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### Public Sector and Non-Profit Contributions to Drug Development: Historical Scope, Opportunities, and Challenges

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**Disruptures in the Dental Ethos: The Birth, Life, & Neoliberal Retirement of Norms in Advertising & Corporatization**

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**Operationalizing the Ethical Review of Global Health Policy and Systems Research: A Proposed Checklist**

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VOLUME 49:1 • SPRING 2021

Symposium Articles

**Public Sector  
and Non-Profit  
Contributions  
to Drug  
Development:  
Historical Scope,  
Opportunities,  
and Challenges**

Guest Edited by  
Ameet Sarpatwari

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*Letter from  
the Editor*

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**Introduction: Public Sector and Non-Profit Contributions to Drug Development — Historical Scope, Opportunities, and Challenges**

*Ameet Sarpatwari and  
Aaron S. Kesselheim*

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**The Government and Pharmaceutical Innovation: Looking Back and Looking Ahead**

*Bhaven N. Sampat*

Current debates about the roles of the public and private sectors in pharmaceutical innovation have a long history. The extent to which, and ways in which, the public sector supports drug innovation has implications for assessments of the returns to public research funding, taxpayer rights in drugs, the argument the high prices are needed to support drug innovation, and the desirability of patenting publicly funded research. Understanding the current division of labor may also point to other configurations that more effectively promote the dual policy goals of drug development and access. This paper reviews the evolution of these debates, summarizes the main arguments, and proposes an agenda for the research and data collection needed to advance the conversation.

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**Opportunities and Challenges in Translational Research: The Development of Photodynamic Therapy and Anti-Vascular Endothelial Growth Factor Drugs**

*Christina Kaiser Marko  
and Joan W. Miller*

The development of photodynamic therapy and anti-vascular endothelial growth factor agents have revolutionized the treatment of retinal diseases, transforming the retina subspecialty by ushering in an age of pharmacological treatments for a wide range of diseases, including age-related macular degeneration (AMD). These translational research efforts remain among the most important

achievements in ophthalmology, dramatically improving vision outcomes and quality of life for millions of people worldwide. Here, we describe the research and development of these landmark therapies, and offer perspective on the relative contributions of industry, academia, non-profits, and government in the translational research process for AMD.

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**The Future of the Pharmaceutical Industry: Beyond Government-Granted Monopolies**

*Dean Baker*

Just as tariffs lead to economic distortions and provide incentives for corruption, so do patent monopolies on prescription drugs, except the impact is often an order of magnitude larger. This paper discusses four mechanisms for getting drug prices closer to free market levels with actions at the state or local level or by private actors: 1) importation from foreign countries with lower prices; 2) having patients travel to these countries; 3) state government financing of research to develop drugs to be sold at generic prices; and 4) philanthropic funding of research to develop drugs to be sold at generic prices.

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**A Non-Profit Approach to Address Foreign Dependence of Generic Drugs**

*Dan Liljenquist, Ge Bai, Ameet Sarpatwari, and Gerard F. Anderson*

The COVID-19 pandemic has revealed the vulnerability of the US generic drug supply chain to foreign production. Many policies have been proposed to mitigate the vulnerability. In this article, we argue that nonprofit drug manufacturers have the potential to make important contributions. With relatively low cost of capital, they may adopt a transparent cost-plus pricing model and enter long-term contracts with institutional partners, including government programs, health systems, insurance companies, and pharmacies. This business model may diminish the cost differential between domestic and overseas production and provide an opportunity to transform the US drug supply chain.

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**Realizing Public Rights Through  
Government Patent Use**

*Amy Kapczynski*

A substantial portion of biomedical R&D is publicly funded. But resulting medicines are typically covered by patents held by private firms, and priced without regard to the public's investment. The Bayh-Dole Act provides a possible remedy, but its scope is limited. A more comprehensive approach to recognize government contributions could be anchored around the existing "government patent use" right. It enables the federal government to buy generic versions of patented medicines, and affords compensation to firms. This commentary uses a COVID-19 treatment, remdesivir, to illustrate how government patent use could be deployed to establish prices that better recognize government contributions.

