United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

DATE 11-30-99 TIME 7 06

NUMBER OF PAGES TO FOLLOW_____

FAX TO Chris Jennings 456-5557

TELEPHONE NUMBER_____

FAX NUMBER_____

OFFICE_____

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FAX FROM David Sandalow

TELEPHONE NUMBER_____

FAX NUMBER_____

OFFICE_____

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MESSAGE: FYI

MDI Intervention

- Thank Costa Rica for well intentioned proposal.

- However, as we view certain aspects of the proposal, we have concerns that it may impede, rather then promote the thoughtful and effective transition to ODS free MDIs in our country.

- While we would have some comments on a number of provisions, we have particular concerns regarding provisions 2(a)(i), 2(b)(ii), 2(b)(i) (insert 2 provision #s)

- While it may not seem so on its face, these two provisions relate to, and could have a significant impact on the continued and future availability of low cost generic drugs which are essential in many countries to meet the needs of poorer members of our society.

- In that regard, we believe the words of the TEAP are very instructive. On page 151 of their report, Volume 2 of they note the following:

> A final subgroup which may have a compelling need for CFC products well into the phaseout is the low income patient (whether in Article 5(1) or non-Article 5(1) Countries)

TEAP then goes on to say in that paragraph:

"The Parties may wish to consider the impact of restricted access to generic or locally branded products which may occur as a result of the transition. Such considerations may need to be included in the formulation of a parties national transition strategy

We agree entirely. We understand that parties are carefully considering this issue in the context of their own transition strategies, and thereby, in the context of their own systems.

We believe this is critical, given the key differences in many systems. As just 1 example of those differences, we would ~~redacted~~ point to pages 133-136 of volume 2 of the TEAP report. Those pages note the cost of MDIs in various countries. Specifically relevant to us, they show that while at that time a ~~redacted~~ Salbutamol MDI in ~~redacted~~ the EU cost $2.86, in the US, the generic ~~redacted~~ of the same MDI costs $20, and the branded MDI even more. Because of that, we agree with the TEAP that the considerations on generics should be included "in the formulation of a party's national transition strategy." Accordingly, we could not, at the meeting this year, agree to these two provisions, as they would need much more consideration in our own context

In addition to those provisions, Mr. Chairman, we do have some concern regarding the Chapeau which notes, as the TEAP does, that that body believes that there will be minimal need for CFCs for MDIs by 2005 in non-A5 parties. Indeed, this body has said this before; however, we believe that it is also important to add the next sentence on page 125 to put the prior sentence in the appropriate context. That sentence says:

> "Remaining technical, patient, safety and regulatory issues for some commonly used drugs still make it difficult to predict the schedule for full phaseout with precision."

Thank you

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

DATE 12/1/99 TIME 5:50

NUMBER OF PAGES TO FOLLOW 1

FAX TO Chris Jennings

TELEPHONE NUMBER 456-5540

FAX NUMBER 456-5557

OFFICE

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FAX FROM David Sandalow

TELEPHONE NUMBER 647-1554

FAX NUMBER 647-0217

OFFICE

****

MESSAGE: Letter to Secretary Albright from Sen. Kennedy.

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

JCAAI

Joint Council of Allergy, Asthma and Immunology

50 N. [illegible] St.
Suite [illegible]
Pe[illegible]
847[illegible]
FAX [illegible]

December 2, 1999

MEMORANDUM via facsimile

Mr. Christopher C. Jennings
Deputy Assistant to the President for
Health Policy Development
Office of Policy Development
Executive Office of the President
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. Jennings:

It was a pleasure to speak to you yesterday. I was pleased that we are both in agreement that new delivery systems for chloroflurocarbons (CFC)-alternative metered dose inhalers (MDI) must be made affordable and competitively priced with the CFC MDIs. However, as a signed member to the Montreal Protocol, it is also our responsibility to ensure the safe transition of the CFC phase-out.

It was rumored that the Administration was going to "renig" on their position to support Decision XI/15 establishing the TEAP recommended "protocol transition framework," – the Costa Rican agreement. Pursuant to the FDA Proposed Rule related to the phase-out of CFCs in MDIs, the FDA would require supply- and cost-equivalence in at least one alternative product prior to labeling a drug product "non-essential." By allowing the approval of generic formulations of CFC MDIs, there will be a CFC phase-out in name only.

It should be the priority of the Administration, to protect and enhance the treatment of the more than 600 million people worldwide who suffer from asthma and other serious respiratory diseases. I believe a smooth transition to CFC-free MDIs would include the TEAP recommended protocol for transition framework previously supported by the White House. I urge the Administration to reconsider and adopt Decision XI/15.

Once again, it was kind of you to take the time to discuss this matter with me, and I look forward to joining the other Stakeholders in discussing this with you in the upcoming meeting you indicated you would be hosting.

Thank you very kindly.

Sincerely,

Albert R. Sheffer | WHG

Albert Sheffer, M.D.
Joint Council of Asthma, Allergy and Immunology
Member, UN-TOC
Chairman, NHLBI/NAEPPCFC Transition Committee

cc: Carol M. Browner

UNITED STATES SENATE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510-6300

JAMES M. JEFFORDS, VERMONT, CHAIRMAN

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PAUL D. WELLSTONE, MINNESOTA
PATTY MURRAY, WASHINGTON
JACK REED, RHODE ISLAND

DATE: 12/1/99

TO: Chris Jennings

FAX: 456-5557

FROM: Senator Kennedy's Office
(202) 224-7675 phone
(202) 224-3533 fax

NUMBER OF PAGES: 12

MESSAGE:

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

Attachment 1

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
Milwaukee, Wisconsin 53202
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
Washington, DC 20036
By: Fran Du Melle, Deputy Managing Director

American Thoracic Society
1740 Broadway
New York, New York 10019
By: Carl Booberg, Executive Director

Asthma and Allergy Foundation of America
1233 20th Street, NW, Suite 402
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
26 Juniper Road
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

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
GlaxoWellcome
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Norton Healthcare Ltd.
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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.

