Ethical Obligation for Research Universities to Expand Access to Essential Medicines

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Introduction

Approximately one-third of the global population lacks access to life-saving medicines, with nearly 100 million people pushed into extreme poverty seeking treatment (Roth et al., 2018; Hazel, 2021). The cost of essential medicines markedly contributes to the life-threatening gaps in accessibility between the Global North and Global South (Hazel, 2021, Grover et al., 2012). Meanwhile, the research-based pharmaceutical sector is one of the most profitable markets in the world. Global pharmaceutical sales were $768 billion in 2016 and are expected to reach $1.5 trillion by 2023 (Hazel, 2021).

Most medical research in the US is conducted at universities with public funding. University licensing agreements with pharmaceutical companies can play a fundamental role in monopolies and price-gouging, rendering medicines unaffordable. It is imperative that these research institutions prioritize the public health benefits of medical innovation over financial profits to ensure medicines are accessible to global citizens (Hoen, 2003).

We are part of a team of students representing the Case Western Reserve University (CWRU) Partners In Health Engage (PIHE) and Universities Allied for Essential Medicines (UAEM) who have been leading collaborations with the CWRU Technology Transfer Office (TTO) to ensure that

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licensing standards are equitable. Categorized as an "R1: Doctoral University" under the Carnegie Basic Classification framework, CWRU is among institutions of higher education holding the highest level of recognition for having "very high research activity" and "at least $5 million in total research expenditures" (Basic Classification Description). As students in medicine, bioethics, biology, and public health at a major research university in the Global North, we believe there is an ethical obligation to both advance the development of biomedical technologies and to ensure these life-saving research products become universally accessible and affordable.

In this paper, we utilize an interdisciplinary approach to understand how history contextualizes our current reality, the importance of lived experiences, and our ethical obligation to adopt the policy recommendations and practices outlined in this paper in order to improve health outcomes locally and globally. We will (1) review a brief history of global health; (2) argue for the ethical duty for institutions to adopt equitable licensing standards; (3) standardize a framework for utilization across research universities; and (4) demonstrate the global health implications of improving access to essential medicines.

Historical Background on Global Health

For centuries, global healthcare was considered a product of missionary and colonial medicine through the lens of Christianity. Protestant tradition sent physicians to the "New World"—land that was illegally stolen from over 100 million indigenous populations through settler colonialism—to open dispensaries and tend to the poor. These efforts were also extended to the Caribbean and China (Grundmann, 1990). This general history overlooks that independent health centers were the norm in the Middle East and parts of Latin America centuries before the 1700s because, as Haitian anthropologist Michel-Rolph Trouillot detailed, "history is the fruit of power," as told by the winners, the colonizers (Trouillot, 1995). We think this brief, albeit insufficient, history of missionary health is central to understanding global health injustice today, especially the lack of robust healthcare infrastructure.

Missionary health was intimately intertwined with international health efforts to control epidemics across countries in the 19th–20th centuries (Brown et al., 2006). Global health initiatives, considering the health of people rather than borders, developed later in the 20th century. Increased globalization (social, economic, and political interdependence) facilitates

the dissemination of technologies (contraception, communication, and potable water), human rights standards, infectious disease, conflict, and other threats which exacerbate poverty (Yach & Bettcher, 1998).

Globalization impacted the way international health and global health were conceptualized and operationalized. The transition from international to global health promoted a shift to frame health in terms of equity (Beaglehole & Bonita, 2010). Partners In Health—and its founders, Paul Farmer, Jim Yong Kim, Ophelia Dahl, and other colleagues—work(ed) tirelessly to decolonize global health from its imperial roots in favor of a biosocial approach that incorporates medicine with anthropology, sociology, history, ethics, and political economy (Farmer et al., 2013). In doing so, global health's powerful role in disease mitigation shifted toward social justice to recognize the role of power in illness and health.

Pharmacology and science are required to develop and manufacture medications but play a lesser role to power and profit in terms of accessing biomedical technology and medicines. We can turn to bioethics to understand our obligation to improve universal access to essential medicines. As we are all based in the United States, our obligations refer to those of the Global North where advanced biomedical research and exclusive licensing are rampant.

