

Kendall, Elizabeth

From: Ferriter, Karin L.
Sent: Friday, May 18, 2012 8:23 AM
To: 'McIffCL@state.gov'; Kendall, Elizabeth
Subject: Fw: Fwd: Message on behalf of Philippe de Buck to Commissioner de Gucht in view of the WHO negotiations on a global R&D Treaty
Attachments: L0516_to Com De Gucht_WHO negotiations global R&D Treaty.pdf; ATT00001.htm; L0516_to Com Dalli_WHO negotiations global R&D Treaty.pdf; ATT00002.htm

FYI

Karin Ferriter, IP Attache, US Mission to the WTO

From: Burns, Thaddeus J (GE, Corporate) [[mailto:\(b\) \(6\)@ge.com](mailto:(b) (6)@ge.com)]
Sent: Friday, May 18, 2012 06:42 AM
To: Ferriter, Karin L.
Subject: Fwd: Message on behalf of Philippe de Buck to Commissioner de Gucht in view of the WHO negotiations on a global R&D Treaty

Hi Karin. Hope all is well and that we can get together soon! Thought the attached would be helpful!

best,

Thaddeus

Sent from my iPad

Begin forwarded message:

From: "Kontreas Ilias" <(b) (6)@businessseurope.eu>
Date: May 18, 2012 10:58:18 AM GMT+02:00
To: "Burns, Thaddeus J (GE, Corporate)" (b) (6)@ge.com>
Subject: FW: Message on behalf of Philippe de Buck to Commissioner de Gucht in view of the WHO negotiations on a global R&D Treaty

Thaddeus,

Please find attached the two letters signed by Philippe.

Ilias

From: [Schmid, Simon](#)
To: [York, George](#)
Cc: [Kendall, Elizabeth](#); [Karpel, Amy](#); [Schaeli, Mathias](#); [von Wattenwyl, Lucas](#); [Girsberger, Martin](#)
Subject: AW: UN Conference on Sustainable Development (Rio+20), WHO R&D Treaty & WTO TRIPS Council
Date: Tuesday, April 17, 2012 10:35:03 AM

Dear George

Many thanks for your mail. Since Mathias is currently absent, we can offer you a phone call with some of my colleagues (Lucas and Martin you have been in touch with before) who cover the topics you had mentioned (Lucas von Wattenwyl for the TRIPS Council; Martin Girsberger for the UN Conference on Sustainable Development and myself regarding the WHO CEWG recommendations on a R&D Treaty).

Regarding the UN Conference on Sustainable Development my colleague Martin and his team are covering exclusively the IPR aspects of it, as you are probably aware.

Content-wise, it would be helpful if you could indicate beforehand what TRIPS Council issues you would like to discuss exactly.

How about a phone call this Thursday 19 April at 16h30 Swiss time, that would be 10h30 D.C. time zone, I assume?

We could call you on your number below.

Thanks for your feedback.

Best

Simon

Simon Schmid
Legal Advisor
Division of Legal & International Affairs

Direct line: (b) (6)
Fax: +41 (0)31 377 79 04
E-mail simon.schmid@ipi.ch

Swiss Federal Institute of Intellectual Property
Staufferstrasse 65/59g, CH-3003 Bern

www.ipi.ch

Von: York, George [mailto:George_E_York@ustr.eop.gov]
Gesendet: Montag, 16. April 2012 23:02
An: Schaeli, Mathias
Cc: Kendall, Elizabeth; Karpel, Amy
Betreff: UN Conference on Sustainable Development (Rio+20), WHO R&D Treaty & WTO TRIPS

Council

Mathias,

I hope you are well. I wonder whether you might have time this week to discuss a few of multilateral intellectual property issues. Specifically, I would be interested in sharing views on the UN Conference on Sustainable Development, the WHO expert group recommendation for an R&D treaty, and on the June TRIPS Council. Would you be available for a call at the end of this week, perhaps on Thursday or Friday at 16:00 hrs?

Best regards,
George

George York
Deputy Assistant USTR
Office of Intellectual Property & Innovation
Office of the United States Trade Representative
Executive Office of the President
Tel: 202.395.3029
Fax: 202.395.3891
gyork@ustr.eop.gov

From: [Jacobs, Corry](#)
To: [York, George](#)
Subject: CEWG recommendation for R+D Treaty at WHA
Date: Wednesday, April 25, 2012 10:03:06 AM

George,
Just checking to make sure you saw the CEWG report that recommends the R+D Treaty and will be discussed at the WHA. Happy to talk to you about it.
Corry
Corry L. Jacobs

Assistant Vice President~ PhRMA~(202)(b) (6) (b) (6) @phrma.org

From: [Hsu, Leah \(HHS/OS/OGA\)](#)
To: [Mamacos, Peter \(HHS/OGA\)](#); [Colin Mciff](#); rachel.bayly@treasury.gov; [Kendall, Elizabeth](#); [Wong, Holly \(HHS/OS/OGA\)](#); [Ann Blackwood \(BlackwoodAS@state.gov\)](mailto:Ann.Blackwood@state.gov); [Dale Gibb \(dqibb@usaid.gov\)](mailto:Dale.Gibb@usaid.gov); [York, George](#)
Cc: [Ferriter, Karin L.](#); revesjt@state.gov
Subject: Strategy call on WHO Consultative Expert Working Group.
Start: Friday, April 13, 2012 11:00:00 AM
End: Friday, April 13, 2012 12:00:00 PM
Location: Conference call line: 866/717-7193; Participant code: 9349158
Attachments: [CEWG Meeting Report - November 18, 2011.pdf](#)
[CEWG Overview.docx](#)
[CEWG Report.pdf](#)

When: Friday, April 13, 2012 11:00 AM-12:00 PM. Eastern Standard Time
Where: Conference call line: (b) (6) Participant code: (b) (6)

~~*~*~*~*~*~*~*~*

Hi, all,

I have now added the final CEWG report to this Outlook invite. Please do note - this report is 226 pages long.

Please let me know if you have any questions.

Thank you,

Leah Hsu

Kendall, Elizabeth

From: Ferriter, Karin L.
Sent: Wednesday, May 02, 2012 9:24 AM
To: York, George; Kendall, Elizabeth; 'Keating, Dominic'
Subject: FW: Report launch: Assembling the pharmaceutical R&D puzzle
Attachments: Assembling the RD puzzle_Excerpt.pdf; Assembling the RD puzzle_MAY1.pdf

FYI

From: McIff, Colin L [<mailto:McIffCL@state.gov>]
Sent: Wednesday, May 02, 2012 3:21 PM
To: Ferriter, Karin L.; Wang, Margaret L; Mamacos, Peter (OS); Kolker, Jimmy (HHS/OGHA); Hsu, Leah (OS); Reves, J. Todd
Subject: FW: Report launch: Assembling the pharmaceutical R&D puzzle

FYI hot off the presses from IFPMA, though still officially a bootleg since the roll-out is not til next Thursday (hurray Karen, you get some vacation reading ☺). It would be great if OGA colleagues could distribute to the rest of the interagency as needed.

Best,

Colin

SBU
This email is UNCLASSIFIED.

Kendall, Elizabeth

From: Urban, JoEllen <UrbanJ@state.gov>
Sent: Thursday, April 05, 2012 6:01 PM
To: Deborah Lashley-Johnson; York, George; Kendall, Elizabeth; Ferriter, Karin L.
Subject: FW: Strategy call on WHO Consultative Expert Working Group.
Attachments: CEWG Report 5 April 2012.pdf; NV for MB April 27 - Eng.pdf; CEWG Overview.docx; CEWG Meeting Report - November 18, 2011.pdf

For your comments .. JoEleIn

From: Blackwood, Ann S
Sent: Thursday, April 05, 2012 5:48 PM
To: Urban, JoEllen; Gardiner, Clinton L; White, Jennifer A (OES); Donofrio, Jennifer L
Subject: FW: Strategy call on WHO Consultative Expert Working Group.

EB and OES colleagues:

Attached is the long awaited CEWG report which you will be interested in as well.

Cheers, Ann, IO/HS

This email is UNCLASSIFIED.

From: McLiff, Colin L
Sent: Thursday, April 05, 2012 11:37 AM
To: 'Mamacos, Peter (HHS/OGA)'; Hsu, Leah (HHS/OS/OGA); rachel.bayly@treasury.gov; george.york@ustr.eop.gov; Elizabeth Kendall (Elizabeth.L.Kendall@ustr.eop.gov); Wong, Holly (HHS/OS/OGA); Blackwood, Ann S; Gibb, Dale(GH/HIDN)
Cc: George York (gyork@ustr.eop.gov); Karin Ferriter (karin_ferriter@ustr.eop.gov); Reves, J. Todd
Subject: RE: Strategy call on WHO Consultative Expert Working Group.

Dear all, attached is the final CEWG report as well as the note verbale for the MS briefing planned for Geneva for April 27.

Best,

Colin

From: Mamacos, Peter (HHS/OGA) [<mailto:Peter.Mamacos@hhs.gov>]
Sent: Thursday, April 05, 2012 10:53 AM
To: Hsu, Leah (HHS/OS/OGA); McLiff, Colin L; rachel.bayly@treasury.gov; george.york@ustr.eop.gov; Elizabeth Kendall (Elizabeth.L.Kendall@ustr.eop.gov); Wong, Holly (HHS/OS/OGA); Blackwood, Ann S; Gibb, Dale(GH/HIDN)
Cc: George York (gyork@ustr.eop.gov); Karin Ferriter (karin_ferriter@ustr.eop.gov); Reves, J. Todd
Subject: RE: Strategy call on WHO Consultative Expert Working Group.

Hi all,

Sorry for the short notice, but we'd like to reschedule this call for next week. It turns out that the CEWG is expected to issue its report today, so we thought it would be more productive to have this conversation once we've had a chance to review the actual recommendations.

We will be in touch soon to reschedule.

Leah, can you please update Outlook to cancel the meeting?

Thanks,

Peter

-----Original Appointment-----

From: Hsu, Leah (HHS/OS/OGA)

Sent: Monday, April 02, 2012 3:54 PM

To: Hsu, Leah (HHS/OS/OGA); Mamacos, Peter (HHS/OGA); Colin Mciff; rachel.bayly@treasury.gov; george.york@ustr.eop.gov; Elizabeth Kendall (Elizabeth_L_Kendall@ustr.eop.gov); Wong, Holly (HHS/OS/OGA); Ann Blackwood (BlackwoodAS@state.gov); Dale Gibb (dgibb@usaid.gov)

Cc: George York (gyork@ustr.eop.gov); Karin Ferriter (karin_ferriter@ustr.eop.gov); revesjt@state.gov

Subject: Strategy call on WHO Consultative Expert Working Group.

When: Thursday, April 05, 2012 12:00 PM-1:00 PM (GMT-05:00) Eastern Time (US & Canada).

Where: Conference call line: 866/717-7193; Participant code: 9349158

When: Thursday, April 05, 2012 12:00 PM-1:00 PM. Eastern Standard Time

Where: Conference call line: (b) (6) Participant code: (b) (6)

~~*~*~*~*~*~*~*~*

Hi, all,

I have added a document shared with us by WHO ADG Marie-Paule Kieny, which gives an overview of the CEWG.

Please also find attached the most recent report of the WHO Consultative Expert Working Group on R&D Financing, which lays out their 6 proposals. Below is a draft agenda for our call:

- 1) Introduction of the CEWG - Peter Mamacos and Colin Mciff
- 2) Recap of the report - Peter Mamacos
- 3) Recap of consultations with the CEWG - Peter Mamacos and Colin Mciff
- 4) Discussion of strategy going forward - all

Please let me know if you have any questions.

Thank you,

Leah Hsu << File: CEWG Meeting Report - November 18, 2011.pdf >> << File: CEWG Overview.docx >>

From: [Kendall, Elizabeth](#)
To: [York, George](#)
Subject: Fw: Clearance requested on WHO EB papers.
Date: Wednesday, January 04, 2012 3:59:58 PM
Attachments: [6.14 - Consultative expert working group on R & D.pdf](#)
[6.14 - CEWG.zip](#)
Importance: High

From: Blackwood, Ann S [mailto:BlackwoodAS@state.gov]
Sent: Wednesday, January 04, 2012 02:49 PM
To: Kendall, Elizabeth
Subject: FW: Clearance requested on WHO EB papers.

Hi Liz, hope all's well.

You all may want to copy me on your feedback to HHS on the counterfeits and CEWG issues. Probably in both of ours interests.

Thanks! Ann

This email is UNCLASSIFIED.

From: Hsu, Leah (HHS/OS/OGA) [mailto:Leah.Hsu@hhs.gov]
Sent: Wednesday, January 04, 2012 2:41 PM
To: 'York, George'; 'Elizabeth Kendall (Elizabeth_L_Kendall@ustr.eop.gov)'
Cc: Mamacos, Peter (HHS/OGA)
Subject: Clearance requested on WHO EB papers.
Importance: High

Hi, George and Elizabeth,

Peter Mamacos has asked me to send you an [additional paper on the Consultative Expert Working Group on financing for research and development](#). I have attached both the original paper from the WHO Secretariat, along with our USG position paper, talking points and the draft resolution in two zip files. As we need to clear these internally at OGA, we would like to request clearance on the attached papers by **COB Tuesday, January 10th**.

Please let me know if you have any questions or if you have trouble opening the attachments.

Thank you!

Leah Hsu, MPH
International Health Analyst
Office of Global Affairs
U.S. Department of Health and Human Services
202/260-1630 (w)
(b) (6) (m)

Leah.Hsu@hhs.gov

From: [Susan Wilson](#)
To: [York, George](#); [Kendall, Elizabeth](#)
Subject: FW: Have you seen this yet? Is this Son of IGWG?
Date: Wednesday, May 02, 2012 2:58:59 PM

Susan F. Wilson
Director, Office of Intellectual Property Rights
International Trade Administration
U.S. Department of Commerce
1401 Constitution Avenue, NW - Room 3051
Washington, DC 20230
Tel: 202-482-0781
Fax: 202-482-6097
Email: Susan.Wilson@trade.gov
www.STOPfakes.gov
www.IPRCenter.gov

From: Jane Earley
Sent: Wednesday, May 02, 2012 2:04 PM
To: Susan Wilson
Subject: Have you seen this yet? Is this Son of IGWG?

http://www.who.int/phi/CEWG_Report_5_April_2012.pdf

From: [Susan Wilson](#)
To: [York, George](#); [Kendall, Elizabeth](#)
Cc: [Jane Earley](#)
Subject: FW: Hi - May we please attend the industry meeting at HHS this afternoon?
Date: Thursday, May 03, 2012 1:49:01 PM

FYI – Heard about this form Santamauro a few hours ago – Jane is sending someone from her office to take notes...will arrange for a readout. Unbelievable.

Susan F. Wilson
Director, Office of Intellectual Property Rights
International Trade Administration
U.S. Department of Commerce
1401 Constitution Avenue, NW - Room 3051
Washington, DC 20230
Tel: 202-482-0781
Fax: 202-482-6097
Email: Susan.Wilson@trade.gov
www.STOPfakes.gov
www.IPRCenter.gov

From: Jane Earley
Sent: Thursday, May 03, 2012 1:25 PM
To: Hill-Herndon, Catherine; Susan Wilson
Subject: RE: Hi - May we please attend the industry meeting at HHS this afternoon?

Thanks, Catherine.

From: Hill-Herndon, Catherine [<mailto:Hill-Herndonc@state.gov>]
Sent: Thursday, May 03, 2012 12:46 PM
To: Susan Wilson; Jane Earley
Subject: FW: Hi - May we please attend the industry meeting at HHS this afternoon?

