Proposed participants in March 2 POTUS vaccine meeting

Total seats: 24 including POTUS
Additional: 24

Major General Porter

Senior Administration – 9 at table

CEOs - 6
10. Aventis/Pasteur Merrieux Connaught -- Jean-Jacque Bertrand, President and CEO
11. Smith Kline Beecham/Glaxo – Jean Stephenne, President, SKB Biologics; to become CEO
12. American Home Products/Wyeth Lederle – John R. Stafford
13. Merck – Ray Gilmartin, CEO
14. VaxGen – Don Francis, President
15. Vical – Alain Schreiber, President and CEO
or Gordon Douglas – Chairman of the Board

Foundations - 3
16. Bill and Melinda Gates Foundation -- Bill Gates, Jr.
17. Rockefeller – Gordon Conway, President
18. Turner/UN – Charlie Curtis, COO; or Tim Wirth, President

get more foundations in — Grantmakers in Health

International Leaders - 3
19. World Bank – Wolfensohn
20. WHO – Brundtland
21. UNICEF – Bellamy
22. President Chissano of Mozambique, Bishop Tutu, or African Minister of Health (Uganda, Kenya)

tie-in to debt initiative

Others
Ebrahim Samba – WHO/Africa (would sit at table if Chissano or Tutu is unavailable)
George Alleyne – WHO/Western Hemisphere
Betty Bumpers/Rossalyn Carter
Jeff Sachs, Harvard
Seth Berkley – Int'l AIDS Vaccine Initiative
Nils Daulaire – Global Health Council
Rotary International - TBD

invite head of GAVI

23rd or 24th

DEPARTMENT OF THE TREASURY
WASHINGTON, D.C. 20220

JODI SAKOL
DIRECTOR
OFFICE OF BUSINESS & PUBLIC LIAISON

1500 Pennsylvania Avenue, NW
Room 3127
Washington, DC 20220
Phone: (202) 622-0087
Fax: (202) 622-7893

FACSIMILE COVER SHEET

Date: _____ NUMBER OF PAGES: 3
(Including Cover Sheet)

TO: Chris Jennings

ADDRESSEE'S FAX NUMBER: 456-5557

ADDRESSEE'S PHONE NUMBER: _____

Vaccine Foundation Meeting
Friday, Feb. 25, 2000
2:00 pm
Roosevelt Room

List of Attendees

William H. Foege, MD, MPH
Senior Advisor, Bill & Melinda Gates Foundation

Dorothy S. Ridings
President & CEO, Council on Foundations

Elaine K. Gallin, PH.D.
Program Director for Medical Research, Doris Duke Charitable Foundation

Andrea Gay
Administration & Evaluation Officer, United Nations Foundation

David Winters
Program Officer, Ford Foundation

Victor Zonana
International Aids Vaccine Initiative

Eno Isong
Kaiser Family Foundation

Debbie Knitt
David and Lucille Packard Foundation

Neen Hunt
Lasker Foundation

Millennium Vaccine Initiative Meeting
U.S. Department of Treasury
February 25, 2000; 2:00 p.m.

AGENDA

I. Opening Remarks & Briefing on President's Millennium Vaccine Initiative (Larry Summers)

-- new financial commitment to purchasing and delivering existing vaccines in poor countries

-- increasing investments in health in developing countries

-- increasing basic research on diseases that affect developing nations

--new tax credit for sales of vaccines for malaria, tuberculosis and HIV/AIDS, and any infectious disease that causes over 1 million deaths annually worldwide

II. Administration Perspective (Gene Sperling)

III. Discussion about Science as it Relates to International Health (Neal Lane)

IV. Potential Role For Foundations (Anthony Fauci/Duff Gillespie)

V. Foundation Perspectives

VI. Next Steps

DEPARTMENT OF THE TREASURY
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FACSIMILE COVER SHEET

Date: _____ NUMBER OF PAGES: 4
(Including Cover Sheet)

TO: Chris Jennings

ADDRESSEE'S FAX NUMBER: 456-5557

ADDRESSEE'S PHONE NUMBER: _____

Revised Agenda

February 24, 2000

MEMORANDUM TO CHRIS JENNINGS

FROM: JODI SAKOL

RE: VACCINES MEETING WITH FOUNDATIONS

Sheryl asked that I inform you that Sec. Shalala has decided to attend tomorrow's vaccine meeting. Please find a revised agenda attached.

Also, Sheryl asked that I inform you that all the calls and invitations to this meeting were made by White House Office of Public Liaison.

Please call if you have any questions. I can be reached at 622-0087. Thanks.

Millennium Vaccine Initiative Meeting
U.S. Department of Treasury
February 25, 2000; 2:00 p.m.