Long-Standing Issues in Access Viewed through the Lens of Bioethics

In the 1960s–70s, hemodialysis, mechanical ventilation, artificial nutrition, and other biomedical innovations were discovered to prolong human life. Medical teams were tasked with deciding who had access and how much life-sustaining treatment was ethical. Simultaneously, journalists published accounts of unethical research, including the Tuskegee Syphilis Study and the Stanford Prison Experiment. Together, these factors formalized a new discipline, bioethics, to answer questions about life and death and to better operationalize the Hippocratic Oath's demand to do no harm (Jonsen, 1991).

In 1979, Tom Beauchamp and James Childress developed principles for biomedical ethics to help dissect ethical issues in medicine, including autonomy, beneficence, non-maleficence, and justice. *Autonomy* states that people who have agency and liberty ought to be able to make their own medical decisions. *Beneficence* is the obligation for healthcare workers to do good by their patients by acting in their best interest. *Non-maleficence* requires that practitioners avoid harm to their patients. *Justice* considers how benefits and burdens are distributed to a population.

These principles have served as a guiding model for determining standards for animal research and drug trials, monitored by the US government, thereby setting a precedent for government intervention to ensure safety and equity through the development process of new biomedical technologies (Menikoff et al., 2017). All four principles, most notably justice, can be applied to our concerns about exclusive licensing and patents for essential medicines. First, by our evaluation, "essential" medicines—including insulin, chemotherapy, immunotherapy, antiretroviral therapy, and tuberculosis regimens, among others—provide extended quality years of life. If a medicine is offered to a patient with the best American health insurance, it ought to be considered essential.

As the field of bioethics emerged, philosopher John Rawls introduced a concept on what he called the "Veil of Ignorance." This thought experiment compels an individual to consider what social support they would want provided if they did not know their class, race, ethnicity, gender, religion, and so forth (Rawls, 1971). Scholars agree that the Veil of Ignorance indicates countries have an obligation to ensure positive rights—to provide essential healthcare (Korobkin, 1998; Fritz and Cox, 2019). Using Rawls' framework, there is a clear beneficent and non-maleficent obligation for people with power to prioritize the provision of fundamental human rights.

Nativism, racism, and neoliberalism prevent solidarity-based approaches in favor of individualism. Yet, for centuries, societies founded their policies on the idea of providing the best outcome for most of their population. Most countries in the Global North countries, with the exception of the US, have a national healthcare system because they value the principles of access, justice, and accountability. In the US, individual autonomy is prioritized over social justice and collective well-being. However, people cannot act autonomously without access to all available options. The liberty component of autonomy is restricted because there is no "independence from controlling influences" (Beauchamp & Childress, 2019). Inadequate power and resources control the decision. By limiting access to life-saving treatments, we are stripping autonomy from millions of people, thus making our protection of the principle inconsequential. We can adopt a consequentialist approach—similar to the justification for national health systems in other countries—to prioritize equitable access to essential medicines over the profits of a few politicians, high-level executives, and shareholders.

Justice Considerations for Global Health Authorities Beyond Universities

With over 450 million cases, including six million deaths worldwide, the response to COVID-19 has been a race of unprecedented speed and unrelenting international research efforts to transition this disease from life-threatening to vaccine-preventable. Although the World Health Organization (WHO) announced that countries representing 64% of the world's population made legally binding commitments to buy and fairly distribute COVID-19 vaccines globally, we have still seen a vaccine apartheid unfold with a surplus of vaccines in the Global North and an insufficient number in the Global South. World leaders have failed to facilitate the equitable distribution and access to publicly funded, life-saving vaccines, ultimately forgoing justice in times of a pandemic and revealing an unacceptably high level of moral negligence.

In order to protect individuals and communities from emerging health threats, world leaders must develop protective measures and procedures taken by state and local health authorities that are ethical, legal, and effective. The devastating consequences on individuals, families, and communities due to weak infectious disease infrastructure cannot be ignored any longer (Lagay, 2004; Margolis, 2001). While outbreaks are sometimes unpreventable, the danger becomes far greater when they are left uncontrolled and unmanaged (CDC, 2015). Failure to "meet the minimum capabilities . . . for readiness" can cause health hazards from emerging infectious diseases to become epidemics, or even pandemics, resulting in unnecessary and largely preventable deaths, especially for those from our most vulnerable communities (Mayer, 2009).

