The 66th World Health Assembly Meeting: A Resolution Passed, Surprising Many

In November 2012, an open-ended meeting of World Health Organization (WHO) member states drafted and recommended a resolution on developing and financing new health technologies for those diseases that disproportionately affect developing countries.1 This resolution—based on the Consultative Expert Working Group’s (CEWG) recommendations—called for the establishment of various financial and coordination instruments to address both a lack of funding and incentives to develop drugs for developing countries. In particular, member states from some high-income countries—the US, European Union members, Japan and Switzerland—objected both to the CEWG’s delinkage concept of separating a drug’s development cost from its final price and the proposed mandatory contribution to support R&D efforts which they perceived as a global tax.2 Although the conversations had continued at the WHO Executive Board’s January 2013 meeting, a consensus was not reached and no clear recommendation was given to the WHA. Instead the issue was addressed yet again in May 2013 at the 66th World Health Assembly (WHA) meeting held in Geneva, Switzerland. Member states had another opportunity to resubmit resolution text changes and amendments to try to develop a resolution that would be agreed upon by the assembly of all 193 member states.

On May 24, 2013, the day the proposed resolution was to be discussed in committee, the US made a surprise proposal calling for WHO to hold an advisory meeting as soon as possible to identify demonstration projects that could illustrate proof of the delinkage concept and find ways to support proposed R&D needs through voluntary financing mechanisms. (See Exhibit 1 for specific text proposed by US.) The US suggested that per the discretion of the WHO Secretariat private sectors and external stakeholders participate in these advisory meetings with member states. Moreover, the US noted that it would be willing to hold the next open-ended meeting before the 69th WHA in 2016 as directed in the draft resolution text that was being considered at the 66th WHA 2013 session. However, the US also indicated that their support for this decision was conditional on member states not reopening or amending the draft resolution in any way.

This case was originally developed by the Harvard Global Health Institute by Rachel Gordon, MBA, Case Studies Manager, John-Arne Røttingen, MD, PhD, MSc, MPA, Visiting Professor, T.H. Chan School of Public Health, Professor of Health Policy, University of Oslo, and Steven J. Hoffman MA, JD, Visiting Assistant Professor, T.H. Chan School of Public Health, Associate Professor of Law and Director of the Global Strategy Lab at the University of Ottawa. It is used and distributed with permission by the Global Health Education and Learning Incubator at Harvard University. Cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

This case is licensed Creative Commons Attribution-Non Commercial-NoDerivs3.0Unported gheli@harvard.edu 617-495-8222
While both member state representatives and civil society organizations supported the US proposal, they did raise some concerns. The representative for the Union of South American Nations (UNASUR) stressed that civil society representatives take part in the meeting, the talks for determining R&D financing for drugs and coordination in developing countries must be ongoing and plans for the demonstration projects must also move forward. Civil society organizations such as Health Action International and Médecins Sans Frontières (MSF/Doctors Without Borders) emphasized the importance of a transparent expert selection process for the advisory meeting that would be led by member states or their representatives.

Over the next day a small informal group of member states led by South Africa focused on addressing members’ concerns regarding the US proposal and finalizing the text on the “decision point” to be brought before the WHA that described the criteria for the development of the demonstration projects. Funding continued to be a major issue. Various delegates engaged in negotiations characterized it as “the greatest area of divergence” and “a subject of ‘robust conversation.’” The US’ initial proposed language that the demonstration projects “demonstrate voluntary and sustainable financing mechanisms” eventually was altered to “propose and foster financing mechanisms including innovative, sustainable and pooled funding” partially due to pressure from UNASUR. The US was the only member state that commented publicly on the decision point arguing that the development of funded demonstration projects was essentially a litmus test for member states’ commitment to creating viable coordination mechanisms and significant meaningful R&D goals for improving drug access. The head of the US delegation remarked, “demonstration projects will not only test the feasibility of the coordination mechanisms, but also, and importantly it will test the willingness of Member States to put new money toward our shared goals. To be very direct, if Member States cannot now begin to put substantial new money into the demonstration projects and support for the Secretariat, we will need to scale back our ambitions. We call on all Member States to now put our money where our mouth is.” (See Exhibit 2 for transcript of full remarks.)

On May 27, 2013, the WHA finally approved both the draft CEWG follow-up resolution agreed to at the November 2012 open-ended meeting as well as a modified version of the decision point initially proposed by the US. The final resolution outlined three areas of action – the establishment of a global health R&D observatory, development of demonstration projects and the creation of norms and standards for health data collection – while the decision point described the process for creating the demonstration projects. Suitable demonstration projects would meet four criteria: 1) address identified R&D gaps related to discovery, development, or delivery which disproportionately affect developing countries and for which immediate action can be taken; 2) utilize collaborative approaches, including open knowledge approaches, for R&D coordination; 3) promote delinkage of the cost of R&D from product price; and 4) propose and foster financing mechanisms including innovative sustainable and pooled funding.

