INTRODUCTION
Promoting Drug and Vaccine Innovation and Managing High Prices: Introducing a Special Symposium

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Abstract: This special JLME symposium addresses ways that federal policy can incentivize innovation in medical therapeutics and make pharmaceuticals more financially accessible.

Prescription drugs are among the most important interventions in medicine, but excessively high drug prices in the U.S. can make breakthroughs unaffordable for many patients, leading to harmful clinical consequences. This dynamic has led to numerous policy discussions in recent years about how to optimally ensure a vibrant pipeline of important new drugs, while also ensuring that they are accessible to the patients who need them. The pharmaceutical industry plays an important role in bringing products forward, which can require substantial resources. In addition, government funding is essential for drug discovery, particularly the billions of dollars the U.S. National Institutes of Health (NIH) spends annually to support research at academic institutes and centers across the country. How can public and private funding of drug innovation optimally interact to bring meaningful new drugs to patients? How can we ensure prices for new drugs that ensure fair access to them while still ensuring a reasonable return on private investment?

In this special issue, we seek to address these questions from several perspectives organized around three policy statements from the issue editors. The first statement (Kesselheim) reviews the two ways that substantial public funding supports drug innovation in the U.S., through the NIH and through government prescription drug insurance systems like Medicare after a drug receives regulatory approval. It also reviews recent legislative proposals that seek to promote drug innovation and analyzes how they would affect the current ecosystem.

The second statement (Sarpatwari) focuses specifically on the case study of the COVID-19 vaccines, which were synthesized and shown to help protect against COVID-19 morbidity and mortality in a remarkably short time period. The U.S. government played a major role in moving that innovation forward both in the support of scientific investigations into mRNA vaccine technology, as well as through purchasing commitments. What responsibility, the piece asks, does that role place on ensuring access to the product for patients in the U.S. and overseas?

The final statement (Rome) addresses key issues in how we pay for prescription drugs in the U.S., examin-

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ing the structure of the insurance coverage system and the particular role played by pharmacy benefit managers (PBMs). Although PBMs exist partly to control spending by negotiating with drug manufacturers and steering patients toward less expensive medications, these entities have been the subject of controversy due to certain business practices that complicate the drug supply chain. This statement reviews the ways that legislators have considered to reform PBM business practices, and whether they will ultimately support or subtract from the ultimate goal of reasonable access to drugs at fair prices.

In recent years, numerous initiatives have helped promote the development of important new drugs and their dissemination to patients, such as the Inflation Reduction Act and the COVID-19 Relief Bill. We hope that the contributions to this symposium support continued thoughtful public policymaking to motivate meaningful progress in public health and patient care.

The symposium also includes numerous commentaries on these statements from distinguished experts in fields ranging from economics to public health to law to health policy. Professor Mariana Mazzucato of the University College London Institute for Innovation and Public Purpose discusses ways that the government can be more proactive about promoting meaningful drug innovation, such as through harnessing collective insights and governing investments to maximize public benefits. Arizona State University economics professor Bhaven Sampat addresses the implications of substantial increases in NIH budgets and the collateral implications on the behaviors of researchers and industry. University of California Law professor Robin Feldman and Research Fellow Zachary Rosen address the role that patent strategies play in drug innovation and propose an NIH free market license approach to meet the dual goals of commercialization and access. Columbia Law School professor Chris Morten addresses the importance of accurately understanding the relative roles of publicly- and privately-funded research in the COVID-19 vaccine discovery process, and how the government can better leverage its contributions to promote access in future public-private partnerships. Dr. Reshma Ramachandran of Yale School of Medicine reviews recent problematic steps taken by Moderna in commercializing the COVID-19 vaccine and how better government oversight can ensure closer adherence of manufacturers to the social contract emerging from publicly funded research. Professor Stacie Dusetzina of Vanderbilt University addresses how access to better information about the drug supply chain could inform targeted pricing and access reform related to PBMs or other market forces. Professor James Robinson at University of California Berkeley discusses how current drug price rebating practices can warp the market for prescription drugs and explains what pathways forward exist for meaningful drug pricing reform. The goal of these commentaries was to generate novel perspectives on and analysis of the ideas in the three statements and their implications for drug innovation and access.

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