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SYMPOSIUM

Promoting Drug and Vaccine Innovation and Managing High Prices: Three Proposals for Policy Reform

GUEST EDITED BY Aaron S. Kesselheim, Ameet Sarpatwari, and Benjamin N. Rome

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and
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INTRODUCTION
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Government Support of Meaningful Drug and Device Innovation: Pathways and Challenges
Aaron S. Kesselheim

The US government supports drug innovation in two important ways. First, through the National Institutes of Health (NIH), it supports the development of transformative drugs. Second, the government is the largest single purchaser of prescription drugs through Medicare and Medicaid, among other programs, and can take steps to ensure that taxpayer funds are used to provide preferential access to meaningful pharmaceutical innovation. It is therefore crucial for the government to distinguish between high-value vs. low-value innovation in purchasing expensive prescription drugs and medical devices. In recent years, the government has tried to do that by (a) issuing a National Coverage Determination to pay for the Alzheimer's disease drug aducanumab, which was initially priced at $56,000 per year despite no clear evidence that it works; (b) proposing special payment models through the Centers for Medicare and Medicaid Innovation that would limit payment for drugs without clear evidence of patient benefits and ensure that cell and gene therapies are reimbursed according to the clinical benefits they provide; and (c) withdrawing a rule that would have forced the government to pay for medical devices authorized by the Food and Drug Administration without clear evidence of important patient benefits. Congress should take other similar steps to ensure the continued discovery of transformative drugs and to ensure that patient and taxpayer funds are not wasted on excessively priced drugs and medical devices that offer little additional meaningful benefits to patients.

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In January 2023, Moderna announced its intent to increase the price of the COVID-19 vaccine it co-developed with the National Institutes of Health (NIH) by 400%. Moderna's justification was three-fold: 1) the value of the vaccine, 2) its need to support research and development, and 3) minimal impact on patients in part owing to a planned patient assistance program. Careful assessment reveals major flaws in these arguments. First, although the NIH-Moderna vaccine has proven highly effective, it was created with substantial taxpayer funding of early- and late-stage research, pivotal clinical trials, and manufacturing—in addition to a $1.5 billion advanced market commitment. For this unprecedented "de-risking," Moderna is not justified in extracting the full value of the vaccine. Second, Moderna had ample funds to invest in research and development, reporting $20 billion in profit in 2021-2022, but elected to spend more on stock buybacks to enrich its executives. Third, contrary to Moderna's assertion, a four-fold price increase of the NIH-Moderna vaccine will harm public health. Even with a patient assistance plan, fewer vaccinations will occur, which will increase the number of infections and deaths from SARS-coV-2 and provide more opportunities for the virus to mutate. The federal government should continue to pressure Moderna to change course and resume buying doses for all Americans, leveraging its purchasing power to obtain a fair price. This response would not threaten innovation but instead allow Moderna to profit handsomely from its efforts under reduced risk while ensuring reasonable access to treatment.

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Symposium articles *are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.*

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Columns *are written or edited by leaders in their fields and appear in each issue of JLME.*

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Addressing High Drug Prices by Reforming Pharmacy Benefit Managers
Benjamin N. Rome

In the US, high prescription drug prices have resulted in many patients struggling to afford necessary medications. Recently, Congress has focused on reforms to address the role that pharmacy benefit managers (PBMs) play in high drug prices for patients. PBMs are middlemen for transactions between drug manufacturers, patients, and insurers. Several PBM business practices are problematic, including negotiating confidential rebates that are not passed on to patients who use expensive medications, charging fees tied to the list prices of medications, and encouraging patients to fill medications at PBM-owned pharmacies. To address these concerns, Congress could prevent PBMs and insurers from setting patient cost-sharing based on pre-rebate list prices, require PBMs to pass rebates along to plan sponsors so they can be used to lower premiums and offer more generous benefits, prevent PBMs from engaging in spread pricing or collecting fees based on list prices, and investigate the potential anti-competitive effects of vertical consolidation between PBMs and pharmacies. In enacting reforms, Congress must be cautious not to impose restrictions that excessively restrict PBMs' ability to negotiate with drug manufacturers; alternatively, PBM reforms could be paired with other policies that directly address the high prices of brand-name drugs set by manufacturers.

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