All people are susceptible to contracting COVID-19, but that does not mean the disease is non-discriminatory. The pandemic has highlighted that individuals with a low socioeconomic status (SES) experience a disproportionate burden of disease since they have restricted access to medical care. Despite the economic growth of the last century, the global distribution of wealth remains intentionally unbalanced due to many systemic injustices including colonialism (now neo-colonialism), through which continued resource and labor exploitation are rampant, widening gaps in access to healthcare, education, potable water, healthy and affordable food options, and sanitary environments (Jones, 2010). Lack of access to other essential supplies increases transmission and mortality risk for COVID-19 among

other diseases and pathological conditions that have their own unique comorbidities (Beauchamp & Childress, 2012).

Moreover, low SES is deeply intertwined with race, ethnicity, education level, citizenship status, and immigration status because societies have been built on the exploitation of the minority groups which experience these covariates most often. Populations at high risk for COVID-19 exposure and mortality have been forced to endure the systemic injustices that actively work to oppress racial and ethnic minority groups. This oppression includes "long-standing racial bias in health care—including the dismissal of legitimate concerns and symptoms—that can help explain poor [health] outcomes even in the case of black [people] with the most advantages" (Villarosa, 2018).

Although COVID-19 has helped shed light on the "deep fault-lines in our medical system . . . that stratify health care along lines of race, class, age, and disability," properly combating public health threats aggravated by systemic injustice necessitates significant mobilization of resources and international cooperation (Ginsburg et al., 2020). These collaborations can help ensure equitable and ethical medical resource distribution for the people who are the most urgently at risk for infection and death with more limited access to treatment or safety measures. Marginalized people have a right to high-quality healthcare, and under-prioritizing them during a global pandemic is a serious threat to their chance of survival (Beauchamp & Childress, 2012).

Therefore, as demonstrated most recently by this pandemic, our world's primary justice consideration must first and foremost speak to protecting the most vulnerable lives from the most disadvantaged nations. Global leaders must adopt a sense of duty and moral obligation to combat the disproportionate burden of disease and death by implementing legislative policies that would improve access to and affordability of medicines for populations who face vulnerability, exploitation, and discrimination.

When health disparities and issues of justice get overlooked or dismissed by the very leaders who claim to be advocates of health equity and social justice, then the goal of providing equitable access to life-saving vaccines and other essential medicines cannot be achieved. Although neoliberalism and contemporary ideas associated with free-market capitalism have made efforts to support vulnerable populations unpopular, now is the time to set a precedent of solidarity and stand firm in our obligation to protect the lives that have, for so long, been forgotten and left behind.

Biomedical Licensing and Barriers to Optimal Health in the US

In the US, nearly one in four people cannot afford healthcare, despite the fact that this country is home to many hubs of pharmaceutical development (Kaiser Family Foundation, 2019). Access is worse in the Global South due to people facing physical inaccessibility to medications as well as generally lower incomes. As reviewed in our brief history of global health delivery, lack of access to medicines is a consequence of colonialism due to inadequate and unsustainable healthcare infrastructure (Kettler et al., 2020; Bigdeli et al., 2013).

Without investment in "stuff, staff, space, and systems"—as promoted by the founders of Partners In Health—many low-income people rely on informal paths to access healthcare resources (Mills et al., 2002; Building Strong Health Systems, 2021). Of all healthcare costs, medicines account for 20–60% of health spending in low- and middle-income countries, with 50-90% of these expenses being billed as out-of-pocket costs, placing an undue burden on already vulnerable populations (Cameron et al., 2009; WHO, 2004; Bigdeli et al., 2013). In Table I, we frame how the cost of medicines affects all five levels of health systems (Bigdeli et al., 2013). These barriers essentially serve to impact the way medicines are licensed and patented, thereby either promoting or restricting access.

There are a host of mechanisms, detailed in an investigation by the US Congressional Research Service, that pharmaceutical companies and institutions use to increase profit, limit competition, and extend monopolies (Richards et al., 2020). Pharmaceutical patents, a form of exclusive licensing for innovation and production, are typically awarded in the US for twenty years from the date of patent filing, and similar licensing policies exist throughout the Global North. Through the 1980 Bayh-Dole Act, American universities gained financial incentives to commercialize innovation and support pharmaceutical profits (Ouellette & Tutt, 2020). Moreover, patent holders can repackage old research products or make minor modifications (such as making changes to the form or dosage) to perpetuate their patent when, in fact, it did not require true innovation. This technique is known as "evergreening," a practice which not only increases prices, but also solidifies monopolies.