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-Hardis
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
Paul Stolpman, EPA
Drusilla Hufford, EPA
Paul Horwitz, EPA
Ian Bowles, CEQ
Frank Loy, Department of State
David Sandalow, Department of State

Attachment 4

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

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

DATE_____ TIME_____

NUMBER OF PAGES TO FOLLOW 4

FAX TO Chris Jennings 456-5557

TELEPHONE NUMBER_____

FAX NUMBER_____

OFFICE_____

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FAX FROM David Sandalow

TELEPHONE NUMBER_____

FAX NUMBER_____

OFFICE_____

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MESSAGE:

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:

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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

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RICHARD D. SIEGEL

OF COUNSEL
MICHELE F. CROWN
JUR. STROBOS, M.D.

November 30, 1999

FACSIMILE TRANSMISSION

TO: Mr. Christopher C. Jennings
Deputy Assistant to the President for Health Policy Development
Office of Policy Development

COMPANY: The White House

FAX: 456-5557

FROM: Marshall L. Matz

RE:

REMARKS:

THE TOTAL NUMBER OF PAGES INCLUDING THIS PAGE IS 3. IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL MY OFFICE.

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+ADMITTED IN OKLAHOMA ONLY
*ADMITTED IN NEW YORK ONLY

November 30, 1999

BY TELECOPY

Mr. Christopher C. Jennings
Deputy Assistant to the President
for Health Policy Development
Old Executive Office Building - Room 216
17th Street & Pennsylvania Avenue, N.W.
Washington, D.C. 20503

Dear Chris:

I am writing on behalf of the National Association of Pharmaceutical Manufacturers (NAPM), a national generic drug trade association. NAPM is concerned about proposals put forward by the government of Costa Rica at discussions in Beijing, China regarding chlorofluorocarbon (CFC) allocations. Specifically, NAPM is concerned about the impact such discussions could have on the availability of generic versions of metered-dose inhalers.

We understand that the Costa Rican proposals would only permit approval of generic metered-dose inhalers if the generic versions of those products are (1) therapeutically superior to the brand name product or (2) demonstrated to meet a previously unmet medical need.

Such proposals are of particular concern because they would effectively prevent any generic metered-dose inhalers from coming to market. As you know, the first proposal defines a non-existing category, since by definition generics are the same as the branded product for which they substitute. The second proposal would be very difficult to implement, and it overlooks the fundamental point – generic versions of metered dose inhalers do not represent an expanded use of CFCs. They merely substitute for expensive branded products.

We would appreciate your assistance in assuring that efforts to control CFC emissions are not transformed into a competitive barrier for generic drug manufacturers.

With best wishes for a Happy Holiday,

I am,

Marshall L. Matz
Counsel, National Association of
Pharmaceutical Manufacturers

MLM:klc

Chris -
Thanks for your attention to this issue.

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.

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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.

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Old Executive Office Building
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Washington, D.C. 20510

DRAFT

A proposed decision on CFC-bearing drugs has been forwarded by Costa Rica for consideration at the 11th Meeting of the Parties to the Montreal Protocol (November 29-December 3, Beijing). We have received strong letters of support for this proposal from a broad spectrum of widely respected groups representing patients, doctors and industry. We have also received a draft letter from Congressman Bilirakis which strongly supports the Costa Rica proposal, and there are indications that a final letter with the signatures of a number of key Congressmen will be forthcoming shortly. The clear implications of the decision, if agreed as requested by these normally disparate groups, could affect the cost and/or availability of drugs in the marketplace.

Background

The Montreal Protocol, as ratified by the Senate, requires all countries to eliminate all production and consumption of CFCs, save for their use in applications agreed by all Parties to be essential. Since the 1996 developed country phase out of CFCs, only one CFC use has been agreed by the Parties to be exempt because of its essentiality - that for metered dose inhalers (MDIs) for asthma and certain heart diseases. In accordance with Protocol requirements, each year the U.S., the EU and a few other countries must put forward a request to the Parties to have specific MDI uses exempted from the Protocol's complete phase out requirement. These requests are reviewed in detail by the Protocol's technical experts, who then make a recommendation to the Parties. For the last five years, the U.S. MDI exemption requests have been granted by the Parties, although with increasing levels of scrutiny. To put the U.S. MDI request in perspective, the amount of the exemption (about 3000 tonnes/year) represents about 1% of our 1986 level of CFC use in the U.S. However, 3000 tonnes also represents the total for all combined uses of CFCs in over 30 African countries - all of which are required by the Protocol to phase out their use.

Understanding that CFCs will eventually be banned from MDI use, U.S. drug companies have been working hard - and spending large amounts of money - to develop CFC-free alternatives. This work has, on its face, often coincided with patent term conclusions. Nevertheless, these companies can be viewed as acting in good faith as good corporate citizens to meet an agreed-upon environmental goal. Now that their development processes are far advanced, they generally believe the transition to CFC free alternatives is taking too long. Many Protocol Parties feel the same way. In an effort to advance the elimination of this last remaining use, most developed countries have been working on the development of transition strategies to phase out the use of CFCs in MDIs as required by the Protocol. The EU, Canadian and Australian plans tend to be aggressive. They generally envision a phase out in the next five years, and strongly discourage or explicitly ban the introduction of new generic drugs. The U.S. plan proposed by FDA is less aggressive, and seeks to be "responsive to, rather than facilitate, the phase out." The proposed FDA rule is silent on the issue of new generic drugs. As a result, in practice, new generics would not be excluded from the market place.

Costa Rica Proposal

With the clear assistance of an international consortium of pharmaceutical companies (IPAC), Costa Rica has put forward a proposal that has many components. The key component discussed here would require that:

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> A Party should not find essential any new drug product using CFCs if that product was approved by the Party's national health authority after the Eleventh Meeting of the parties (December 3, 1999), "unless that authority has determined that the product will serve an otherwise unmet medical need." (Non-quoted portions are paraphrased.)

We believe that IPAC support for the Costa Rican proposal stems from a belief that it would prevent the introduction of new generics into the market. Their interest in this point can be seen as protecting both competitive interests, and arguably environmental interests. We say arguably, because it is possible that once the threat of generic competition is removed, the IPAC companies may have less incentive to quickly commercialize CFC-free alternatives. IPAC disputes this, noting that they are spending huge amounts of R&D dollars during CFC-free product development, and have a strong incentive to commercialize as soon as possible, to recoup some of these costs. Regardless of IPACs motivations or incentives, groups like the American Lung Association also support this provision, because they fear that if new generics are allowed on the market, their use will proliferate, complicating the eventual phase out of CFC drugs. In supporting the Costa Rican decision "which would serve the goals of the Montreal Protocol while protecting patients that use MDIs," those Congressmen who sign on to the expected letter also apparently support this provision.

