



SUBMISSION TO THE CONSULTATIVE EXPERT WORKING GROUP ON R&D

Background: Universities Allied for Essential Medicines

Universities Allied for Essential Medicines (UAEM) is a non-profit, international student organization working to ensure that all people worldwide have access to medical treatments developed from the innovative research of universities and publicly-funded institutions.

UAEM harnesses the power of students in medicine, law, biomedical research and other disciplines to pursue new approaches to health research and intellectual property that make university-discovered medicines affordable to the communities that need them most. We believe that academic institutions must live up to their ideals of public service by using patenting and licensing in socially responsible ways that promote global access to the medicines they help discover—and we believe that tomorrow’s doctors, lawyers and public servants can be leaders in advancing global health today.

UAEM works primarily on the campuses of more than 70 premiere medical, legal, and research institutions across six continents, including Harvard University, Yale University, Johns Hopkins University, the University of California, Oxford University, Charité - Universitätsmedizin Berlin, and the University of São Paulo. UAEM students also collaborate with leading global health NGOs that need access to affordable medicines in order to treat their patients in the field.

UAEM’s submission to the Consultative Expert Working Group (CEWG) proposes new practices, processes and incentive mechanisms for publicly-funded research that will a.) spur innovation of medicines and related health technologies to meet the most pressing health needs of low-income patients and communities worldwide, and b.) ensure that these treatments are accessible and affordable for all.

Executive Summary

Publicly-funded research institutions, including many universities, have been shown to play a greater role in medical research and health innovation than is commonly understood (1). Many of these institutions have a public commitment to create and disseminate knowledge for the common good through research and education. In our view, this means that publicly-funded institutions should foster medical research that offers the greatest potential benefits for public health, and that innovations and technologies with roots in university research should be disseminated in ways that maximize global health impact and ensure access to low-income communities in greatest need.

Unfortunately, too many publicly-funded research institutions are not fulfilling their mission to advance science in the public interest. However, we believe the CEWG can advance policies and

programs that will bring the current practice of academic medical research closer to the publicly-minded ideals to which these institutions aspire.

UAEM believes it is critical for CEWG to:

- a) acknowledge and respond to the increasing importance of academic and publicly-funded research institutions in advancing global health through medical research and development.
- b) promote socially responsible intellectual property management for innovations derived from publicly-funded medical research, so as to improve the global distribution of these potentially life-saving products to the patients who most need them but can least afford them. We particularly recommend “global access-” or “humanitarian licensing.”
- c) consider how the proposals to be reviewed by CEWG will impact publicly-funded research institutions, and support proposals that will enhance the global health focus and benefits of such research, such as:
 - open source research and publishing,
 - pre-competitive research and development platforms,
 - patent pools,
 - prize funds and other mechanisms that break the link between R&D costs and the price of the resulting treatments.

Introduction

By the World Health Organization’s own estimate, 10 million people will die this year simply because they cannot access or afford essential medicines that already exist.⁽¹⁾ Many more patients will suffer because the diseases that afflict them receive far too little health research investment or innovation—and even those suffering from heavily-researched diseases like cancer, heart disease or diabetes will rarely benefit from innovative new treatments unless they are wealthy enough to afford the high cost of patent-protected brand-name medications.

Global action is desperately needed to address this two-pronged crisis in innovation and access. The Consultative Expert Working Group (CEWG) has a unique opportunity to review and support new models for medical research that will both increase innovation in traditionally neglected areas of global health research, and expand the affordability and accessibility of all treatments resulting from new models of research. By taking bold action, the CEWG can dramatically improve the lives of millions of people in low-income communities worldwide, and particularly in developing countries.

Universities and other publicly-funded research institutions have a pivotal role to play in these efforts to expand health innovation and access. A special article in the *New England Journal of*

Medicine by Ashley J. Stevens et al (2), published earlier this year, highlighted the role of public-sector research institutions in the discovery of drugs and vaccines. 143 of 1541 FDA-approved drugs in the last 40 years resulted from publicly-funded research (9.3%). When the authors focused on the priority review drug-applications (drugs anticipated to provide substantial benefit over currently marketed treatments), 66 of 348 (19.0%) resulted from investments made by the public sector. Additionally, 46% of new-drug applications from the public sector received priority reviews, compared with only 20% of applications from the private-sector. 13.6% of new molecular entities were derived from publicly-funded research – and when examining the number of new molecular entities that received priority reviews, the study found that public-sector research institutions accounted for 21.1%.