AGENDA

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-- new financial commitment to purchasing and delivering existing vaccines in poor countries

-- increasing investments in health in developing countries

-- increasing basic research on diseases that affect developing nations

--new tax credit for sales of vaccines for malaria, tuberculosis and HIV/AIDS, and any infectious disease that causes over 1 million deaths annually worldwide

II. Partnerships for prevention (Donna Shalala)

III. Administration Perspective (Gene Sperling)

IV. Discussion about Science as it Relates to International Health (Neal Lane)

V. Potential Role For Foundations (Anthony Fauci/Duff Gillespie)

VI. Foundation Perspectives

VII. Next Steps

Vaccine Foundation Meeting
Friday, Feb. 25, 2000
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Kaiser Family Foundation

Debbie Knitt
David and Lucille Packard Foundation

Neen Hunt
Lasker Foundation

GRANT MAKERS IN HEALTH

FACSIMILE TRANSMITTAL COVER SHEET

DATE: February 28, 2000

TO: Chris Jennings

FAX #: 202.456.5557 **PHONE #:**

FROM: Saba Brelvi

Sending 4 pages plus cover page

Note:

Chris,

Lauren LeRoy, President and CEO of Grantmakers In Health, forwarded your request for information on funders involved in vaccine development to me. I am faxing to you a preliminary list of funders involved in these efforts. Sorry about the delay in getting this information to you -- our annual meeting is beginning tomorrow down in Miami and the pace here is hectic. I am sure that there are other grantmakers involved in vaccine research, and will be happy to pursue this topic further if necessary once I return to the office.

Take care.

Sincerely,

Saba Brelvi
Program Associate
Grantmakers In Health

1100 CONNECTICUT AVE, NW ■ SUITE 1200 ■ WASHINGTON, DC 20036 ■ 202.452.8331 ■ FAX 202.452.8340 ■ www.gih.org

GRANT MAKERS IN HEALTH

Helping grantmakers

improve the nation's health

MEMORANDUM

To: Chris Jennings

From: Saba Brelvi

Subject: Foundation Involvement in Vaccine Development

Date: February 28, 2000

Lauren LeRoy, the President and CEO of Grantmakers In Health, forwarded your request for information on funders involved in vaccine development to me. The following is a preliminary list of funders and some general information on their areas of interest.

FOUNDATIONS AND CORPORATE GIVING PROGRAMS

Bill and Melinda Gates Foundation
Seattle, WA
206.709.3100
www.gatesfoundations.org

AIDS Vaccine
Awarded to the International AIDS Vaccine Initiative to speed development of an AIDS vaccine. The grant will allow IAVI to begin work on up to three new vaccine candidates, in addition to two others IAVI is already funding. Moving multiple vaccine candidates forward simultaneously will yield the fastest results. An integral part of the IAVI strategy is to ensure that the vaccines will be available in developing countries at a reasonable price.
Amount: $25 million

Malaria Vaccine
The Foundation created the Malaria Vaccine Initiative with a grant to the Program for Appropriate Technology in Health (PATH) to accelerate the development of promising malaria vaccine candidates. Funds may be directed toward the support of laboratories, the coordination and management of pilot production and release of products for clinical trials, as well as the design and execution of clinical trials in malaria-endemic regions.

Amount: $50 million

Tuberculosis Vaccine
Awarded to the Sequella Global Tuberculosis Foundation to create the Tuberculosis International Vaccine Collaborative. The goal of the program is to speed up the development of one or more TB vaccines that will increase the efficacy of the current BCG vaccine for children and reduce the morbidity and mortality of childhood TB in areas of the world where BCG is ineffective.
Amount: $25 million

The Rockefeller Foundation
New York, NY
www.rockfound.org

Foundation-administered project
Funding to undertake an inventory of public/private collaborations for vaccine research and development.
Amount: $325,000
World Health Organization
- Continued support for the activities of the Children's Vaccine Initiative.
  Amount: $575,000
- Continued support for its Global Programme for Vaccines and Immunization.
  Amount: $700,000

International AIDS Vaccine Initiative
for continued funding of its activities to ensure development of safe, effective, preventive HIV vaccines for use throughout the world.
Amount: $1,250,000

United Nations Foundation
Washington, D.C.
202.887.9040
www.unfoundation.com

Support to Sustainable Vaccination Activities in Madagascar
United Nations Children's Fund (UNICEF)
Amount: $630,000 over three years

Strengthening Surveillance and Control of Vaccine-Preventable Diseases
World Health Organization (WHO)
Amount: $5 million over three years

California HealthCare Foundation
Oakland, CA
510.238.1040
www.chcf.org

(domestic vaccine development funding)
University of California, San Francisco
To create the California HealthCare Foundation Administrative Office to direct and manage the Valley Fever Vaccine and STD Prevention and Control projects.
Amount: $2,924,982

Valley Fever Vaccine Project
Grantees: California State University, Bakersfield; University of California, San Francisco, Department of Epidemiology andBiostatistics
To support the first phase of development of a vaccine against Valley Fever through a two year program of coordinated research with five leading scientists in the area of research.
Amount: $1.65 million

Until There's A Cure Foundation
International AIDS Vaccine Initiative
Amount: $550,000

AIDS Vaccine Advocacy Coalition
Founded in 1995, AVAC is a coalition of volunteer advocates located throughout the country. AVAC seeks to provide a well-informed, independent, and honest critique of current efforts by the U.S. government, the pharmaceutical and biotechnology industry, and other sectors toward developing an HIV vaccine.
Amount: $343,000

Merck Company Foundation
Whitehouse Station, NJ
www.merck.com

The Enhancing Care Initiative (ECI)
Provides a grant to the Harvard AIDS Institute. The initiative's objective is to customize concrete, practical improvements to help advance the quality, delivery and outcomes of HIV care in developing countries. Merck also supports AIDS vaccine research.
Amount: $3 million

National Foundation for Infectious Diseases
Bethesda, MD
301.656.0003
www.nfid.org

The mission of the National Foundation for Infectious Diseases (NFID) is:
- to support research that will lead to a better understanding of the causes, cures, and prevention of infectious diseases;
- to encourage and sponsor public and professional education programs;
- to aid in the prevention of infectious diseases.