More recently IPAC has apparently come to realize that the language in Costa Rica's proposal may not in fact keep generics out of the market. That is because FDA could conclude that generics would, under the terms of the proposed decision, "serve an otherwise unmet medical need" by providing low cost drugs to poorer patients. As a consequence, IPAC has recently been promoting language that would allow new drug introductions only if the new products would provide "a significant therapeutic advance." This language would clearly exclude generic MDIs while allowing for the possibility that, for example, a future cancer or AIDS formulation might require the use of CFCs. While the letter from doctor and patient groups is more general, the draft letter of support received from the Hill indicates support for the Costa Rica provision as it now stands, without reference to any fix that IPAC may support.

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Options for Consideration

Option 1. Approve the no new CFC-based MDI provision as currently contained in the Costa Rica proposal

Primary public argument - The Montreal Protocol, as agreed to by the U.S. and ratified by the Senate, requires a total phase out of CFCs, including those used in MDIs. A coherent public policy requires that in pursuit of an obligation to phase out CFCs, we not allow unnecessary new uses of CFCs. In taking this decision, we have the support of medical and user groups, as well as key members of Congress. We also advance environmental goals while ensuring that patients continue to have access to existing products until FDA has determined that safe and effective CFC-free alternatives exist. We will continue to aggressively seek and obtain exemptions for existing CFC based MDIs until such alternatives are available.

Pros:

This provision may keep new CFC-based MDIs off of the market. By halting the proliferation of CFC-based MDIs, it may advance our goal of reducing, and then eliminating the use of CFCs in MDIs. It could also decrease the aggrieved constituency that might express concern when, inevitably, all CFC-based drugs will have to be taken off of the market to comply with the Montreal Protocol.

Cons:

The language as proposed by Costa Rica may not prevent the introduction of new CFC-based generics. That is because it could allow FDA to advance new generics by finding that generics represent an unmet medical need by virtue of price (about 20% cheaper than currently available MDIs). If this should happen, and the U.S. advanced an essential use request to the Parties for a new generic based on this interpretation, the Parties (including the EU and other countries who have banned new generics) could reject it, finding cost an unacceptable factor to consider in granting an exemption. Further, it is possible that to achieve their desired goal of stopping the introduction of new generics, the IPAC companies would stimulate this opposition by other countries. In that regard it is important to note that in accordance with the Protocol rules, it takes the consensus of all countries to approve an essential use exemption - one country can block consensus. If, on the other hand, the provision does keep new generics off the market, related stakeholders could argue that the U.S. was taking low-cost drugs away from patients. Related stakeholders may include representatives of generic companies that may have been preparing to enter the market when the next MDI drug went off patent (as early as mid-December of this year), or political advocates seeking to discredit others on health care issues.

Option 2. Approve a tightened version of the no new CFC-based MDI language (eg: New MDI products would not be exempt unless the represent a significant therapeutic advance).

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Primary public argument: Same as for option 1

Pros:

Same as for option 1 - except the goal is accomplished, and the constituencies who are pressing us on this issue would presumably be thankful.

Cons:

Aggrieved stakeholders could argue that by taking this decision, the U.S. and/or the UN was taking away low cost drugs from poor patients. Related stakeholders may include representatives of generic companies that may have been preparing to enter the market when the next MDI drug went off patent (as early as mid-December of this year), or other political advocates seeking to discredit others on health care issues.

Option 3. Defer a decision on the new CFC-based MDI issue

Primary public argument: We are concerned about the potential impact that this decision may have on both the availability of low cost drugs to needy patients, and the disincentives it may provide to quickly commercialize CFC-free drugs. Accordingly, we need additional time to discuss these issues with key stakeholders.

Pro:

Allows for additional time to understand the full implications of the decision, and come to a common understanding with a broader group of stakeholders.

Con:

New generics could enter the market. If this were to happen, they create a vocal constituency that will be aggrieved when CFC-based MDIs are taken off of the market. If our next essential use request includes a request for these new generics (low probability - more likely in 2001), the Parties could oppose it, creating a perception that the UN was stopping the use of cheap drugs in the U.S. U.S. pharmaceutical companies who have been striving to commercialize alternatives could slow down or stop their investments based on an already articulated belief that if we are unwilling to stop new CFC based MDIs, we will not have the will to remove existing MDIs from the market.

Option 3b. During the period between Montreal Protocol meetings, work with FDA to develop a domestic policy to ensure that any new generics only address poorer users with needs that are currently unmet due to the high price of branded drugs. (In theory, this could be accomplished through production quotas and/or sunset provisions on new drug licenses.)

Primary Public Argument: We are balancing the protection of the environment with legitimate needs of asthma patients, protecting the ozone layer while at the same time preserving the interests of poorer patients who currently lack access to affordable drugs during the transition.

Pro: Could avoid the argument that we were taking away low cost drugs from poor people Would likely be acceptable to the interests pushing for the Costa Rica decision.

Con: May not be implementable within the current framework of FDA legal requirements. Could create the argument that FDA is stopping all consumers from benefitting from low cost drugs, and in the process, ensuring the market share of large pharmaceutical companies who are charging higher prices..

Groups

Lung Assn

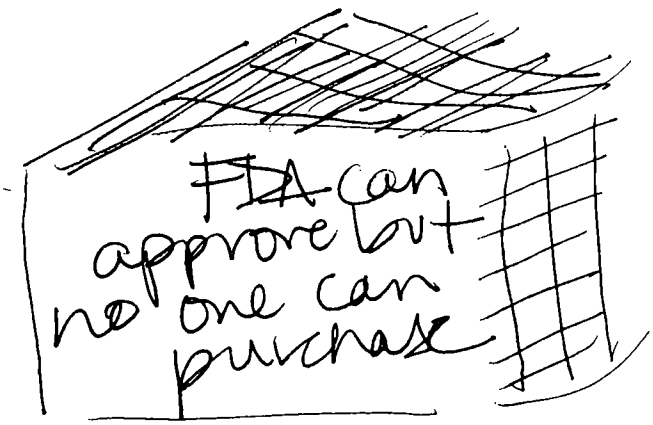
Cystic Fibrosis

Asthma groups

Congress

Hatch

Waxman



FDA

should approve b/c ① generic drugs lower hc costs (general benefit) ant-pollution these cause are infinitesimal; ② pts can't afford hc drug. not millions, but 10s of thous.

one non CFC propellant, but ~~FDA~~ is not forever more

IPAC

INTERNATIONAL PHARMACEUTICAL AEROSOL CONSORTIUM

1301 K Street NW • Suite 900 • East Tower • Washington DC • 20005-3317
Telephone +1 202 408 7189 • Telefax +1 202 289 1504
Internet: http://www.ipacmdi.com

20 October 1999

The Honorable Michael Bilirakis
Chairman, Subcommittee on Health and Environment
United States House of Representatives
2369 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Bilirakis:

As you may know, the 11th Meeting of the Parties to the Montreal Protocol will be held November 29 - December 3 in Beijing, China. At this meeting, the Parties will be considering proposed Decision XI/15 to facilitate the transition for CFC metered-dose inhalers (MDIs) used in the treatment of asthma and other serious respiratory disease.

