Yates, MaryAlice/President's Office

From: Jordan, Elke (NIH/OD) [JordanE@OD.NIH.GOV]

Sent: Friday, October 03, 2003 4:25 PM

To: Yongyuth Yuthavong (Yongyuth Yuthavong); Carol Dahl (cdahl@earthlink.net); Walt, Connie E./President's Office;

Christine Debouck (christine.m.debouck@gsk.com); Fotis Kafatos (Fotis Kafatos); Francis Nkrumah (Francis

Nkrumah); Fwambugu (fwambugu@ahbfi.or.ke); Gustav Nossal (Gustav Nossal); Jane Cardosa

(janecardosa@yahoo.co.uk); Julio Frenk (Julio Frenk); Kafatos Office (kafatos office); Krista@gatesfoundation.org; Linda B. King; Marvin Kalt (marvink@gatesfoundation.org); Mary Jane Cardosa (jcardosa@dominomail.unimas.my); Nirmal Ganguly (Nirmal Ganguly); Odile Puijalon (omp@pasteur.fr); Peter. Singer (peter.singer@utoronto.ca);

Rachel Ingrum (Rachel@gatesfoundation.org); Rick Klausner (rick@gatesfoundation.org); Singhkk

(singhkk@icmr.delhi.nic.in); Varmus, Harold/President's Office; Williamf (williamf@gatesfoundation.org); Yates, MaryAlice/President's Office; Yiming Shao (yshao@public3.bta.net.cn); Zerhouni, Elias (NIH); Blount, Stephen B. (CDC); Fauci, Anthony (NIH/NIAID); Fletcher, Mollie (NIH/FIC); Gerberding, Julie (CDC); Jordan, Elke (NIH/OD); Keusch, Gerald (NIH/FIC); Mccall, Kristen L. (CDC); McCleaf, Linda (NIH/OD); OSteen, Karen (NIH/OD); Pamela Dewhurst; Roy Anderson; Shao, Yiming (NIH/VRC); Skousen, Patricia A. (CDC); victor arriaga; Wiener, Susan

(NIH/OD)

Cc: Sanhai, Wendy (NIH/OD); Barbarash, Gary (NIH/OD); Lee, Michael (NIH/OD); McGuire, Amy L. (NIH/OD); Pucie, Charles (NIH/NCI); Richard, Tibberly (NIH/OD)

Subject: GCGH: Highlights of the Airlie Meeting

Dear SB members.

Attached is a brief summary of the highlights of the Airlie meeting. This summary does not do justice to the tremendous depth and intensity of the discussion that took place, however I hope it is useful as a record of consensus reached on various points. The real product of the meeting is, of course, the set of documents that will become public on October 17. Hopefully October 17 will produce a lot of publicity and result in a multitude of inquiries about letters of intent.

On or about October 17, I will forward to all of you the email that will go out alerting the community to the grand challenges and the grants program. I hope you will then forward this email to all your scientific friends and acquaintances to help get the word out.

Regards, Elke

Elke Jordan, Ph.D. Associate Director for Scientific Initiatives Foundation for the National Institutes of Health 1 Cloister Court Suite 152 Bethesda, MD 20814 301- 451- 9556

Grand Challenges in Global Health

Highlights of the first Scientific Advisory Board Meeting

Airlie Conference Center

August 17-18, 2003

Opening Remarks and Introductions

The meeting opened with a welcome and introductions, followed by brief statements from each member about the goals of the meeting.

Rick Klausner described the origins of the grand challenges in global health initiative and stated that the goal in his mind was to increase attention on the big problems in global health and to fund innovative research to solve them. Although the idea of announcing grand scientific challenges may seem straightforward, it has actually been very hard to come up with novel ideas or new questions and to formulate what the roadblocks are.

Elias Zerhouni expressed his excitement about the grand challenges concept and hoped that this program would be able to do some of the things that NIH cannot do, by taking advantage of the greater degrees of freedom inherent with foundations. We should be looking for context sensitive strategies that will actually work in the developing world.

