isn't a breakthrough drugs since thorazine. They may have better side effects, they may be a little more efficacious, closer green, you can argue is a little more efficacious. But because we don't demand that, we show superiority to the existing class of drugs, they all get on the formulary crew. Craig Howe, um, really, I mean, how related to market forces is this and are there so many barriers that there's lots of inefficiencies in this market process? I mean it's a question about what people want to have access to and so you know, 10 make the decision for your

CraigGarthwaite: employees. Some other, some other businesses have employees that really want to have access to some of these products. Let's keep in mind that in the

end employer insurance is just the benefit you provide to your employees. So you're trying to figure out what you want to give them and if they want more expensive benefits you pay them a little less in cash. And so you're just balancing those things. I would note that when it comes to sort of what Stacy can set together, those costs assessments, there's cost effectiveness. Those are being done by formulary teams. They're being done by pharmaceutical manufacturers and they're being done in the u s and we use them. The real difference is this walkaway point like we will that we won't take those studies and then use them to walk away until you end up at a higher price. But the relative price of these drugs tends to generally align to value.

CraigGarthwaite: Like if you look on average in there in the data, drugs that are higher priced are ones that are in higher demand and do better on cost effective. So we can argue about how much the for the gradient is, right. You're a little bit better and you get a lot more money or a little better. You get a little bit more money. We can talk about what that is. But in general the system tends to get better. Drugs get higher prices. We have things like next year, the private sector, Ken's talking about, um, these are what we refer to as like a true, me too. So me too is a therapeutic substituted. True. Me Too was like, listen, this is basically the same drug, right? It's different enough to get a patent, but it works the same if you look go in the, in the pricing data we did put next year out, but next to you had to give a 70% rebate to get on formulary.

CraigGarthwaite: Right? So it's not like the formulary managers were saying, okay, we'll just let you charge you charge for Prilosec. Right. They said, okay, you want to be on here, people want the new purple pill. Doctors are writing prescriptions for the new purple pills. So people want to fill them fine, but you've got to give us a really big discount. So there's all, I mean, there's a lot more market forces that work in this pricing that'd be all are willing to give credit for. But part of it is that it reflects our own design, our own sort of preferences as, as an American society where we want everything. And whether, I mean that, that's what, that's what this reflects. And until we're willing to come to grips with the fact that we are, that we can't get everything we'll pay, we'll pay for getting everything. We'll pay these high prices, they go hand in hand.

Corby Kummer: Great. Stacy, um, can you tell us a little something about this case history you gave me about citrate free, a smaller board needle drug and sudden demand for it, which will be a somewhat dramatic example to lead into Peggy's, uh, what can we do to make this more sane and rational in the future? Just to give you a little heads up there. Sure. So,

StacieDusetzina: um, you know, one of the things when people talk about spending on drugs that, um, we look for as helping to bend the cost curve I guess is having generic entry eventually. So even though it's expensive to treat a disease, now we're relying on generics coming into the market to reduce the cost for treating a disease. Now one of the things that's really complicated about that are the ways that companies will work to extend their patent life, uh, through these minor

innovations. And I think Humira is a product that has been a blockbuster drug. We've heard about it for years. There's been a lot of gaming of the patent system to delay biosimilar entry, but we know that in, I think it's 2023 we're expecting a biosimilar to come onto the market now that's significantly delayed, um, from what I think we had expected it to be.

StacieDusetzina: Now, one of the things that I noticed pretty recently was I was watching television and there was an ad for citrate free small needle Humira. And I was thinking, this is exactly the problem. So citrate free, small needle. That sounds amazing, right? Who wants citrate in their drugs? I mean, does anybody know what that is? I mean like probably Candace, you get a small right at the small needle. It's very, very enticing to consumers. So I was talking with a group of medical students and they said already we have everyone coming in asking for this. And so what happens is the companies can use marketing to physicians, marketing to consumers to drive demand to the new product that has a patent on this new device, which gets everybody shifted to the new small needle version, citrate free version of Humira, which means that when the biosimilar comes on the market, we have far fewer people benefiting from that and our spending doesn't come down.