I am pleased to provide you with a copy of IPAC's position statement for the 11th Meeting. Our position statement urges the Parties to adopt Decision XI/15 incorporating the recommendations of the Technology and Economic Assessment Panel regarding the ongoing transition to CFC-free MDIs.

This Decision will add important elements necessary to ensure the transition is protective of patients, while providing flexibility for each Party to implement national strategies based on their unique regulatory, economic and heath-care requirements. It will also help to ensure that CFC MDIs currently marketed in the U.S. remain available for patients while the U.S. national strategy is progressed and implemented by FDA.

IPAC is an association of leading manufacturers of MDIs worldwide. Our position statement for the 11th Meeting reflects the consensus view of our Consortium of research-based and generic MDI companies and is supported by each of its members: AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, Glaxo Wellcome, Medeva Americas, Inc., Norton Healthcare Ltd., Rhône-Poulenc Rorer Inc., and 3M Pharmaceuticals.

This Decision is also endorsed by all the major medical and patient organizations involved in asthma and respiratory disease. See attached letter.

We respectfully urge you to convey your support for this Decision to the U.S. delegation to the 11th Meeting.

I would be pleased to answer any questions you may have about IPAC or its position statement. My telephone number is 202-408-7189.

Sincerely,

Ballard Jamieson, Jr.
Secretary and Legal Counsel

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-

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

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

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

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cc: Carol M. Browner, Esq.
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Jane Henney, M.D.
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Summary of FDA Notice of Proposed Rulemaking Published September 1, 1999
Use of Ozone-Depleting Substances; Essential Use Determinations

(Based on a Presentation to the CFC (Chloroflourocarbon) Stakeholder's Meeting, September 30, 1999 given by Robert Meyer, MD, Director Division of Pulmonary and Allergy Drug Products, CDER/FDA)

- **Overview of FDA's Proposed Transition Strategy**
  - * Define acceptable alternatives to CFC-based metered-dose inhalers (MDIs): alternate propellants MDIs, multidose dry powder inhalers, others
  - * Monitor availability of alternatives for each drug product/class
  - * Define criteria that have to be met to make determinations of products no longer being "essential"
  - * As CFC-free alternatives become available and prove to be medically acceptable, evaluate continuing essentiality of existing CFC MDIs
  - * Modify existing FDA regulations that confer essentiality on CFC products to allow for determination of non-essentiality
  - * Allow adequate times for public input
  - * Involve the Advisory committees where appropriate
  - * Work with Environmental Protection Agency (EPA) and other interest groups to coordinate efforts

- **FDA NPR Summary**
  - * Revises 21 CFR 2.125 (Regulation which lists "essential" medical products) to list individual moieties
  - * Adds provision for IND (Investigational New Drug) use of CFCs with high standards
  - * Modifies criteria for new uses of CFCs to "raise the bar"
  - * Essentiality Criteria
    - At least one non-ODS (ozone depleting substance) product with the same active moiety, the same indication, route of administration, about the same level of convenience
    - At least 1 year of post-marketing data is available for the non-ODS product
    - Production capabilities and supplies are adequate
    - Patients who require the CFC product are adequately served
  - * Essentiality Criteria for moieties with more than one available product/strength:
    - At least 2 non-ODS products with the same active moiety, the same indication, route of administration, about the same level of convenience
    - Other criteria are the same
  - * The rule proposes to remove essential use listings for the following:
    - Products that are no longer marketed
    - Nasal corticosteroid
    - Beginning anytime after January 1, 2005, FDA can institute a review of the market and remove products without an ODS-moiety alternative if all other criteria are met (i.e., patients are adequately served by the marketed

alternatives)

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A proposed decision on CFC-bearing drugs has been forwarded by Costa Rica for consideration at the 11th Meeting of the Parties to the Montreal Protocol (November 29-December 3, Beijing). We have received strong letters of support for this proposal from a broad spectrum of widely respected groups representing patients, doctors and industry. We have also received a draft letter from Congressman Bilirakis which strongly supports the Costa Rica proposal, and there are indications that a final letter with the signatures of a number of key Congressmen will be forthcoming shortly. The clear implications of the decision, if agreed as requested by these normally disparate groups, could affect the cost and/or availability of drugs in the marketplace.

Background

The Montreal Protocol, as ratified by the Senate, requires all countries to eliminate all production and consumption of CFCs, save for their use in applications agreed by all Parties to be essential. Since the 1996 developed country phase out of CFCs, only one CFC use has been agreed by the Parties to be exempt because of its essentiality - that for metered dose inhalers (MDIs) for asthma and certain heart diseases. In accordance with Protocol requirements, each year the U.S., the EU and a few other countries must put forward a request to the Parties to have specific MDI uses exempted from the Protocol's complete phase out requirement. These requests are reviewed in detail by the Protocol's technical experts, who then make a recommendation to the Parties. For the last five years, the U.S. MDI exemption requests have been granted by the Parties, although with increasing levels of scrutiny. To put the U.S. MDI request in perspective, the amount of the exemption (about 3000 tonnes/year) represents about 1% of our 1986 level of CFC use in the U.S. However, 3000 tonnes also represents the total for all combined uses of CFCs in over 30 African countries - all of which are required by the Protocol to phase out their use.