Harold Varmus noted that health is a driver of economic development and thus there is urgency in dealing with health problems in the developing world. He stated that the goal of the meeting will be to arrive at a list of grand challenges that all can agree on. They should deal with the scientific or technological problems of the greatest magnitude that are most amenable to a solution at the current time. While the goal is creation of new knowledge, indirect benefits such as capacity building, may occur as well. It is hoped that the challenges will attract creative scientists to work on the problems of developing countries.

The specificity of the grand challenges should be such that each will attract a reasonable number of grant applications, not too many and not too few. We do not have to exhaust all possible grand challenges this year, but will have a chance to add additional challenges in future years. It is important to keep the momentum of the program going.

The other members of the SB then described what they thought were some key issues to consider in selecting grand challenges.

Roy Anderson pointed out that there are currently no vaccines to variable organisms. However, recent progress gives him hope that success in this area might be possible.

Jane Cardosa stressed the need to consider how the results of the research would be delivered in resource challenged settings.

Christine Debouck said that her experience with drug development has made clear to her that developing drugs for the developing world is a very different challenge, where implementation must be a prime consideration.

Toni Fauci pointed out that his Institute funds a great deal of global health research. One urgent unsolved problem is finding a cure for latent infections.

Bill Foege declared himself intrigued by the approach of asking field workers what they need as in the call for ideas. He hoped we could change the reward structure to give more credit for discoveries that are easily implementable.

Julio Frenk stated that the social sciences are a key to improving health in many situations. New knowledge has to be accepted and internalized to be useful. Poor countries are burdened not only by infectious diseases, but more recently also by the non-infectious diseases common in the developed world.

Nirmal Ganguly agreed that behavioral issues are a great challenge in dealing with health. He would like to see do-it-yourself tests that give control to the individual.

Julie Gerberding felt that it was important for vaccine technology to keep up with the pace of new emerging infections. She also wondered how we would measure the success of the GCGH?

Fotis Kafatos indicated that the GCGH has already had a big impact on the field of vector biology, where the fast pace of new discoveries has led the laboratory and field researchers to work together to address urgent problems.

Jerry Keusch expressed interest in the role of the social sciences in learning how to change risk taking behavior, and in global bioethics.

Francis Nkrumah saw himself as a voice for Africa, which is the least developed continent. The cycle of poverty, disease, and ignorance must be broken, and perhaps better health will be a way to achieve this. He thought partnerships between the developing and developed countries would be critical.

Gustav Nossal declared his great interest in vaccines, but wanted to see at least one grand challenge on non-communicable diseases.

Odile Puijalon stressed the need for accurate diagnostics as a key to treatment and control.

Yiming Shao was interested in seeing a proper balance between innovation and feasibility and hoped the GCGH would take more risks than NIH customarily does.

Peter Singer wanted to be sure that bioethics concerns were addressed along with the science to assure that real problems were tackled in a practical way. Florence Wambugu pointed out the major role of malnutrition in health and hoped that a grand challenge to address that would be included.

Yongyouth Yuthavong wanted to make sure that the GCGH becomes a success story and advised building in evaluation strategies at the beginning. Hearing the voices of the developing world will be important as the program proceeds.

Selecting the Grand Challenges

The board then discussed the series of topics for grand challenges that had been developed by the Executive committee, based on the more than 1,000 submissions received in response to the call for ideas published on May 1, 2003. Each topic had been formulated in a standard format that briefly stated the background, the roadblock, the challenge, the potential benefits and, in some cases, the desired priority areas.

SB members had been assigned to the topics and those assigned presented their views, followed by extensive discussion. In the course of the discussion, many of the issues raised by SB members at the beginning of the meeting featured prominently. It was clear that identifying grand challenges that have all the desired characteristics is not simple. As the discussion proceeded, some of the topics were combined, others were grouped together under broader goals, and all were refined and edited extensively. At several points, members were assigned to rewrite and reformulate specific topics based on the discussion. Some topics were dropped due to low probability of impact, others were dropped because they were deemed not ready for definition of a grand challenge.

After much discussion, 14 grand challenges grouped under 7 broad goals were selected for the first installment. See attached table of final grand challenges. Although the challenges in the table were selected at the meeting, the texts were edited and refined to some extent subsequent to the meeting.