As if my blood pressure wasn't high enough as it is. Doesn't look like they included USTR either.

This email is UNCLASSIFIED.

From: Blackwood, Ann S
Sent: Thursday, May 03, 2012 12:39 PM
To: Hill-Herndon, Catherine; Meawad, Maggie Habib; Coleman, Kimberly D; White, Jennifer A (OES); Donofrio, Jennifer L; Gardiner, Clinton L; Urban, JoEllen; Mamacos, Peter (HHS/OGA); Hsu, Leah (HHS/OS/OGA)
Cc: Jane Earley; Susan Wilson
Subject: RE: Hi - May we please attend the industry meeting at HHS this afternoon?

Copying HHS, plus providing the attached on attendees and topics.
Thanks, Ann

This email is UNCLASSIFIED.

From: Hill-Herndon, Catherine
Sent: Thursday, May 03, 2012 12:25 PM
To: Meawad, Maggie Habib; Coleman, Kimberly D; Blackwood, Ann S; White, Jennifer A (OES); Donofrio, Jennifer L; Gardiner, Clinton L; Urban, JoEllen
Cc: Jane Earley; Susan Wilson
Subject: RE: Hi - May we please attend the industry meeting at HHS this afternoon?

I don't know anything about this, does anyone else know what this is?

This email is UNCLASSIFIED.

From: Jane Earley [<mailto:Jane.Earley@trade.gov>]
Sent: Thursday, May 03, 2012 12:10 PM
To: Meawad, Maggie Habib; Susan Wilson; Hill-Herndon, Catherine
Subject: RE: Hi - May we please attend the industry meeting at HHS this afternoon?

This is a meeting that State and HHS have arranged with PhRMA and other industry to discuss the CEWG at the WHA. We would like to attend. Believe it's at HHS.

From: Meawad, Maggie Habib [<mailto:HabibMF@state.gov>]
Sent: Thursday, May 03, 2012 12:08 PM
To: Susan Wilson; Catherine Vial
Cc: Jane Earley
Subject: Re: Hi - May we please attend the industry meeting at HHS this afternoon?

Do you have more on this?

From: Susan Wilson [<mailto:Susan.Wilson@trade.gov>]
Sent: Thursday, May 03, 2012 12:00 PM
To: Catherine Vial <Catherine.Vial@trade.gov>; Meawad, Maggie Habib
Cc: Jane Earley <Jane.Earley@trade.gov>
Subject: Hi - May we please attend the industry meeting at HHS this afternoon?

Susan F. Wilson
Director, Office of Intellectual Property Rights
International Trade Administration
U.S. Department of Commerce
1401 Constitution Avenue, NW - Room 3051
Washington, DC 20230
Tel: 202-482-0781
Fax: 202-482-6097
Email: Susan.Wilson@trade.gov

www.STOPfakes.gov

www.IPRCenter.gov

From: [Blackwood, Ann S](#)
To: [Michaelson, Lori J](#); [Urban, JoEllen](#); [York, George](#); [Kendall, Elizabeth](#); [Ferriter, Karin L.](#)
Subject: FW: INPUT REQUESTED: Preparation for CEWG Member State Consultation
Date: Friday, November 16, 2012 4:35:39 PM
Attachments: [Bellagio_report_final.pdf.pdf](#)

From: Burris, Hannah (HHS/OGA) [mailto:Hannah.Burris@hhs.gov]
Sent: Friday, November 16, 2012 4:25 PM
To: Eiss, Robert (NIH/FIC) [E]; Blackwood, Ann S; Coleman, Kimberly D; Rohrbaugh, Mark (NIH/OD) [E]; Smith, Nicole (CDC/CGH/OD)
Cc: McIff, Colin L; Mamacos, Peter (HHS/OGA)
Subject: RE: INPUT REQUESTED: Preparation for CEWG Member State Consultation

I also want to share with you the report from the Bellagio meeting. This was a meeting that included some member states plus other stakeholders and also focuses on the three areas of collaboration. Should be useful in terms of where the discussion/ negotiation seems to be heading. Please see attached.

Thanks,
Hannah

Hannah Burris, MSc
International Health Advisor
Office of Global Affairs, US Department of Health and Human Services
(p) 202.260.1812 (e) hannah.burris@hhs.gov

From: Burris, Hannah (HHS/OGA)
Sent: Friday, November 16, 2012 4:04 PM
To: Eiss, Robert (NIH/FIC) [E]; Ann S Blackwood (BlackwoodAS@state.gov); Coleman, Kimberly D; Rohrbaugh, Mark (NIH/OD) [E]; Smith, Nicole (CDC/CGH/OD)
Cc: Colin McIff; Mamacos, Peter (HHS/OGA)
Subject: INPUT REQUESTED: Preparation for CEWG Member State Consultation

Hello All,

We are preparing for the CEWG Member State Consultation which is taking place Nov 26-28 and would very much appreciate your input. The Secretariat released their Report (attached), which will be used to guide much of the discussion. The Report considers three areas of collaboration in turn: monitoring, coordination and financing. This meeting is critical for developing the underlying principles and structures for this collaboration, so please focus your review on these three areas. I am also attaching a **rough** draft of a briefing document to give everyone a starting point in pulling their thoughts together.

I would appreciate any edits/ comments by **no later than NOON Tuesday, Nov 20th**. I apologize for the quick turnaround, but next week is Thanksgiving, and I want to be able to compile all comments and get the draft back out to the broader group before the holiday.

Thank you in advance!

Hannah

Hannah Burris, MSc
International Health Advisor
Office of Global Affairs, US Department of Health and Human Services
(p) 202.260.1812 (e) hannah.burris@hhs.gov

2PM Global Health Meeting with Ambassador Jim Kolker, Peter Mamacos, and Ann Blackwood

Corry Jacobs, PhRMA

Andrew Rudman, PhRMA

Joxel Garcia, International Healthcare Solutions Group

Claudia Poteet, Pfizer

Sean Callinicos, Sanofi-Pastuer

Carlos Espinal, Sanofi Pastuer (pending clearance)

Jonathan Santamauro, Abbott

Bradley Rossin, AstraZeneca

Christine Bugos, Emdserono

Rodney Lopez, Merck

Meeting Agenda

2PM Global Health Meeting with Ambassador Jim Kolker, Peter Mamacos, and Ann Blackwood

- I. WHO and the WHA:
 - Conflict of Interest
 - CEWG (R&D Treaty)
 - SSFFC
 - NCDs
 - Millenium Development Goals (MDGs)
 - Essential Medicines Pricing Guidelines
 - UNEP Mercury Discussions
- II. PAHO
 - PAHO Director General Elections

Kendall, Elizabeth

From: Blackwood, Ann S <BlackwoodAS@state.gov>
Sent: Thursday, September 06, 2012 5:33 PM
To: York, George
Cc: Kendall, Elizabeth
Subject: RE: International Organizations

That's it, thanks. Ann

From: York, George [mailto:George_E_York@ustr.eop.gov]
Sent: Thursday, September 06, 2012 5:29 PM
To: Blackwood, Ann S
Cc: Kendall, Elizabeth
Subject: RE: International Organizations

Perfect. We can call you. Is (202) (b) (6) the best number?

From: Blackwood, Ann S [<mailto:BlackwoodAS@state.gov>]
Sent: Thursday, September 06, 2012 5:22 PM
To: York, George
Cc: Kendall, Elizabeth
Subject: RE: International Organizations

How about Monday 2:30 pm?

From: York, George [mailto:George_E_York@ustr.eop.gov]
Sent: Thursday, September 06, 2012 5:20 PM
To: Blackwood, Ann S
Cc: Kendall, Elizabeth
Subject: RE: International Organizations

Great. How about Monday? We're free from 11-noon and from 2 pm onwards.

I'll be on the CEWG call tomorrow.

Thanks,
George

From: Blackwood, Ann S [<mailto:BlackwoodAS@state.gov>]
Sent: Thursday, September 06, 2012 4:56 PM
To: York, George
Cc: Kendall, Elizabeth
Subject: RE: International Organizations

Sure thing. I'm in all next week. Let me know a couple of suggested times if you want.

Are you all joining the HHS conference call on the WHO CEWG Friday?

From: York, George [mailto:George_E_York@ustr.eop.gov]
Sent: Thursday, September 06, 2012 4:49 PM
To: Blackwood, Ann S
Cc: Kendall, Elizabeth
Subject: International Organizations

Ann,

We were wondering if you have time for a quick call to discuss the Fall calendar for public health issues. We are trying to map out the multilateral landscape for the next few months and would be grateful for your views on what's coming down the road. Would you have time tomorrow or Monday/Tuesday?

Thanks,
George

George York
Deputy Assistant USTR for Intellectual Property and Innovation
Office of the United States Trade Representative
Executive Office of the President
600 17th Street, N.W.
Washington, D.C. 20508
Tel: 202.395.3029
Fax: 202.395.3891

From: [Ferriter, Karin L.](#)
To: ["McLff, Colin L"](#)
Cc: [York, George](#)
Subject: RE: CEWG edits
Date: Monday, January 09, 2012 5:14:13 AM
Attachments: [6 14 - CEWG - TALKING POINTS \(3\) kif.docx](#)

Thank you for sharing. I just made a few changes in the section related to WIPO Re:Search- I thought that the paragraph was confusing, and hopefully I made it less so. From what I can see, WIPO Re:Search is both the name of the database and the name of the new consortium. Also, made some minor changes – changing “patented information” to “patent disclosures,” because information isn’t patented, and to try to emphasize that the database has a lot of information beyond simply patent disclosures.

Karin Ferriter
Intellectual Property Attaché
U.S. Mission to the WTO
11, Route de Pregny
1292 Chambesy, Switzerland

Telephone: 41 22 749 5281

From: McLff, Colin L [mailto:McLffCL@state.gov]
Sent: Friday, January 06, 2012 5:49 PM
To: Ferriter, Karin L.
Subject: FW: CEWG edits

Thanks for SSFFC comments. I've not reviewed this position paper on CEWG yet either (I think George does have this one too though), but would welcome your thoughts on this one too.

Colin

This email is UNCLASSIFIED.

From: Blackwood, Ann S
Sent: Friday, January 06, 2012 12:14 AM
To: 'leah.hsu@hhs.gov'; peter.mamacos@hhs.gov; McLff, Colin L
Subject: CEWG edits

What do you all think? Could be improved I'm sure. I really agree we need to let the CEWG finish its job but I've also attempted some comments (b) (5) [REDACTED] thanks. Ann

This email is UNCLASSIFIED.

From: [Hsu, Leah \(HHS/OS/OGA\)](#)
To: [York, George](#)
Cc: [Mamacos, Peter \(HHS/OGA\)](#); [Ferriter, Karin L.](#); [Colin Mciff](#); [Kendall, Elizabeth](#); [Ann Blackwood \(blackwoodas@state.gov\)](#)
Subject: RE: Clearance requested on WHO EB papers.
Date: Thursday, January 12, 2012 11:42:40 PM

Hi, George,

Sorry for not responding to your email on this earlier. Peter, Colin and Ann, please jump in and correct me if I'm misstating or incorrect.

(b) (5)

As for the next steps, my understanding is that the CEWG will issue a report sometime this spring - I'm told it will be released in March. As for what happens once the report is released, I think it's really up to Member States to see where they want to take it and if the WHA wants to draft a resolution based on the report (as there currently is not a resolution going before the EB). I don't believe it automatically triggers any sort of process to start the drafting of a treaty. (b) (5)

With regards to your last question on the US expert, we originally did have an expert on the CEWG - Christy Hanson from USAID. However, she left government for another job and stepped down at that time. Given the expert nomination process and the EB evaluation of the roster, I believe that we were not able to replace her with another US expert without reopening the entire group.

Please let me know if you have any additional questions - I hope this clarifies things somewhat.

Thank you,

Leah Hsu

From: York, George [George_E_York@ustr.eop.gov]
Sent: Tuesday, January 10, 2012 6:36 PM
To: Hsu, Leah (HHS/OS/OGA)
Cc: Mamacos, Peter (HHS/OGA); Ferriter, Karin L.; Colin Mciff; Kendall, Elizabeth
Subject: RE: Clearance requested on WHO EB papers.

Leah,

Regarding the CEWG position paper and talking points, my basic question is with respect to the

(b) (5)

Several of the six proposal (e.g., binding instrument on R&D and innovation for health) under consideration as well as the nine proposals (e.g., green technology), which were found by the CEWG to be less suitable for consideration at this time (b) (5)

Could you also provide a little more background regarding next steps in the CEWG's work, i.e., what happens when they recommend a binding R&D instrument? Does the WHA vote to proceed with such negotiations?

I also recall that the U.S. has not had a representative on the CEWG. Is that right or am I confusing this working group with something else?

Thanks,
George

From: Hsu, Leah (HHS/OS/OGA) [<mailto:Leah.Hsu@hhs.gov>]
Sent: Wednesday, January 04, 2012 2:41 PM
To: York, George; Kendall, Elizabeth
Cc: Mamacos, Peter (HHS/OGA)
Subject: Clearance requested on WHO EB papers.
Importance: High

Hi, George and Elizabeth,

Peter Mamacos has asked me to send you an additional paper on the Consultative Expert Working Group on financing for research and development. I have attached both the original paper from the WHO Secretariat, along with our USG position paper, talking points and the draft resolution in two zip files. As we need to clear these internally at OGA, we would like to request clearance on the attached papers by COB Tuesday, January 10th.

Please let me know if you have any questions or if you have trouble opening the attachments.

Thank you!

Leah Hsu, MPH
International Health Analyst
Office of Global Affairs
U.S. Department of Health and Human Services
202/260-1630 (w)
202/603-2300 (m)
Leah.Hsu@hhs.gov

From: [York, George](#)
To: [McCoy, Stanford](#)
Cc: [Lindsay, Rhonda](#); [York, George](#)
Subject: Re: ECAT NAM NFTC ChamberUSCIB WHO CEWG 23Jan12 draft
Date: Monday, January 23, 2012 8:38:29 PM

Will do.

From: McCoy, Stanford
Sent: Monday, January 23, 2012 07:21 PM
To: York, George
Cc: Lindsay, Rhonda
Subject: ECAT NAM NFTC ChamberUSCIB WHO CEWG 23Jan12 draft

Attached are my proposed edits. George could you please indicate whether these are OK at your earliest convenience tomorrow so that Rhonda can send this on its way? Thanks.

From: [Jake Colvin](#)
To: [York, George](#)
Subject: RE: U.S. business letter on WHO proposal for global R&D Treaty
Date: Friday, January 13, 2012 10:16:29 AM

Thanks George. I also found the USTR white paper on TEAM, which was useful in helping me round out our paper on what's next for the WTO. I hope to have something to share with you soon.

Jake Colvin
National Foreign Trade Council
Tel: (202) (b) (6)

From: York, George [mailto:George_E_York@ustr.eop.gov]
Sent: Friday, January 13, 2012 9:57 AM
To: Jake Colvin
Cc: McCoy, Stanford
Subject: RE: U.S. business letter on WHO proposal for global R&D Treaty

Many thanks, Jake. We have been following this issue closely and will be sure to keep you posted on developments.

