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FROM THE EDITOR-IN-CHIEF

Ethics of Prescription Medication Access, Innovation, and Prescribing Audiey C. Kao, MD, PhD

It wasn't that long ago when few prescription medications were available to treat what ailed patients. Today, more than three-quarters of all physician office visits involve some kind of drug therapy ranging from analgesics and antihypertensives to antibiotics and antidepressants. In 2017, prescription medications made up about 10% of all personal health care spending, or almost \$335 billion. While these medications offer important benefits, they can also be very expensive, as 1 in 4 patients report having difficulty paying for their medications. Therefore, it isn't surprising that more than two-thirds of Americans see it as a top priority for Congress to lower prescription medication costs.

This issue of the AMA Journal of Ethics explores the topic of prescription medications from many angles. Novel—and very costly—medications designed to cure and not simply treat medical conditions have arrived. Pete Croughan and Rebekah E. Gee examine how physicians can better allocate medication via a subscription payment model—in this case, for curing hepatitis C infections—when there are limited Medicaid resources to cover the health care needs of low-income patients. Currently, 1 in 5 Americans rely on Medicaid coverage.⁵ Jennifer A. Ohn and Anna Kaltenboeck evaluate state Medicaid programs' reliance on drug rebates from pharmaceutical companies in exchange for maintaining an open formulary and consider whether closed formularies too narrowly restrict access to some medications. Leah Rand and Govind Persad argue that Medicaid closed formularies are ethically justifiable as a way of restraining drug spending if they result in public expenditures on other socially valuable uses that promote health, such as early childhood education. To further promote more equitable drug access, Michael J. DiStefano and Jonathan S. Levin advocate using cost-effectiveness analysis alongside decision-making tools that incorporate equity considerations and promote transparency to inform prescribing policy and decisions.

Pharmaceutical and biotechnology companies are motivated in part by profits they make from medications they bring to the market. Balancing this profit motive with promoting affordable access to medications has been a policy focus for decades. In her review of the Drug Pricing Competition and Patient Term Restoration Act of 1984 (more commonly referred to as the Hatch-Waxman Act), Jordan M. Warhol argues that the act's goal of balancing drug innovation and availability has been undermined by pay-for-delay arrangements that slow market arrival of competing generic drugs. As part of the Patient Protection and Affordable Care Act of 2010, Congress passed the Biologics Price

Competition and Innovation Act, modeled loosely on the Hatch-Waxman Act. Mike Z. Zhai, Ameet Sarpatwari, and Aaron S. Kesselheim examine why few <u>biosimilars</u> are currently available and argue that one reason for the lack of competitors could be biologics companies' delay arrangements.

For those who prescribe medications, it is safe to say that many have no idea how generic drug names are assigned. Gail B. Karet describes the United States Adopted Names (USAN) Program, which is overseen by the American Medical Association, the Unite States Pharmacopeial Convention, and the American Pharmacists Association. She shows that USAN assignments of generic drug names have wide-ranging implications, from patient safety to drug pricing. From a medical education perspective, Rohanit Singh and Gary W. Pushkin argue that more ethics training is necessary to better prepare physicians to appropriately prescribe opioids.

Finally, 3 works of art are presented in this issue. Alana Noelle Snyder assembled a mixed media collage from magazine drug advertisement fragments to promote reflection about the influence of <u>pharmaceutical marketing</u> on patient-physician relationships. Tracy Meyer created a series of drawings inspired by seeds, which suggest that the <u>innovation ecosystem</u> must be nurtured for future medication breakthroughs to occur. Through graphic narrative, Hannah Rebeccah Abrams tells a story of how hospitals struggled through a <u>shortage of normal saline solution</u> after Hurricane Maria devastated key pharmaceutical suppliers based in Puerto Rico.

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