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**A Market Shaping Approach for the  
Biopharmaceutical Industry: Governing  
Innovation Towards the Public Interest**

*Mariana Mazzucato and Henry Lishi Li*

Enhancing research and development and ensuring equitable pricing and access to cutting-edge treatments are both vital to a biopharmaceutical innovation system that works in the public interest. However, despite delivering numerous therapeutic advances, the existing system suffers from major problems: a lack of directionality to meet key needs, inefficient collaboration, high prices that fail to reflect the public contribution, and an overly-financialized business model. COVID-19 has magnified and focalized these challenges. We review these problems and argue that overcoming them requires a fundamental reframing of the role of the state in innovation from market-fixing to market co-creation and co-shaping, in which risks and rewards are shared across a symbiotic public-private relationship.

Independent Articles

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**Healthcare Professionals' Experience,  
Training, and Knowledge Regarding  
Immigration-Related Law Enforcement  
in Healthcare Facilities: An Online Survey**

*Jaime La Charite, Derek W. Braverman,  
Dana Goplerud, Alexandra Norton,  
Amanda Bertram, and Zackary D. Berger*

**Context:** U.S. immigration policies and enforcement can make immigrants fearful of accessing healthcare. Although current immigration policies restrict enforcement in "sensitive locations" including healthcare facilities, there are reports of enforcement actions in such settings.

**Methods:** Cross-sectional survey of forty-two healthcare professionals.

**Findings:** Most respondents were attending physicians (69%) at academic medical centers (91%) in outpatient settings (83%). Nearly 1 in 5 reported immigration enforcement activities in or near their workplace; no staff members involved had received training beforehand. Many (83%) were not aware of workplace immigration-related law enforcement policies. Few (5%) received relevant training. Only 24% of respondents considered their facility prepared to respond to immigration enforcement. Commonly cited reasons included lack of training (36%), lack of known policies (36%), and deference to law enforcement (10%). Most respondents recommended staff training (70%) and/or policy development (57%).

**Conclusions:** Clinicians were largely unaware of workplace policies; few received training regarding responses to immigration enforcement. Most felt their facility would not be prepared to respond. Institutions should coordinate responses to immigration enforcement. Although current immigration policies restrict enforcement in "sensitive locations" including healthcare facilities, there are reports of enforcement actions in such settings.

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**A Survey of Overlapping Surgery Policies  
at U.S. Hospitals**

*Margaret B. Mitchell, Catherine M.  
Hammack-Aviran, Ellen W. Clayton, and  
Alexander Langerman*

The authors surveyed hospitals across the country on their policies regarding overlapping surgery, and found large variation between hospitals in how this practice is regulated. Specifically, institutions chose to define "critical portions" in a variety of ways, ultimately affecting not only surgical efficiency but also the autonomy of surgical trainees and patient experiences at these different hospitals.

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**Disruptures in the Dental Ethos: The Birth, Life, & Neoliberal Retirement of Norms in Advertising & Corporatization**

*Na'eel Cajee*

This paper argues that the trends in advertising and corporatization in dentistry since the 1970s have resulted in processes of de-professionalization and de-regulation, respectively. Rather than merely an expected outcome, these processes parallel the spread of neoliberal logic in terms of the reconceptualization of the profession as a commercial trade and the unraveling of ethical and legal frameworks established and upheld over a century ago. The implications of this investigation concern not only the field of dental medicine, but the delivery of healthcare at large.

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**Operationalizing the Ethical Review of Global Health Policy and Systems Research: A Proposed Checklist**

*Abbas Rattani and Adnan A. Hyder*

There has been growing consensus to develop relevant guidance to improve the ethical review of global health policy and systems research (HPSR) and address the current absence of formal ethics guidance. Guideline development is an iterative and deliberative process requiring involvement from a multitude of stakeholders internationally. The need for guidance necessitates initial steps toward providing a protocol for use by research ethics committees (RECs) in the immediate future and a catalyst from which an iterative guideline development process can germinate. To this end, we build on our group's efforts to operationalize the ethical review of HPSR and provide an initial proposal for a practical "living" checklist. This work aims to reflect and incorporate important HPSR ethics scholarship to date and serve as a tool for both researchers and RECs.

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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.

**Independent articles** are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

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

*Next Issue:*

**Race and Ethnicity**

A Symposium Guest Edited by Robert M. Sade