The foundation supports a number of vaccine-related programs, including an annual conference on vaccine research.

OTHER ORGANIZATIONS OF INTEREST

Funders Concerned About AIDS
New York, NY
212.573.5533
E-mail: paul@fcaaids.org

Funders Concerned About AIDS mobilizes philanthropic leadership and resources, domestically and internationally to eradicate the HIV/AIDS pandemic and to address its social and economic consequences.

BROWN UNIVERSITY SCHOOL OF MEDICINE

Division of Biology and Medicine — *Providence, Rhode Island*

October 27, 1999

cc: Chris Jennings ✓
Dan Mendelson

Mr. John Podesta
President Clinton's Chief of Staff

30% income tax credit for vaccine R&D

RE: Vaccine Tax Credit

Dear Mr. Podesta:

I enthusiastically welcome the President's leadership on vaccine development, recently demonstrated at the United Nations when he committed the United States to helping stimulate private sector investment on vaccines for TB, malaria, and HIV.

I believe that the tax credit for vaccine development is doable this year. The Congressional Research Service has concluded that, "the proposed credits can be expected to spur increased investment in vaccine R&D by the private sector," and "there is some reason to believe that the proposed vaccine research tax credit would eventually be as cost effective as direct spending by the federal government on vaccine R&D." Taking this single strong, affordable step now will make a real difference in beginning to achieve the President's goal to stimulate private sector investment in vaccine development. We urge you to place it on your priority list for inclusion in the final budget agreement.

Again, I really hope that this tax credit can be implemented this year.

Sincerely,

Charles Carpenter

Charles C.J. Carpenter, M.D.
Professor of Medicine
Brown University School of Medicine
Chair, NIH Office of AIDS Research Advisory Council

CCJC/bsr

Brown University/Miriam Hospital 164 Summit Avenue, Providence, RI 02906

FAX

Date: 10-27-99

Number of pages including cover sheet: 2

To:

Mr. John Podesta

Phone: 202-456-6797

Fax phone: 202-456-1907

CC:

From:

Charles C.J. Carpenter, M.D.

Phone: 401-793-4025

Fax phone: 401-793-2099

REMARKS: ☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please comment

VaxGen

cc: Chris Jennings ✓
Dan Mendelson

Via facsimile (202) 456-1907

October 26, 1999

John Podesta
Chief of Staff
The White House
Washington, D.C. 20500

Dear Mr. Podesta:

VaxGen, Inc., as the leader in clinical research of vaccines to prevent HIV infection, greatly values the President's leadership on vaccine development, as recently demonstrated at the United Nations when he committed the United States to helping stimulate private sector investment on vaccines for TB, malaria, and HIV.

I am writing to urge your support of the Lifesaving Vaccine Technology Act of 1999. As you may know, the Congressional Research Service has concluded that, "the proposed credits can be expected to spur increased investment in vaccine R&D by the private sector." The CRS also reported that the proposed vaccine research tax credit would eventually be as cost effective as direct federal spending on vaccine R&D. Taking this bold, affordable step now will assure the President's goal to stimulate private sector investment in vaccine development is furthered. We urge you to place it on your priority list for inclusion in the final budget agreement.

We also feel that continued work on other approaches to stimulate vaccine development and delivery is vitally important, and we ask that such efforts continue under your leadership.

Thank you for your consideration.

Sincerely yours,

Carter A. Lee
Senior Vice President
Finance and Administration

1000 Marina Boulevard, Brisbane, CA 94005-1841 TEL: (650) 624-1000 FAX: (650) 624-1001

CHIRON

CC: Chris Jennings ✓
Dan Mendelson

Chiron Corporation
4560 Horton Street
Emeryville, CA 94608
510.655.8730

October 26, 1999

John Podesta
Chief of Staff
The White House
Washington, DC 20515

VIA FAX
202-456-1907

Re: **Support for Vaccine Tax Credit Legislation**

Dear Mr. Podesta:

Chiron Corporation, headquartered in Emeryville, California, is a leading biotechnology company which is developing innovative products for preventing and treating cancer, infectious diseases and cardiovascular disease. We support The Lifesaving Vaccine Technology Act of 1999 (H.R. 1274), which provides a 30% income tax credit for certain qualified vaccines research and development costs. We believe this legislation provides an important incentive for private sector investment in the development of vaccines for the most deadly infectious diseases, such as malaria, tuberculosis, and HIV.

Similarly, the Congressional Research Service recently concluded that "the proposed tax credits can be expected to spur increased investment in R&D by the private sector," and "there is some reason to believe that the proposed vaccines research tax credit would eventually be as cost effective as direct spending by the federal government on vaccine R&D."

We appreciate President Clinton's commitment to the stimulation of vaccine development by the private sector. Implementing the tax credit this year would be strong and affordable initial step toward the achievement of this commitment, and would clearly signal the President's leadership on this important issue. We therefore urge you to place the vaccines tax credit legislation on your priority list for inclusion in the final budget agreement.

