Chairwoman Eshoo, Chairman Pallone, Ranking Member McMorris Rodgers, Ranking Member Guthrie, and members of the committee, I am Dr. Gaurav Gupta, and I am a physician and biotechnology investor. Thank you for the opportunity to testify today on legislation before the committee, particularly H.R. 3 and the deleterious effect it would have on biopharmaceutical innovation and on patients.

First, let there be no doubt that we are living at the dawn of a golden age of therapeutic innovation, enabled by a convergence of advances in genomics, biomarkers, data science, and manufacturing. The first FDA approvals of oligonucleotide, bi-specific, oncolytic virus, CAR-T, and AAV and lentiviral gene therapy all took place within the last decade, representing an unprecedented expansion of the armamentarium that physicians have at their disposal to treat and cure disease.

The biopharmaceutical engine in America has yielded extraordinary medicines for many diseases. Novel small molecule drugs have cured thousands of Americans of hepatitis C, added decades to the lifespan of patients with cystic fibrosis, and positively impacted the lives of patients with sickle cell disease, which disproportionately affects people of color. Immunotherapies have transformed the lives of patients with cancer and are an important step in the quest to end cancer as we know it. Promising technologies such as targeted protein degradation and gene editing are perhaps not far behind, and future rewards will be greater still if we preserve our current system of incentivizing innovation.

Today, the United States is the global epicenter of accelerated drug development. 57% of all new medicines are invented by US biopharma companies, and bulk of the remainder are developed by foreign companies for the US market. Small biopharma companies in particular are driving US innovation – such companies now account for more than 70% of the nearly 3,000 drugs in phase III clinical trials.[1] An indirect benefit of this is that most novel therapeutics undergo clinical development and early commercial launch here in the US. The rest of the world understands that the American patient has earlier and broader access to groundbreaking therapies via these mechanisms.

Having had the privilege of practicing medicine, what I most want for patients is that they be able to take the medications that are prescribed for them— medications that can treat or cure their diseases. However, it is undeniable that our healthcare system does not equally distribute innovations, with high out-of-pocket costs presenting barriers to medication access for many Americans.

All of us and our loved ones are now or some day will be patients - I don't believe anyone working in the biopharmaceutical industry is on the other side of this issue.

Our current healthcare system is complex, costly, and stacks the deck against patients. Insurance companies, pharmacies, and pharmacy benefit managers (PBMs) all sit between a medication and the patient who needs it. There is an incredibly confusing

[1] https://www.cbo.gov/publication/57126

system of discounts and rebates that obscures how much money goes to manufacturers and how much goes to middlemen. Patients are voiceless in these negotiations, and consequently the system routinely places undue out-of-pocket burdens on patients and their families.

The scientific literature is unequivocal about the improved health outcomes generated from pharmaceutical purchasing. The 1.4% of GDP we currently spend on branded medications incentivizes future research and development, and ensures that the global center of gravity of the pharmaceutical industry remains here in the US where our citizens can enjoy the fruits of early access. Beyond this, the biopharmaceutical industry's economic output in 2017 was estimated at $1.1T, and the sector employed over 800,000 workers, one-third in key STEM occupations.

Of course, actions to improve access to medications and reduce out-of-pocket costs for patients are long overdue. I believe it is possible for us to achieve these goals while preserving America's unique capacity for innovation.

For many of the ideas that I am going to outline in my remaining time, I must give credit to the outstanding work of the organization No Patient Left Behind. I would particularly like to thank Jim Greenwood and Peter Kolchinsky – I've benefitted from the vast body of excellent thought leadership they've produced on this key topic.

I would like to begin by contextualizing pharmaceutical spending to other cost drivers in the health care system. It is well-established that the growth in overall national health expenditure is predominantly attributed to hospital spending; branded drugs account for only 8% of the total. Overall expenditure on prescription drugs encompasses not only what is paid to pharmaceutical companies but also what is paid out of the system to middlemen, including insurance companies, pharmacies, and PBMs. Consequently, I would submit to the committee that a good faith effort to meaningfully curb health care spending demands addressing both the largest drivers (hospitals) and hidden costs (prescription drug middlemen).

In the context of prescription drugs, the very existence of out-of-pocket costs doesn't make sense. No patient gets a medication without a doctor prescribing it, and in many cases, insurance plans require that the doctor seek their explicit prior authorization. It doesn't follow that insurance companies, having agreed that a patient needs a particular medicine based on FDA labeling for that product, then ask a patient to "put skin in the game" by paying a portion of the cost. They have skin in the game – their disease.