Richard Keller published a similar review in *Nature* in November 2010 (3), where he analysed the origin of 252 FDA-approved drugs between 1998 and 2007, and found that 24% came from university research where the intellectual property later was licensed to a biotechnology company or the pharmaceutical industry. Furthermore, when Keller looked at the 123 priority review drugs during that time period, he found that fully 30% were attributed to universities.

These and other studies demonstrate that while academic and public-sector research may not be the dominant source of medical innovations, it still accounts for a substantial and growing portion of drug discovery. Furthermore, when priority drugs and new molecular entities are taken into account, drugs discovered by the public sector have a proportionately larger therapeutic effect and a more immediate impact on public health than the drugs developed solely by the private sector, as concluded by Stevens and co-workers in the *New England Journal of Medicine*.

The contributions of public-sector research institutions in the discovery of new drugs are particularly visible when looking at the funding for research on neglected tropical diseases (NTDs)—diseases that predominantly afflict low-income communities and receive disproportionately little research investment. Moran et al (4) found that public-sector research institutions and non-profits collectively invested over 90% of the total funding for NTD research in 2007. The amount of funding for R&D on neglected diseases is still too low to address global needs, but public research institutions are playing an increasingly large part in its financing.

The Manchester Manifesto Group at Manchester University (5), chaired by Dr John Sulston and Dr Joseph Stiglitz, defined three core goals for science and innovation by the public sector.

- 1) Public-sector research institutions should disseminate knowledge for the purpose of education and research in order to ensure improvements in our societies.
- 2) Science must be open to public scrutiny, which enables the understanding of its purpose and implications. At the same time, society needs to provide just and effective conditions for the increased use of scientific knowledge. This goal was defined as the reciprocal responsibility of science and society.

- 3) The research should be used to apply knowledge to current challenges in addition to the pursuit of unapplied scientific research. An interpretation of “knowledge for the public good” would therefore be that innovations derived from public-sector research institutions should be managed to meet the needs of the global society.

Publicly-funded research has a strong and important role to play in driving innovation toward the fulfillment of these goals. However, its potential can only be properly exploited after analysing current issues concerning the management of scientific discoveries and intellectual property in the public sector.

Challenges in accessing medicines resulting from publicly-funded research

A key piece of legislation dealing with intellectual property for public-funded research was the U.S. “Bayh-Dole Act” of 1980. The Bayh-Dole Act enabled universities and non-profits to systematically pursue ownership of promising research findings by acquiring intellectual property rights in the form of patents for these innovations. Universities then seek to license their patented medical innovations to biotechnology or pharmaceutical companies, typically negotiating licensing agreements that grant the private sector entity exclusive rights to develop, produce and market the technology in exchange for royalties paid to the patent-holding institution.

This process of patenting academic research and then licensing it to the private sector is now the dominant means by which publicly-funded medical innovations are developed into commercial medical products in the US and other industrialized countries. Legislation similar to the Bayh-Dole Act has now been implemented in European countries and in emerging economies like Brazil and South Africa.

The Bayh-Dole Act was implemented on the assumption that it would give academic institutions stronger incentives to patent and commercialize research, thereby spurring innovative research that resulted in production of socially beneficial products. Patenting activity at universities has indeed significantly increased since the passage of Bayh-Dole, but numerous scientific papers over the 30 years since its enactment have cast doubt on the assumption that increased patenting, licensing, and intellectual property claims for publicly-funded research have actually advanced the broader goal of increasing socially beneficial innovation at academic institutions (6,7,8,9).

In fact, many experts have concluded that the increasingly aggressive academic intellectual property claims spurred by Bayh-Dole-like legislation have created new barriers to innovation that slow the pace of medical research and development. Publicly-funded research results are often “upstream technologies,” which serve primarily as the basis for further research and development in order to produce “downstream” technologies such as discrete, marketable medicines. The patenting of early-stage biomedical research may lead to a complicated intellectual property landscape (10). For instance, secrecy has led to duplicated efforts in drug discovery efforts as researchers have tested compounds that have already have been discarded by other groups pursuing highly similar screens (11, 12,13). Furthermore, evaluation of university-derived technologies according to their potential

contribution to institutional IP portfolios has skewed academic research away from some of the world's most pressing global health challenges.

These concerns about the current state of academic innovation and intellectual property practices are highly relevant to the broader focus area that CEWG aims to address, namely the failure of a medical technology sector that measures success in terms of income (usually bolstered through patent monopolies) to produce affordable medicines that meet the world's critical health needs.

Alternative models for spurring innovative global health research are as essential for the publicly-funded research sector as they are for overall biomedical R&D, and many of the proposals before the CEWG can effectively address the particular needs of this arena. We will now take a closer look at the most promising proposals and their implications for publicly-funded research.