Some topics were judged to be of great importance but since no convincing challenge had emerged by the time of the meeting, they were deferred for future consideration. Such consideration may take the form of a workshop to explore ideas in more depth. For example the problem of providing clean water was thought to be appropriate for such a workshop approach. The whole area of non-communicable diseases was also deemed to need more analysis and thought before additional satisfactory grand challenges could be selected.

The Grants Program

The discussion next turned to how the grants program would be conducted. A number of points were made.

- The larger grants are likely to need a ramp up period.
- The LOI application should include information about other support.
- Applicants should present a comprehensive IP and sharing plan before funds are awarded.
- The application must focus on solving the grand challenge problem.
- Collaboration with the developing world is desirable but not mandatory, depending on the problem.
- The potential for implementation in the developing world should be a major review criterion.
- The budget must be realistic and commensurate with the research proposed. The study section may recommend that only a pilot grant be awarded initially.
- A planning grant of \$10,000 to 20,000 to help applicants develop their full application where multi- institution collaborations are involved was recommended. Travel between institutions can be costly, especially if collaborations with the developing world are contemplated.
- Small grants should be encouraged if they otherwise meet the criteria.
- Review of the IP plans should include individuals expert in this area.
- Innovation in research should be stressed.
- We must maintain the ability to freeze funds if things don't go well.
- It is desirable to strongly encourage publication in open access journals to make the research results available as widely as possible. However, it is not appropriate to require this at this time. Publication costs should be allowed as a direct cost to the grants.
- An indirect cost of 15% should be allowed without the need for justification. This is well below the level institutions actually incur.
- Applicants should be asked to address any ethical, legal, social or cultural concerns raised by their research in their application. Although this need not be part of the LOI, applicants should be alerted that this will be required in the full application.

Disposition of the Submissions Received in Response to the Call for Ideas

It was agreed that a thank you note should be sent to all those who submitted ideas. In this note, submitters should be asked to indicate whether they are willing to share their submissions with others. Specifically, are they willing to share information with the Bill & Melinda Gates Foundation? On a public Web site? Are they willing to share name, address and title only, or also full text?

Communication Plan

There was not enough time to discuss the communications plan in detail, but members urged that various International Unions and Academies be added to the distribution list, as well as the individuals who submitted ideas.

Next Steps

The chosen Grand Challenges will be published, hopefully around October 1, through press release, on the Web and also in a paper that describes the process by which they were arrived at.

Workshops will be organized on selected topics to get a better sense of what the grand challenges in those areas are. Possible topics are Clean Water, Drug Development, and Non-communicable Illnesses. Experts in these fields will be asked to organize the workshops.

The next face to face meeting of the SB will be on August 28, 29 and possibly 30, 2004. At this meeting additional grand challenges will be selected and grants recommended for award from the first round of applications.

As the SB is likely to be in action for a number of years, a scheme for terms of service and staggered appointment of replacement members will need to be developed. However, all current members should expect to have terms of at least two years.

GOALS AND GRAND CHALLENGES

To improve childhood vaccines:

- GC #1 Create effective single-dose vaccines that can be used soon after birth;
- GC #2 Prepare vaccines that do not require refrigeration;
- GC #3 Develop needle-free delivery systems for vaccines.

To create new vaccines:

- GC #4 Devise reliable tests in model systems to evaluate live attenuated vaccines;
- GC #5 Solve how to design antigens for effective, protective immunity;
- GC #6 Learn which immunological responses provide protective immunity.

To control insects that transmit agents of disease:

- GC #7 Develop a genetic strategy to deplete or incapacitate a disease-transmitting insect population;
- GC #8 Develop a chemical strategy to deplete or incapacitate a disease-transmitting insect population.

To improve nutrition to promote health:

GC #9 Create a full range of optimal, bioavailable nutrients in a single staple plant species.

To improve drug treatment of infectious diseases:

GC #10 Discover drugs and delivery systems that minimize the likelihood of drug resistant microorganisms.

To cure latent and chronic infections:

- GC #11 Create therapies that can cure latent infections;
- GC #12 Create immunological methods that can cure chronic infections.

To measure disease and health status accurately and economically in developing countries:

- GC#13 Develop technologies that permit quantitative assessment of population health status;
- GC#14 Develop technologies that allow assessment of individuals for multiple conditions or pathogens at point-of-care.