StacieDusetzina: So I think this is a real risk. We see this also, I'm not just in these type of devices, but in other companies coming out with just marginally beneficial treatments over existing treatments. Um, there is a blood cancer treatment, uh, for um, chronic myeloid leukemia, Gleevec, which is one of the best cancer drugs ever developed. It had a couple of other treatments. They came onto the market. There were second generation drugs. If you look at the survival benefits overall, no difference. There was some differences in side effects. There's tiny tweaks, but it's been enough to move the market to the newer drugs where the patent life still exists. So even though today we have a generic version of this very expensive treatment, we have far fewer people starting on it because of these small innovations that have, have been coming to the market after it and

CraigGarthwaite: give us a little refresher on Pharma marketing expenses versus research expenses just in the grossest biggest term.

StacieDusetzina: So I don't really do so much on it. I know that there are statistics out there about there being some magnitude.

CraigGarthwaite: Those are terrorists. Those are, there are statistics.

StacieDusetzina: Yeah, but they're not, they're not great.

CraigGarthwaite: Is this their bad because our n d that's done by buying up an early stage company doesn't count as r and D on your balance sheet. So when the world has gone more to buying early stage biotech and you it up, that's not r and d on your balance sheet. And so the statistic is, tends to be the one that people will hear is that Pharma does more and marketing than R and, d which one? I don't

know how much I care about that fact because I care about the bout of r and d. They do compared to other industries, uh, in to the R and d numbers wrong in general. I'm marketing. I just want to say, I think this is probably, I know you're probably not gonna be super popular in this room. Um, but farmer advertising gets a pretty bad rap. There's a bunch of studies have come out recently.

CraigGarthwaite: Um, so studies out of Northwestern, University of Chicago about statens getting antidepressants where we get a big increase in adherence and a big increase in uptake particular for antidepressants for people coming in who come in because they saw the advertising and often they actually don't even get the advertised drug. They get advertise, they get a generic within the class. And those studies have found that the advertising is actually cost effective. In fact, that article on Stanton's found that even if you gave zero benefit to every other type of pharmaceutical advertising, the simple health benefits of getting a greater adherence and take up of style ends dwarfs all of that because that is are a particularly cost effective drug for people. And so I think we rushed the bang on farm advertising and nobody likes watching pharmaceutical advertisements. I don't like understand why people don't like them. Um, but I don't think the economic case is as clear as people want it to be.

Corby Kummer: Stacy, just before we get to Peggy, um, when you were saying something about a vcs and small research companies have just the kind that the big farmers are buying up, what are the incentives often for those small startup companies?

StacieDusetzina: Well, I mean I, I think, and Craig weighed this out yesterday pretty pretty well is that, you know, we have venture capital coming in to invest in drug development now. It kind of drives the direction of a lot of um, the science. So if the money wants to go where it can get a fast return and a large return. And um, as I said, I study cancer treatments and I know that that is an area where there is a tremendous amount of investment. And one of the things that's a bit of a downside is that means that if there's something that looks promising, a whole lot of money goes towards different companies doing trials of the same type of product. Whereas instead, you know, we may actually want some of that money to be distributed more equitably across other products that we need, like antibiotics or other things.

StacieDusetzina: But in fact, those are not things where we would expect or a guarantee, a large return. So I think, um, having our system kind of rely on venture capital to get a lot of the drug development going these days kind of means that money dictates where, um, our drug development is happening. And in a session I was in at, uh, the cancer large cancer meeting, um, there was a person in venture capital is talking with us about the decision making process and he said, you know, money doesn't care about public health. And I think it's a really important issue is that if we want to get drugs that benefit public health and diversify the portfolio, then we have to have models that aren't just relying on getting a quick return and a return for shareholders.

Corby Kummer: So Peggy re moving into the realistic utopia phase of the panel, which is going to lead into your questions. Um, since we're trying to be realistic utopians can this system be changed and does regulation play any part in bringing about that kind of rethinking?

MargaretHamburg: Well, you know, I don't honestly know how to answer your question. Um, in the sense that it's a huge, um, you know, we haven't even begun to tap the complexities of the drug pricing world and the various components of the drug development system and the various incentives that have been created over time, et cetera. I think, you know, to try though to get to the core of your question that we, I personally believe that we need to recognize that the development of medical products to treat, um, you know, serious medical and public health conditions is a public good. That we really do all have a vested interest in making sure that the system works and that we are at a point in time now where we have many demonstrations of the fact that if we just rely on the market, it doesn't drive all of the research and development that we need to better align what's needed and what's going to be developed and what's in the pipeline.