Models with potential to increase publicly-funded medical innovation

Here, we take a closer look at several specific models that have the potential to increase the pace, scope, and global health impact of publicly-funded medical innovation: humanitarian or “global access” licensing; open research, publishing, and R&D platforms; patent pools; and de-linkage models such as prize funds.

Humanitarian/Global Access Licensing (14)

The responsible management of intellectual property (IP) rights by publicly-funded research institutions is crucial for accessibility and affordability of end products developed from their innovations. It is particularly important that these institutions act responsibly during the licensing process, when they transfer potentially beneficial innovations to private-sector entities for development into marketable products.

Universities and publicly-funded institutions have great power and flexibility to negotiate these licenses with terms that promote the affordability and accessibility of end products, and thereby fulfill academic commitments to advance the public good. For example, universities can require licensees to allow the generic manufacture of any end products developed from the licensed technology for distribution at affordable prices in low- and middle-income countries. This and similar approaches are gaining recognition at leading research centers and by academics worldwide (15, 16, 17).

Universities Allied for Essential Medicines (UAEM) (18) has developed a framework for universities to follow in negotiating licenses and managing IP in order to maximize access to innovations and global health impact. The Global Access Licensing Framework proposes that every university-developed technology with potential for further development into a drug, vaccine, or medical diagnostic should be licensed with a concrete and transparent strategy to make affordable versions available in resource-limited countries for medical care. Licenses are complex and each will be

unique. Universities should therefore implement Global Access Policies that adhere to the following six principles:

Goals

1. Access to medicines and health-related technologies for all is the primary purpose of technology transfer of health-related innovations. This includes protecting access to the final end product needed by patients (e.g. formulated pills or vaccines).
2. Technology transfer should preserve future innovation by ensuring that intellectual property does not act as a barrier to further research.

Strategies

3. Generic competition is the most efficient method of facilitating affordable access to medicines in resource-limited countries. Legal barriers to generic production of these products for use in resource-limited countries should therefore be removed. In the cases of biologic compounds or other drugs where generic provision is forecast to be technically or economically infeasible, “at-cost” or other provisioning requirements should be used as a supplement to generic provisioning terms but should never replace those terms.
4. Proactive licensing provisions are essential to ensure that follow-on patents and data exclusivity cannot be used to block generic production. Other barriers may need to be addressed for the licensing of biologics.
5. University technology transfer programs should facilitate future innovation by patenting only when truly necessary to promote commercialization, utilizing non-exclusive licensing, creating streamlined processes for materials transfer, and reserving broad rights to use licensed technology in future research.
6. A global access licensing policy should be systematic in its approach, sufficiently transparent to verify its effectiveness, and based on explicit metrics that measure the success of technology transfer by its impact on access and continued innovation.

UAEM urges the CEWG to consider this Global Access Licensing Framework as a model to be applied to all publicly-funded medical research at universities, government laboratories, and other institutions. The widespread adoption of these standards would be a major step toward ensuring that the resulting innovations serve both pressing global health needs and the interests of the public communities who provided the research investment, by managing intellectual property with socially responsible methods that yield affordable end-products and eliminate barriers to future innovation.

Open Research, Development and Publishing

For decades, the concept of “open source” research, development and publishing has thrived in the software industry. It has provided the foundation for many of today’s most innovative and successful technologies, including Google’s Android smartphone platform, Mozilla’s Firefox web browser, many components of Apple’s Mac OS operating system, and Apache web server software.

We believe that open source approaches have equal potential to spur innovation in medical technologies for the advancement of global health. Three specific elements of the open-source software model are particularly applicable to medical R&D:

- 1) Open management of intellectual property (IP) rights for medical technologies,
- 2) Public-domain or “open access” publication of research, and
- 3) “Pre-competitive research,” or open cooperation on research among varying stakeholders without expectation of immediate or exclusive financial benefit.

1. Open management of intellectual property (IP) rights for medical technologies

“Open source” derives its name from its IP management principles: the source code for software developed under these principles is made available for others to view, share, copy, modify, build upon, or develop derivative or complimentary technologies (such as new “apps” that function on the original developer’s operating system). Open source approaches may include some minimal requirements for the use of the source material, such as attribution, notification of the original developers, or application of the same open standards to products developed from the source. In all cases, the ultimate goal is to foster a collaborative, “crowdsourced” development environment, on the principle that this approach dramatically increases the pace, scope, and quality of innovation.