Also, as discussed, please find below a link to the article we discussed:

The Economics of Access to Medicines: Meeting the Challenges of Pharmaceutical Patents, Innovation, and Access for Global Health, By Kristina M. Lybecker

http://www.harvardilj.org/2011/12/online_53_lybecker/

Thanks,
George

[George York](#)
[Deputy Assistant USTR](#)
[Office of Intellectual Property & Innovation](#)
[Office of the United States Trade Representative](#)
Tel: 202.395.3029
Fax: 202.395.3891
gyork@ustr.eop.gov

From: Jake Colvin [mailto:(b) (6)@nftc.org]
Sent: Friday, January 13, 2012 9:52 AM
To: Ferriter, Karin L.; RevesJT@state.gov; mciffcl@state.gov; York, George; McCoy, Stanford
Subject: U.S. business letter on WHO proposal for global R&D Treaty

All,

I wanted to highlight the attached letter from the Emergency Committee for American Trade, National Association of Manufacturers, National Foreign Trade Council, United States Council for International Business, and the U.S. Chamber of Commerce urging Ambassador Kirk and Secretaries

Geithner and Sebelius to review proposals made by the WHO's Consultative Expert Working Group (CEWG) on Research and Development Financing and Coordination, and to reject any proposal that would undermine IP or innovation incentives or diverge from longstanding methods of revenue-related institutional policymaking.

Sincerely,

Jake Colvin
National Foreign Trade Council
Tel: (b) (6)

From: [Susan Wilson](#)
To: [York, George](#); [Jane Earley](#); [David and Judith Hohman](#); [Kendall, Elizabeth](#)
Subject: RE: WHO CEWG Report
Date: Thursday, May 03, 2012 10:52:52 AM

Tues pm is clear at the moment - after 2 please 202-482-0781

Susan F. Wilson
Director, Office of Intellectual Property Rights
International Trade Administration
U.S. Department of Commerce
1401 Constitution Avenue, NW - Room 3051
Washington, DC 20230
Tel: 202-482-0781
Fax: 202-482-6097
Email: Susan.Wilson@trade.gov
www.STOPfakes.gov
www.IPRCenter.gov

-----Original Message-----

From: York, George [mailto:George_E_York@ustr.eop.gov]
Sent: Wednesday, May 02, 2012 3:31 PM
To: Jane Earley; David and Judith Hohman; Kendall, Elizabeth
Cc: Susan Wilson
Subject: RE: WHO CEWG Report

Many thanks, Jane!

-----Original Message-----

From: Jane Earley [<mailto:Jane.Earley@trade.gov>]
Sent: Wednesday, May 02, 2012 3:26 PM
To: York, George; David and Judith Hohman; Kendall, Elizabeth
Cc: Susan Wilson
Subject: RE: WHO CEWG Report

David, I'm including Susan Wilson, who can also send her number. I'm at 202-482-6241. I'm available Tuesday morning and afternoon in the same time window as George, but not at all on Monday or Wednesday. Good luck and best wishes, George!

-----Original Message-----

From: York, George [mailto:George_E_York@ustr.eop.gov]
Sent: Wednesday, May 02, 2012 10:34 AM
To: Jane Earley; David and Judith Hohman; Kendall, Elizabeth
Subject: RE: WHO CEWG Report

David,

I would be happy to discuss. I have also included my colleague Elizabeth Kendall, who is also covering WHO IPR issues. My number is 202.395.3029, and I am available next week on Monday (from 11-3), Tuesday (from noon-4:30) and Wednesday (from 11:30-2:30 and from 4:30 onwards). That said, my wife is due any day now and I may be out on paternity leave next week. You will be in excellent hands with Elizabeth.

Thanks,
George

George York

Deputy Assistant USTR
Office of Intellectual Property & Innovation Office of the United States Trade Representative Executive
Office of the President
Tel: 202.395.3029
Fax: 202.395.3891
gyork@ustr.eop.gov

-----Original Message-----

From: Jane Earley [<mailto:Jane.Earley@trade.gov>]
Sent: Wednesday, May 02, 2012 10:11 AM
To: David and Judith Hohman; York, George
Subject: RE: WHO CEWG Report

David, I have not been following this but looks like I should - let's talk next week.

-----Original Message-----

From: David and Judith Hohman [[mailto:\(b\) \(6\)@gmail.com](mailto:(b) (6)@gmail.com)]
Sent: Wednesday, May 02, 2012 10:09 AM
To: York, George; Jane Earley
Subject: WHO CEWG Report

George and Jane - Nils has asked me to help OGA with the CEWG issue at the Health Assembly - this is the report on funding for R&D on neglected diseases, and specifically the recommendation around negotiating an R&D treaty.

I would like to chat with each of you about this if this is an issue you are following, early next week. If you're interested, would you send me your phone numbers?

Thanks.

From: [Ferriter, Karin L.](#)
To: "McIffCL@state.gov"
Cc: [York, George](#); [Kendall, Elizabeth](#)
Subject: Re: WHO Executive Board papers
Date: Thursday, January 05, 2012 7:09:57 PM

I haven't seen any papers, so if you can send them, I will make sure USTR is properly looped in.
Karin Ferriter, IP Attache, US Mission to the WTO

----- Original Message -----

From: McIff, Colin L <McIffCL@state.gov>
To: Ferriter, Karin L.
Sent: Fri Jan 06 00:06:24 2012
Subject: WHO Executive Board papers

Hi Karin, Happy New Year! I wanted to check and make sure that USTR is fully looped into the clearance process for the Executive Board coming up starting the 16th. In particular the papers for SSFFC and CEWG, but you guys will probably want to review NCDs and PIP as well.

Let me know if not and I'll get that fixed in the am.

Best,

Colin

From: [Urban, JoEllen](#)
To: [Deborah Lashley-Johnson](#); [York, George](#); [Kendall, Elizabeth](#); [Ferriter, Karin L.](#)
Subject: FW: Strategy call on WHO Consultative Expert Working Group.
Date: Thursday, April 05, 2012 6:00:56 PM
Attachments: [CEWG Report 5 April 2012.pdf](#)
[NV for MB April 27 - Eng.pdf](#)
[CEWG Overview.docx](#)
[CEWG Meeting Report - November 18, 2011.pdf](#)

For your comments .. JoEleIn

From: Blackwood, Ann S
Sent: Thursday, April 05, 2012 5:48 PM
To: Urban, JoEllen; Gardiner, Clinton L; White, Jennifer A (OES); Donofrio, Jennifer L
Subject: FW: Strategy call on WHO Consultative Expert Working Group.

EB and OES colleagues:

Attached is the long awaited CEWG report which you will be interested in as well.

Cheers, Ann, IO/HS

This email is UNCLASSIFIED.

From: McIff, Colin L
Sent: Thursday, April 05, 2012 11:37 AM
To: 'Mamacos, Peter (HHS/OGA)'; Hsu, Leah (HHS/OS/OGA); rachel.bayly@treasury.gov; george.york@ustr.eop.gov; Elizabeth Kendall (Elizabeth_L_Kendall@ustr.eop.gov); Wong, Holly (HHS/OS/OGA); Blackwood, Ann S; Gibb, Dale(GH/HIDN)
Cc: George York (gyork@ustr.eop.gov); Karin Ferriter (karin_ferriter@ustr.eop.gov); Reves, J. Todd
Subject: RE: Strategy call on WHO Consultative Expert Working Group.

Dear all, attached is the final CEWG report as well as the note verbale for the MS briefing planned for Geneva for April 27.

Best,

Colin

From: Mamacos, Peter (HHS/OGA) [<mailto:Peter.Mamacos@hhs.gov>]
Sent: Thursday, April 05, 2012 10:53 AM
To: Hsu, Leah (HHS/OS/OGA); McIff, Colin L; rachel.bayly@treasury.gov; george.york@ustr.eop.gov; Elizabeth Kendall (Elizabeth_L_Kendall@ustr.eop.gov); Wong, Holly (HHS/OS/OGA); Blackwood, Ann S; Gibb, Dale(GH/HIDN)
Cc: George York (gyork@ustr.eop.gov); Karin Ferriter (karin_ferriter@ustr.eop.gov); Reves, J. Todd
Subject: RE: Strategy call on WHO Consultative Expert Working Group.

Hi all,

Sorry for the short notice, but we'd like to reschedule this call for next week. It turns out that the CEWG is expected to issue its report today, so we thought it would be more productive to have this conversation once we've had a chance to review the actual recommendations.

We will be in touch soon to reschedule.

Leah, can you please update Outlook to cancel the meeting?

Thanks,

Peter

-----Original Appointment-----

From: Hsu, Leah (HHS/OS/OGA)

Sent: Monday, April 02, 2012 3:54 PM

To: Hsu, Leah (HHS/OS/OGA); Mamacos, Peter (HHS/OGA); Colin Mciff; rachel.bayly@treasury.gov; george.york@ustr.eop.gov; Elizabeth Kendall (Elizabeth_L_Kendall@ustr.eop.gov); Wong, Holly (HHS/OS/OGA); Ann Blackwood (BlackwoodAS@state.gov); Dale Gibb (dgibb@usaid.gov)

Cc: George York (gyork@ustr.eop.gov); Karin Ferriter (karin_ferriter@ustr.eop.gov); revesjt@state.gov

Subject: Strategy call on WHO Consultative Expert Working Group.

When: Thursday, April 05, 2012 12:00 PM-1:00 PM (GMT-05:00) Eastern Time (US & Canada).

Where: Conference call line: 866/717-7193; Participant code: 9349158

When: Thursday, April 05, 2012 12:00 PM-1:00 PM. Eastern Standard Time

Where: Conference call line: (b) (6) Participant code: (b) (6)

~~*~*~*~*~*~*~*~*

Hi, all,

I have added a document shared with us by WHO ADG Marie-Paule Kieny, which gives an overview of the CEWG.

Please also find attached the most recent report of the WHO Consultative Expert Working Group on R&D Financing, which lays out their 6 proposals. Below is a draft agenda for our call:

- 1) Introduction of the CEWG - Peter Mamacos and Colin Mciff
- 2) Recap of the report - Peter Mamacos
- 3) Recap of consultations with the CEWG - Peter Mamacos and Colin Mciff
- 4) Discussion of strategy going forward - all

Please let me know if you have any questions.

Thank you,

Leah Hsu << File: CEWG Meeting Report - November 18, 2011.pdf >> << File: CEWG Overview.docx >>

Kendall, Elizabeth

From: Kendall, Elizabeth
Sent: Wednesday, May 23, 2012 4:08 AM
To: Ferriter, Karin L.; 'susan.wilson@trade.gov'
Subject: Fw: CEWG and R+D Treaty

Hey guys,

I apologize if I have been out of pocket, and unfortunately I am a little under the weather so I am hoping to sleep a bit in the next few hours.

(b) (5)

Keep me posted if there's anything I need to do - if I do fall asleep I will leave my cell on, (b) (6), that will get me up. Best,

Elizabeth

----- Original Message -----

From: Jacobs, Corry [[mailto:\(b\) \(6\)@phrma.org](mailto:(b) (6)@phrma.org)]
Sent: Wednesday, May 23, 2012 03:54 AM
To: Kendall, Elizabeth
Subject: Re: CEWG and R+D Treaty

Elizabeth,

The US seems pretty firm and well versed, including the resolution co-sponsored. I am just being proactive since it could be a roller coaster with the tabling of the resolution by UNASUR (Brazil). Just wanted to check if you were the person to contact if USTR needed to be involved if things turned. They have agreed to enter into a drafting group tonight to deal with the 4 resolutions.

Why are you still awake?

Corry
Corry L. Jacobs

Assistant Vice President~ PhRMA~ (b) (6) (b) (6) [@phrma.org](mailto:(b) (6)@phrma.org)

----- Original Message -----

From: Kendall, Elizabeth [<mailto:Elizabeth.L.Kendall@ustr.eop.gov>]
Sent: Wednesday, May 23, 2012 03:48 AM
To: Jacobs, Corry
Subject: Re: CEWG and R+D Treaty

We have been, have views changed?

----- Original Message -----

From: Jacobs, Corry [[mailto:\(b\) \(6\)@phrma.org](mailto:(b) (6)@phrma.org)]
Sent: Wednesday, May 23, 2012 02:46 AM
To: Kendall, Elizabeth

Subject: CEWG and R+D Treaty

Hi Elizabeth,

I am in Geneva for the WHA. The CEWG and R+D Treaty discussions will begin this morning and I am sure you know the US has been quite active including sponsoring a resolution. I have spoken with the del but was also wondering though USTR is not here, will you be monitoring?

Thanks,

Corry

Corry L. Jacobs

Assistant Vice President~ PhRMA~ (b) (6) (b) (6) [@phrma.org](mailto:corry@phrma.org)

Kendall, Elizabeth

From: Jacobs, Corry <(b) (6) @phrma.org>
Sent: Wednesday, May 23, 2012 9:18 AM
To: York, George; Kendall, Elizabeth
Subject: Re: CEWG

George,
Congrats! Glad you are getting some time at home. I have been in touch with Elizabeth and actively meeting with the del here. It has been a very heated day of discussion and the US has shown great leadership. Happy to catch up when you are back.

Corry
Corry L. Jacobs

Assistant Vice President~ PhRMA~(b) (6) <(b) (6) @phrma.org

----- Original Message -----

From: York, George [mailto:George_E_York@ustr.eop.gov]
Sent: Wednesday, May 23, 2012 09:14 AM
To: Jacobs, Corry; Kendall, Elizabeth <Elizabeth_L_Kendall@ustr.eop.gov>
Subject: Re: CEWG

Corry,

Thanks for the e-mail. We have been actively engaged in developing the US position w/r/t the CEWG R+D treaty recommendation. USTR has significant concerns with the CEWG recommendation.

I am currently on paternity leave and Elizabeth (copied above), who has also been following this from the beginning, will be in the best position to give you the latest.

Best,
George

----- Original Message -----

From: Jacobs, Corry [[mailto:\(b\) \(6\) @phrma.org](mailto:(b) (6) @phrma.org)]
Sent: Wednesday, May 23, 2012 02:42 AM
To: York, George
Subject: CEWG

Hi George,

I am in Geneva for the WHA. The CEWG and R+D Treaty discussions will begin this morning and I am sure you know the US has been quite active including sponsoring a resolution. I have spoken with the del but was also wondering though USTR is not here, will you be monitoring?

Thanks,
Corry
Corry L. Jacobs

Assistant Vice President~ PhRMA~(b) (6) <(b) (6) @phrma.org



UNITED STATES COUNCIL FOR
INTERNATIONAL BUSINESS

January 13, 2012

The Honorable Timothy Geitner
Secretary of the Treasury
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

The Honorable Ronald Kirk
United States Trade Representative
Office of the United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Washington, D.C. 20201

Dear Secretaries Geithner and Sebelius and Ambassador Kirk:

In anticipation of the upcoming World Health Organization Executive Board meeting on January 16-23, 2012, we wish to draw your attention to item 6.14 of the provisional agenda: the WHO's Consultative Expert Working Group (CEWG) on Research and Development Financing and Coordination.

We understand that the CEWG is currently preparing a report that reportedly will recommend, among other measures, that Member States enter into a globally binding treaty to regulate the financing and coordination of health-related research and development (R&D), with an emphasis on supporting developing countries' needs. Our companies are deeply committed to innovation in public health for the benefit of the developed and developing world. We are concerned, however, that proposals made concerning a binding R&D treaty seek to reopen debate on controversial matters that have been resolved through a delicately-balanced consensus, and may ultimately undermine one of the key drivers for innovation in health products and technologies: intellectual property rights (IPR). In so doing, important innovations in health technologies of particular relevance to emerging markets may never be developed or, if they are, may never reach those markets. Moreover, critical competitive advantages that U.S. industries have spent years to develop may be lost and a dangerous precedent in terms of IPR erosion for other sectors and industries could be set.