Once a doctor prescribes a medication and the insurance plan confirms that drug is right for the patient, insurance should be designed to get that medication to the patient, rather than creating additional financial barriers. The whole reason people pay insurance premiums is to be able to afford appropriate care. Yet out-of-pocket costs have skyrocketed over the last decade - recent data show that out-of-pocket costs continue to climb despite reductions in the net price of drugs, and patients can see a

33% increase in mortality caused by just a $10 increase in insurance copayments. Out-of-pocket costs are effective only at reducing adherence and creating undue financial burdens.

Of course, some drugs are more expensive than others. But the kinds of drugs that are expensive today are not the ones that people are likely to want to take unless they need them. There is no rationale for using out-of-pocket costs as a deterrent against over-use of prescription drugs. Healthy people don't seek medications for cancer, multiple sclerosis, or diabetes. But for those who need a medication, we can make sure patient out-of-pocket costs charged by insurance companies are not a barrier to accessing care prescribed by their doctor.

Insurance reforms that cap or even eliminate out-of-pocket costs – not just in Medicare Part D, but also for Americans who receive coverage through their employers, through health care exchanges, and other types of health plans - would be a high impact step towards ensuring broad access.

The critical flaw of H.R. 3 is that it conflates drug prices and patient out-of-pocket costs. Importing foreign pricing would only marginally reduce what patients with high-deductible plans, including Medicare, are forced to pay. It wouldn't solve their problem - what it would do is dramatically undermine the ability of American biopharmaceutical companies to develop innovative medicines that could treat and cure innumerable diseases in the future.

Many are concerned about the drug prices that insurance plans pay. But the only drugs we pay attention to seem to be the ones that happen to be expensive today, overlooking that the hundreds of medicines that used to be expensive are no longer so, because they went generic. Medicines going generic at the end of their patent life is the natural price control we've had for nearly 40 years, since the passage of the Hatch-Waxman Act. We save $200B each year by using generic drugs - and could likely save more if insurers adjusted their policies to increase the utilization of already-approved generic alternatives to brand-name medications. Generics also play an important role in spurring continuous innovation, because the established lifespan of a patent creates a natural incentive for drug companies to keep innovating to stay afloat.

That being said, the generics system would benefit from certain reforms. Over the past decade, we've seen a smaller fraction of drugs go generic, due to a number of factors. For example, some drugs are too scientifically complex to copy. In other cases, some companies are abusing the patent system. As an investor, I believe a stronger generics system promotes a better environment for innovation. Consequently, I would submit to the committee to consider what actions regulatory bodies should be taking to ensure that all drugs go generic without undue delay once their market exclusivity and core patents expire.

I'd like to conclude with a point about American competitiveness. The ability for parts of today's hearing to take place in-person today was made possible by the whirlwind

development of vaccines and monoclonal antibodies for COVID-19. The remarkable innovation capacity of our biopharmaceutical industry during the pandemic ought to be a source of national pride. My perception as a biotechnology professional is that other countries are eager to siphon our pharmaceutical prowess. This is particularly true of China, which has made biotechnology a strategic pillar.

In 2016, the market capitalization of all Chinese biopharma companies was $1B. Only 5 years later, the combined market cap of all Chinese biopharma companies is north of $200B. In 2019, for the first time ever, a drug developed in China was approved by the US FDA. While China's innovation capacity remains far behind America's, they are doing everything they can to catch up and catch up fast.

When I speak to Chinese biotechnology executives and Chinese physicians, they boast that they can run clinical trials faster than their US counterparts. The danger of H.R. 3 is not only that it will disincentivize pharmaceutical innovation, but that it will effectively drive that same innovation to China, which is clearly signaling to its companies that it wants them to catch up, and that they can charge relatively high prices in China. If we close off the market in the US at the same time that China is opening their market to innovative new products, we will see companies launching impactful novel medicines in China, based on clinical trials conducted in China, before they consider running trials to the FDA standards for the US market. The FDA rarely accepts data generated entirely outside the US, so if we want companies to pursue expensive research on American

soil, we need to offer the incentives to match. In order for patients to be able to “Buy American”, we have to first protect America’s capacity to be a home for innovation.

As a physician, scientist, and investor, I have seen firsthand the transformative impact that biomedical innovation can offer to Americans at all stages of life. Preserving the health of America’s innovation ecosystem will enable us to improve the health of all Americans. Let’s continue to nurture this important work on our soil.

Thank you.