Understanding that CFCs will eventually be banned from MDI use, U.S. drug companies have been working hard - and spending large amounts of money - to develop CFC-free alternatives. This work has, on its face, often coincided with patent term conclusions. Nevertheless, these companies can be viewed as acting in good faith as good corporate citizens to meet an agreed-upon environmental goal. Now that their development processes are far advanced, they generally believe the transition to CFC free alternatives is taking too long. Many Protocol Parties feel the same way. In an effort to advance the elimination of this last remaining use, most developed countries have been working on the development of transition strategies to phase out the use of CFCs in MDIs as required by the Protocol. The EU, Canadian and Australian plans tend to be aggressive. They generally envision a phase out in the next five years, and strongly discourage or explicitly ban the introduction of new generic drugs. The U.S. plan proposed by FDA is less aggressive, and seeks to be "responsive to, rather than facilitate, the phase out." The proposed FDA rule is silent on the issue of new generic drugs. As a result, in practice, new generics would not be excluded from the market place.

Costa Rica Proposal

With the clear assistance of an international consortium of pharmaceutical companies (IPAC), Costa Rica has put forward a proposal that has many components. The key component discussed here would require that:

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> A Party should not find essential any new drug product using CFCs if that product was approved by the Party's national health authority after the Eleventh Meeting of the parties (December 3, 1999), "unless that authority has determined that the product will serve an otherwise unmet medical need." (Non-quoted portions are paraphrased.)

We believe that IPAC support for the Costa Rican proposal stems from a belief that it would prevent the introduction of new generics into the market. Their interest in this point can be seen as protecting both competitive interests, and arguably environmental interests. We say arguably, because it is possible that once the threat of generic competition is removed, the IPAC companies may have less incentive to quickly commercialize CFC-free alternatives. IPAC disputes this, noting that they are spending huge amounts of R&D dollars during CFC-free product development, and have a strong incentive to commercialize as soon as possible, to recoup some of these costs. Regardless of IPACs motivations or incentives, groups like the American Lung Association also support this provision, because they fear that if new generics are allowed on the market, their use will proliferate, complicating the eventual phase out of CFC drugs. In supporting the Costa Rican decision "which would serve the goals of the Montreal Protocol while protecting patients that use MDIs," those Congressmen who sign on to the expected letter also apparently support this provision.

More recently IPAC has apparently come to realize that the language in Costa Rica's proposal may not in fact keep generics out of the market. That is because FDA could conclude that generics would, under the terms of the proposed decision, "serve an otherwise unmet medical need" by providing low cost drugs to poorer patients. As a consequence, IPAC has recently been promoting language that would allow new drug introductions only if the new products would provide "a significant therapeutic advance." This language would clearly exclude generic MDIs while allowing for the possibility that, for example, a future cancer or AIDs formulation might require the use of CFCs. While the letter from doctor and patient groups is more general, the draft letter of support received from the Hill indicates support for the Costa Rica provision as it now stands, without reference to any fix that IPAC may support.

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Options for Consideration

Option 1. Approve the no new CFC-based MDI provision as currently contained in the Costa Rica proposal

Primary public argument - The Montreal Protocol, as agreed to by the U.S. and ratified by the Senate, requires a total phase out of CFCs, including those used in MDIs. A coherent public policy requires that in pursuit of an obligation to phase out CFCs, we not allow unnecessary new uses of CFCs. In taking this decision, we have the support of medical and user groups, as well as key members of Congress. We also advance environmental goals while ensuring that patients continue to have access to existing products until FDA has determined that safe and effective CFC-free alternatives exist. We will continue to aggressively seek and obtain exemptions for existing CFC based MDIs until such alternatives are available.

Pros:

This provision may keep new CFC-based MDIs off of the market. By halting the proliferation of CFC-based MDIs, it may advance our goal of reducing, and then eliminating the use of CFCs in MDIs. It could also decrease the aggrieved constituency that might express concern when, inevitably, all CFC-based drugs will have to be taken off of the market to comply with the Montreal Protocol.

Cons:

The language as proposed by Costa Rica may not prevent the introduction of new CFC-based generics. That is because it could allow FDA to advance new generics by finding that generics represent an unmet medical need by virtue of price (about 20% cheaper than currently available MDIs). If this should happen, and the U.S. advanced an essential use request to the Parties for a new generic based on this interpretation, the Parties (including the EU and other countries who have banned new generics) could reject it, finding cost an unacceptable factor to consider in granting an exemption. Further, it is possible that to achieve their desired goal of stopping the introduction of new generics, the IPAC companies would stimulate this opposition by other countries. In that regard it is important to note that in accordance with the Protocol rules, it takes the consensus of all countries to approve an essential use exemption - one country can block consensus. If, on the other hand, the provision does keep new generics off the market, related stakeholders could argue that the U.S. was taking low-cost drugs away from patients. Related stakeholders may include representatives of generic companies that may have been preparing to enter the market when the next MDI drug went off patent (as early as mid-December of this year), or political advocates seeking to discredit others on health care issues.

Option 2. Approve a tightened version of the no new CFC-based MDI language (eg: New MDI products would not be exempt unless the represent a significant therapeutic advance).

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Primary public argument: Same as for option 1

Pros:

Same as for option 1 - except the goal is accomplished, and the constituencies who are pressing us on this issue would presumably be thankful.

Cons:

Aggrieved stakeholders could argue that by taking this decision, the U.S. and/or the UN was taking away low cost drugs from poor patients. Related stakeholders may include representatives of generic companies that may have been preparing to enter the market when the next MDI drug went off patent (as early as mid-December of this year), or other political advocates seeking to discredit others on health care issues.

Option 3. Defer a decision on the new CFC-based MDI issue

Primary public argument: We are concerned about the potential impact that this decision may have on both the availability of low cost drugs to needy patients, and the disincentives it may provide to quickly commercialize CFC-free drugs. Accordingly, we need additional time to discuss these issues with key stakeholders.

Pro:

Allows for additional time to understand the full implications of the decision, and come to a common understanding with a broader group of stakeholders.

Con:

New generics could enter the market. If this were to happen, they create a vocal constituency that will be aggrieved when CFC-based MDIs are taken off of the market. IF our next essential use request includes a request for these new generics (low probability - more likely in 2001), the Parties could oppose it, creating a perception that the UN was stopping the use of cheap drugs in the U.S. U.S. pharmaceutical companies who have been striving to commercialize alternatives could slow down or stop their investments based on an already articulated belief that if we are unwilling to stop new CFC based MDIs, we will not have the will to remove existing MDIs from the market.