UAEM urges the CEWG to support proposals for similarly open IP management approaches in medical research, in order to enhance the innovative potential of this research. For example, as discussed further below, an ideal prize fund system would require all resulting technologies to be placed in the public domain, essentially opening up the source material for immediate generic production and downstream research. Patent pools can also enable open access to patented technologies for the purposes of generic manufacturing, combination or redevelopment to meet needs of low-income populations. We laud the Medicines Patent Pool for pursuing this approach, and for publishing the text of its first patent license on its website. Transparent licensing practices like this are another step toward embracing open source principles.

2. Public-domain or “open access” publication of research

Medical research publishing in the public domain or under open copyright licenses can enhance innovation by allowing other researchers to quickly and easily access the results of previous work. Open access publication of academic research articles still ensures that the original authors receive credit, but dramatically increases the range of individuals and institutions who can take immediate

advantage of the published results to inform related or downstream research, while increasing the collaborative nature and reducing the overall cost of innovation. As university researchers in particular fund their research through grants, it is unclear that closed-copyright, fee-for-access research publications provide any incentives for innovation that outweigh the barriers created by limiting other researchers' swift and open access to the latest developments in related medical research.

As concrete examples of laudable open-access publication, UAEM would point first to the Public Library of Science (PLOS), which publishes a wide range of scientific articles “under an open access license that allows unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.” (19) PLOS is a nonprofit organization that charges authors only for the reasonable cost of publication, and does not consider an author's ability to pay when making publication decisions.

The U.S. National Institutes of Health has also taken positive steps to promote open access to research through the adoption of its Public Access Policy in 2008. This policy requires peer-reviewed articles resulting from NIH-funded research to be submitted to the PubMed Central digital archive when they are accepted for publication, and made accessible to the public through the archive within 12 months of publication (20). While UAEM believes that timeframe for public posting can and should be shortened, the NIH Public Access Policy ensures eventual open access to an extensive body of key research.

We would urge CEWG to support proposals that promote timely, universal open-access publication of medical research while granting the original researchers/authors due credit.

3. Pre-competitive Research

Precompetitive cooperation is the sharing of resources between competitors in the early stages of research, with the goal of providing benefits to all parties. The aim of this data sharing is to increase efficiency, avoid excessive and counterproductive patenting, and reduce parallel or duplicative research conducted by different institutions. By sharing both positive and negative research results early, medical researchers can avoid wasting resources on, for example, investigating disease targets that have already been shown to give undesirable results.

One model that has emerged from this concept for development of specific drug candidates is ARCH2POCM (21). This is a public-private partnership made up of four constituent groups; academics, regulators, citizens and the health industry, which focuses on high-risk, high-opportunity disease targets and operates in an open-access format to identify molecules that explore proof of clinical mechanism (POCM). The aim of this model is to reduce the rate of candidate molecules that fail in phase 2 of clinical trials, the first time POCM is evaluated in humans. An open access model like ARCH2POCM can foster rapid clinical validation of pioneer targets in a manner that would 1) increase patient safety and 2) rapidly disseminate knowledge to inform research bodies about targets for which POCM has been successfully demonstrated, and thus increase the efficiency of drug

development and decrease expenses of research. For this model to work, it is a precondition that all results are published without IP claims through the POCM stages, through an open access model, or in the free domain.

It is worth noting that the previous Expert Working Group on R&D, in their conclusion about this model, said the following:

“Investment into precompetitive research and development platforms targeted at products relevant to developing countries can result in substantial cost savings for all programmes in the same disease area. Platform research and development for developing countries targets nevertheless tends to be poorly supported because of issues related to public good and economic free riding. Greater political will in this area would expedite research and development and reduce costs.”

We stress that the CEWG has the opportunity to explore this model more closely in relation to publicly-funded research, and, through its proposals and recommendations, contribute to the growing momentum and political will for this model of R&D.

Patent Pools:

Barriers to medical innovation and access created by intellectual property claims can be greatly reduced through the use of patent pools. Broadly speaking, patent pools are independent institutions that take on the task of responsibly managing a collection of related patents claimed by varying private companies or publicly-funded research institutions, in order to maximize the benefits of the collected technologies for public health and future research.

As a concrete example, the UNITAID-supported Medicines Patent Pool, in operation since late 2010, negotiates with patent-holders for key HIV/AIDS medications to enable efficient and low-cost generic production of those medicines for low-income populations. Once these patents are licensed into the pool, generic drug companies can acquire production rights directly from the pool and manufacture affordable versions for low-income populations based on the terms of the pool’s negotiated licenses with the original patent holders (22).

In addition to increasing access, the Medicines Patent Pool also spurs innovation by enabling companies to draw upon multiple patented products in the pool to create new formulations or fixed-dose combinations of various existing treatments, in order to better serve the needs of specific patient populations.