MargaretHamburg: I think we have enough experience now to also know though that isolated programs to incentivize product development in for for one particular class of drugs or one particular disease condition can start to create, you know, kind of a very unstable framework in terms of, of all of these systems where you, you create one incentive but it actually creates an unexpected disincentive somewhere else or other complexity. One example is there's something called priority review vouchers. I, I guess I should say that I used to be the commissioner of the Food and Drug Administration should say the chief regulator of the entire country did, why he was asking me about, we're talking about, but people were concerned that there were a set of so-called neglected infectious diseases where there weirdly wasn't a market, um, to drive serious development. And so let's incentivize development in that area. So let's, if you as a company develop a drug for a neglected, um, uh, disease, then we'll give you a voucher, which is worth a lot of money because that voucher you can sell or use and you'll get a quicker review at the FDA will get a priority review at the FDA, which if you have a blockbuster drug, getting a couple extra months in the marketplace means lots and lots of money.

MargaretHamburg: So it is a real incentive in these priority review vouchers have sold for, you probably know what the highest one is. I'm not sure how much a hundred million dollars in, you know, in the many tens of million dollars. So then other people said, oh, this is a great mechanism to incentivize. So let's give a priority review voucher for this and a priority review voucher for that. And, and you can see down the road that you then reach a point where the FDA is so busy responding. The priority review vouchers, in fact giving priority review to me too, drugs where the company wants to get them into the marketplace and make extra money that they in fact don't have the time and resources to review the things that are actually priorities. So that's one example of an incentive

that's created with a really good intention in mind. And it works for a while, but if you keep doing it, it actually undermines the whole purpose.

MargaretHamburg: And we have a lot of examples of that. The orphan drug act is another one that has been enormously successful in incentivizing companies to develop drugs for rare diseases. But now there are concerns that, that, that so much of the entire drug development marketplace has now gone to developing drugs for rare diseases. And there are still lots of really serious diseases that are creating a huge burden in terms of disease and disability and morbidity, but also to our overall economy. And, and those drugs aren't being developed as much. So it, you know, we have to really look at where the science is, where the incentives are, um, and how we can align better with this context of, of, at the end of the day, we all have a vested interest in getting the system to work. And that as we think, and this is where the utopia comes in, um, as we think about how to move forward from where we are, which is a bit of a mess, I think we all can agree, maybe, maybe some learn that we shouldn't just keep trying to, to, you know, nip and Tuck.

MargaretHamburg: We really should try to have a thoughtful conversation and, and look at what is working and why and what hasn't worked and, and, and try to really create a system that will be much stronger and more effective, uh, for the longer term future. And it will be mean making some difficult choices. It will mean that we really do have to look at cost effectiveness and make some decisions. And we sometimes have to say no, we have to be willing to, um, uh, create special programs when we need them. We, we have to be willing to find the right balance between government investment in research and industry investment in research, but with this notion of a shared common good shared common.

CraigGarthwaite: That sounds what I think we just support the FDA and I think the FDA has done an amazing job in becoming, you talked about industry, they no longer talk about the FDA as a problem. 20 years ago I was like, we can't get any new drugs because the FDA, we solve that and I need to know now the FDA, we're pushing them to be too loose in what they approve and that can be pretty dangerous in a world where we won't say no to drugs. So we have accelerated approval for drugs now or continuing to approved drugs on scanner and scans or evidence of efficacy. Um, but we're going to pay for them anyway. We don't ever figure out if they work. We have patient advocacy groups, particularly for rare diseases going after the FDA. So they were Sarepta as product. I think I always feel that can be described as not working, I think will be the technical term for the clinical trial evidence. But they were bullied in their pro, definitely was bullied into putting it to market and we paid $350,000 for that drug. And let me be clear, there is no insurer that's going to say no to that drug blended or while United health care. Yeah. And then they came to the k because you got a picture of a very sick kid on the front of the paper and United health care's name right above it.

MargaretHamburg: Um, and, and I think just to underscore that point, we need to think about in the context of, I mean, imagine going back to what, um, Ken said about Alzheimer's. If we got a drug that had the slightest indication of value and efficacy, um, in reducing the, the progression of Alzheimer's and it was approved, it would break the bank.