Option 3b. During the period between Montreal Protocol meetings, work with FDA to develop a domestic policy to ensure that any new generics only address poorer users with needs that are currently unmet due to the high price of branded drugs. (In theory, this could be accomplished through production quotas and/or sunset provisions on new drug licences.)

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Primary Public Argument: We are balancing the protection of the environment with legitimate needs of asthma patients, protecting the ozone layer while at the same time preserving the interests of poorer patients who currently lack access to affordable drugs during the transition.

Pro: Could avoid the argument that we were taking away low cost drugs from poor people Would likely be acceptable to the interests pushing for the Costa Rica decision.

Con: May not be implementable within the current framework of FDA legal requirements. Could create the argument that FDA is stopping all consumers from benefitting from low cost drugs, and in the process, ensuring the market share of large pharmaceutical companies who are charging higher prices..

Draft Preliminary Highlights of the BBA Adjustment Bill of 1999

Title I – Part A

Changes to Skilled Nursing Facility Payments

- 25% increase for 12 clinically complex, special services, and extensive care RUGS and 3 Rehab RUGs effective from April 1, 2000 through October 1, 2000. Temporary payment increases for all RUGs of 3.5 % for FY 2001 and 2002.
- Allow SNFs to elect immediate transition to federal rate
- Carve out certain ambulance services, prostheses, and chemotherapy drugs from SNF PPS
- Allow Part B add-on payments for SNFs participating in the Nursing Home Case-Mix demonstration
- Special payments for nursing homes specializing in treatment of AIDS patients (e.g., Bailey Boushay) for 2 years

PPS Hospitals

- Modify the BBA IME percentages to: 6.5% in FY 2000, 6.25% in FY 2001, 5.5% for FY 2002 and thereafter
- Modify the BBA DSH reductions to: 3% in FY 2001 and 4% in FY 2002

PPS Exempt Hospitals

- Allow for wage adjustments of the TEFRA caps
- Payment increases for long-term care and psychiatric hospitals for FY 2001 and 2002
- Requirement for a report to Congress on PPS for long-term care hospitals by 10/1/2001 and requirement for implementation of the budget neutral PPS on 10/1/2002
- Requirement for a report to Congress on a PPS for psychiatric hospitals by 10/1/2001 and requirement for implementation of the budget neutral PPS on 10/1/2002
- Changes to the Rehab hospital PPS to require the use of a per discharge system and FIM-FRG patient classification system. The language does not preclude the Secretary from implementing a transfer policy.

Hospice

- Increase in the payment update for FY 2001 and 2002 – amount undetermined

Other Provisions

- Classifies Northwest MS Regional Medical Center as a rural referral center
- Reclassifies Iridell County, NC and Orange County, NY as part of urban MSAs
- Requires the Secretary to consider Heartland Manor's application for certification as a new facility
- Reclassifies hospitals in Lake County, IN to the Chicago MSA
- Corrects the wage index calculation for Hattiesburg MS
- Reclassifies hospitals in Hamilton-Middletown, OH to the Cincinnati MSA

- Requires the Secretary to calculate the wage index for the Allentown, PA MSA without regard to the reclassification of the Lehigh Valley Hospital
- Establishes special payment for SNFs in Baldwin or Mobile County, AL

Title II – Part B

Hospital Outpatient Departments

- Includes a budget neutral outlier adjustment not to exceed 2.5% in 2000, 2001, and 2002; and 3% thereafter. HCFA's suggested technical changes to the outlier were accepted.
- Includes transitional pass-throughs for the additional costs of medical devices, drugs, and biologicals. The Secretary is required to provide for an additional payment for these categories for at least two years, but not more than 3 years. These payments are budget neutral and are limited to 2.5% in 2000, 2001, and 2002; and 2% thereafter.
- Requires that APCs cannot include items that are more than 2 times greater than the lowest median (or mean) cost. The Secretary can make exceptions for low-volume services.
- Requires the Secretary to consult with an expert outside advisory panel to review the APCs.
- Establishes a transitional corridor for OPD PPS through 2003 that is simliar to the House transition, but uses the 1996 payment to cost ratio.
- Small rural hospitals with less than 100 beds are held harmless for 2000-2003
- Cancer hospitals are held harmless permanently
- Limits beneficiary copays for outpatient procedures to the inpatient hospital deductible

Physician Services

- Changes to the Sustainable Growth Rate to limit oscillations and require the Secretary to correct estimation errors
- Requires the secretary to establish a process to accept and use practice expense data collected by organizations

Therapy Caps

- 2-year moratorium on the BBA therapy caps for 2000 and 2001
- Requires the Secretary to conduct focused medical review of therapy claims during the moratorium
- Expands the BBA study and requires the Secretary to report on methods to effect the utilization of therapy services

ESRD

- Increase in the composite rate of 1.2 percent for 2000 and 2001

Inherent Reasonableness

Other Provisions

- Classifies Northwest MS Regional Medical Center as a rural referral center for FY 2000 [Lott]
- Reclassifies Iredell County, NC to the Charlotte-Gastonia-Rock Hill NC-SC MSA [Helms] and Orange County, NY to New York, NY [Moynihan] for FYs 2000 and 2001
- Requires the Secretary to consider Heartland Manor's application for certification as a new facility [Levin]
- Reclassifies hospitals in Lake County, IN to the Chicago MSA for FYs 2000 and 2001 [McIntosh, Visclosky]
- Corrects the wage index calculation for Hattiesburg MS for FY 2000 [Lott/Cochran, cost approx $1.3m]
- Reclassifies hospitals in Hamilton-Middletown, OH to the Cincinnati MSA for FYs 2000 and 2001
- Requires the Secretary to calculate the wage index for the Allentown, PA MSA without regard to the reclassification of the Lehigh Valley Hospital for FYs 2000 and 2001
- Special payments for nursing homes specializing in treatment of AIDS patients (e.g., Bailey Boushay) for 2 years [Dunn, McDermott]
- Establishes special payment for SNFs in Baldwin or Mobile County, AL [Callahan]
- Requires the Secretary to make an award for the BBA authorized demonsration on informatics, telemedicine, and education within 3 months [Columbia University, Rangel]
- Direct appropriation for Georgetown Hospital as part of coordinated care demo.
- Extends SHMO demonstration authority and mandates the Secretary to have an aggregate cap of $324,000 [SCAN, Los Angeles, Health Plan of NV].
- Extends CNO demonstration for two years and requires the Secretary to reduce payments so that extension does not increase expenditures [Urbana, Ill, Tucson, AZ, Minneapolis, MN, New York, NY].
- Extends municipal health services demonstration projects until December 31, 2001 [Baltimore, San Jose, Milwaukee, Cincinnati -- Cardin]

