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SYMPOSIUM: PHARMACEUTICAL ETHICS

Lead Essay: Money, Equity and Access to Medicines

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The prescription of medicines is the most ubiquitous medical intervention. In Australia, a country of 25 million people, almost 300 million publicly funded prescriptions (not including those provided to in-patients in hospitals) are filled per annum (Australian Institute of Health and Welfare 2018), while in the United States over 4 billion prescriptions are filled per annum (Mikulic 2018), and almost half of US citizens report having taken a prescription drug in a given month (Martin et al. 2019). By 2023 it is estimated that over USD1.5 trillion will be spent on medicines per annum (IQVIA Institute 2019), which is roughly equivalent to the annual gross national product of Australia or Mexico. An increasing proportion of this spending is directed towards expensive "specialty drugs" which are predicted to account for up to 50% of pharmaceutical spending in developed countries by 2023 (IQVIA Institute 2019). For example, in the United States it is reported that in 2014, 1% of prescriptions accounted for 32% of medicine spending (American's Health Insurance Plans 2015). For the same year, the Australia Department of Health reported that cancer drugs accounted for 17% of spending, but only represented 1% of all scripts (Community Affairs Reference Committee 2015). In 2010, for the first time, more "specialty drugs" were approved by the US Food and Drug Administration than "traditional drugs" (America's Health Insurance Plans 2015). These trends paint a troublesome picture for health systems already struggling to provide fair and equitable access to health care.

This is not to negate the tremendous medical advances that have occurred as a result of drug development. Hepatitis C is now curable, and its eradication is a realisable goal and some cancers have been transformed from death sentences to chronic diseases. However, technological advances are not sufficient on their own and have the potential to introduce their own inefficiencies and inequities. Regulatory systems, payment models, research paradigms, healthcare systems and the interests of various stakeholders must therefore align in order to translate scientific and technological advances into improved outcomes across the health system. In the process, important ethical questions need to be tackled in a way that is alert to the broader political, economic and social context in which medicines are developed, regulated, funded, marketed and used.

Importantly, these ethical questions, which cut across the entire medicines lifecycle, cannot be constrained to a single branch of applied or practical ethics, such as clinical, research or public health ethics. Rather, what is needed is an integrated "pharmaceutical ethics" that acknowledges the ways in which apparently disparate

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processes and issues are linked. This is not to argue for a new subdiscipline of bioethics, but rather for approaches to practical problems that draw on insights from multiple bioethical domains.

In this symposium we have collected a diverse series of articles on pharmaceutical ethics by leading experts in the field. These articles do not shy away from "wicked problems". Addressing drug prices, Spencer Hey argues that treating the future price of a medicine as entirely unknowable means that ethics committees and research participants cannot meaningfully assess the relative risks and benefits of research participation (Hey 2020). This is because, for benefits to be realised in society, medicines must be accessible, and price modifies access. In ignoring this fact, Hey argues that the research enterprise has failed to uphold its foundational ethical obligations to facilitate informed consent and provide social benefit.

Marcello Ienca and Effy Vayena explore the ethical dimensions of participant-led research (PLR) (Ienca and Vayena 2020). They frame PLR as a morally justified extra-judicial mode of justice-seeking that is similar to, but also fundamentally differs from, vigilantism. In their support for PLR, Ienca and Vayena are not naive to the ethical uncertainties and risks that it poses—most notably implicit coercion by for-profit companies, conflicts of interests, and inadequate epistemic standards. They call upon the research community to actively engage in negotiating and implementing a new social contract that will allow biomedical research to leverage the benefits of PLR activities, while protecting these activities from the risks identified.

Continuing the theme of public involvement, Sharon Batt and colleagues provide an illuminating account of the social history of grassroots activism in the United States, focusing on the evolving relationship between pharmaceutical companies and advocacy groups (Batt et al. 2020). This article is accompanied by a commentary from Ray Moynihan, who supports concerns about undue influence of industry over patient groups, while acknowledging that "opting for a binary conception, a yes or no to accepting industry funds" is overly simplistic and neglects the spectrum of relationships that can exist between both (Moynihan 2020).

Renaud Boulanger and colleagues highlight how power dynamics and divergent interests can perpetuate ethical issues in their presentation of the results of a qualitative study investigating the ethical challenges associated with developing and implementing new tuberculosis (TB) technologies (Boulanger et al. 2020). Their results confirm that equity of access to, and the risk-benefit of, TB technologies remains a serious ethical challenge.

While access to medicines is generally viewed as an unconditional good, Pace and Colleagues illustrate the need for access to be appropriate and sustainable (Pace et al. 2020). They describe the pressures that regulators and payers face to speed up access to medicines, which often means approving medicines on the basis of less rigorous evidence. They systematically articulate the challenges of relying on disinvestment when technologies do not meet clinical expectations. They articulate the procedural and substantive principles that could be used to justify disinvestment decisions, while also recognising that access to medicines is driven by moral intuitions and psychological biases and that decisions to remove such access cannot be reduced to a purely rational calculus.

In the final contribution to this symposium, we present a critique of consumer engagement as it relates to decisions about the funding of new medicines (Ghinea, Lipworth and Kerridge 2020). While consumer engagement is often presented as a good in itself, in the context of health it was originally conceived as a means to address inequities. We examine the ways in which consumer engagement can in fact undermine equity, and we articulate the challenges that need to be overcome if the consumer engagement movement is to stay true to its original purpose.

Over the past century, medicines have become one of the most effective, powerful, ubiquitous and costly parts of the healthcare system. While the articles in this symposium deal with diverse issues, they all ultimately converge on the question of who should bear the risks and costs of drug development, how the benefits that arise from such development can be maximised and distributed in equitable and ecologically responsible ways, and who should make these decisions. We hope that this symposium will be the start of a movement amongst bioethicists and policymakers to work together in addressing these critical questions.

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