Today, healthcare innovators invest heavily and consistently in R&D. As documented by WHO's Global Initiative on Health Technologies, for example, the medical device industry spends up to 12% of its income on R&D and, when the needs are known, innovates specifically to address global health issues. Indeed, many major providers of health technologies engineer solutions for use

in the developing world with price points suited for those markets. Our industry also undertakes product development on the ground in many emerging markets, in close collaboration with health ministries in order to ensure that their products fully reflect developing countries' priorities and needs. In short, innovation is no longer limited to serving the needs of developed-country markets. Today's innovation ecosystem for healthcare products and technologies is truly global.

Intellectual property rights play a critical role in incentivizing these investments in global innovation. For example, the research-intensive and highly competitive nature of the medical device and technology sectors renders these sectors uniquely dependent on robust IPR protections. The large capital costs and significant risks associated with the development of ever more complex medical technologies, along with their adaptation to developing country applications, have rendered patents and trade secrets a critically important way that research is rewarded, value is protected and innovation, as well as the dissemination and broad deployment of technologies, is sustained. IPRs are a key part of the solution to health challenges around the world.

The CEWG dialogue on financing and coordination for research and development is important. The outcome of this process must reflect the reality that research and development will be most robust and can best be sustained when it is led by the private sector, driven by market need, and supported by strong IP protections. In light of this, we are concerned that a proposed global treaty on R&D will open the door to weakening IP protections. An R&D treaty could ultimately serve as an unnecessary distraction from successful and repeatedly proven market-based approaches to innovation in the field of health products and technologies.

We also want to express our concern regarding recommendations for different forms of revenue generation to meet R&D funding commitments. Specifically, we oppose recommendations to levy taxes or fees, either nationally or internationally, on industry as a method of funding R&D commitments. We oppose an increased role for international organizations in areas such as tax policy and the application of revenue measures, which have rightly been the domain of sovereign governments. Recommendations that would move away from traditional decision-making methods in this policy area would have profound implications for business.

In the interests of global public health, as well as the U.S. economy's global competitiveness, U.S. exports and the high-value U.S. jobs that IPR, technological development and manufacturing help create, it is crucial that the U.S. Government protect and promote intellectual property. Any efforts to erode IP, in this or any other sector, must be rejected. Furthermore, the United States should resist efforts to create through this forum what amounts to new international regimes aimed at generating revenue from industry. Given the immediacy of the WHO proposals, we urge you to review proposals made by the CEWG and support efforts that preserve incentives for innovation while rejecting any proposal, including those to negotiate a global R&D treaty, that would undermine such incentives or diverge from longstanding methods of revenue related institutional policymaking. Meanwhile, we stand ready to work with you on efforts to protect and promote intellectual property, with a view to fostering innovation to improve global health and to secure the economic, trade and investment interests of the United States.

Sincerely,

Emergency Committee for American Trade
National Association of Manufacturers
National Foreign Trade Council
United States Council for International Business
U.S. Chamber of Commerce

**GE AFRICA**

The Courtyard, General Mathenge Drive
P. O. Box 41608
00100 NAIROBI

T +254 20 421 5000

F +254 20 3748609

www.ge.com

May 23, 2012

Hon. Prof. Peter Anyang' Nyong'o, EGH, MP
Minister for Medical Services
Afya House, Cathedral Road,
P.O. Box: 30016-00100,
Nairobi, Kenya.

Dear Hon. Prof. Anyang' Nyong'o,

RE: INTELLECTUAL PROPERTY RELATED ASPECTS OF POSSIBLE WHO TREATY GOVERNING BIOMEDICAL R&D

As you know, the World Health Organization is holding its ministerial-level World Health Assembly (WHA) in Geneva this week. We understand that pending before the WHA is a proposal by the Government of Kenya to commence negotiations to create a global treaty on R&D.

As a leader in global innovation in the field of transformational health technology, GE is one of many innovator companies that believe that an R&D treaty will not be an effective instrument to bring about timely development of new medicines and technologies to combat disease in the developing world. In fact, many of the proposals relating to the R&D treaty concept will, in our view, adversely affect the current system of intellectual property (IP) protections and incentives for innovators and thus impede the development of badly needed new health products and technologies for developing countries. IP directly benefits developing countries now more than ever as products and technologies are being both developed for use and often engineered in developing countries via public-private partnerships.

From a practical standpoint, we are aware that Kenya's efforts at the WHA are very likely to be opposed by a wide variety of Member States that do not believe a multi-year R&D treaty negotiation is a viable way to improve health outcomes in the developing world. If this is the case, the likelihood of such a global legal instrument achieving the avowed goals is low—indeed it may delay the development of relationships and technologies that are crucial to the goal of making quality health care and treatment more available.

GE Healthcare has a long tradition of partnership and shared commitment with many stake holders in Kenya to create better health for more people. This has been achieved through the sharing of imaginative ideas, proven solutions, and innovations in healthcare technology that increase access and reduce the long-term cost of healthcare. We are also proud of the progress made in Kenya and other African countries through our Developing Health Globally™ program, focused on improving primary healthcare for some of Africa's most vulnerable populations. The program allows GE to partner with national Ministries of Health to upgrade hospitals and health centers and to boost clinical and technical capacity to ensure sustained improvement in healthcare delivery.



We believe that cooperative partnerships such as these are a better route to improving healthcare access and outcomes in Kenya and other countries because they build on mutual understanding and shared goals that encompass the concerns of all stakeholders. We would hope that a constructive alternative to a treaty negotiation at the WHA could be obtained in the coming days.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Nils Tcheyan'.

Nils Tcheyan
Director, Government Affairs and Policy

- cc. Hon. Samwel Kazungu Kambi, Assistant Minister, Ministry of Medical Services
- Ms Mary Wairimu Ngari, CBS, Permanent Secretary, Ministry of Medical Services
- H.E. Dr. Tom Mboya Okeyo, Ambassador/Permanent Representative, Permanent Mission of the Republic of Kenya to the United Nations Office in Geneva



John Dalli
Commissioner for Health and Consumers
Directorate General Health and Consumers
European Commission
Rue de la Loi 200
B-1049 Brussels

16 May 2012

Dear Commissioner Dalli,

In anticipation of the World Health Organization (WHO) World Health Assembly (WHA) in Geneva on 21-26 May 2012, we would like to reiterate to you our serious concerns regarding tabled proposals for a binding R&D treaty.

We welcome the response by Commissioner De Gucht to our 12 January 2012 letter on this issue that an international health-related R&D tool is not the appropriate tool to modify the existing international IPR system. However, developments at the WHO are moving rapidly. The Consultative Expert Working Group (CEWG) on Research and Development released on 5 April 2012 a report calling for negotiation of a binding treaty to regulate the financing and coordination of research and development (R&D). If WHO Member States were to agree on the desirability of an R&D treaty, the Assembly could in effect authorize the beginning of a treaty negotiation process.

In particular, the CEWG report details worrying proposals suggesting open approaches to R&D that would involve flexible use of IPRs, which could require companies to make public information that they typically hold in confidence or undermine a market-based approach of innovation. If IPRs are weakened or curtailed, important innovations in health technologies that would greatly benefit emerging markets may never occur, and European industry may lose critical competitive advantage.

Such an R&D treaty could risk undermining intellectual property rights protection (IPRs) a key driver of innovation, economic growth and job creation for Europe's health products and technologies. At the same time, IPR protection also benefits developing markets now more than ever, as products and technologies are being both developed for use and often engineered in developing countries, via public private partnerships. In addition, a WHO R&D treaty could also set a dangerous precedent of IPR erosion with a possible spill-over effect to other sectors.

Despite these concerns, it appears that the WHO Secretariat overseeing the CEWG process supports the idea of a binding treaty, as proposed by the CEWG report that could also be endorsed by Member States such as China, Brazil and India.



For these reasons, we urge you to oppose any effort at the WHA to form a consensus that would enable negotiation of a binding R&D treaty to commence. If treaty negotiations begin, it could prove difficult to challenge particularly detrimental to IPR protection proposals in any resulting treaty. We are convinced that sustained innovation is most likely when it is led by the private sector, driven by market needs, and supported by strong IPR protection.

We remain at your disposal to discuss our concerns further.

A similar letter is being sent to Commissioner De Gucht.

Yours sincerely,

Philippe de Buck



Karel De Gucht
Commissioner for Trade
Directorate General Trade
European Commission
Rue de la Loi 200
BE-1049 Brussels

16 May 2012

Dear Commissioner De Gucht,

In anticipation of the World Health Organization (WHO) World Health Assembly (WHA) in Geneva on 21-26 May 2012, we would like to reiterate to you our serious concerns regarding tabled proposals for a binding R&D treaty.

We welcome your response to our 12 January 2012 letter on this issue that an international health-related R&D tool is not the appropriate tool to modify the existing international IPR system. However, developments at the WHO are moving rapidly. The Consultative Expert Working Group (CEWG) on Research and Development released on 5 April 2012 a report calling for negotiation of a binding treaty to regulate the financing and coordination of research and development (R&D). If WHO Member States were to agree on the desirability of an R&D treaty, the Assembly could in effect authorize the beginning of a treaty negotiation process.

In particular, the CEWG report details worrying proposals suggesting open approaches to R&D that would involve flexible use of IPRs, which could require companies to make public information that they typically hold in confidence or undermine a market-based approach of innovation. If IPRs are weakened or curtailed, important innovations in health technologies that would greatly benefit emerging markets may never occur, and European industry may lose critical competitive advantage.

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Despite these concerns, it appears that the WHO Secretariat overseeing the CEWG process supports the idea of a binding treaty, as proposed by the CEWG report that could also be endorsed by Member States such as China, Brazil and India.



For these reasons, we urge you to oppose any effort at the WHA to form a consensus that would enable negotiation of a binding R&D treaty to commence. If treaty negotiations begin, it could prove difficult to challenge particularly detrimental to IPR protection proposals in any resulting treaty. We are convinced that sustained innovation is most likely when it is led by the private sector, driven by market needs, and supported by strong IPR protection.

We remain at your disposal to discuss our concerns further.

A similar letter is being sent to Commissioner Dalli.

Yours sincerely,

*avec toute la gratitude,
Philippe*

Philippe de Buck



GE AFRICA

The Courtyard, General Mathenge Drive
P. O. Box 41608
00100 NAIROBI

May 23, 2012

T +254 20 421 5000

F +254 20 3748609

www.ge.com

Ms Malebona Precious Matsoso
Director General
Ministry of Health
Civitas Building
Corner Andries and Struben Streets
Pretoria
001
Republic of South Africa

Dear Director General,

As you may know, the World Health Organization is holding its ministerial-level World Health Assembly (WHA) in Geneva this week. We understand that pending before the WHA is a proposal by one of the member states to commence negotiations to create a global treaty on R&D.

As a leader in global innovation in the field of transformational health technology, GE is one of many innovator companies that believe that an R&D treaty will not be an effective instrument to bring about timely development of new medicines and technologies to combat disease in the developing world. In fact, many of the proposals relating to the R&D treaty concept will, in our view, adversely affect the current system of intellectual property (IP) protections and incentives for innovators and thus impede the development of badly needed new health products and technologies for developing countries. IP directly benefits developing countries now more than ever as products and technologies are being both developed for use and often engineered in developing countries via public-private partnerships.

From a practical standpoint, we are aware that the proposal being made to the WHA is very likely to be opposed by a wide variety of Member States that do not believe a multi-year R&D treaty negotiation is a viable way to improve health outcomes in the developing world. If this is the case, the likelihood of such a global legal instrument achieving the avowed goals is low—indeed it may delay the development of relationships and technologies that are crucial to the goal of making quality health care and treatment more available.

GE has a long tradition of working in South Africa in partnership with many stake holders to provide wide-reaching solutions in the field of health technology. We are very proud of our recent work in cardiology with the eThekweni Hospital and Heart Centre in Durban. We believe that cooperative arrangements such as these are a better route to improving healthcare access and outcomes in South Africa and other countries because they build on mutual understanding and shared goals that encompass the concerns of all stakeholders.



We very much hope that your representative to the WHO would work with other Member States to seek a constructive alternative to the proposed resolution at the WHA and that this would help advance the shared goal of expanding health care access and quality in Africa.

Sincerely,
For GE Africa

A handwritten signature in blue ink, appearing to read 'Nils Tcheyan'.

Nils Tcheyan
Director, Government Affairs and Policy

From: [Susan Wilson](#)
To: [Jane Earley](#); [York, George](#); [Kendall, Elizabeth](#); "[UrbanJ@state.gov](#)"
Cc: [Farah Naim](#)
Subject: RE: Readout of HHS meeting...
Date: Thursday, May 03, 2012 5:41:42 PM

Yeah. Right.

Susan F. Wilson
Director, Office of Intellectual Property Rights
International Trade Administration
U.S. Department of Commerce
1401 Constitution Avenue, NW - Room 3051
Washington, DC 20230
Tel: 202-482-0781
Fax: 202-482-6097
Email: Susan.Wilson@trade.gov
www.STOPfakes.gov
www.IPRCenter.gov

From: Jane Earley
Sent: Thursday, May 03, 2012 5:28 PM
To: Susan Wilson; 'George_E_York@ustr.eop.gov'; 'Elizabeth_L_Kendall@ustr.eop.gov'; 'UrbanJ@state.gov'
Cc: Farah Naim
Subject: Re: Readout of HHS meeting...

Next time we hope for advance notice!

From: Susan Wilson
Sent: Thursday, May 03, 2012 05:16 PM
To: York, George <George_E_York@ustr.eop.gov>; Kendall, Elizabeth <Elizabeth_L_Kendall@ustr.eop.gov>; Urban, JoEllen <UrbanJ@state.gov>
Cc: Jane Earley; Farah Naim
Subject: Readout of HHS meeting...

CEWG – R&D Treaty meeting at HHS today. Farah Naim who works with Jane attended and gave this readout: (b) (5)

[REDACTED]

Thank you, Farah, for covering!

From: [Susan Wilson](#)
To: [Christine Peterson](#); [Andrea Cornwell](#); [York, George](#); [Kendall, Elizabeth](#)
Cc: [Michael Rogers](#)
Subject: RE: Speaking of health... for your radar
Date: Tuesday, November 22, 2011 2:54:46 PM
Attachments: [image001.png](#)

(b) (5)

[REDACTED]

[REDACTED]


[REDACTED]

From: Christine Peterson
Sent: Tuesday, November 22, 2011 2:50 PM
To: Susan Wilson; Andrea Cornwell
Cc: Michael Rogers
Subject: Speaking of health... for your radar

Doha+10: MSF Asks, What's Next For TRIPS And Health?

Published on 22 November 2011 @ 7:21 pm

<http://www.ip-watch.org/weblog/2011/11/22/doha10-msf-asks-what%E2%80%99s-next-for-trips-and-health/>

   [Print This Post](#)

By [Rachel Marusak Hermann](#) for Intellectual Property Watch

For Médecins Sans Frontières (MSF, or Doctors Without Borders), the 10th anniversary of the Doha Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health marks an opportunity to look forward.

MSF organised a conference entitled, “Revising TRIPS for Public Health: Can TRIPS be reformed to meet public health needs” [on 21 November](#). The event gathered many of the policymakers, academics and stakeholders integral to the Doha Declaration to discuss and debate the way ahead in the pursuit of access to medicines for all.

“We are concerned about the future,” said Michelle Childs, director of policy and advocacy for the MSF Access Campaign. “The reality is that we and others have relied on generic competition in a pre-TRIPS world in order to treat and scale up, particularly in HIV, and that is a warning of things to come because we are seeing in relation to HIV that many of the new medicines are under patent.”