Manufacturers also promote "product hopping," which is defined as removing an old product or introducing a new, but similar product as a new patent with a later date, thus extending the exclusive licensing agreement. Repeated "evergreening" and "product hopping" leads to "patent thickets," thereby limiting space for generics. Further, companies can negotiate "Pay-for-Delay"

agreements by offering settlements to other companies to delay releasing a generic alternative. On average, there were 125 patent applications filed for each of the top twelve grossing medications of 2017; approximately seventy-one patents were successfully issued for each, blocking nearly forty years of competition (Initiative for Medicines, Access, and Knowledge, 2020). No statutes exist in the US to forbid these tactics and global initiatives spearheaded by non-governmental organizations lack enforcement.

Table I
Barriers to accessing medicines categorized by health system level.

Extrapolated from Bigdeli et al. article and table on strengths and weaknesses of existing frameworks (2012).

Level of health system	Barriers to accessing medicines
Individual, household and community	Cost of medicines and services
Health service delivery	High medicine prices
	Irrational prescription and dispensing
Health sector	Pharmaceutical sector governance
	Medicines price control
Public policies cutting across sectors	Low public accountability and transparency
	Low priority attached to social sectors
	Conflict between trade and economic goals for pharmaceutical markets and public health goals
International and regional level	Unethical use of patents and intellectual property rights
	Distorted research and development, not targeting disease burden in low- and middle-income countries

Another practice, previously invisible to many people across the world, is the effect of licensing on access to COVID-19 vaccines compounded with the implications of institutionalized racism. In October 2021, Moderna Therapeutics refused to share their vaccine recipe; in response, the WHO hired a biotechnical company in South Africa to reverse engineer it (Aizenman, 2021; Maxmen, 2022). The South African company succeeded in replicating the vaccine in February 2022, paving the way for increased vaccination rates on the continent (Maxmen, 2022). While Moderna agreed to not enforce intellectual property rights—at least during the pandemic—by

refusing to disclose the vaccine's ingredients, the company is prioritizing their profits over the health and well-being of people during a public health emergency, further inflating global transmission and mortality rates.

To further expand on the context and consequences of these actions, it is essential to note that in 2019, Moderna's revenue was $60 million, and in 2021, they were projected to generate at least $20 billion (Robbins, 2021). Additionally, from a comparative perspective, while the United Kingdom had succeeded in vaccinating 85% of its population by December 2021, only 6% of the continent of Africa had completed a full, two-dose vaccine regimen (Ivanova, 2021). This reality is known as a *vaccine apartheid* because it communicates how the disparity is a direct result of intentional decisions around power, profit, and medicinal access.

In addition to making biomedical licensing more equitable, efforts must be made to implement large social investments, such as appropriate financial reparations, which work to address centuries of colonization and oppression. For example, in a study done by medical anthropologists comparing COVID-19 transmission rates in Louisiana and South Korea, researchers found that if descendants of enslaved people in the US had been recipients of financial reparations in the years prior to the COVID-19 pandemic, transmission rates in Louisiana could have been 31–68% lower (Richardson, et al., 2021). Reparations can help develop generational wealth, which ultimately allows people to experience greater opportunities for access to healthcare. Social investments, outside of improving biomedical licensing, are crucial to both acknowledging historical violations of human rights and directly seeking to improve quality of life.

Global Health Implications of Licensing

The urgency of addressing licensing issues cannot be separated from their global health implications. Therefore, it is important to discuss the threats to public health and well-being when we fail to take these negative tradeoffs into consideration, highlighted by current issues with the prescription medications Xtandi, Daraprim, dt4, and the recently developed COVID-19 vaccine.

Xtandi is a treatment for late-stage prostate cancer that was developed at the University of California Los Angeles (UCLA) in the early 2000s. Although Xtandi is the only medication available to the 1.5 million people diagnosed with prostate cancer in India, it is priced at over forty times the average per capita income, making it inaccessible to those who need

it most. UCLA sold its royalty interests to Royalty Pharmaceuticals and Japanese-based pharmaceutical company, Astellas (Hampton, 2016). The university then filed a patent claim on its ~43% royalty share which was denied by the Indian Patent Office (Mukherjee, 2016). Mumbai-based BDR Pharma produced an affordable alternative, threatening the profits of Xtandi, leading UCLA to appeal the patent denial to the high court.