Kenneth L Davis: I have Medicare, the cutting of the drug systems over at that point. Like I'm gonna try it. Yeah, no, Ken. Yes, sir. Utopia. What would improve your life? Both as a researcher and a formulary wizard, you know, I want to develop drugs for the biggest health care needs. You know, I want to be able to address the issues of the opiate epidemic. So I want non addictive analgesics. Um, I want to do something about insulin resistance in type two diabetes so that we can reverse the effect, you know, downstream consequences of type two diabetes. I want to do something about obesity. Um, and I want to do something about Alzheimer's. And what happens is that when the pathway isn't clear, we need to find incentives. And the pathway isn't clear because science is in all that clear and you have to take risks. And those risks are sometimes very often not going to have payoffs.

Kenneth L Davis: So how do we incentivize the industry to go after the things that the country needs and not necessarily what industry needs. And you know, to me, I think there is an implicit social contract or there should be between Pharma and between the American people because I'm both need each other. And this is different from other industries. This isn't like selling toasters or cars. And I'd think sometimes that social contract is a in jeopardy. And I'd like to see leadership in Pharma that, you know, unreal understands what the role of that industry has to be and more people in Congress who understands what has to be done to incentivize people to do the right.

CraigGarthwaite: Thanks Craig. Everything's Hunky Dory, right? No change necessary. I didn't say that is, I mean I think we have this question. What people are making light of a couple of times now is we started with this premise that drug costs are too high and we have to bring them down. And I don't think that's clearly true. I think we have to figure out what we want that price to do. And prices are signals to the market about what we're willing to pay for and what we value as society. And so we have to, it's not prices that have to come down and it's our willingness to walk away from products that has to emerge and we have to say, listen, we're not willing to pay for that. You have to settle competitive structures. We have to get government out of the way. And that's not only that, it's like a sort of concerned and talking point, but like when it comes to protected classes we created, we created the oncology market that exists today, right?

CraigGarthwaite: We pass Medicare part d we said you have to pay for every drug in oncology. Unsurprisingly I think [inaudible] that was like 42% of venture funds now are going after oncology. Of course they are also because of where the science is, those go hand in hand. We fund the science because we know there's a return we're willing to look at. We know that there's money in oncology and so we're

going to go there and I think that yes, there's been science on car t and stuff like that, but there's also like that's not why venture saying, Hey, I want to put money there and I don't want to put it into oncology. But one more [inaudible]

Kenneth L Davis: thing about this comment about this is where the science went and because it is where the science went, let's remember where the science came from. The science comes from the NIH that comes from tax payers, gets tax payer dollars. And the question is through the tax payers then be raped when they have to pay for those drugs.

CraigGarthwaite: Well, it's, well, [inaudible] very long question. I'll be very quick on this point I like very quick. We want the NIH science to be involved in every single drug. The NIH solves a true public good problem, which is that [inaudible] science can't be appropriate or we can't make a profit off it, but we should be very careful about creating disincentives for using NIH research and disincentives. If you say you can't charge high prices, that's a distance. I think it should be fair prices. Their show. We were actually going to have continued into a series of mistakes each. You want to make a last point now or after questions? I'll just say quickly if I, I had my utopia

Corby Kummer: would basically be for people to be able to have really good access to high value drugs, make it really clear for consumers which drugs are good value for the money and make them affordable for people. That'll let you go. Go to values. Okay. We have to quit. Actually, we're going to take three questions right now and answer them all at once. And those three are the first three hands up, um, next to each other. And then the gentleman in the back. Um, no door. What are the first, sorry,

Speaker 6: I've been a physician for over 30 years. I've seen countless patients who cannot.

Corby Kummer: You have to ask a question right away and quick series.

Speaker 6: Okay. Um, number one, um, medicare cannot negotiate pricing. Um, that's incredibly wrong. Um, we play much more than, sorry. You have to ask the question right away. Okay. Why are we paying much more for direct in this country than in Europe and in Canada by a long shot? My Azman Hillard costs five times as much here as that. Okay. Next question. Thanks.

Speaker 7: Thought experiment. Little company comes up with what it thinks can prevent Alzheimer's or cure diabetes or something like that. It needs $1 billion to get to where it can go to the FDA. It has to go to the capital markets or it has to go to big Pharma. How can it get its drug to be sold for a moderate price and make a moderate profit?