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FACSIMILE TRANSMISSION INFORMATION

DATE:	December 6, 1999
SEND TO:	**Christopher C. Jennings**
COMPANY:	Health Policy Development, The White House
CITY, STATE	Washington, DC
FACSIMILE #:	**456-5557**
TELEPHONE #	456-5560
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December 6, 1999

VIA FACSIMILE

Mr. Christopher C. Jennings
Deputy Assistant to the President
for Health Policy Development
The White House
1600 Pennsylvania Avenue
Washington, DC 20502

Re: Opposition of Generic Pharmaceutical Industry to Montreal Protocol - Decision XI/15

Dear Mr. Jennings:

The Generic Pharmaceutical Industry Association ("GPIA") and the National Pharmaceutical Alliance ("NPA") – trade associations comprised of manufacturers and distributors of safe, effective and affordable pharmaceuticals, and providers of technical services and goods to these firms – write this letter to inform you of a grave risk to the public health and to request your assistance in addressing this risk. We are referring to a Protocol Decision ("Decision XI/15") proposed by the Costa Rican delegation to the Montreal Protocol on Substances that Deplete the Ozone Layer ("Montreal Protocol") during the 19th meeting of the Open-Ended Working Group of the Parties. It is our understanding that Decision XI/15 was considered by the participants of the 11th meeting of the Parties, scheduled for November 29 – December 3, 1999, in Beijing, China.

Decision XI/15, which purports to facilitate the worldwide transition to a chlorofluorocarbon-free environment, would greatly hinder the availability of generic pharmaceutical products packaged in metered dose inhalers ("MDI") that contain chlorofluorocarbons ("CFC"), by setting an arbitrary deadline after which new drugs utilizing CFC MDIs cannot enter the U.S. market. According to the U.S. Food and Drug Administration ("FDA"), these CFC-containing MDIs are the most widely accepted delivery system for administering drugs by oral inhalation for the treatment of asthma and chronic obstructive pulmonary disease ("COPD").[1] These

medical conditions affect over 20 million children and adults in the United States.[2] In essence, the proposal would erect an impenetrable wall against the market entry of CFC-containing drugs, providing an unearned and potentially unending monopoly for those MDI manufacturers who had obtained FDA approval of their drug applications prior to November 29, 1999. The proposal erects this wall by requiring the U.S., as a party to the Montreal Protocol, to prohibit the marketing of any "new" CFC-containing MDI drug products after that date. To the extent that the Decision's prohibition against "new drugs" includes generic equivalents to previously-approved drug products, GPIA and NPA are opposed to Decision XI/15.

Background. The production of ozone-depleting substances is being phased out worldwide under the terms of the Montreal Protocol.[3] In accordance with this treaty, and under authority of Title VI of the Clean Air Act,[4] the manufacture of CFCs in the U.S. was generally banned as of January 1, 1996.[5] Since that time, however, essential use exemptions have been routinely granted in the U.S. for the production of CFCs for MDIs used in treating asthma and COPD. According to FDA, this medical need is supported by the United Nations Environment Program ("UNEP") Technical and Economic Assessment Panel ("TEAP"). The medical need is so great that the essential use exemption for MDI drugs represents the only commercial purpose for which CFCs can be produced in the U.S.[6]

Through Decision XI/15, however, the medical need for CFC-containing MDI drugs would be thwarted by setting an arbitrary deadline after which new products of this type, including generic drugs, cannot enter the U.S. market. For example, Decision XI/15 recommends that the Parties determine "essentiality", which governs the essential use exemption that permits the continued marketing of MDI drugs, according to the following criteria: (1) the MDI product has been approved by the national health authority prior to the Eleventh Meeting of the Parties to the Montreal Protocol (November 29, 1999), unless that authority has determined that the product will serve an otherwise unmet medical need; (2) the MDI product is not intended for export to a Party that has determined the product to be non-essential; (3) the company requesting CFCs is actively pursuing research and development for CFC-free alternatives for its products; (4) the company does not increase its strategic reserves of CFCs beyond reasonable levels; (5) the company decreases its strategic reserves of CFCs in line with the declining annual demand; and (6) the company commits to destroying any of its remaining strategic reserves of CFCs upon completion of its MDI transition. The implementation of these unreasonable criteria would jeopardize the health of American consumers and prohibit the marketing of cost-effective generic drugs.

Issues of Concern. GPIA and NPA understand that, by prohibiting "new drugs", Decision XI/15 may be interpreted to prohibit FDA approval of generic drugs that are equivalent to previously-approved (i.e., "old") brand-name MDI drugs, in addition to prohibiting FDA approval of new brand-name drugs. As such, GPIA and NPA oppose Decision XI/15 for the five reasons explained below. We need your help to combat this overreaching international law and to protect American consumers.

First, Decision XI/15 endangers the health of millions of Americans who suffer from respiratory conditions by limiting patient access to affordable medications. Current medical and scientific knowledge supports the view that many MDI drugs formulated with CFCs are essential use products. Although the Decision would likely prohibit the marketing of generic drugs, currently-marketed brand-name MDI drugs would continue to be marketed. Yet, the essential use of the product, whether brand-name or generic equivalent, would remain the same. Thus, CFC-containing MDI drugs should not be internationally regulated in a way that would result in the continued marketing of brand-name, essential-use drugs but not essential-use generic equivalents.