UCLA must be held accountable by accepting profit cuts and increasing the accessibility of Xtandi to millions. Their goals, which revolve around leadership in research, grants, and patents, are incompatible with their current practice of prioritizing profit over the lives of people with prostate cancer (Stout et al., 2018). Additionally, large, networked institutions like UCLA set the precedent for patent royalties in partnerships, given that nearly 25% of the 252 medications approved by the Food and Drug Administration (FDA) between 1998 and 2007 were initially developed at universities (Panditrao & Aditi Mridul, 2017).

Pharmaceutical lobbyists in the US Congress also play a major role in limiting biomedical licensing regulation. Turing Pharmaceuticals CEO, Martin Shkreli, increased the price of Daraprim, an HIV medication, by 5000% overnight and hired lobbyists to combat the congressional outreach and public outcry against drug pricing alterations that ensued. The pharmaceutical industry heavily fortifies federal lobbying in Congress (including $300 million in campaign donations) to ensure medicine costs do not decrease, even with major insurance reforms like the Affordable Care Act (CREW, 2018; Geubert & Bubela, 2014).

Profit-seeking behaviors are preventing people around the world from receiving healthcare and life-saving therapies. In South Africa, the country with the highest number of new HIV/AIDS infections annually, pharmaceutical profits are prioritized over the health of millions (Laher et al., 2020). Despite the incidence of the disease, less than 1% of the HIV positive population in SA receive proper care due to overwhelming financial barriers. In the 1980s, Yale University developed the antiretroviral medication, d4T, and negotiated a patent agreement with Bristol-Myers Squibb (BMS) that would have resulted in a high cost barrier once this product hit the market (Borger & Boseley, 2001). However, due to pressure from negative media attention organized by student advocates, Yale-BMS decreased the cost of d4T in SA to 1/34th of its original price (Post, 2003).

In Latin America, Pfizer Pharmaceutical, which was providing vaccines to the region, demanded that Brazil and Argentina put up assets such as

military bases as collateral to cover any legal fees Pfizer could incur from civil suits or negligence accusations during vaccine dissemination (Davies, 2021). Similar abuse of power exists in Colombia, where the government paid $27–30 per dose for Moderna vaccines while the US paid $15–16 per dose (Robbins, 2021). These events, among others, culminated in government officials releasing statements expressing how they felt as though they were being "held for ransom" for daring to gain access to life-saving vaccines for their populations (Davies, 2021). Soon thereafter, Pfizer announced that they would collaborate with a Brazilian pharmaceutical company to manufacture vaccines for the region (Pfizer, 2021).

Even though this action is a step in the right direction, Pfizer's decision to help manufacture more vaccines in the region was likely an effort to escape negative press, thereby reaffirming their power in this twisted dynamic. It is these systemic, intentional decisions made by manufacturers without accountability that cause and perpetuate vaccine apartheid and other instances of global health injustice.

Collaborating with TTOs to Improve Licensing Standards

Renowned research institutions maintain a high magnitude of innovation and experimental processes required to further research and development. Since the 1970s, the Carnegie Classification of Institutions has categorized universities based on degrees awarded and research expenditure (Basic Classification Description). R1 (very high research activity) and R2 (high research activity) schools are doctoral universities which award at least 20 doctoral degrees in a given year and receive at least $5 million in total research expenditure as reported by the National Science Foundations (Basic Classification Description).

These schools have the stuff, staff, space, and systems to conduct high-level biomedical research with the potential to treat and cure disease and disability. As such, R1 and R2 institutions must lead equitable framing initiatives. These schools have the most interaction with pharmaceutical and manufacturing companies and, thus, the most power to improve access. The licensing standards and contracts negotiated with pharmaceutical companies are what ultimately determine pricing, length of monopoly, and competition. We will review how currently intellectual property standards threaten essential medicine access and how constituents of R1 and R2 universities can collaborate with technology transfer offices to improve licensing standards.

Innovation, as intellectual property (IP), is often patented so that it can be protected. However, protecting IP over access to necessary health care is antithesis to the stated values of most R1 and R2 schools. Universities are guided by pillars of engagement, integrity, and stewardship, seeking to improve the lives of people around the world. However, their actions within the realm of biomedical advances may not always reflect this sentiment. By not taking aggressive, intentional action to improve biomedical licensing, universities are falling short of the goals and commitments they have outlined in their missions.

Due to the substantial role of universities in developing biomedical technology, managing IP responsibly can improve access to medical innovations globally (Hoen, 2003). Moreover, most of this research is funded by American taxes through National Institute of Health (NIH) grants. NIH funding has contributed to every medication—210 in total—approved by the FDA between 2010-2016 (Cleary, et al., 2018; Mamidi, 2021). Yet, there is not widespread access to medicines, nor does the US believe there ought to be universal healthcare, distinguishing itself from the rest of the world with its fatal individualism complex.