Very truly yours,

CHIRON CORPORATION

Jay E. Grover

Jay E. Grover
Director, Government Affairs

CHIRON

FAX TRANSMISSION ■

Chiron Corporation
4560 Horton Street
Emeryville, CA 94608

From: Jay Grover

Phone No: (510) 923-2483
Fax No: (510) 654-5360
E-mail: jay_grover@cc.chiron.com

Date: October 26, 1999

To: John Podesta, Chief of Staff

Company: The White House

Fax No: 202-456-1907

No. of Pages: (including cover sheet) 2

Message:

Please see the attached.

GlaxoWellcome Fax

Federal Government Relations

To	Christopher Jennings, Deputy Assistant to the President for Health Policy Development	Fax	202-456-5557
		Date	2/24/00
		Total Pages	24
From	Sally Walsh Director, Federal Government Relations		
Telephone	(202) 715-1000		
Fax	(202) 715-1001		

Mission

Glaxo Wellcome is a research-based company whose people are committed to fighting disease by bringing innovative medicines and services to patients throughout the world and to the healthcare providers who serve them.

Values

High Standards

Valuing Customers

Valuing People

Teamwork

Embracing Change

Achievement

Corporate Citizenship

Glaxo Wellcome Inc.

1500 K Street NW
Suite 650
Washington, DC 20005

Telephone
(202) 715-1000

Fax
(202) 715-1001

E-mail

INTERNATIONAL PHARMACEUTICAL AEROSOL CONSORTIUM

Metered Dose Inhaler Transition Issues at the 11th Meeting of the Parties

Beijing, China — 29 November – 3 December 1999

Introduction

At the 19th Meeting of the Open-Ended Working Group (OEWG) in June 1999, the delegates:

- forwarded for consideration by the Parties a draft decision incorporating recommendations of the Technology and Economic Assessment Panel (TEAP) concerning a global framework for the transition to CFC-free MDIs (Decision XI/15); and

- recommended to the Parties that MDIs be designated an essential use of CFCs for 2001 and that CFC volumes for MDIs be approved for that year (Decision XI/13).

The International Pharmaceutical Aerosol Consortium (IPAC) requests that the 11th Meeting of the Parties adopt: (i) Decision XI/15, incorporating TEAP's recommendations concerning a global transition framework and (ii) Decision XI/13, authorising 'essential' use allowances for the year 2001.

Protocol Transition Framework

In its April 1998 and 1999 Reports, TEAP requested that the Parties consider a global framework to guide the transition to CFC-free MDIs. At the 19th OEWG Meeting, Costa Rica proposed a decision that incorporates many of TEAP's recommendations. This decision would underpin national transition strategies and ensure that they would provide flexibility for each Party to implement a national strategy in light of its unique regulatory structure, level of economic development, and requirements for patient care.

The elements proposed by Decision XI/15 include:

- *Measures to discourage the introduction of new CFC-containing products*

As TEAP noted, continued approval of new CFC-containing MDIs is likely to discourage reformulation efforts and impede the MDI transition. It would also raise doubts in the minds of physicians and patients about whether a change in medications will actually be required. Finally, continued approval of new CFC MDIs would create health risks and confusion for patients who would need to switch medications twice — once to the new CFC-containing MDI and a second time to a CFC-free MDI.

IPAC therefore requests that the Parties not allocate essential use volumes for new CFC products approved after the 11th Meeting of the Parties, unless the new product represents a significant therapeutic advance.

- *Measures to address exports and imports of CFC MDIs*

TEAP cited the need to address "transition issues that transcend national boundaries, such as the flow of CFC MDIs from exporting countries to importing countries," in a Protocol transition framework. The non-Article 5(1) Parties where most MDIs currently are manufactured will likely complete their domestic transition to CFC-free MDIs before many of the Parties that rely on imported CFC MDIs. Patient care in importing countries requires an uninterrupted supply of essential MDIs until the transition is completed in those countries. For that reason, the transition framework should urge essential use nominating Parties to provide for the continued export of CFC MDIs, as long as they remain essential in these importing countries.

Where, however, the transition to CFC-free MDIs is completed in an importing country, TEAP recommended that national measures be adopted to stop the inward flow of CFC MDIs to that country. As part of a transition framework, IPAC supports measures to discontinue authorisation of essential use volumes for the manufacture of any CFC MDI for export to any country which has determined that product to be non-essential. IPAC also believes that the Parties themselves should discontinue the allocation of essential use allowances previously approved by the Parties for any such product.

- *Development of national transition strategies*

In both the 1998 and 1999 Reports, TEAP encouraged all Parties, including Article 5(1) and CEIT Parties, to develop their own national and regional transition strategies. TEAP noted that for some countries, if a national transition strategy had been in place, it may have triggered a reduction in essential use requests. IPAC supports TEAP's recommendation.

TEAP also recommended having a Protocol goal for completing the transition in non-Article 5(1) Parties by 2005 in order to give physicians and other health professionals in those countries a sense of the overall timing in which the transition should be completed. IPAC supports this recommendation, provided the target date is structured as a flexi-

IPAC

AstraZeneca
Boehringer Ingelheim
Chiesi Farmaceutici
Glaxo Wellcome
Medeva Americas, Inc.
Norton Healthcare Ltd.
Rhône-Poulenc Rorer Inc.
3M Pharmaceuticals

1301 K Street, NW
Suite 900, East Tower
Washington, DC
20005-3317 USA

+1 202 408 7208
telephone

+1 202 289 1504
facsimile

ble goal, which can be reassessed periodically in light of uncertainties in development and approval and patient acceptance of CFC-free MDI products.