Some of the key challenges evoked during the panel discussion included protecting and building on the gains from Doha such as country implementation of intellectual property and licensing flexibilities under TRIPS and extending the transitional period for least developed countries on medicines patent protection implementation beyond 2016. Another area of debate was on how best to ensure a sustainable system for both innovation and access to medicines.

The Next Big Idea

In this context, MSF launched an “Ideas Contest” on if and how TRIPS could be revised in order to better meet public health needs. Of the 30 entries received, three winners were selected by a blind jury including Fred Abbott, professor at Florida State University College of Law and panellist; Tenu Avafia, policy specialist on intellectual property at the United Nations Development Programme; Michelle Childs, Carlos Correa, special advisor on trade and IP at the South Centre; Susan Sell, professor at George Washington University and panellist.

All of the winners answered MSF’s question in the affirmative and presented their ideas for reform during the MSF event. Constance Georgina Khaendi Walyro, of the Citron Wood Foundation, a development organisation based out of Kenya, put international human rights treaties at the centre of her proposal. “TRIPS should be amended to ensure that it primarily and intentionally promotes and protects the right to health and remains fully compliant with all national and regional public health promoting protocols and conventions.”

Dr Ruben Abete, secretary general of the Latin American Association of the Pharmaceutical Industry (ALIFAR) presented his association’s winning reform idea. **ALIFAR suggested an Automatic License System (ALS) for prescription medicines in developing and least developed countries. “The ALS allows exploiting the patented product or process related to a prescription drug by paying a reasonable royalty.” The system is based on a formula where developing and least-developed countries participate in financing the R&D costs required in the development of new medicines.**

Elements of Walyro and ALIFAR’s reform suggestions were also found in the proposal presented by Dr Suerie Moon, from the Harvard School of Public Health and the Kennedy School of Government. Moon also put human rights as a “central driving rationale for the TRIPS agreement” and made specific text suggestions of how TRIPS could be amended to incorporate such language. Also in pursuit of a “sustainable mechanism for ensuring that public health and access to medicines come first,” she suggested “excluding essential medicines from patentability.” Although it was not the central focus of Moon’s proposal, she also supported a political agreement in which all member states would contribute to R&D.

Government Perspectives

In an interview following the event, **Francisco Cannabrava, head of Mercosur (Southern Cone Common Market) negotiations, said that he found ALIFAR’s idea of particular interest, “This is an idea that I could see putting forward in negotiations.”** The Brazilian diplomat was posted to Brazil’s mission to the WTO TRIPS Council that negotiated the Doha Declaration on Public Health. He spoke on the panel session entitled, “Knowing what I know now, would I have agreed to this deal? What was Doha about and has it delivered?”

In a short answer to the question, Cannabrava said during his intervention, “The declaration

has delivered. Yes. But, had you asked me the same question regarding TRIPS as a whole, the answer would probably be no.” Going forward, he emphasised the importance of developing countries’ role in putting the Doha Declaration to use. “The declaration alone will not deliver any results by itself if WTO members do not make use of it in their legislation and in any other situation that they feel the need to.”

During the same panel session, Buba Mairgari of the permanent mission of Nigeria cited commercial and political pressure as issues hindering developing countries from taking advantage of TRIPS flexibilities. He also mentioned that it is critical to find new access solutions for least developed countries as the transitional “window” to acquire generic medicines under TRIPS comes to a close. For the future, Mairgari said, “The only way out that I think is workable for African countries is a voluntary licence as opposed to a compulsory licence... Whereby you can negotiate favourable terms with those companies, I think that it will go a long way in helping.”

During her presentation, Karin Ferriter of the US mission to the WTO highlighted the importance of the protection and enforcement of intellectual property, saying that is an essential part of the R&D process as well as ensuring that medicines on the market are safe and effective. In terms of the future of innovation and access to medicines, Ferriter said that wider national and international action is necessary and pointed to a study sponsored by the International Federation of Pharmaceutical Manufacturers and Associations, which identified several factors impacting these areas. It showed that political will has an important role as well as overcoming stigma, international funding, negotiations and procurement. Compulsory licensing was shown as less important in this study than political will in terms of innovation and access, she said.

Redefining R&D Incentive

Beyond the winners of MSF’s “Ideas Contest”, a number of panellists evoked the question how to finance the development of new medicines in the future. During the last panel session, James Love, director of Knowledge Ecology International (KEI), repeated a message that he delivered in a KEI event last week ([IPW, Public Health, 21 November 2011](#)). “The sustainability of access at the end of the day is going to come back to the issue how you finance R&D,” he said. Love argued that it is essential to de-link the prices of medicines and the development of new medicines in order to fulfil “the promise of Doha” and access to medicines for all.

He applauded progress made on the issue by the WHO’s Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) which met 16-19 November. The working group, mandated to “examine R&D financing and coordination proposals for diseases that principally affect developing countries,” announced its **recommendation for a binding convention for R&D related to diseases affecting developing countries at an open briefing 18 November.**

Christine R. Peterson
International Trade Specialist
Office of Intellectual Property Rights
International Trade Administration

U.S. Department of Commerce

Christine.Peterson@trade.gov

T: 202-482-1432

F: 202-582-6097

www.stopfakes.gov

From: [Susan Wilson](#)
To: [York, George](#); [Jane Earley](#); [Kendall, Elizabeth](#); [\(b\) \(6\) @gmail.com](#)"; ["BonillaJA@state.gov"](#); [Ferriter, Karin L.](#)
Subject: RE: WHO CEWG Recommendations on a Binding R&D Treaty
Date: Tuesday, May 08, 2012 5:32:38 PM

Go Karin, Go Karin, Go Karin!

Susan F. Wilson
Director, Office of Intellectual Property Rights
International Trade Administration
U.S. Department of Commerce
1401 Constitution Avenue, NW - Room 3051
Washington, DC 20230
Tel: 202-482-0781
Fax: 202-482-6097
Email: Susan.Wilson@trade.gov
www.STOPfakes.gov
www.IPRCenter.gov

-----Original Message-----

From: York, George [mailto:George_E_York@ustr.eop.gov]
Sent: Tuesday, May 08, 2012 4:50 PM
To: Susan Wilson; Jane Earley; Kendall, Elizabeth; [\(b\) \(6\) @gmail.com](#)'; 'BonillaJA@state.gov'; Ferriter, Karin L.
Subject: Re: WHO CEWG Recommendations on a Binding R&D Treaty

Looping in Karin Ferriter, who has reviewed the report in detail.

----- Original Message -----

From: York, George
Sent: Tuesday, May 08, 2012 03:31 PM
To: Susan Wilson <Susan.Wilson@trade.gov>; Jane Earley <Jane.Earley@trade.gov>; Kendall, Elizabeth; David and Judith Hohman [\(b\) \(6\) @gmail.com](#)>; Bonilla, Jean A <BonillaJA@state.gov>
Subject: WHO CEWG Recommendations on a Binding R&D Treaty

Dear all,

Here is a link to the CEWG report on a binding R&D treaty:
http://www.who.int/phi/CEWG_Report_5_April_2012.pdf

And here is the link to the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Rights: http://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf

Thanks,
George

George York
Deputy Assistant USTR
Office of Intellectual Property & Innovation Office of the United States Trade Representative Executive
Office of the President
Tel: 202.395.3029
Fax: 202.395.3891
gyork@ustr.eop.gov

-----Original Message-----

From: Susan Wilson [<mailto:Susan.Wilson@trade.gov>]

Sent: Tuesday, May 08, 2012 2:51 PM

To: Jane Earley; Kendall, Elizabeth; David and Judith Hohman; York, George

Subject: RE: Swiss Draft Resolution

Kira is going down the hall to find someone - stand by

Susan F. Wilson

Director, Office of Intellectual Property Rights International Trade Administration U.S. Department of Commerce

1401 Constitution Avenue, NW - Room 3051 Washington, DC 20230

Tel: 202-482-0781

Fax: 202-482-6097

Email: Susan.Wilson@trade.gov

www.STOPfakes.gov

www.IPRCenter.gov

-----Original Message-----

From: Jane Earley

Sent: Tuesday, May 08, 2012 2:30 PM

To: Susan Wilson; Kendall, Elizabeth; David and Judith Hohman; York, George

Subject: RE: Swiss Draft Resolution

No, but we become pumpkins pretty soon - unless George decides to be a father..

-----Original Message-----

From: Susan Wilson

Sent: Tuesday, May 08, 2012 2:21 PM

To: Kendall, Elizabeth; David and Judith Hohman; York, George; Jane Earley

Subject: RE: Swiss Draft Resolution

Thanks all - have we set a time?

Susan F. Wilson

Director, Office of Intellectual Property Rights International Trade Administration U.S. Department of Commerce

1401 Constitution Avenue, NW - Room 3051 Washington, DC 20230

Tel: 202-482-0781

Fax: 202-482-6097

Email: Susan.Wilson@trade.gov

www.STOPfakes.gov

www.IPRCenter.gov

-----Original Message-----

From: Kendall, Elizabeth [<mailto:Elizabeth.L.Kendall@ustr.eop.gov>]

Sent: Tuesday, May 08, 2012 12:58 PM

To: David and Judith Hohman; York, George; Jane Earley; Susan Wilson

Subject: RE: Swiss Draft Resolution

Thanks so much for this.

If you're comfortable, I'd like to loop State IPE into this conversation as well (Just because they're traditionally part of our interagency group and tend to share our IP point of view). I think Jean Bonilla would be the one. Defer to you, (b) (5)

-----Original Message-----

From: David and Judith Hohman [[mailto:\(b\) \(6\) @gmail.com](mailto:(b) (6) @gmail.com)]
Sent: Tuesday, May 08, 2012 12:20 PM
To: York, George; Kendall, Elizabeth; Jane Earley; Susan Wilson
Subject: Swiss Draft Resolution

Attached is a pdf of the Swiss text.

Kendall, Elizabeth

From: Jane Earley <Jane.Earley@trade.gov>
Sent: Tuesday, May 15, 2012 9:51 AM
To: Susan Wilson; Kendall, Elizabeth
Subject: FW: CLEARANCE REQUESTED: WHO Papers on Consultative Expert Working Group on R&D Financing and Coordination
Attachments: DRAFT - TALKING POINTS - 13.14 - CEWG.docx; DRAFT - POSITION PAPER - 13.14 - CEWG.docx; DRAFT - RESOLUTION - 13.14 - CEWG.doc; DRAFT - TALKING POINTS - 13 14 - CEWGJCErev.doc; DRAFT - RESOLUTION - 13 14 - CEWGJCErev.doc; DRAFT - POSITION PAPER - 13 14 - CEWGJCErev.doc
Importance: High

Susan, Elizabeth, I've noted some of the awkward parts of these in the latter three docs and have floated some language. (b) (5)

From: Hsu, Leah (HHS/OS/OGA) [<mailto:Leah.Hsu@hhs.gov>]
Sent: Monday, May 14, 2012 5:31 PM
To: Glass, Roger (NIH/FIC) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Susan Wilson; Jane Earley
Cc: Colin Mciff; Mamacos, Peter (HHS/OGA); Burriss, Hannah (HHS/OGA)
Subject: CLEARANCE REQUESTED: WHO Papers on Consultative Expert Working Group on R&D Financing and Coordination
Importance: High

Hi, all,

Many apologies for the short turnaround but OGA would like to request your review and clearance on the attached papers on the WHO Consultative Expert Working Group on R&D Financing and Coordination by **COB Thursday, May 17, 2012**. Please let me know if you have any questions or if you have difficulty opening the attachments.

Thank you!

Leah Hsu, MPH
International Health Analyst
Office of Global Affairs
U.S. Department of Health and Human Services
202/260-1630 (w)
202/603-2300 (m)
Leah.Hsu@hhs.gov

From: [Burris, Hannah \(HHS/OGA\)](#)
To: [Mamacos, Peter \(HHS/OGA\)](#); [Colin Mciff](#); ["BlackwoodAS@state.gov"](#); [Kolker, Jimmy \(HHS/OGA\)](#); [Wong, Holly \(HHS/OS/OGA\)](#); [Bell, Tammie Jo \(OC/OIP\) \(FDA/OC\)](#); [Smith, Nicole \(CDC/CGH/OD\)](#); [Handley, Gray \(NIH/NIAID\) \[E\]](#); [Herrington, James \(NIH/FIC\) \[E\]](#); [McAuliffe, Jay \(CDC/CGH/OD\)](#); [Rohrbaugh, Mark \(NIH/OD\) \[E\]](#); [Eiss, Robert \(NIH/FIC\) \[E\]](#); [York, George](#); [Ferriter, Karin L.](#); ["SorensonRA@state.gov"](#); ["Faux-GableLP@state.gov"](#); ["Rachel.Bayly@treasury.gov"](#); ["sthollaug@usaid.gov"](#); ["dgibb@usaid.gov"](#); ["Jonathan.Rose@treasury.gov"](#); ["GardinerCL@state.gov"](#); ["UrbanJ@state.gov"](#); ["Andrea.Cornwell@trade.gov"](#); [jane.earley@trade.gov](#); [Kendall, Elizabeth](#); ["bonillja@state.gov"](#); [Spengler, Robert \(CDC/CGH/OD\)](#)
Subject: CEWG Briefing Document and Talking Points - for your review
Date: Friday, September 14, 2012 1:12:20 PM
Attachments: [DRAFT-POSITION PAPER 4.13 CEWG Regional Consultation Report CSP28.18Rev1 - for review.docx](#)
[4.13 CEWG National Consultation Report CSP28-18Rev1.pdf](#)
Importance: High

Hello all,

As we discussed during the call a couple of weeks ago, we are getting ready for next week's Pan American Sanitary Conference (PAHO annual meeting). The Report summarizing the outcomes of the CEWG regional consultation was released yesterday morning and is on the agenda.

Please find attached our draft briefing document based on the Report and our talking points on this item. I have also attached the Report, for your reference.

Please pay particular attention to the talking points as those will become public record (the briefing document will only be viewed by the U.S. delegation). Nils Daulaire will be delivering the talking points on this item. This language is very similar to the USG contribution to the regional consultation, which you have all seen.

I apologize for the tight turnaround, but please **send me any comments/ concerns by COB TODAY, Friday, Sept 14th.**

Thank you in advance,
Hannah

Hannah Burris, MSc
International Health Advisor
Office of Global Affairs, US Department of Health and Human Services
(p) 202.260.1812 (e) hannah.burris@hhs.gov

From: [Hsu, Leah \(HHS/OS/OGA\)](#)
To: [Rohrbaugh, Mark \(NIH/OD\) \[E\]](#); [Herrfurth, George \(NIH/FIC\) \[E\]](#); [Herrington, James \(NIH/FIC\) \[E\]](#); [York, George](#); [Kendall, Elizabeth](#); [Ferriter, Karin L.](#)
Cc: [Mamacos, Peter \(HHS/OGA\)](#); [Colin Mciff](#); [Burris, Hannah \(HHS/OGA\)](#); ["Blackwood, Ann S"](#); [Rasayon, Judnefera A](#); ["Gibb, Dale\(GH/HIDN\)"](#)
Subject: FW: URGENT - CEWG resolution: draft resolution for Amb/PR to UN on Health R&D Convention
Date: Tuesday, May 15, 2012 2:41:35 PM
Attachments: [WHO Framework Convention on R&D Financing and Coordination - draft resolution-Kenya .pdf](#)
Importance: High

Hi, all,

Please find attached a resolution from Kenya calling for the formation of a negotiating body to develop the R & D convention. It is not formally on the table, but is out in broad circulation here in Geneva and with NGOs as well. There may be a third alternative text in development by Bangladesh/Brazil, but we are not sure its status now that this and the Swiss proposal is out there.