A university's groundbreaking research can only enrich and improve people's lives insofar as it is affordable and accessible to those who need it. Concerned that our university was not fulfilling its obligation to make technology accessible, we organized meetings with the TTO to develop a greater understanding of how the office makes negotiations with manufacturing companies and secures licensing agreements for research products made at the university. As students, we felt an obligation to (1) understand our own university's policies and practices as it relates to limited access and (2) advocate that we promote justice and universal access to healthcare. Figure I outlines our general process for engaging with university TTOs and recommending licensing improvements.

During the initial meetings with TTOs, student leadership groups will focus on acquiring a stronger understanding of the office's main goals, interests, and hesitations with biomedical licensing. After engaging in these conversations and establishing a relationship with the TTO, students can work on outlining their main concerns surrounding any lack of transparency in the licensing process, insufficient exploration and use of non-exclusive licensing alternatives, and inadequate oversight on manufacturing companies with whom we have agreements.

Given the precedent of exclusive licensing as the standard for awarding innovation, many TTOs may have the misguided belief that, without

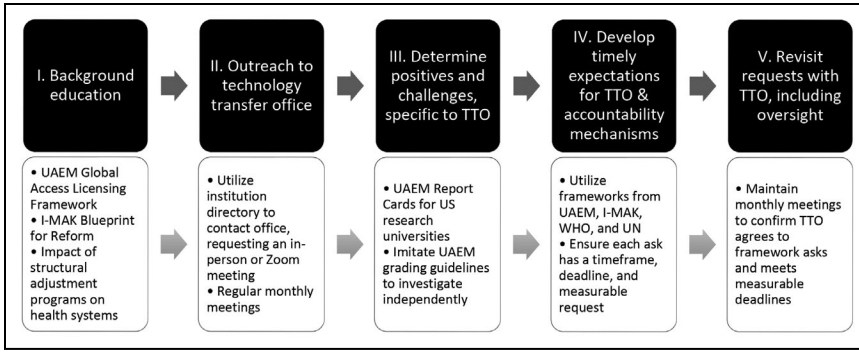

Figure I. *Overview of the process used to engage with TTOs at research institutions.*

patents, we would not have biomedical technology advancement. Conversations with TTOs should also determine the level of support and interest in changing the licensing *status quo.* Offices may verbally acknowledge equity as an important consideration, but delay or refuse adoption of alternative licensing practices. TTOs, at the minimum, should be receptive to meeting with university students and being transparent about their licensing standards. Excellent TTOs will consider recommendations from students and alter policies for maximum transparency and accountability. Figure II indicates common discourses of delay that TTOs will use to limit or prolong licensing changes.

Prior to, and throughout meetings with TTOs, students will need to be responsible for conducting their own independent research on licensing policies. UAEM produces report cards outlining positive actions and areas for improvement for leading American research universities. They also author the UAEM Evidence Wordpress blog to collate information and evidence in support for alternatives to exclusive licensing (UAEM Evidence). We heavily relied on this research and interdisciplinary discussions with other health organizers around the country.

Based on our experience working with TTOs, we developed a framework explaining the biomedical licensing process and areas for improvement. We highly recommend this approach for other institutions, as it can help educate the university, raise awareness, outline university accomplishments and areas of concern, and list institution-specific action items to improve access. We have included general categories related to licensing and sample action steps and practices that R1 and R2 institutions would be able to adopt if they are truly committed to addressing the outstanding issues that

shape and are shaped by access to biomedical innovations (Table II). These policies and guidelines were developed using the UAEM report card grades which rate research institutions' commitment to transparency, equitable licensing, research for neglected health needs, and student empowerment.

Table II

Policy recommendations and action items for R1 and R2 universities. These can be adapted to be university-specific and incorporated into a framework presented to the technology transfer office. The items should be prioritized and include expected timelines and measures for accountability.