- *Evidence of satisfactory progress in the transition*

TEAP recommended that as a condition for the authorisation of essential use volumes, the Parties should verify whether manufacturers are actively pursuing research and development efforts on non-CFC alternatives or actively entering into licensing arrangements. Such a measure will send an appropriate signal to all MDI manufacturers that they must expeditiously pursue development of non-CFC alternative treatments. IPAC agrees with this recommendation.

- *Measures to encourage the rapid introduction of CFC-free inhalers and technologies into Article 5(1) and CEIT Parties*

In its 1999 Report, TEAP recommended encouraging "a rapid introduction of CFC-free inhalers and technologies into Article 5(1) and CEIT Parties." IPAC fully supports this recommendation, and IPAC's members stand ready to assist Article 5(1) and CEIT Parties in their transition efforts. IPAC believes that a smooth and patient-protective transition can best be accomplished by developing national transition strategies that include measures for encouraging educational programs for health professionals and patients in those countries.

TEAP recommended that Parties consider assisting Article 5(1) and CEIT Parties to develop national transition strategies from the Multilateral Fund. IPAC believes that whether the Multilateral Fund is the appropriate vehicle for such assistance should first be assessed by the Executive Committee to the Multilateral Fund, as provided for in Decision XI/15.

- *Reasonable strategic reserves*

In its April 1999 Report, TEAP noted that strategic reserves "of reasonable size are prudent to safeguard public health needs." TEAP also expressed concern, however, that strategic reserves, if maintained at unreasonably high levels, could impede the MDI transition.

IPAC members have made the following commitments concerning CFC strategic reserves:

- Members of IPAC will not maintain strategic reserves beyond reasonable levels as determined by the nominating Party;

- Members of IPAC will decrease strategic reserves in conjunction with declining annual requirements for CFCs, with the goal of completely eliminating strategic reserves by the completion of the MDI transition; and

- Members of IPAC will destroy any strategic reserves remaining at the close of the MDI transition, using UNEP approved technologies, or transfer them as provided by the Parties.

IPAC supports Decision XI/15's inclusion of these commitments so that they apply to non-IPAC members as well.

- *Inter-MDI company transfers of essential use CFC volumes*

In its 1998 Report, TEAP recommended that Parties consider "developing a process that allows movement of CFCs between MDI manufacturers [holding] an authorised essential use exemption." This approach would avoid the adverse environmental impacts of CFC destruction. It would also reduce the need for additional production of new CFCs. IPAC recommends that the Protocol transition framework include a provision allowing MDI companies to transfer CFC volumes, subject to essential use limits.

IPAC therefore requests that the Parties adopt Decision XI/15 to establish a Protocol transition framework incorporating TEAP's recommendations at their 11th meeting in Beijing, China.

Essential Use Allowances

2001 Nominations

In its April 1999 Report, TEAP recommended that the MDI be designated an essential use of CFCs through the year 2001, and that CFC volumes nominated by the European Union, Japan, Hungary, and the United States be authorised for the manufacture of essential products in the year 2001. The 19th Meeting of the OEWG forwarded this recommendation for approval by the Parties at their 11th Meeting as Decision XI/13. IPAC requests that the Parties adopt this decision.

Conclusion

In conclusion, IPAC requests that the 11th Meeting of the Parties adopt: (i) Decision XI/15, incorporating TEAP's recommendations concerning a global transition framework; and (ii) Decision XI/13, authorising essential use allowances for the year 2001

Distr.
GENERAL

UNEP/OzL.Pro.11/8
19 July 1999

ORIGINAL: ENGLISH

ELEVENTH MEETING OF THE PARTIES TO THE MONTREAL PROTOCOL ON SUBSTANCES THAT DEPLETE THE OZONE LAYER
Beijing, 29 November - 3 December 1999

[DRAFT DECISIONS]

The Eleventh Meeting of the Parties decides:

• • •

[Decision XI/15. Measures to facilitate the MDI transition

Having reviewed with appreciation the assessment by the Technology and Economic Assessment Panel (TEAP) on the transition to CFC-free treatments for asthma and chronic obstructive pulmonary disease and the Panel's recommendations for a transition framework under the Montreal Protocol that facilitates a rapid CFC phase-out while protecting patient health;

Noting that the Technology and Economic Assessment Panel has predicted that, by the year 2000, the transition will be making good progress in Parties not operating under Article 5 and that, by the year 2005, there will be minimal need for CFCs for metered-dose inhalers in these Parties;

1. To urge all Parties not operating under Article 5, and to encourage Parties operating under Article 5, to develop and implement national transition strategies, with the goal of completing the transition in their domestic markets as expeditiously as possible while protecting patient health;

2. To require each nominating Party to apply the following criteria, in addition to the

criteria in decision IV/25, to determine essentiality for purposes of Article 2 of the Protocol:

(a) That the MDI product for which quantities of CFCs are requested:

(i) Has been approved by the Party's national health authority prior to the Eleventh Meeting of the Parties to the Montreal Protocol, unless that authority has determined that the product will serve an otherwise unmet medical need;

(ii) Is not intended for export to any other Party that has determined the product to be non-essential and has so notified the Secretariat;

(b) That the company requesting the quantities of CFC demonstrates that it is:

(i) Actively pursuing research and development for CFC-free alternatives for its products, individually or jointly with another company, or engaging in good faith legal negotiations with another company in order to obtain such alternatives;

(ii) Not increasing its strategic reserves of CFCs beyond reasonable levels, as determined by the nominating Party;

(iii) Decreasing its strategic reserves of CFCs in line with declining annual demand for CFCs;

(iv) Committed to, upon completion of its MDI transition, destroying any of its remaining strategic reserves of CFCs, using technologies approved by the Protocol, or transferring such remaining reserves in accordance with paragraph 5 of the present decision;

3. To urge each nominating Party to apply the criteria in paragraph 2 of the present decision with respect to essential uses already authorized by the Parties but not yet allocated to MDI companies by the nominating Party;

4. To strongly urge all nominating Parties to continue to nominate and license the quantities for use in CFC-containing MDIs for export to other Parties, except for products which the importing Party has determined to be non-essential;

5. To allow transfers of CFCs for essential uses between MDI companies as a means of avoiding production of new CFCs, provided that the recipient company has the essential-use authorization and that any such transfer is subsequently reported in the essential-use accounting framework;

6. To request the Executive Committee of the Multilateral Fund for the implementation of the Montreal Protocol to assess the need for financial and technical assistance for Parties operating under Article 5 to develop and implement national transition strategies, and to

report to the Twelfth Meeting of the Parties on the results of this assessment;

7. To request the Technology and Economic Assessment Panel to revise its Handbook on Essential Use Nominations to incorporate the criteria in paragraph 2 of the present decision and to utilize these criteria when reviewing essential-use nominations;]

(Source: para. 138 of the report of the nineteenth meeting of the Open-ended Working Group and UNEP/OzL.Pro/WG.1/19/CRP.1, introduced by Costa Rica)

21 September 1999

Mr. Ibrahim Abdel Gelil
Co-Chair, Open-Ended Working Group
c/o Egyptian Environmental Affairs Agency
30 Misr Helwan El-Zyrae Road, Maadi
Cairo, Egypt

Mr. Jukka Uosukainen
Co-Chair, Open-Ended Working Group
c/o Ministry of the Environment
Deputy Director, International Affairs
P.O. Box 399
00121 Helsinki, Finland

Re: Support for Montreal Protocol Decision to Facilitate the Transition to CFC-Free Metered-Dose Inhalers (MDIs)

Dear Mr. Gelil and Mr. Uosukainen:

We represent some of the world's leading patient groups and medical organisations. One of our primary missions is to protect and enhance treatment of the more than 600 million people worldwide who suffer from asthma and other serious respiratory diseases. Patients and their care-givers have a strong interest in a smooth transition to CFC-free MDIs. We are therefore writing to request your support for Decision XI/15 establishing the TEAP recommended "Protocol transition framework" at the 11th Meeting of the Parties in Beijing.

A Protocol transition framework is now needed to provide predictability and assurance to all stakeholders. With the framework in place, healthcare professionals would know how much time they have to convert patients to the new products. It is vitally important that patients and physicians receive clear and consistent messages about the transition. For instance, making newly-approved CFC MDIs available to the patient community, while educating them on the need to transition, is confusing and counterproductive.

Given patient loyalty to existing products, gaining widespread patient familiarity with and confidence in new CFC-free products will require a systematic, cooperative effort on the part of healthcare professionals, pharmaceutical companies, and the government. The guidelines provided by a Protocol transition framework would greatly bolster stakeholder efforts to facilitate the completion of the transition.

As you know, the Technology and Economic Assessment Panel has recommended the adoption of such a transition framework to underpin national transition strategies and ensure that they are complementary. The transition framework recommended by TEAP in its April 1998 and 1999 Reports includes measures for (i) ceasing the introduction of new CFC-containing products, (ii) making availability of

essential use allowances contingent upon active pursuit of CFC-free alternatives, (iii) specifying a goal for completing the transition, (iv) ensuring a continuous supply of MDIs to Article 5(1) Parties, and (v) prudent management of strategic CFC reserves. At the 19th Meeting of the Open-Ended Working Group in June 1999, the delegates forwarded for consideration by the Parties draft decision XI/15 incorporating the recommendations of TEAP concerning a transition framework.

We urge the Parties to adopt Decision XI/15 establishing a Protocol transition framework consistent with the TEAP recommendations. We stand ready to work with you further on this important issue. Together we can achieve our commonly shared goals of protecting the health of respiratory disease patients and the environment in which they live.

Very truly yours,

Allergy and Asthma Network/Mothers of Asthmatics, Inc.
2751 Prosperity Avenue, Suite 150
Fairfax, Virginia 22031
By: Nancy J. Sander, President

American Academy of Allergy, Asthma and Immunology
611 East Wells Street
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By: James Kemp, President

American College of Allergy, Asthma and Immunology
85 West Algonquin Road, Ste. 550
Arlington Heights, Illinois 60005
By: Robert Miles, President

American Lung Association
1726 M Street, N.W., Suite 902
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By: Fran Du Melle, Deputy Managing Director

American Thoracic Society
1740 Broadway
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By: Carl Booberg, Executive Director

Asthma and Allergy Foundation of America
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Washington, DC 20036
By: Mary Worstell, Executive Director

Cystic Fibrosis Foundation
6931 Arlington Road
Bethesda, Maryland 20814
By: Robert J. Beall, President & CEO