(b) (5) [Redacted]

Please let me know if you have any questions or if you have trouble opening the attachment.

Thanks very much,
Leah Hsu

From: [Urban, JoEllen](#)
To: [York, George](#); Rachel.Bayly@treasury.gov; [Blackwood, Ann S](#); [McIff, Colin L](#); Peter.Mamacos@hhs.gov; Jimmy.Kolker@hhs.gov; Holly.Wong@hhs.gov; Tammie.Bell2@fda.hhs.gov; [Ferriter, Karin L](#); [Sorenson, Robert A](#); [Thollaug, Susan \(LAC/RSD/PHN\)](#); [Dehgan, Alexander \(PPL/ST\)](#); herrfurg@mail.nih.gov; handleygr@niaid.nih.gov; RohrBauM@OD.NIH.GOV; nbs8@cdc.gov; zfc7@cdc.gov; [Gardiner, Clinton L](#); Rasayon, Judnefera A; Jonathan.Rose@treasury.gov
Cc: Hannah.Burris@hhs.gov; [Wein, Michelle](#); [Gardiner, Clinton L](#); [LaCrosse, Carrie](#)
Subject: CEWG Consultation at PAHO
Date: Monday, August 06, 2012 3:03:20 PM
Attachments: [PAHO CEWG Consultation - USG response v3 -ab.clm.gy.docx](#)

A few small suggestions on top of those by USTR. (b) (5)

Also, I am not certain but might (b) (5)

Just a suggestion for background only.

Thanks!

JoEllen Urban
Office of International Intellectual Property Enforcement
U.S. Department of State
Washington, DC 20520
urbanj@state.gov
Tel: 202-647-1432
Fax: 202-647-1537

[Home - Intellectual Property Enforcement
Innovation Community](#)

From: York, George [mailto:George_E_York@ustr.eop.gov]
Sent: Monday, August 06, 2012 2:02 PM
To: Rachel.Bayly@treasury.gov; [Blackwood, Ann S](#); [McIff, Colin L](#); Peter.Mamacos@hhs.gov; Jimmy.Kolker@hhs.gov; Holly.Wong@hhs.gov; Tammie.Bell2@fda.hhs.gov; [Ferriter, Karin L](#); [Sorenson, Robert A](#); [Thollaug, Susan \(LAC/RSD/PHN\)](#); [Dehgan, Alexander \(PPL/ST\)](#); herrfurg@mail.nih.gov; handleygr@niaid.nih.gov; RohrBauM@OD.NIH.GOV; nbs8@cdc.gov; zfc7@cdc.gov; [Urban, JoEllen](#); [Gardiner, Clinton L](#); Rasayon, Judnefera A; Jonathan.Rose@treasury.gov
Cc: Hannah.Burris@hhs.gov
Subject: RE: CEWG Consultation at PAHO

USTR comments attached. (b) (5) Also, we should discuss our draft answers to question 9. My concern (b) (5)

Thanks,
George

From: Rachel.Bayly@treasury.gov [mailto:Rachel.Bayly@treasury.gov]
Sent: Monday, August 06, 2012 1:22 PM
To: BlackwoodAS@state.gov; McIffCL@state.gov; Peter.Mamacos@hhs.gov; Jimmy.Kolker@hhs.gov; Holly.Wong@hhs.gov; Tammie.Bell2@fda.hhs.gov; York, George; Ferriter, Karin L.; SorensonRA@state.gov; sthollaug@usaid.gov; adehgan@usaid.gov; herrfurg@mail.nih.gov; handleyr@niaid.nih.gov; RohrBauM@OD.NIH.GOV; nbs8@cdc.gov; zfc7@cdc.gov; UrbanJ@state.gov; GardinerCL@state.gov; RasayonJA@state.gov; Jonathan.Rose@treasury.gov
Cc: Hannah.Burris@hhs.gov
Subject: RE: CEWG Consultation at PAHO

My two cents: (b) (5)

From: Blackwood, Ann S [mailto:BlackwoodAS@state.gov]
Sent: Monday, August 06, 2012 1:06 PM
To: McIff, Colin L; Mamacos, Peter (HHS/OGA); Kolker, Jimmy (HHS/OGA); Wong, Holly (HHS/OS/OGA); Bell, Tammie Jo (OC/OIP) (FDA/OC); Bayly, Rachel; York, George; Ferriter, Karin L.; Sorenson, Robert A; Thollaug, Susan (LAC/RSD/PHN); Dehgan, Alexander (PPL/ST); Herrfurth, George (NIH/FIC) [E]; Handley, Gray (NIH/NIAID) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Smith, Nicole (CDC/CGH/OD); McAuliffe, Jay (CDC/CGH/OD); Urban, JoEllen; Gardiner, Clinton L; Rasayon, Judnefera A
Cc: Burris, Hannah (HHS/OGA)
Subject: RE: CEWG Consultation at PAHO

Colin, thanks and (b) (5)

FYI, the Guidance for U.S. delegations document (b) (5)

Thanks, Ann

From: McIff, Colin L
Sent: Monday, August 06, 2012 11:45 AM
To: Blackwood, Ann S; Mamacos, Peter (HHS/OGA); Kolker, Jimmy (HHS/OGA); Wong, Holly (HHS/OS/OGA); Bell, Tammie Jo (OC/OIP) (FDA/OC); Rachel.Bayly@treasury.gov; York, George; Ferriter, Karin L.; Sorenson, Robert A; Thollaug, Susan (LAC/RSD/PHN); Dehgan, Alexander (PPL/ST); Herrfurth, George (NIH/FIC) [E]; Handley, Gray (NIH/NIAID) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Smith, Nicole (CDC/CGH/OD); McAuliffe, Jay (CDC/CGH/OD); Urban, JoEllen; Gardiner, Clinton L; Rasayon, Judnefera A
Cc: Burris, Hannah (HHS/OGA)
Subject: RE: CEWG Consultation at PAHO

Dear all, here are some more comments and suggested edits, on top of Ann's. Great job on this draft – I think it's an excellent tone and clarity for the target audience.

Best,

Colin

SBU

This email is UNCLASSIFIED.

From: Blackwood, Ann S

Sent: Monday, August 06, 2012 3:49 PM

To: Mamacos, Peter (HHS/OGA); McIff, Colin L; Kolker, Jimmy (HHS/OGA); Wong, Holly (HHS/OS/OGA); Bell, Tammie Jo (OC/OIP) (FDA/OC); Rachel.Bayly@treasury.gov; York, George; Ferriter, Karin L.; Sorenson, Robert A; Thollaug, Susan (LAC/RSD/PHN); Dehgan, Alexander (PPL/ST); Herrfurth, George (NIH/FIC) [E]; Handley, Gray (NIH/NIAID) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Smith, Nicole (CDC/CGH/OD); McAuliffe, Jay (CDC/CGH/OD); Urban, JoEllen; Gardiner, Clinton L; Rasayon, Judnefera A

Cc: Burris, Hannah (HHS/OGA)

Subject: RE: CEWG Consultation at PAHO

Thanks Peter and agree it is a good draft. My edits attached for consideration and, given the short turnaround needed, am looping in EEB colleagues here also.

thanks, Ann

From: Mamacos, Peter (HHS/OGA) [<mailto:Peter.Mamacos@hhs.gov>]

Sent: Friday, August 03, 2012 7:07 PM

To: McIff, Colin L; Kolker, Jimmy (HHS/OGA); Wong, Holly (HHS/OS/OGA); Bell, Tammie Jo (OC/OIP) (FDA/OC); Rachel.Bayly@treasury.gov; York, George; Ferriter, Karin L.; Sorenson, Robert A; Blackwood, Ann S; Thollaug, Susan (LAC/RSD/PHN); Dehgan, Alexander (PPL/ST); Herrfurth, George (NIH/FIC) [E]; Handley, Gray (NIH/NIAID) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Smith, Nicole (CDC/CGH/OD); McAuliffe, Jay (CDC/CGH/OD)

Cc: Burris, Hannah (HHS/OGA)

Subject: CEWG Consultation at PAHO

Inter-agency colleagues,

Following the decision by the WHA to move forward with regional consultations on the recommendations of the CEWG on health R&D for developing countries, we are about to begin the

consultation at the PAHO regional meeting.

PAHO has presented a set of questions on the CEWG recommendations, and OGA has put together the attached draft response (thanks to Hannah for putting together a good first draft), which we will submit through the electronic consultation process.

With apologies for the short fuse, but if there is any way you could review this by COB Monday, it would be much appreciated. We would like to submit these comments early in the process. NIH colleagues, note that we have included a few areas where we would welcome additional inputs you may have.

I'm happy to answer any questions on this process.

Many thanks,

Peter Mamacos

Multilateral Branch Chief

Office of the Secretary

Office of Global Affairs

U.S. Department of Health and Human Services

Washington, DC 20201

+1-202-205-4677

From: [Ferriter, Karin L.](#)
To: [York, George](#)
Subject: Fw: CEWG draft resolution as of 27 Nov at 21:15
Date: Wednesday, November 28, 2012 1:58:35 AM
Attachments: [CEWG_draft_resolution_2012-11-27AS_OF_21H15.pdf](#)

Fyi-

We will be working on this until 9 tonight. Then it will be revised by the EB in Jan.

Karin

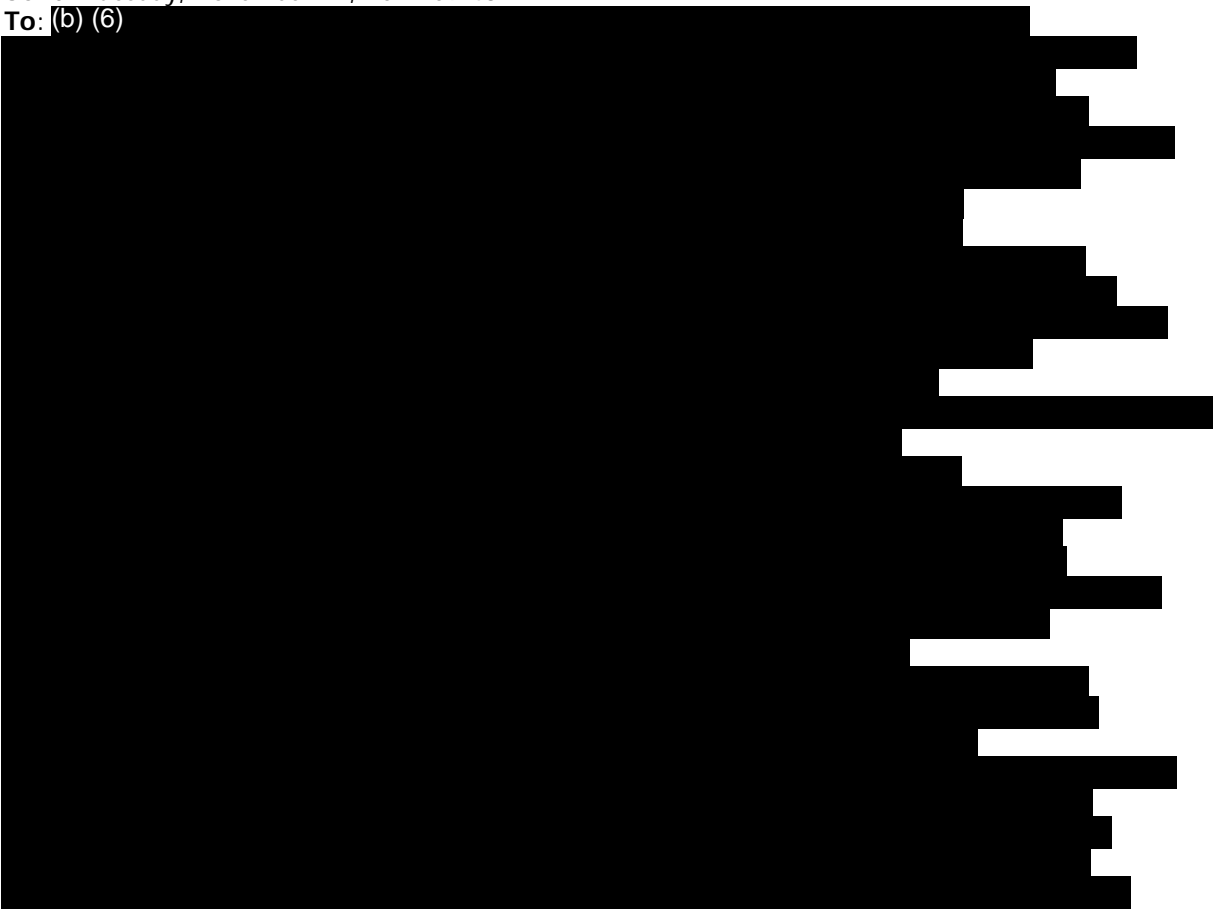
Karin Ferriter, IP Attache, US Mission to the WTO

From: McIff, Colin L [mailto:McIffCL@state.gov]
Sent: Wednesday, November 28, 2012 01:17 AM
To: Nils.Daulaire@hhs.gov <Nils.Daulaire@hhs.gov>; peter.mamacos@hhs.gov <peter.mamacos@hhs.gov>; Michaelson, Lori J <MichaelsonLJ@state.gov>; Ferriter, Karin L.
Subject: Fw: CEWG draft resolution as of 27 Nov at 21:15

Here's the text as of last evening.

Colin

From: VEA, Gina Rene [mailto:(b)@who.int]
Sent: Tuesday, November 27, 2012 09:48 PM
To: (b) (6)



(b) (6)

[REDACTED]

(b) (6)

[REDACTED]

(b) (6)

(b) (6)

(b) (6)

Subject: re: CEWG draft resolution as of 27 Nov at 21:15

Dear Mission Focal Points,

With reference to the open ended meeting of Member States on the follow up to the CEWG Report and the drafting group which met this evening, please find attached the text as of 27 November 2012 at 21:15. This also includes the (b)(1)

As agreed, the Secretariat will prepare some text on the preambular paragraphs in accordance with the issues raised during the drafting group and a revised text of the draft will be shared by 9:00 tomorrow morning.