General Policy Recommendations	Specific Action Steps and Practices
Publicly support UAEM's Equitable Technology Access Framework	Waive market and data exclusivities when at all possible. This includes abstaining from applying for extensions on market and data protections. Promotion of these exclusivities can often block or delay competition and thus increase monopolies and cost. The Food and Drug Administration permits up to 5 years of exclusivity for most small molecules that have not previously been approved. This length should never be exceeded, unless by the discovery of a drug to treat an orphan condition (fewer than 200,000 individuals in the US), at which 7 years of exclusivity is permitted (Hennebry, 2018).
	Increased transparency about meetings with manufacturers and pharmaceutical companies. Notes should be taken during these meetings to record concerns and agreements. Notes should be made available.
	All (most likely, but not limited to, federal) funding sources and amounts should be disclosed in annual reports and made available online. This includes the amount of funding for the research and development process with markers indicating the use of the funds. Given the necessity of grant proposals, researchers should be able to easily compile an itemized list of funding.
	Include step-in rights: Universities should be able to intervene and alter or end the agreement with a manufacturer if they are not meeting the obligations of the agreement. This can ensure higher equity standards are included and being met.
Publicly support at least one COVID-19 open technology framework	• Open COVID Pledge (OCP) • Coronavirus Technology Access Pool (C-TAP) • Stanford/Harvard/MIT COVID-19 Technology Access Framework

General Policy Recommendations	Specific Action Steps and Practices
Transparency about technology transfer negotiation process	More disclosure about the processes, funding, goals, and outcomes within the technology transfer office. A public website should include more information about how commercialization of university intellectual property is conducted and approved.
	Answers to the following questions are a start to outline the technology transfer process: • How does the office seek out manufacturers and pharmaceutical companies to license technology to? • What, if any, standards are set for these companies? • How does the university decide whether licensing will be pursued for an innovation or product? • How does the university decide with whom this licensing agreement will be made? • How does the university monitor compliance with the licensing agreement? • What decisions by manufacturers and pharmaceutical companies will not be tolerated? • When is information shared with the university/public about licensing agreements? • Does the amount of public money invested in the product impact licensing decisions? • What amount of transparency is required from manufacturers and pharmaceutical companies?
Include people outside the technology transfer office in licensing negotiations	The technology transfer office should include at least one undergraduate and two graduate students (if possible, one from medical school and one from law school) in the licensing review process. These students will be able to raise concerns about the equity of an agreement and their opinions should hold equal power.
Ensure accountability and regular follow-up meetings	The technology transfer office should seek out, agree to, and continue collaborations with students and interested entities. This should include, at least, 3 meetings per year to review updates. The university should mandate reporting for all clinical trial results and funding.

General Policy Recommendations	Specific Action Steps and Practices
Ensure obligations are met of current agreement, if applicable. *Many R1 and R2 universities have agreed to a UAEM Global Access Licensing Framework.*	Legally prevent manufacturers and pharmaceutical companies from engaging in tactics that can block generic competition, especially for production in resource-limited countries. The following should not be permitted: • Follow-on patents, including product, process, and use patents. These types of patents promote multiple licensing agreements for incremental developments.
	Other provisions can be included into agreements to promote equity and competition. The following should be included: • At-cost provisions: Licensed technology should be made available for no profit when: (1) "[a] component of the licensed product is too complex to be feasible for replication and generic production;" and/or (2) "the demand for the product…is too small to induce a generic company to enter the production" (UAEM 2010).
	"Do not seek patents on research platforms, diagnostic tests, and other technologies that can be adapted for commercial use in a short period with little additional investment." (UAEM 2010). • Patent on these types of inventions hinder innovation by adding costly licensing fees and can promote patent thickets
Actively promoting equitable licensing	For all patents, rely on non-exclusive licensing. All rights to the products should be reserved by the university. The product should be shared widely to encourage competition (UAEM 2010).
	Review pending and future license agreements—including students—to limit all exclusive licensing agreements.
	Collaborate with other universities (public and private) to learn best methods for prioritizing non-exclusive licensing, including communication with manufacturers and pharmaceutical companies.