Corby Kummer: Boy, that's a tough question. Okay. Gentleman in the back and then the lady in the front, we're going to have four in a quick row. I have a specific question about

Speaker 8: Alzheimer's and uh, The Washington Post article in the beginning of June, how, uh, Pfizer found the signal about like using number people treated with embrel TNF blocker had a 64% decreased risk of developing Alzheimer's. But the theory is that they either the science wasn't totally there, but they didn't pursue it because the patent was going to go up in 2022. So for that specific example, um, where you address patents, incentives, disclosing research, I mean, this was leaked, I think it was, um,

Corby Kummer: question, how would you have purchased? Okay. Okay. How would you approach that then quickly, I'll repeat the question.

Speaker 7: Okay. Um, how in God's name, like, um, God, the bad blood company elicit

Corby Kummer: Theranos

Speaker 7: how did that ever get on the market and how have the already died from fecal transplants? How has this happened in [inaudible]?

Corby Kummer: Okay. That's a very broad question, but less or less related. Can we have, can we have lightning round answer?

CraigGarthwaite: Medicare doesn't negotiate for drugs so we get less because we pay more cause we won't walk away. But they're the biggest Bernard that exist in drug pricing is that Medicare doesn't negotiate for

Corby Kummer: as opposed to foreign countries. This was in uh, in, in [inaudible].

CraigGarthwaite: No, I know like we negotiate for drugs and put part D and Stacy would agree even though I think our politics are not at the same, uh, cause they're empirical back using PBMs on the private market and they do a good job.

Kenneth L Davis: Hi. Research costs. How can they ever be recouped?

StacieDusetzina: I mean, I think once you've gone, once you have partnered with pharmaceutical companies, if they're publicly traded, it's, I think it's out of their hands. As far as pricing. I've seen um, uh, interesting things around the, some of the researchers who've been involved from day one in developing these rare disease, uh, treatments. And then when they're coming to market, they are hoping for a certain price to help improve access. And then the prices set much, much higher than that and they've been very upset by it. But the prices are made sometimes at the board level, sometimes at the level that is not necessarily the people who were developing the science initially. So I think it's, it's hard to guarantee that you could get a return or get the price to a certain level if you've partnered with a company that has shareholders. Peggy, did you have any responses,

MargaretHamburg: uh, to any of the questions? Yeah, I'll just answer the, the what the Theranose product never came to market. Um, but it's an example of how when there's an anticipated market windfall, the value of a company can get terribly, terribly inflated. Walgreens and other places to get them. Um,

Speaker 7: yes, because people, nobody fortunately died because they went to other doctors just read bad blood. Well that correct

MargaretHamburg: her product never actually got God created. But um, but, but I, I take your point that it was, but it was, it was always something different than what she was actually claiming that she got it.

Kenneth L Davis: And do you know, the point about the Alzheimer's drug is if the signal is small, if the patent isn't, you know, have much more life in it. Um, but if the science isn't robust, you know, you really aren't going to take the risk, particularly when the particularly, you know, in that area. Um, there are of the 35 drugs that failed in Alzheimer's disease, every one's succeeded in animal models. Everyone's succeeded in vitro. So there's always these signals that turn out to be false positives from subgroups and small and out and small sample sizes. Emerald study, right, was like a, it was a retrospective

CraigGarthwaite: insurance study where they just went back into the data and said, hey, here's some people who got embrel. Here's some people who did in the ones who got embroiled here not to have Alzheimer's symptoms, but it's likely you might prescribe emerald differentially based on whether someone had Alzheimer's symptoms in the first place. It was also a publicly published study or you can look at it. It's online. So, well, I don't the post that's in fact wrong in the study. But the big thing is it's terrible science. Like it's like the worst possible way could design a drug trial.

MargaretHamburg: The Pfizer example I think is an interesting one more broadly in that, and it speaks to the fact that investing in drug development is a very risky business and a very expensive business. And sometimes, um, things that may have real opportunity actually get shelved because, um, a company decides it's just not worth taking the risk and making the investment. Pfizer decided to get out of neuroscience recently. Some of their product portfolio has now been sort of moved over into another company that hopefully will have success developing them. Um, but, but you know, one of the concerns as you look at this whole complex ecosystem is that sometimes things that actually have a lot of promise may never get that promise realized because of, of decisions that companies have to make about where they're gonna invest their, their time and resources.

Corby Kummer: So I think that we have set up the entire next year as agenda for Aspen ideas. Uh, we have, in the meantime, we will be seeing various episodes on Davis and Garthwaite. And we hope we're all going to be guests on the series and that you'll all come back for next year's aspen ideas. Help and enjoy this year's Aspen ideas festival.

Corby Kummer: Thank you all.