With best wishes,
Gina

Gina VEA
Technical Officer
Department for Governing Bodies and External Relations
World Health Organization
tel: (b) (6)
mob: +(b) (6)

Kendall, Elizabeth

From: Blackwood, Ann S <BlackwoodAS@state.gov>
Sent: Friday, September 14, 2012 5:51 PM
To: Gibb, Dale(GH/HIDN); Sorenson, Robert A; Burris, Hannah (HHS/OGA); Mamacos, Peter (HHS/OGA); McIff, Colin L; Kolker, Jimmy (HHS/OGA); Wong, Holly (HHS/OS/OGA); Bell, Tammie Jo (OC/OIP) (FDA/OC); Smith, Nicole (CDC/CGH/OD); Handley, Gray (NIH/NIAID) [E]; Herrington, James (NIH/FIC) [E]; McAuliffe, Jay (CDC/CGH/OD); Rohrbaugh, Mark (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; York, George; Ferriter, Karin L.; Faux-Gable, Laura P; 'Rachel.Bayly@treasury.gov'; Thollaug, Susan (LAC/RSD/PHN); Rose, Jonathan; Gardiner, Clinton L; Urban, JoEllen; 'Andrea.Cornwell@trade.gov'; jane.earley@trade.gov; Kendall, Elizabeth; 'bonillja@state.gov'; Spengler, Robert (CDC/CGH/OD)
Subject: RE: CEWG Briefing Document and Talking Points - for your review
Attachments: 09142012 DRAFT-POSITION PAPER 4 13 CEWG Regional Consultation Report CSP28.docx

All, good here also. My edits are to the Talking Points. Thanks, Ann

From: Gibb, Dale(GH/HIDN) [<mailto:DGibb@usaid.gov>]
Sent: Friday, September 14, 2012 3:12 PM
To: Sorenson, Robert A; Burris, Hannah (HHS/OGA); Mamacos, Peter (HHS/OGA); McIff, Colin L; Blackwood, Ann S; Kolker, Jimmy (HHS/OGA); Wong, Holly (HHS/OS/OGA); Bell, Tammie Jo (OC/OIP) (FDA/OC); Smith, Nicole (CDC/CGH/OD); Handley, Gray (NIH/NIAID) [E]; Herrington, James (NIH/FIC) [E]; McAuliffe, Jay (CDC/CGH/OD); Rohrbaugh, Mark (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; 'George_E_York@ustr.eop.gov'; 'Karin_Ferriter@ustr.eop.gov'; Faux-Gable, Laura P; 'Rachel.Bayly@treasury.gov'; Thollaug, Susan (LAC/RSD/PHN); Rose, Jonathan; Gardiner, Clinton L; Urban, JoEllen; 'Andrea.Cornwell@trade.gov'; jane.earley@trade.gov; 'elizabeth_l_kendall@ustr.eop.gov'; 'bonillja@state.gov'; Spengler, Robert (CDC/CGH/OD)
Subject: RE: CEWG Briefing Document and Talking Points - for your review

USAID clears and appreciates these edits. Thanks.

From: Sorenson, Robert A
Sent: Friday, September 14, 2012 2:03 PM
To: Burris, Hannah (HHS/OGA); Mamacos, Peter (HHS/OGA); McIff, Colin L; Blackwood, Ann S; Kolker, Jimmy (HHS/OGA); Wong, Holly (HHS/OS/OGA); Bell, Tammie Jo (OC/OIP) (FDA/OC); Smith, Nicole (CDC/CGH/OD); Handley, Gray (NIH/NIAID) [E]; Herrington, James (NIH/FIC) [E]; McAuliffe, Jay (CDC/CGH/OD); Rohrbaugh, Mark (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; 'George_E_York@ustr.eop.gov'; 'Karin_Ferriter@ustr.eop.gov'; Faux-Gable, Laura P; 'Rachel.Bayly@treasury.gov'; Thollaug, Susan (LAC/RSD/PHN); Gibb, Dale(GH/HIDN); Rose, Jonathan; Gardiner, Clinton L; Urban, JoEllen; 'Andrea.Cornwell@trade.gov'; jane.earley@trade.gov; 'elizabeth_l_kendall@ustr.eop.gov'; 'bonillja@state.gov'; Spengler, Robert (CDC/CGH/OD)
Subject: RE: CEWG Briefing Document and Talking Points - for your review

All - This looks fine substantively to OES/IHB. I have made some editorial suggestions. Bob

This email is UNCLASSIFIED.

From: Burris, Hannah (HHS/OGA) [<mailto:Hannah.Burris@hhs.gov>]

Sent: Friday, September 14, 2012 1:12 PM

To: Mamacos, Peter (HHS/OGA); McIff, Colin L; Blackwood, Ann S; Kolker, Jimmy (HHS/OGA); Wong, Holly (HHS/OS/OGA); Bell, Tammie Jo (OC/OIP) (FDA/OC); Smith, Nicole (CDC/CGH/OD); Handley, Gray (NIH/NIAID) [E]; Herrington, James (NIH/FIC) [E]; McAuliffe, Jay (CDC/CGH/OD); Rohrbaugh, Mark (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; 'George_E_York@ustr.eop.gov'; 'Karin_Ferriter@ustr.eop.gov'; Sorenson, Robert A; Faux-Gable, Laura P; 'Rachel.Bayly@treasury.gov'; Thollaug, Susan (LAC/RSD/PHN); Gibb, Dale(GH/HIDN); 'Jonathan.Rose@treasury.gov'; Gardiner, Clinton L; Urban, JoEllen; 'Andrea.Cornwell@trade.gov'; jane.earley@trade.gov; 'elizabeth_l_kendall@ustr.eop.gov'; 'bonillja@state.gov'; Spengler, Robert (CDC/CGH/OD)

Subject: CEWG Briefing Document and Talking Points - for your review

Importance: High

Hello all,

As we discussed during the call a couple of weeks ago, we are getting ready for next week's Pan American Sanitary Conference (PAHO annual meeting). The Report summarizing the outcomes of the CEWG regional consultation was released yesterday morning and is on the agenda.

Please find attached our draft briefing document based on the Report and our talking points on this item. I have also attached the Report, for your reference.

Please pay particular attention to the talking points as those will become public record (the briefing document will only be viewed by the U.S. delegation). Nils Daulaire will be delivering the talking points on this item. This language is very similar to the USG contribution to the regional consultation, which you have all seen.

I apologize for the tight turnaround, but please **send me any comments/ concerns by COB TODAY, Friday, Sept 14th.**

Thank you in advance,
Hannah

Hannah Burris, MSc
International Health Advisor
Office of Global Affairs, US Department of Health and Human Services
(p) 202.260.1812 (e) hannah.burris@hhs.gov

From: [McIff, Colin L](#)
To: peter.mamacos@hhs.gov; [Blackwood, Ann S](#); Jimmy.Kolker@hhs.gov; Leah.Hsu@hhs.gov; Holly.Wong@hhs.gov; [Hill-Herndon, Catherine](#); [York, George](#); [Ferriter, Karin L.](#)
Subject: Re: CEWG notes from this week
Date: Saturday, April 21, 2012 1:10:54 PM

One thing this exchange and the recent discussion with IFPMA has me thinking on is (b) (5)

We should have more information soon from the IFPMA study to augment your consultations back home and this could be a productive way to redirect this discussion.

In the Friday GRUA, when Maria Luisa was making her pitch to the group (quite strong attendance actually), (b) (5)

Colin

From: Mamacos, Peter (HHS/OGA) [mailto:Peter.Mamacos@hhs.gov]
Sent: Thursday, April 19, 2012 01:22 AM
To: Blackwood, Ann S; Kolker, Jimmy (HHS/OGHA) <Jimmy.Kolker@hhs.gov>; McIff, Colin L; Hsu, Leah (HHS/OS/OGA) <Leah.Hsu@hhs.gov>; Wong, Holly (HHS/OS/OGA) <Holly.Wong@hhs.gov>; Hill-Herndon, Catherine; York, George <George_E_York@ustr.eop.gov>; Ferriter, Karin L. <Karin_Ferriter@ustr.eop.gov>
Subject: RE: CEWG notes from this week

And Colin, the chart on page 82 is particularly interesting. It is notable that (b) (5)

(b) (5)

From: Blackwood, Ann S [mailto:BlackwoodAS@state.gov]
Sent: Wednesday, April 18, 2012 6:32 PM
To: Kolker, Jimmy (HHS/OGHA); Colin McIff; Mamacos, Peter (HHS/OGA); Hsu, Leah (HHS/OS/OGA); Wong, Holly (HHS/OS/OGA); Hill-Herndon, Catherine; York, George; Ferriter, Karin L.
Subject: RE: CEWG notes from this week

Thanks also Colin for the thorough readout, and Jimmy I appreciate your take on this. (b) (5)

(b) (5)

(b) (5)

Thanks, Ann

This email is UNCLASSIFIED.

From: Kolker, Jimmy (HHS/OGHA) [mailto:Jimmy.Kolker@hhs.gov]
Sent: Wednesday, April 18, 2012 4:51 PM
To: McIff, Colin L; Mamacos, Peter (HHS/OGA); Hsu, Leah (HHS/OS/OGA); Wong, Holly (HHS/OS/OGA); Blackwood, Ann S; Hill-Herndon, Catherine; York, George; Ferriter, Karin L.
Subject: RE: CEWG notes from this week

Colin
Thanks for the comprehensive update.

My own view is that (b) (5)

(b) (5)

Good luck
Jimmy

[Amb] Jimmy Kolker
Office of Global Affairs
US Department of Health and Human Services
Room 639-H, 200 Independence Av SW, Washington, DC
202-690-6174

From: McIff, Colin L [mailto:McIffCL@state.gov]
Sent: Wednesday, April 18, 2012 9:45 AM
To: Kolker, Jimmy (HHS/OGHA); Mamacos, Peter (HHS/OGA); Hsu, Leah (HHS/OS/OGA); Wong, Holly (HHS/OS/OGA); Blackwood, Ann S; Hill-Herndon, Catherine; York, George; Ferriter, Karin L.
Subject: CEWG notes from this week

Hey all, discussion has very rapidly intensified here on CEWG and its report. (b) (5)

[Redacted]

(b) (5)

[Redacted]

(b) (5)

[Redacted]

[Redacted]

(b) (5)

[Redacted text block]

[Redacted text block]

[Redacted text block]

Please also note the attached flyer for a CEWG discussion event on May 4. I am happy to participate in this, but would appreciate guidance. I'll also be meeting with Japan tomorrow and the Group of Americas on Friday and I expect this to be a centerpiece of those discussions, more soonest.

Colin

SBU

This email is UNCLASSIFIED.

From: Jonathan.Rose@treasury.gov
To: Rachel.Bayly@treasury.gov; Peter.Mamacos@hhs.gov; [Ferriter, Karin L.](mailto:Ferriter_Karin_L.); McIffCL@state.gov; [York, George](mailto:York_George); Holly.Wong@hhs.gov; Jimmy.Kolker@hhs.gov; BlackwoodAS@state.gov; Tammie.Bell2@fda.hhs.gov
Cc: Hannah.Burris@hhs.gov
Subject: RE: Language on repatriation...
Date: Thursday, August 09, 2012 1:47:19 PM

Peter,

Treasury supports your approach and the proposed response below.

Thanks.

Jon

Jonathan N. Rose, Ph.D.
International Economist
U.S. Department of the Treasury
(202) 622-1516
jonathan.rose@treasury.gov

From: Bayly, Rachel
Sent: Tuesday, August 07, 2012 9:21 PM
To: 'Peter.Mamacos@hhs.gov'; 'Karin_Ferriter@ustr.eop.gov'; 'McIffCL@state.gov'; 'George_E_York@ustr.eop.gov'; 'Holly.Wong@hhs.gov'; 'Jimmy.Kolker@hhs.gov'; 'BlackwoodAS@state.gov'; 'Tammie.Bell2@fda.hhs.gov'
Cc: 'Hannah.Burris@hhs.gov'; Rose, Jonathan
Subject: Re: Language on repatriation...

Looping in Jon Rose.

From: Mamacos, Peter (HHS/OGA) [<mailto:Peter.Mamacos@hhs.gov>]
Sent: Tuesday, August 07, 2012 07:39 PM
To: Bayly, Rachel; Ferriter, Karin L. <Karin_Ferriter@ustr.eop.gov>; Colin Mciff <McIffCL@state.gov>; York, George <George_E_York@ustr.eop.gov>; Wong, Holly (HHS/OS/OGA) <Holly.Wong@hhs.gov>; Kolker, Jimmy (HHS/OGA) <Jimmy.Kolker@hhs.gov>; Blackwood, Ann S <BlackwoodAS@state.gov>; Bell, Tammie Jo (OC/OIP) (FDA/OC) <Tammie.Bell2@fda.hhs.gov>
Cc: Burris, Hannah (HHS/OGA) <Hannah.Burris@hhs.gov>
Subject: FW: Language on repatriation...

All,

One issue that Rachel raised when we spoke yesterday was (b) (5)

[REDACTED]

(b) (5)

I'm sure many of you can improve on this. Thanks

(b) (5)

(b) (5)

From: [Blackwood, Ann S](#)
To: [McIff, Colin L](#); [Kolker, Jimmy \(HHS/OGHA\)](#); [David Hohman](#); [Mamacos, Peter \(HHS/OGA\)](#); [Hsu, Leah \(HHS/OS/OGA\)](#); susan.wilson@trade.gov; jane.earley@trade.gov; [York, George](#); [Kendall, Elizabeth](#); bonillja@state.gov; [Hill-Herndon, Catherine](#); [Ferriter, Karin L](#); [Bonilla, Jean A](#)
Cc: [Daulaire, Nils \(HHS/OS/OGA\)](#)
Subject: RE: Revisions to Swiss CEWG Resolution
Date: Wednesday, May 09, 2012 9:50:14 AM

Colin, since you ask, (b) (5)

[REDACTED]

Thanks, Ann

-----Original Message-----

From: McIff, Colin L
Sent: Wednesday, May 09, 2012 8:37 AM
To: Blackwood, Ann S; Kolker, Jimmy (HHS/OGHA); David Hohman; Mamacos, Peter (HHS/OGA); Hsu, Leah (HHS/OS/OGA); susan.wilson@trade.gov; jane.earley@trade.gov; george_e_york@ustr.eop.gov; elizabeth_1_kendall@ustr.eop.gov; bonillja@state.gov; Hill-Herndon, Catherine; Ferriter, Karin L.
Cc: Daulaire, Nils (HHS/OS/OGA)
Subject: RE: Revisions to Swiss CEWG Resolution

Here are my proposed edits and comments on top of others. (b) (5)

[REDACTED]

My proposal (b) (5)

[REDACTED]

Best,

Colin

SBU

This email is UNCLASSIFIED

-----Original Message-----

From: Blackwood, Ann S
Sent: Wednesday, May 09, 2012 12:28 AM
To: Kolker, Jimmy (HHS/OGHA); David Hohman; Mamacos, Peter (HHS/OGA); McIff, Colin L; Hsu, Leah (HHS/OS/OGA); susan.wilson@trade.gov; jane.earley@trade.gov; george_e_york@ustr.eop.gov; elizabeth_1_kendall@ustr.eop.gov; bonillja@state.gov; Hill-Herndon, Catherine
Cc: Daulaire, Nils (HHS/OS/OGA)
Subject: RE: Revisions to Swiss CEWG Resolution

David,

Thanks and agree with all edits as well. My main concern at this

point is (b) (5)

Also, for Member States to take the report forward, (b) (5)

See attached. Thanks. Ann

This email is UNCLASSIFIED

-----Original Message-----

From: Kolker, Jimmy (HHS/OGHA) [<mailto:Jimmy.Kolker@hhs.gov>]

Sent: Tuesday, May 08, 2012 5:12 PM

To: David Hohman; Mamacos, Peter (HHS/OGA); McIff, Colin L; Blackwood, Ann S; Hsu, Leah (HHS/OS/OGA); susan.wilson@trade.gov; jane.earley@trade.gov; george_e_york@ustr.eop.gov; elizabeth_l_kendall@ustr.eop.gov; bonillja@state.gov

Cc: Daulaire, Nils (HHS/OS/OGA)

Subject: RE: Revisions to Swiss CEWG Resolution

David

I like your suggestions and edits.

My own thought is that the final paragraph -- (b) (5)

If we are coming around to the view that (b) (5)

Jimmy

[Amb] Jimmy Kolker

Office of Global Affairs

U.S. Department of Health and Human Services Room 639-H, 200 Independence Av SW, Washington, DC

202-690-6174

-----Original Message-----

From: David Hohman [[mailto:\(b\) \(6\)@gmail.com](mailto:(b) (6)@gmail.com)]

Sent: Tuesday, May 08, 2012 3:59 PM

To: Mamacos, Peter (HHS/OGA); Colin McIff; blackwoodas; Hsu, Leah (HHS/OS/OGA);

susan.wilson@trade.gov; jane.earley@trade.gov; george_e_york@ustr.eop.gov; elizabeth_l_kendall@ustr.eop.gov; bonillja@state.gov

Cc: Daulaire, Nils (HHS/OS/OGA); Kolker, Jimmy (HHS/OGHA)

Subject: Revisions to Swiss CEWG Resolution

Colleagues, I attach for your consideration some suggested edits to Gaudenz's draft CEWG resolution. Colin told me this morning he expects more drafts to emerge, particularly from AFRO and SEARO, but the Swiss proposal is circulating widely and gaining some support.