Civil society representatives following the negotiations were pleased but surprised with the US’ seeming shift in policy since the initial release of the April 2012 CEWG report. According to reports the US had indicated that it would not change any part of the resolution during the 66th WHA but then essentially reopened parts of the negotiations with its proposed decision point but without touching the resolution. Observers noted that the US’ actions illustrated the disproportional influence they had on the outcomes. For example, the director of Knowledge Ecology International, an NGO that had followed this issue closely, remarked, “Then they [US] posed basically a new resolution last Friday. It just shocked everyone. So, one message you have is that apparently the US can decide whether or not you can re-negotiate the terms of reference because what happened was a significant change. That said, we agreed with the significant change and happy the US did it.” The US had also indicated meeting support especially after the WHO secretariat had noted resource challenges but the US had not clarified whether their promise of support referred to “funding” or just “hosting.”

In addition, the pharmaceutical industry appeared open to supporting and participating in the demonstration projects. The director of public affairs and global health policy at the International Federation of Pharmaceutical Manufacturers and Associations commented that the projects could be used to “…identify the priority needs and how we can leverage current efforts to achieve progress on diseases disproportionately affecting the developing world.”

Afterword

In December 2013 approximately 20 experts met to discuss 22 proposals for demonstration projects based on three sets of criteria which were decided on by experts. Eight projects went forward to the WHO Executive Board in January 2014 which called for the WHO secretariat and chair and vice-chair of the CEWG to recommend four projects to be first presented at May 2014 stakeholder meetings with researchers, funders, private sector and civil society representatives, and then at the 67th WHA. As of April 2014, no clear source of funding has been identified or promised to actually finance the demonstration projects.
Exhibit 1: Proposed Text by US

“Member States direct the WHO Secretariat to convene an advisory meeting including government representatives as well as, the discretion of the Secretariat, technical experts from external stakeholders and the private sector, at the earliest possible date, in order to take forward action in relation to monitoring, coordination and financing for health R&D, in accordance with the terms of Resolution A66/XX. Such a meeting should particularly include members of the biomedical research community at a technical level and those currently involved in managing funds for research and development, with a mandate to 1) assist in the identification of translational research projects and the methodologies for coordinating research for the demonstration projects, in ways that emphasize the de-linkage of cost of R&D from product price; and 2) identify ways to promote advocacy for identified R&D needs, and seek voluntary financing for the demonstration projects.”


Exhibit 2: Remarks of Nils Daulaire US Assistant Secretary for Global Affairs

Follow-up of the report of the CEWG – Second Intervention

Agenda Item 17.2

Geneva, Switzerland, May 27, 2013

The United States is pleased that Member States were able to come to agreement on our proposed Decision Point on this item. This has helped to bring concrete clarity to our steps forward. We believe this Decision will help provide momentum to the Resolution that has just been approved.

This Resolution, agreed by consensus during the open-ended meeting of Member States, represents our best opportunity in decades to increase research and development for diseases primarily affecting developing countries and the world’s poor.

As part of our longstanding commitment to R&D for neglected diseases, U.S. federal agencies are currently working with other partners to support development of 200 of the 365 products currently in the pipeline that will deliver the next generation of life saving global health products.

This investment has gone into nearly every type of arrangement that delinks the price of products from some or all R&D costs, including direct grants to developing country research institutions, technology transfer to enable local production of vaccines, donation of intellectual property to patent pools, and tax incentives to companies.

When I spoke on this issue at the World Health Assembly a year ago, I stated, "We recognize that market forces are not sufficient to bring adequate attention to this vital area, and that IP protections are unlikely to be a major contributor to progress in R&D for neglected diseases of the poor." I also called for the Director General to hold consultations with Member States to identify those areas of consensus upon which we could collectively move forward, including on additional areas absent from the CEWG report.

At the PAHO Directing Council in September 2012, The United States reiterated my government's strong support for WHO to propose a framework or mechanisms that would create incentives for these types of R&D mechanisms that delink costs, as well as for voluntary financing mechanisms -- including pooled financing -- and other measures, such as regulatory reform, that can help eliminate obstacles to innovation.
Exhibit 2 (continued)

In support of these goals, at the end of 2012 we also initiated a request for the U.S. Institute of Medicine to undertake an independent consultation with biomedical research experts on the problem of research market failures. Their report highlighted the particular need for late-stage product development research, and noted the importance of setting targets around specific R&D and product needs, rather than financial targets.

It was in furtherance of the findings articulated through these reports and forums over the past year that we decided to ask Member States to consider the additional Decision Point now before us. We hope this Decision will help the Secretariat undertake demonstration projects, informed by the experience of some of the world’s top experts in managing biomedical research funds and fostering innovation.

This brings me to my last point, and the most important issue now before Member States. We have laid the foundation for a long-awaited mechanism to coordinate research for neglected health concerns. Now we need to pay for it.

The recommendation in the CEWG report that drew the widest divergence of views was the call for a binding global treaty, with mandatory contributions by all countries that would have amounted to nearly $3 billion. Most of this new money would have come from countries other than the handful that are already investing heavily in these areas.

So the demonstration projects will not only test the feasibility of the coordination mechanism, but also, and importantly, it will test the willingness of Member States to put new money toward our shared goals. To be very direct, if Member States cannot now begin to put substantial new money into the demonstration projects and support for the Secretariat, we will need to scale back our ambitions. We call on all Member States to now put our money where our mouth is.

We have never had a better chance to address the problem of R&D market failures for the world’s poor.

Thank you.

Endnotes