
MEMORANDUM

Date: November 13, 2006
To: Dean Arthur Rubenstein and Vice Dean for Research Glen Gaulton
From: Universities Allied for Essential Medicines at Penn
Correspondence to: Nicholas Stine, nstine@mail.med.upenn.edu
Re: **Neglected Disease Research at Penn: Concrete Steps for Moving Forward**

Over the course of the past year, there has been considerable dialogue among students, faculty and administrators around how to actualize a shared interest in promoting neglected disease (ND) research at the University of Pennsylvania.¹ While some steps proposed in these discussions invite broader structural change, a number of smaller-scale, actionable ideas have also emerged. These policy proposals could provide an immediate and visible demonstration of Penn's commitment to developing urgently needed therapies for some of the world's most devastating diseases.

1. Remove Restrictions on Accepting Funding for ND Research.

Global ND research has traditionally received minimal funding from the National Institutes of Health and other large grantmakers. However, in recent years this funding pool has expanded as public-private partnerships (PPPs, e.g. the Malaria Vaccine Initiative) and well-funded foundations (e.g. the Bill & Melinda Gates Foundation) have entered the field of biomedical research. These non-profits represent a significant funding source (the Gates Foundation, for example, has spent over \$6.7B on global health programming, much of this for ND research).² Still, these funders do not fit the traditional model offered by the NIH. For example, foundation/PPP grants often provide indirect cost rates significantly below the NIH rate of 54%. Penn already designates priority research areas for which investigators can accept all grants regardless of indirect cost rates. Elevating ND research to similar priority status would ensure that none of these nontraditional funds are refused.

Foundations also encourage collaborative approaches to investigations, and often prefer funding consortia over single institutions. However, grant agreements based on these relationships have been slow in moving through administrative channels at Penn and elsewhere, as universities have struggled to harmonize grant language and stipulations across institutions. In order to avoid such problems in the future, we can look to past experience with non-traditional funding arrangements and develop appropriate new strategies.

2. Coordinate Policies to Waive University Share of Indirect Costs for ND Grants.

In previous meetings, the Office of the Vice Provost for Research has expressed interest in adopting policies at the university level which, in concert with changes at the medical school, could facilitate a broader, more cohesive initiative to promote ND research at Penn. A joint commitment at the university level might involve waiving the university share of the indirect cost rate for ND grants. This would ease any budget squeeze that might come from accepting nontraditional ND grants with lower indirect cost rates.

3. Provide Access to Penn's Intellectual Property for the Purpose of ND Research.

A number of neglected disease innovations have stemmed from products created for developed-country applications. For example, *ivermectin*, developed for animal health markets in the U.S., is now used to fight

¹ For the purposes of this memo and the policies outlined within, we are defining a neglected disease (ND) as "any disease, condition, or affliction that either affects less than 200,000 persons in the United States or for which there is no reasonable expectation that the cost of developing and making available in the United States a treatment, prophylaxis, or device for such disease, condition, or affliction can be recovered from sales in the United States of such treatment, prophylaxis, or device." (from the FDA Orphan Drug Act). A number of other definitions could also be used depending on the context.

² <http://www.gatesfoundation.org/Grants/default.htm>

river blindness in Africa.³ More recently, the Institute for One World Health began investigating the use of a cardiac medication to treat schistosomiasis.⁴ These examples and others like them demonstrate the largely untapped potential of existing medical discoveries.

Unfortunately, intellectual property restrictions often impede ND investigations of this sort. Therefore, we propose that Penn facilitate ND innovation by opening access to university-derived IP. This would involve issuing a “research exemption,” allowing all non-profit institutions to access Penn’s IP solely for the purpose of ND research. This exemption would not cover non-ND investigations, and any efforts to apply Penn’s IP to research on other conditions would constitute actionable infringement of the university’s rights. Such exemptions can be constructed in a way that creates a ‘dual-market opportunity,’ allowing one licensee to develop a university innovation for developed-country use while carving out rights for research entities working on therapies for neglected diseases, which predominantly affect the developing world. Indeed, peer universities such as Yale, Berkeley, and the University of Washington have already negotiated such progressive technology-transfer agreements.

4. Create a Center for Neglected Diseases Research

In order to demonstrate and institutionalize its commitment to ND research, Penn should create a Center for Neglected Diseases Research at Penn. The goals of this center would include 1) promoting engagement in ND research by existing faculty members, 2) organizing new funding opportunities for researchers and students, and 3) facilitating collaboration between researchers at Penn and drug-development entities outside of the university.

Activities could include:

- Providing seed funding for incipient ND research projects;
- Assisting investigators in the preparation of grant materials for foundations and public-private partnerships;
- Recruiting talented ND researchers by marketing a comprehensive program to support ND research;
- Endowing a professorship for the director of the center. This leadership will help Penn attract and/or retain top researchers in the ND field; and
- Formalizing annual review practices aimed at identifying new or currently-shelved technologies with promising potential for application to ND end product development.

To realize a broader vision of leadership in global health, the Center’s mission could further include:

- Working with the Global Health Programs Office to shape the GH research agenda for the university; and
- Collaborating with clinical sites in developing countries on applied research in the field of neglected diseases.

5. Create an Advisory Committee to Monitor Progress

We have outlined a number of changes to Penn’s existing research practice that have come up in our discussions. While we believe that these will drive significant advancement for ND work at the university, we also know that implementation of these proposals will yield new lessons and ideas for improvement. Therefore, we suggest the creation of an ND Advisory Committee to monitor progress. This committee would report directly to the Dean of the School of Medicine and could include scientists involved in current ND research, CTT representatives, students, and selected external funding partners.

³ http://www.merck.com/cr/enabling_access/developing_world/mectizan/

⁴ <http://www.ia.ucsb.edu/pa/display.aspx?pkey=1105>