Moral Duties and a Call to Action for All Global North Institutions

We call on R1 and R2 universities to share our process and framework to educate other members of the institution on the urgency and implications of licensing decisions and to pressure administrators to transition away from grandstanding and profit-driven decisions toward real accountability. We

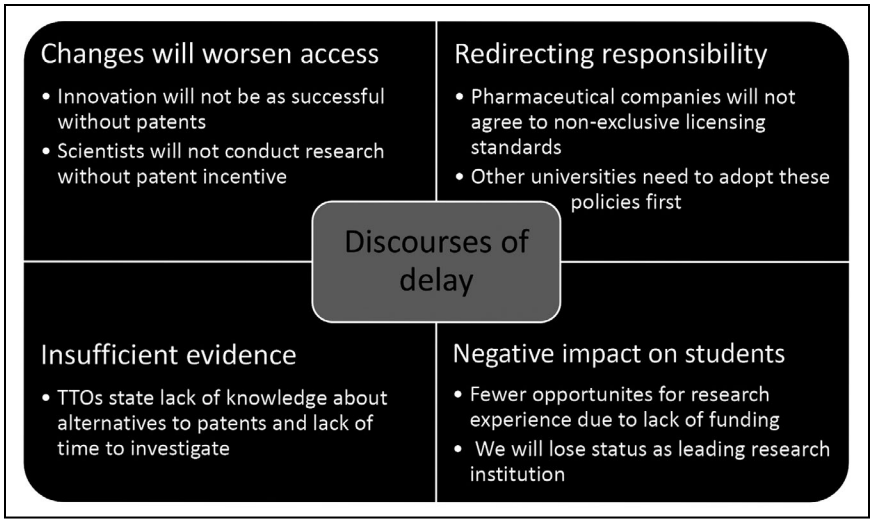

Figure II. *Common discourses of delay from TTOs and universities who are hesitant to transition away from exclusive licensing standards. Adapted from Lamb et al. article and figure on discourses of climate delay (2020).*

urge these biomedical research institutions in the Global North to adopt alternatives to exclusive agreements, such as open-source listing, which makes details of innovation freely available to others in academia and the broader public. In addition to promoting competition, open-source listing also prevents others from patenting the invention, which helps to protect the institution's innovative achievement while also increasing accessibility to a potentially life-saving product.

University research is upstream from the development process. Using an open-source listing model means that there is a chance for early leverage, with blind foresight to predict marketability. In order to effectively fight against limited accessibility to life-saving medicines, universities need to acknowledge that research is intended to meet public needs, including health care advancements. As such, global public health concerns should be considered in the patenting and licensing process.

Research universities across the Global North need to reassess their role in promoting or preventing accessible medicines worldwide. Developing biomedical technology is one small part of improving healthcare. Universities are responsible for leading conscious efforts to limit exclusive agreements and make ethical decisions about licensing. While equitable licensing is a clear mechanism for universities to promote global health justice and

to hold pharmaceutical companies more accountable, these actions must be adopted in tandem with other efforts which seek to strengthen health systems while also addressing discrimination globally.

Ultimately, the benefits of such an approach can be demonstrated by the events of the COVID-19 pandemic detailed in the Justice Considerations for Global Health Authorities section above. Therefore, in addition to committing to more equitable licensing standards, universities must improve transparency about the process and strive to educate researchers, students, and other members of the institution on the gravity of licensing decisions within the context of global health access.

Conclusion

Global health justice will only advance through collaborations between organizations, disease control authorities, health departments, and ministries of health. These health advocates and leaders must address preventive health practices, infectious disease treatment goals, obstacles to accessing healthcare, and disparities in health outcomes with the knowledge that integrative approaches to healthcare build stronger, more sustainable health infrastructures, and prepare systems for crises.

Together, with community input, these groups can enact effective strategies, address health disparities, offer constructive feedback, and expand support systems. However, when health authorities at the university and global levels fail to prioritize justice and access in their policy decisions and innovation licensing, individuals and populations die from preventable and treatable conditions. Academic biomedical research institutions and governmental bodies around the world must adopt the values of justice by actively addressing the gaps in essential medicine access and affordability.

We recognize that research universities, especially those designated as R1 (very high research activity) and R2 (high research activity), are a small part of a larger system designed for the Global North to profit off the exploitation of the Global South. We hope our framework demonstrates the tangible actions that biomedical institutions must take to fulfill their obligation to the world. These obligations extend past perfunctory pledges and value statements to genuine system-level change and robust mechanisms of accountability. We believe that adopting these general guidelines and specific action steps will provide practical implications for the betterment of humankind. Universities can further use their connections to urge other sectors to invest in global health justice.

Leaders in bioethics, medicine, and public health are some of the loudest voices for change. We urge leaders across these and other disciplines to join us in combating preventable morbidity and mortality, investing in education around the urgency of social justice, and building resiliency to continue the fight for justice. Through these developments we will help our world move through this pandemic to a brighter future with accessible healthcare, potable water, humane housing, fair labor laws, and sincere dedication to addressing the climate crisis.

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