Second, Decision XI/15 is contrary to FDA's science-based decision on the appropriate U.S. transition away from CFC-containing MDI drugs. FDA's primary objective is to ensure that the millions of asthma and COPD patients in the U.S. continue to have access to an adequate number of safe and effective treatment options for these life-threatening conditions.[7] There is no question that the U.S. Government should meet its obligation under the Montreal Protocol by implementing its own unique transition strategy to a CFC-free environment. Nevertheless, competing public health concerns also exist and have been carefully balanced by FDA and EPA. In so doing, FDA's Medical Policy Coordinating Committee worked strenuously to evaluate all the scientific, technical, regulatory and clinical issues affected by the transition to CFC-free drug products and to develop a transition strategy that would account for all of the U.S. stakeholders who have competing concerns in the area.[8]

In keeping with its balanced transition strategy, FDA has greatly limited the numbers of pharmaceuticals that may contain CFCs, by declaring that all such products are "new drugs" that cannot be lawfully marketed in the U.S. unless they are FDA-approved through the new (or abbreviated) drug application process or fall within one of the few exceptions permitted for drugs. 21 C.F.R. § 2.125 (1999).[9] Moreover, FDA provides a scientifically rigorous mechanism with which drug manufacturers must comply before obtaining an exception to market their products

(i.e., "essential use" status). Specifically, drug manufacturers must provide FDA with data showing that: (1) there are no technically feasible alternatives to the use of CFCs in the product; (2) the product provides a substantial health benefit that would not be obtained without the CFC; and (3) the use does not involve a significant nor unwarranted release of CFCs into the atmosphere. 21 C.F.R. § 2.125 (1999).[10] FDA's approach is reasonable, scientifically-based, and addresses the competing regulatory concerns, including the market entry of equivalent and affordable generic drugs. FDA's approach should not be supplanted by Directive XI/15.

Third, Decision XI/15 is contrary to law because it provides an unwarranted monopoly within the pharmaceutical industry, which is directly opposed to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act.[11] That law represents Congress' efforts to delicately balance the competing objectives of encouraging pharmaceutical innovation while providing American consumers with affordable generic drugs. In contrast to these balanced objectives, Decision XI/15 will result in an artificially preserved marketplace for CFC-containing MDI drugs with little competition. Such monopoly periods almost always lead to inflated prices. Thus, Decision XI/15 will wield a double-blow to patients by limiting their medical treatment choices while also likely forcing them to pay exorbitant prices for the few choices they have remaining.

Decision XI/15 also defies the Hatch-Waxman Act by requiring research and development into CFC-free technology. Such testing is prohibited for generic manufacturers, who cannot include that type of clinical test within the drug application required by FDA for a generic drug.[12]

Fourth, Decision XI/15 is contrary to public policy. Implementation of the Decision will adversely affect members of the generic drug industry who have worked for years with FDA's Office of Generic Drugs to develop safe and effective generic alternatives to brand-name MDI products based on currently available propellant technologies. And the development of CFC-free technologies is no solution, since generic manufacturers will be locked out of the market for new FDA-approved drugs for at least 20 years under current U.S. patent law. Moreover, the

Decision would interfere with the practice of medicine by unreasonably limiting the MDI choices available to the physician. The Decision also would interfere with the patient's right to receive a cost-effective drug that the patient considers the most beneficial for his or her medical condition.

Fifth, the recommendations made by Decision XI/15 are unwieldy and unnecessary given the progress of FDA and the pharmaceutical industry in this area. In its preamble, Decision XI/15 acknowledges that the transition to CFC-free technology will have progressed satisfactorily by the year 2000. Furthermore, the use of CFC propellants by the pharmaceutical industry is minimal when compared to the use of CFC propellants in products sold by other industries. For example, the total worldwide use of CFC propellants for pharmaceutical MDI products is less than 0.5% of the total worldwide use of CFCs for all purposes. Moreover, GPIA and NPA believe that the use of CFC propellants in pharmaceuticals has a minimal impact on the environment. It is our understanding that pharmaceutical MDI products contribute less than 1% of the total CFC emissions into the atmosphere. Given the minimal number of CFC-containing pharmaceutical products and their overall diminutive effect on the environment, the Costa Rica Protocol Decision is not warranted.

Finally, FDA has maintained that the best way to accomplish the transition to non-CFC alternative drug products is for each country to develop a national transition strategy that matches the unique characteristics of the regulatory, health care, and marketing environment of the particular country.[13] FDA recognizes that developing a "one size fits all" international strategy is unacceptable because a strategy devised by one country could cause significant problems if it were "imported" and wholly applied to the U.S. legal and regulatory system.[14] Such is the case here.

In conclusion, we ask that you notify the U.S. delegation to the Beijing meeting that the U.S. is opposed to the adoption of Decision XI/15.

Respectfully submitted.

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cc: Alfonso Liao Lee, Costa Rica National Ozone Commission
Jane Henney, M.D., Commissioner of U.S. FDA
Madeleine K. Albright, U.S. Secretary of State
Carol M. Browner, Esq., Administrator of U.S. EPA

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1 62 Fed. Reg. 10242, 10245 (Mar. 6, 1997).

2 Tamar Nordenberg, *CFC-Free Medication for an Ailing Ozone Layer*, FDA Consumer Magazine (May-June 1997).

3 S. Treaty Doc. No. 10, 100th Cong., 1st Sess., 26 I.L.M. 1541 (Sept. 16, 1987).

4 42 U.S.C. § 7671.

5 64 Fed. Reg. 47719 (Sept. 1, 1999).

6 Statement of Murray M. Lumpkin, M.D., Deputy Director for Review Management, Center for Drug Evaluation and Research, Food and Drug Administration, before the Subcommittee on Health and Environment, Committee on Commerce, U.S. House of Representatives, July 30, 1997 ("1997 FDA Statement by Dr. Lumpkin").

7 1997 FDA Statement by Dr. Lumpkin.

8 1997 FDA Statement by Dr. Lumpkin.

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9 FDA's current proposed rule on the use of ozone-depleting substances recharacterizes a violation of the new drug approval process as a "nonessential" use under the Clean Air Act. 64 Fed. Reg. 47719 (Sept. 1, 1999).

10 FDA proposed slight modifications to these data requirements in 64 Fed. Reg. 47719 (Sept. 1, 1999).

11 See Mead Johnson Pharmaceutical Group v. Bowen, 838 F.2d 1332, 1333 (D.C. Cir. 1988); H.R. Rep. No. 98-857, 98th Cong., 2d Sess., Pt. 1 at 14-15, reprinted in 1984 U.S. Code Cong. & Admin. News 2647-8; 57 Fed. Reg. 17,950-951 (April 28, 1992); Abbott Laboratories v. Young, 920 F.2d 984, 985 (D.C. Cir. 1990), cert. denied, Abbott Laboratories v. Kessler, 502 U.S. 819 (1991).

12 21 U.S.C. § 355(j).

13 1997 FDA Statement by Dr. Lumpkin.

14 1997 FDA Statement by Dr. Lumpkin.