Joint Council of Asthma, Allergy and Immunology
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Weston, Massachusetts 02193
By: Albert Sheffer

cc:

Mr. K.M. Sarma
Executive Secretary
The Secretariat for the Vienna Convention and the Montreal Protocol

Dr. Stephen O. Andersen
Co-Chair
Technology and Economic Assessment Panel

Dr. Suely Maria Machado Carvalho
Co-Chair
Technology and Economic Assessment Panel

Dr Lambert Kuijpers
Co-Chair
Technology and Economic Assessment Panel

Mr. Jose Pons Pons
Co-Chair
Aerosols, Sterilants, Miscellaneous Uses and CTC Technical Options Committee

Dr. Helen Tope
Co-Chair
Aerosols, Sterilants, Miscellaneous Uses and CTC Technical Options Committee

Dr. Ashley Woodcock
Co-Chair
Aerosols, Sterilants, Miscellaneous Uses and CTC Technical Options Committee

ALLERGY AND ASTHMA NETWORK/MOTHERS OF ASTHMATICS, INC.

By: [signature]
Name: Allergy & Asthma Network
Title: PRESIDENT

AMERICAN ACADEMY OF ALLERGY, ASTHMA AND IMMUNOLOGY

James P. Kemp, MD FAAAAI
President, AAAAI

AMERICAN COLLEGE OF ALLERGY, ASTHMA AND IMMUNOLOGY

By: Robert M Miles

Name: ROBERT M. MILES, M.D

Title: PRESIDENT

Mktg Assn.

AMERICAN ~~TRADE SOCIETY~~

By: [signature]
Name: Ron De Nelle
Title: Deputy Managing Director

AMERICAN ~~LUNG ASSOCIATION~~ Thoracic Society

By: Carl Boorberg
Name: Carl Boorberg
Title: Executive Director

ASTHMA AND ALLERGY FOUNDATION OF AMERICA

By: Mary E. Oberstar

Name: MARY E. OBERSTAR, MPH

Title: EXECUTIVE DIRECTOR

CYSTIC FIBROSIS FOUNDATION

By: _____

Name: _____

Title: _____

JOINT COUNCIL OF ASTHMA, ALLERGY & IMMUNOLOGY

By: Clifford L Sheffer

Name: _____

Title: _____

Congress of the United States

Washington, DC 20515

November 5, 1999

Madeleine K. Albright
Secretary of State
Department of State
2201 C Street, N.W.
Washington, D.C. 20520

Dear Secretary Albright:

As you know, the 11th Meeting of the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer will convene November 29, 1999. At that meeting, the Parties will consider a proposed decision put forward by Costa Rica ("Decision XI/15") that seeks to facilitate the transition to CFC-free metered-dose inhalers (MDIs). With the exception of two unacceptable provisions noted below, we believe that this decision would serve the goals of the Montreal Protocol while protecting patients that use MDIs. We therefore urge the U.S. delegation to the 11th Meeting to actively seek adoption of this decision with the two changes noted below.

First, the second preambular sentence in the decision refers to a prediction by the Protocol's Technology and Economic Assessment Panel (TEAP) that "by the year 2005, there will be minimal need for CFCs for metered-dose inhalers in [developed country] Parties". As it is written, this paragraph could be interpreted as signaling that the transition must be completed in developed counties by that date. However, the 1999 TEAP Report caveats its assessment by stating that "[r]emaining technical, patent, safety, and regulatory issues for some commonly used drugs still make it difficult to predict the schedule for full phaseout with precision." Therefore, the second preambular paragraph in Decision XI/15 should be deleted, or at a minimum, revised to reflect this uncertainty in predicting the completion of the transition in developed countries.

Second, paragraph 2(b)(i) of Decision XI/15 would establish, as a condition of essential use status, that the company requesting essential use CFC quantities must demonstrate that it is "actively pursuing research and development for CFC-free alternatives for its products . . . ." However, the judgment as to the adequacy of a company's R&D program should be left for national authorities -- not ceded to an international body. A prior Protocol decision already contains an "active pursuit" provision, which obligates Parties to request that companies show that they are

conducting R&D on non-CFC alternatives "with all due diligence" (see Decision VIII/10 par. 1). That provision in Decision VIII/10 -- unlike paragraph 2(b)(i) in proposed Decision XI/15 -- puts the locus for the assessment where it should be, at the national level. Therefore, paragraph 2(b)(i) in proposed Decision XI/15 should be deleted.

As noted at the outset, we believe that, with the exception of the two provisions noted above, Decision XI/15 is sound. We therefore urge the U.S. delegation to seek the two changes discussed above prior to and during the negotiations, and to actively support adoption of Decision XI/15 by the 11th Meeting of the Parties.

Thank you very much for your consideration and attention to this matter.