The addition of the (b) (5)

(b) (5) [REDACTED]

I have also (b) (5) [REDACTED]

The addition (b) (5) [REDACTED]

The new (b) (5) [REDACTED]

Finally, (b) (5) [REDACTED] this will be a very tough sell.

I welcome your thoughts on this, including next steps - i.e., (b) (5) [REDACTED]

SBU

This email is UNCLASSIFIED.

WORLD HEALTH ORGANIZATION (WHO)
SIXTY-FIFTH WORLD HEALTH ASSEMBLY
GENEVA, SWITZERLAND
May 21-26, 2012

**Consultative Expert Working Group on Research and Development: Financing and
Coordination**
Agenda Item 13.14

ISSUE

The World Health Assembly (WHA) will consider the final report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). One or more resolutions are expected to be tabled on this item.

U.S. POSITION

(b) (5) [Redacted text block]

Commented (b) (5) [Redacted comment]

(b) (5) [Redacted text line]

- (b) (5) [Redacted bullet point]
- (b) (5) [Redacted bullet point]
- (b) (5) [Redacted bullet point]

- (b) (5) [Redacted]

Commented [JE2]: (b) (5) [Redacted]

- (b) (5) [Redacted]

Therefore, we believe the most appropriate action moving forward is (b) (5) [Redacted] particularly in ways that draw upon the expertise in and build capacity within developing country research institutions themselves.

(b) (5) [Redacted]

(NOTE: the Swiss proposal, with suggested US revisions, is attached.)

The goals of this consultation process should be to identify:

- Areas of broad agreement or consensus among Member States;
- Which proposals for R&D promotion enjoy the strongest support among Member States, and which do not;
- Concepts in which action could begin on a voluntary basis among Member States (such as (b) (5) [Redacted] and
- Steps that countries could take at smaller scale, with the possibility of scaling them up through time-bound financial or programmatic commitments; and
- Place CEWG follow-up in the context of the Strategy and Plan of Action, which will broaden recommendations considered beyond only those contained

in CEWG and also consider proposed next steps in the context of WHO reform and its constrained resource environment.

(b) (5)

BACKGROUND:

The CEWG was mandated to develop a report based on deeper analysis of the work of its predecessor, the Expert Working Group on R&D financing and coordination (EWG), consideration of additional submissions and proposals from Member States and from other stakeholders, and examination of the appropriateness of different R&D financing approaches and the feasibility of implementation of these approaches.

The CEWG considered a number of criteria to inform its analysis, which included:

- potential public health impact in developing countries
- rational and equitable use of resources/efficiency considerations
- cost-effectiveness
- technical feasibility, scaling-up potential, replicability, speed of implementation
- financial feasibility and sustainability
- additionality
- intellectual property management issues
- potential for delinking R&D costs and the price of products
- equity/distributive effect, including on availability and affordability of products and impact on access and delivery
- accountability/participation in governance and decision making
- impact on capacity building in, and transfer of technology to, developing countries
- potential synergy with other mechanisms/potential for combining with others.

The CEWG found the following proposals to best meet its criteria:

- a globally binding instrument for R&D and innovation for health, which would be established under article 19 of the WHO Constitution for R&D related to Type II and III diseases and the specific R&D needs of developing countries in relation to Type I diseases, and potentially incorporate the following principles: open knowledge innovation, de-linkage of price from product, competition, enhanced access and strengthening of innovative capacity in developing countries, increased and committed public investment, a mechanism for redistributing resources, pooling of funds to meet these aims

- open approaches to research and development and innovation, which includes precompetitive R&D platforms, open source, open access and equitable licensing
- pooled funds
- direct grants to companies in developing countries
- milestone prizes and end prizes
- patent pools

The CEWG found the following proposals did not principally contribute to improved financing or coordination of R&D:

- regulatory harmonization
- removal of data exclusivity

The CEWG found the following proposals did not meet its criteria very well:

- tax breaks for companies
- orphan drug legislation
- green intellectual property
- priority review vouchers
- transferable intellectual property rights
- Health Impact Fund
- purchase or procurement agreements

Working Group History

Expert Working Group

In November 2008, in accordance with WHA61.21, the Director-General established a results-oriented and time-bound Expert Working Group (EWG) to examine current financing and coordination of research and development, including proposals for new and innovative sources of funding. The Expert Group, composed of internationally-recognized policymakers and technical experts (Mark Rohrbaugh of NIH represented the U.S.), issued its report in December 2009.

126th Session of the WHO Executive Board

During the 126th Session of the WHO Executive Board (EB), in January 2010, a number of Board Members raised concerns regarding alleged leaks of the first Expert Working Group's report to the pharmaceutical industry. The Chair of the Working Group, Sir George Alleyne, responded that such allegations were unfounded. Nevertheless, several delegations implied that the entire work product of the first EWG was tainted. In response to the concerns raised at the EB, the WHO Director-General said she would investigate the allegations.

WHO Member State Consultation

At the request of that 2010 Executive Board, the WHO convened a consultation of Member States on May 13 to discuss the report of the EWG. Western countries generally supported the work of the EWG and saw the report as a menu of options for Member States to take forward in an effort to improve financing of R&D for neglected diseases. Developing countries, and particularly middle-income countries and the UNASUR countries (South America), criticized the EWG both for the process it followed and the incompleteness of its report. These countries called for further work, either in an intergovernmental process (middle-income countries) or by

a second EWG (African countries). There was little discussion of the recommendations in the report and the summary prepared by the Secretariat.

63rd World Health Assembly

During the 63rd World Health Assembly in May 2010, views expressed at the consultation were repeated. A drafting group deliberated on the way forward, trying to reconcile differences between those countries, U.S. included, who were satisfied with the Expert Report and WHO's work to implement the Global Strategy on Public Health, Innovation, and IP, and those countries, led by Brazil and India, who were displeased with the results of the Expert Report and sought to start over with an intergovernmental working group. Bolivia and Barbados also made statements voicing concern with the mandate of the group. Member States agreed to convene a Consultative Expert Working Group to be formed by the Director-General following input from Member States, in consultation with Regional Committees, for participation in the CEWG. None of the experts who were on the first EWG were allowed to participate in the CEWG. Its mandate has been to take forward the Report and consider ideas not taken up by the previous Expert Group (which included the proposal championed by Brazil to tax the profits of R&D Pharmaceutical companies) and conclude its work in a two-year timeframe. An expert from USAID was named to the CEWG, did not participate in any meetings, and was not replaced.

128th Session of the Executive Board

At the January 2011 EB session, a number of Member States raised concerns with the proposed roster of 21 experts, as submitted by each of the six WHO Regional Offices and selected by the Secretariat. Brazil and Thailand raised questions regarding conflicts of interest, specifically ties to the pharmaceutical industry, for several proposed experts. After a presentation by the Secretariat on the implementation to date of the global strategy and plan of action on public health, innovation and intellectual property and a spirited discussion on the need to take into account conflicts of interest and ensure transparency, the Board approved the proposed roster of experts.

From: jamespackardlove@gmail.com on behalf of [Jamie Love](#)
To: [York, George](#)
Subject: Re: Friday
Date: Wednesday, November 14, 2012 2:38:05 PM

The WHO negotiations on the R&D Treaty/CEWG. As well as a related suggestion regarding the types of analysis that might be useful to USTR in looking at optimal trade policy as regards both R&D and IPR issues.

On Wed, Nov 14, 2012 at 2:09 PM, York, George
<George_E_York@ustr.eop.gov> wrote:
> Thanks, Jamie. What are you interested in discussing?
>
>
> ----- Original Message -----
> From: Jamie Love [<mailto:james.love@keionline.org>]
> Sent: Wednesday, November 14, 2012 02:04 PM
> To: York, George
> Subject: Friday
>
> Hi George, are you around on Friday?
>
> --
> James Love. Knowledge Ecology International
> <http://www.keionline.org>, +1.202.332.2670, US Mobile: +1.202.361.3040,
> Geneva Mobile: +41.76.413.6584, efax: +1.888.245.3140.
> twitter.com/jamie_love

--
James Love. Knowledge Ecology International
<http://www.keionline.org>, +1.202.332.2670, US Mobile: +1.202.361.3040,
Geneva Mobile: +41.76.413.6584, efax: +1.888.245.3140.
twitter.com/jamie_love

Statement from U.S. Head of Delegation to the Pan American Sanitary Conference (PAHO), the Honorable Nils Daulaire, concerning the Regional Consultation of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

Aside from yesterday's election of our new Director, this is perhaps the most important agenda item before us at this Regional Committee meeting.

The United States thanks PAHO for its hard work and dedication on this issue, including its efforts in convening a regional consultation and preparing the Report ahead of this conference. We were impressed with the quality of the Secretariat's work in this regard, and commend the Report for its clear reflection of the dialogue that took place.

The United States firmly believes that far more needs to be done to address the health research and development needs of developing countries. It is clear that market forces alone are not sufficient to attract appropriate resources to these concerns and to get critically important new health tools to those who need them most. We do indeed need to find alternate and improved ways to advocate, coordinate, and create incentives for new investments that address the needs of the poorest of the world's poor.

While the Report of WHO's Consultative Expert's Working Group contained many useful insights, there were two major recommendations that the U.S. Government could not support – first, the call for a binding global treaty to commit a set percentage of each nation's gross domestic product to these R&D needs, and second, a requirement to put a set portion of such funds into a pooled financing mechanism. After having seen the results of the regional consultations that have taken place in the South East Asia Region,

the European Region, and now PAHO, it is clear that very few of the world's major economies support such instruments either.

That now leaves us with two fairly clear choices: either interested parties can move forward on the many areas of consensus, in ways that are promising and results-oriented but perhaps less narrowly prescriptive than some would like; or stakeholders can cling to the most contentious recommendations. It seems to us that the health needs of the world's poorest citizens will be poorly served by digging trenches on these most contentious items.

We believe the experience of the Global Fund to Fight AIDS, Tuberculosis and Malaria is instructive – the creators of the Fund knew that the best advocacy for the fight against the three diseases was their ability to demonstrate measurable results to stakeholders. The Fund's ability to point to the number of people it had put onto anti-retrovirals and anti-tuberculosis drugs, and children under bed nets, is what has opened the checkbooks of donor governments and national ministries. For the Fund, robust contribution levels and dollar figures have been the consequence, not the starting point.

In an era of increased austerity, experience demonstrates that there is no credible argument that creating an instrument that starts with a dollar figure is likely to gain acceptance – and I make that point despite the fact that the United States is the only country in the world that already meets the CEWG's recommended funding levels. What we need is a mechanism that begins with gap analysis of the problems, that sets *specific* targets for the development of new tools against top priority conditions, and then matches these targets with realistic budgets, work-plans, and timelines. This type of analysis must then set goals not only in terms of the types and number of new products developed, but in terms of outcomes in creating access to these new products to people most in need, and their impact on human health. And these processes and outcomes must be subject to rigorous independent evaluation. This is the way development cooperation works in the

21st century. Taking these steps as a starting point will create a powerful and sustainable foundation for advocacy for financing.

So we believe it is important to move forward. In fact, we do not believe there is a benefit to launching a cumbersome and time-consuming formal negotiation process or inter-governmental working group. Such efforts could drag on for two years or five years or more, and put us back exactly where we appear to be now. It could even serve as a negative incentive for important new efforts that are needed now.

Rather, there is a path forward that Member States could embrace that could lead to the establishment of new R&D mechanisms quite quickly. We do not need to think in terms of years of discussion, but rather months. We could begin building consensus around these items as early as the WHO Member State consultations scheduled to take place in November of this year, with a goal of approving a resolution at the May 2013 World Health Assembly.

I would just like to highlight a few of the points in the PAHO Report that received strong support from PAHO Member States and with which the U.S. strongly agrees:

1. The basic premise of the need for increased funding to address the health research needs of developing countries;
2. The need to strengthen R&D capacity in the world's poorest countries, and the encouragement of voluntary and mutually-agreed technology transfer to address the capacity needs of academic, public, and private research organizations in developing countries, including improved governance;
3. The creation of a global health research, development and innovation observatory and relevant advisory mechanisms;
4. Consideration of a voluntary pooled funding mechanism and the possibility of multiple funding pools designed to meet geographical or otherwise defined needs and priorities;
5. Direct grants to small- and medium-sized companies and non-profits in developing countries;
6. Use of advance market commitments;

7. Coordination of procurement agreements, for the simple reason that sometimes new products – even those with no intellectual property right protections – may still be too expensive for the poorest populations; and
8. Use of prizes to stimulate research and development, recognizing the need for the award components of the prize to be complementary.

We should build on experience from positive models for coordinating and prioritizing research such as IARC, TDR and CERN.

As noted in the Report, through the regional consultation, countries expressed support for the development of each nation's regulatory framework, because inefficient regulatory systems can often constitute significant barriers to access themselves. Here we would also like to emphasize the advantages of regulatory collaboration, and the U.S. stands ready to expand our efforts in this regard.

In addition, we wish to highlight that this is not just about products, it is about the impact those products have. An enhanced global response will not be effective if we are not able to get the pharmaceuticals and other products to the end user. Ongoing discussion of the CEWG Report's recommendations should include consideration of implementation, health services and operational research. Consideration of the most effective way to deliver a product is critical to achieve access and make the best use of limited resources.

We also think it is important to recognize that while there is much to be done, we are not starting from a zero point. The past decade has seen considerable progress through public private partnerships and heightened international collaboration that encourages global health R&D while obtaining the broadest public benefit. Examples include commitments to humanitarian royalty-free licensing and new pathways through which public sector innovations can reach a broader population of researchers and innovative firms for ongoing development and application.

Finally, I want to present two points of clarification the United States would like to submit for the record of the discussion of this agenda item, with regard to the PAHO Report of the regional consultation.

- First, paragraph 34 of the Report states:

*34. **The** countries received the proposal for open approaches to research favorably, noting potential advantages over the traditional application of intellectual property rights. **The** countries also emphasized contributions made*

toward eliminating impediments to research, development, and innovation, and noted the impact of delinking the price of a product from the cost of research, development, and innovation.

The United States is not in agreement with the assertion, and would like to note that it is only accurate to state that “some” countries, not “the” countries, noted the advantages of open approaches over traditional systems. The same change should be applied to the second sentence of the paragraph.

- Second, paragraph 46 of the Report states:

46. Some countries considered taxes on repatriated earnings by the pharmaceutical industry a way to fund part of health technology research and development for the treatment of Type II and Type III diseases and believed that this could also have a positive impact on transfer pricing practices, although this mechanism should be analyzed in relation to fiscal mechanisms in each country.

This paragraph is of particular concern to the United States. A call for taxation on repatriation of profits moves us from the realm of public health to the much broader realm of international trade policy, on which the global economy rests. This would be problematic for many reasons, including the fact that it could actually serve to exacerbate access issues. It would also hand this important issue over to trade negotiators; health may not benefit from such a move. We would like to stress the use of voluntary frameworks and mechanisms to raise funds.

To conclude, the United States strongly supports further discussion and action around all of the areas we just mentioned. We thank PAHO for including these points in the recommendations being submitted to WHO to inform the global consultations.