Expanded use of patent pools for medical technologies could further spur innovation by pooling patented treatments for other diseases, or by pooling upstream research to reduce patent thickets and enable others to quickly draw on a wide range of previously-conducted research, even if the results are tied to IP claims.

Universities and other publicly-funded research institutions are essential to the successful development of patent pools, and also stand to benefit greatly from their success:

- a.) The Medicines Patent Pool has already identified key university-held patents for many of its priority HIV/AIDS medications, so the willingness of these academic institutions to license their patents to the pool will substantially impact its success. The same need will apply for the pooling of other medical patents and IP claims. At the same time, the publicly-funded U.S. National Institutes of Health was the first institution to contribute a patent to the Medicines Patent Pool, providing important leadership and incentive for other commercial and non-profit institutions.
- b.) Patent pools could dramatically enhance future innovation in publicly-funded medical research by reducing IP barriers to accessing and building upon previously-conducted research, or to improving, combining and repurposing patented medical technologies.

We urge the CEWG to support the patent pool model and explore its broad application for all diseases, medical research areas and countries.

“De-linking” R&D Costs from Drug Prices

The pharmaceutical and medical device industries make well-known claims about high research and development costs for new health products, which they cite as justification for extensive IP monopolies, high pricing for patent-protected treatments, and a reluctance to conduct research on certain disease areas—most notably “neglected diseases” (ND)—where potential consumers of new treatments may not be able to pay enough to recoup the costs of R&D.

While the true costs of R&D have been called into question by recent studies (e.g. Light & Warburton, “Demythologizing the high costs of pharmaceutical research,” BioSocieties, 2011), it remains essential to reduce or break the link between these expenditures and the price of new treatments.

The CEWG has a mandate to explore potential ways to “de-link” R&D costs from drug pricing, as referenced in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property adopted by the 61st World Health Assembly. **Publicly-funded research has a key role to play in potential de-linkage models.**

The Medical Innovation Prize Fund (23, 24), proposed for the US Senate by Vermont Senator Bernie Sanders, is a model for de-linkage where a prize fund equal of 0.55 percent of US GDP (more than \$80 billion per year at current GDP levels) is created in order to fund R&D for drugs. In return, the patents on these drugs are placed in the public domain, thus enabling price-lowering competition through generic production. The cost of the prize funds would be more than offset by the overall health care system savings induced by competitive generic pricing of products. As described in the bill proposed by Senator Sanders, *“by de-linking research and development incentives from product prices, and by eliminating legal monopolies to sell products, it is possible to induce investments that are medically more important, procure products at low prices from competitive suppliers, radically lower pricing barriers for*

access to new medicines, reduce wasteful marketing and research and development activities, and dramatically lower the overall costs of acquiring innovation, while expanding access to that innovation.”

The bill also has an open source dividend element, which would direct at least five percent of the prize funds to persons or communities—including universities and publicly-funded research institutions—that contribute knowledge, data, materials or technology into the public domain, or provide royalty free and non-discriminatory access to patents and other intellectual property rights. A model like the Medical Innovation Prize Fund could provide \$4 billion (at 2010 levels of GDP) in incentives for open source research if adopted. As previously described, the use of open source approaches for publicly-funded research could contribute to a pre-competitive research and development model, which would further reduce costs of R&D.

In the long run, by spending money to “purchase” public-domain patents through prizes and ensuring generic competition for discovered drugs, millions of government dollars currently spent on prescription drugs could be saved. Some of this money could be directed to further downstream research and development of promising findings from the academic research sector. A pre-condition for this funding would be that all future results would be fully available to researchers and the general public. This would further strengthen the current role of publicly-funded research.

We strongly encourage the CEWG to consider endorsement and tailored application of this model on a global scale.

Conclusions

Publicly-funded research institutions are an important source of medical innovations, and can play a substantial role in determining the accessibility and affordability of end-products resulting from their innovations. Medical discoveries in the public sector have a disproportionately large and immediate effect on public health. During the last decade we have seen the share of new drugs that originate from publicly-funded institutions increase, and these institutions will play an even more important role in the future. To meet the challenges global society is facing concerning medical innovation, new models are needed. In our submission we have presented several different models to increase the efficiency of basic research and overall innovation. We have also presented a model for publicly-funded research institutions to influence and negotiate the affordability of end products developed from their innovative research through humanitarian licensing frameworks.

We hope the CEWG will take a closer look at these proposals and consider the important role and great potential of publicly-funded medical research throughout its deliberations. Universities Allied for Essential Medicines is happy to provide further input and assistance in this process, and we look forward to future collaboration.

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