Sincerely,

Michael Bilirakis
Chairman, Health and
Environment Subcommittee

John D. Dingell
Ranking Member
Committee on Commerce

Richard M. Burr
Member of Congress

Ron Klink
Ranking Member
Oversight and Investigations

Clifford Stearns
Member of Congress

Chris Smith
Member of Congress

Mark Foley
Member of Congress

Patrick Kennedy
Member of Congress

cc: Carol M. Browner, Esq.
Administrator
Environmental Protection Agency
Room 1200 ST/1101
401 M Street, S.W.
Washington, D.C. 20460

Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

George Frampton
Chairman of the Council on Environmental Quality
Old Executive Office Building
17th Street and Pennsylvania Avenue, N.W.
Washington, D.C. 20510

EDWARD M. KENNEDY
MASSACHUSETTS

United States Senate

WASHINGTON, DC 20510-2101

December 1, 1999

Madeleine K. Albright
Secretary of State
Department of State
2201 C Street, N.W.
Washington, D.C. 20520

Dear Madeleine:

I'm writing in connection with the 11th Meeting of the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer, which convened earlier this week. The Parties are considering a decision (Decision XI/15) that will facilitate a phase-out of chlorofluorocarbons used in metered-dose inhalers (MDIs) while protecting patient health.

I believe that Decision XI/15 is a well thought out proposal that has wide support from the entire spectrum of those interested in this issue. The Decision has the support of major respiratory physician and patient organizations (see Attachment 1). In addition, environmentalists and MDI manufacturers, including the two largest generic MDI producers, support adoption of the Decision (see Attachments 2 and 3). My colleagues in the House (see Attachment 4) have urged the U.S. delegation to seek two changes to Decision XI/15 and actively support its adoption at the 11th Meeting of the Parties.

It is clearly our obligation to serve the needs of patients who rely on MDIs to breathe. Full and active support of their request for adoption of the Decision at this current Montreal Protocol meeting is essential. I join my colleagues in the House and urge the U.S. delegation to actively support Decision XI/15.

Respectfully,

Edward M. Kennedy

cc: Jane Henney, Commissioner, FDA
Carol M. Browner, Administrator, EPA
George Frampton, Chairman, Council on Environmental Quality

BY HAND AND FACSIMILE

November 16, 1999

Ms. Carol M. Browner
Administrator
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Mr. George T. Frampton, Jr.
Chair, Council on Environmental Quality
722 Jackson Place, N.W.
Washington, D.C. 20503

Re: Adoption of Decision XI/15 at the Eleventh Meeting of the Parties to the Montreal Protocol on Substances That Deplete the Ozone Layer

Dear Ms. Browner and Mr. Frampton:

Later this month, the parties to the Montreal Protocol on Substances That Deplete the Ozone Layer ("Protocol") will be meeting in Beijing, China to consider a number of important measures to reduce the use of chemicals that deplete the ozone layer. While many of the undersigned organizations have previously contacted the administration or other Protocol parties about these initiatives, we are now writing as a group to urge the U.S. delegation to this meeting to support adoption of Decision XI/15. That Decision would establish additional criteria and a tighter framework for phasing-out the use of chlorofluorocarbons ("CFCs") in metered dose inhalers ("MDIs").

Specifically, Decision XI/15 would, among other things, limit the conditions under which CFCs can be granted for any new MDI products. The Decision would also require each company seeking the production of CFCs for MDIs to demonstrate that it is actively pursuing development of CFC-free alternatives. These additional requirements would strengthen the existing criteria governing allocation of CFCs for MDIs under the Protocol, which were adopted by the Protocol parties in 1992 (Decision IV/25) and revised in 1996 (Decision VIII/10). Although some administration officials contend that Decision XI/15 adds nothing new to the existing scheme and they appear ready to oppose this measure, we believe that this Decision is vitally important to achieving the objectives of the Protocol.

Indeed, Decision XI/15 would not only expedite the phase-out of CFCs in MDIs -- it would establish a transition framework that provides predictability to patients who use MDIs and physicians that prescribe such drugs. For this reason, virtually all of the major patient groups and medical organizations concerned with asthma and other respiratory diseases have expressed their strong support for Decision XI/15. As you will see from the attached letter, these organizations are troubled by the current regulatory scheme, which subjects patients to substantial confusion and involves interim switches to new CFC-containing MDIs that provide no new therapeutic advance over existing products.

On a broader policy level, we believe that opposition to Decision XI/15 will inevitably make it more difficult for the United States to press other parties to eliminate production of CFCs and other ozone depleting substances. The quantity of CFCs that the United States seeks for MDIs each year actually exceeds the amount of CFCs used by perhaps as many as one hundred developing countries. If the U.S. delegation resists measures to phase-out the use of CFCs for MDIs, it will be in a weak position to object to requests from other countries to continue their use of even smaller quantities of ozone depleting substances. Of course, the cumulative impacts of such actions will further delay the recovery of the ozone layer.

Accordingly, we strongly urge you to ensure that the United States supports adoption of Decision XI/15 at the forthcoming meeting of the Protocol parties.

Sincerely,

Annie Petsonk
International Counsel
Environmental Defense Fund

Jessica Vallette Revere
Atmosphere Campaign Director
Friends of the Earth

Dan Lashoff
Senior Scientist
Natural Resources Defense Council

Christopher Ball
Director of Outreach
Ozone Action

Karen Hopfle-Harris
Associate Director for Policy
Physicians for Social Responsibility

Kenneth A. Cook
President
Environmental Working Group

Joseph Mendelson
Legal Director
International Center for Technology Assessment

Enclosure: as stated

copies: Charles Burson, Office of the Vice-President
Robert Perciasepe, EPA
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Drusilla Hufford, EPA
Paul Horwitz, EPA
Ian Bowles, CEQ
Frank Loy, Department of State
David Sandalow, Department of State