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Mr. Chairman, Members of the Committee, thank you for the opportunity to testify before you on the important public health goal of assuring that asthmatics continue to have access to safe and effective medications, and on protection of the stratospheric ozone layer. I have been asked to provide the Committee with information on how CFCs in asthma inhalers contribute to harming the ozone layer, on any time line for product substitution and CFC use in medical products imposed on the U.S. by virtue of its status as a signatory to the Montreal Protocol, and on the collaboration between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) in this area, and on EPA's role in advising FDA on the March 6, 1997 Advanced Notice of Proposed Rulemaking (ANPRM). If you remember nothing else from my testimony today, Mr. Chairman, Senators, I hope you will remember these points:

1. EPA is not taking away asthma inhalers from any asthma sufferer: in fact, we are committed to making sure MDIs using CFC propellants remain available until there are safe, effective and acceptable alternatives for all who need them; and

2. Because the pharmaceutical industry is moving to develop and provide safe and effective alternatives, we do not have to choose between protecting our children from higher rates of skin cancer caused by ozone depletion and protecting patients -- many of them children -- with asthma. We at EPA are committed to healthy children and a healthy environment, but to healthy children *first*.

I would like to begin my testimony with a few general observations. As you know, the U.S. in partnership with many other governments ceased production of CFCs on January 1, 1996. Remaining production continues pursuant to an "essential use" provision which allows countries to request continuing production in cases where health, safety or national security are at risk because alternatives to a particular CFC-based use do not exist. Since the inception of the essential use process in 1996, the U.S. has put forward a limited number of requests, including requests for additional production of CFCs for use as propellants in MDIs for some 30 million Americans suffering from asthma and other chronic respiratory diseases.

Within the U.S., the strong partnership between the public sector and industry should be credited with the limited number of U.S. essential use requests. This partnership has resulted in tremendous success over the past decade in finding reliable substitutes for CFCs in a wide range of industrial and consumer uses, and this has translated into an enormous competitive edge in environmental technologies worldwide. While scientists do not expect the ozone layer to fully recover until the middle of the next century, researchers at the National Oceanic and Atmospheric Administration have

already measured stratospheric declines in concentrations of ozone-depleting compounds, providing early proof of the success of the Montreal Protocol.

Unfortunately, good faith efforts by pharmaceutical manufacturers and government agencies have led to confusion among users of MDIs and in the medical community. Some fear the job of protecting the ozone layer can only be completed by ignoring the legitimate needs of those who rely on these important medications, in some cases for their lives. I hope to address this confusion in my remarks today, because I believe the responsible course for protecting public health is to put patient protection first, in a process laid out in the Clean Air Act Amendments of 1990 (CAAA). This bipartisan course aimed at two goals which were not then, and are not now, in competition: to assure the best possible care for those with asthma and other respiratory disease and to prevent skin cancer and other health effects caused by ozone layer depletion.

Abandoning this course now would exalt misinformation over sound policy. It would ignore the urgent need to encourage open and timely continuing action by FDA, the Agency with the medical expertise to effectively achieve patient safety, and to make appropriate decisions about the efficacy of new medications. It would wreak havoc in the pharmaceutical industry, which has invested large sums of money, talent, and effort to develop a world competitive advantage in research on improved and innovative asthma care therapies for the future. Finally, it would send an ominous message to developing countries, which have yet to complete their phase out of ozone depleting chemicals, that it may not be important for them to do so.

Now I would like to turn to specific questions raised in the Committee's letter of invitation. Some have expressed the belief that the use of CFCs in MDIs is small, and that continuing that use does not matter. Throughout the CFC phaseout, many individual users have argued that their use contributes so little that it should be exempted. In the aggregate, however, small uses can have significant environmental effects, and exempting one on the basis of smallness encourages others to come forward using similar logic.

The contribution of CFC use in MDIs to ozone layer destruction is an excellent case in point. The U.S. forwarded an essential use request for the year 1999 for CFCs as MDI propellants of approximately 4,000 metric tons. Some point out that this is small compared to historical U.S. use of CFCs. However, it is larger than uses in all sectors combined for close to 100 of the world's developing countries. If the U.S. were to argue that our remaining uses are small enough to be permitted indefinitely, many countries could make similar arguments about their uses. The aggregate effect on the ozone layer of such a change to the Montreal Protocol would be significant. A permanent exemption for some uses would continue damage to the ozone layer indefinitely, meaning that complete recovery could no longer be envisioned.

Such continued damage to the ozone layer is not a theoretical matter of concern to environmentalists, but has real effects on ordinary people. Recent data from the National Cancer Institute and the Centers for Disease Control and Prevention show that while incidence of most cancers has begun to decline, new cases of the most-often fatal form of skin cancer, malignant melanoma, continue to rise. While many genetic and behavioral

factors contribute to skin cancer, this upward trend should reinforce our commitment to protect Americans from skin cancer. As we will hear today, another unfortunate public health trend in our country is the rise of asthma. While such information is sobering, it is important to emphasize that the right policy will not choose between these public health concerns, but will assure effective care for respiratory diseases and lower risk of skin cancer from ozone depletion.

Only when an adequate number of safe, effective and acceptable CFC-free alternatives are available, can we safely ensure the healing of the ozone layer. MDI use is growing, which is appropriate as the incidence of disease is growing. Because health care is a priority worldwide, and standards of living are slowly improving, future standards of care will mean asthmatics in New Delhi and Beijing will rely on the same dependable therapies as are now being introduced in developed countries. As growth happens, we want to make sure it happens in ways that protect the ozone layer.

As to the possible time line for availability of new CFC-free asthma therapies, I can report good news about that, based on industry information submitted to EPA in support of the annual U.S. essential use exemption request. Of the more than thirty MDIs now on the market, most are moving ahead at some stage of the process of reformulation. There is already an approved MDI available which supplies albuterol, without relying on CFCs as the propellant to deliver the medication.

The pharmaceutical industry reports that, to date, it has invested over $1 billion to identify safe and effective ways to reformulate CFC-based MDIs so its medications can

be delivered without damaging the ozone layer. A survey performed in 1996 of member companies by the International Pharmaceutical Aerosol Consortium (IPAC), the industry trade group that represents many major pharmaceutical companies involved in reformulating MDIs, found that by 2000, 11 CFC-free MDIs would be available, and that 35 could be available by 2005. These figures have proven in the time since the survey was made to be optimistic, but they do demonstrate the commitment this industry has shown in the number of products being reformulated. Even taking a more conservative view, soon after 2001, we should have additional CFC-free albuterol inhalers on the market, and by that time, CFC-free versions of other important MDI-based therapies should be available as well.

To reassure patients that no changes being contemplated would leave them without the medications they need, EPA together with the National Institutes of Health and representatives from industry, the Allergy and Asthma Network/Mothers of Asthmatics, the American Lung Association, the Asthma and Allergy Foundation, and other public health agencies such as the FDA, developed a brochure which I have here and which I would be happy to submit for the record, if there is interest in the Committee. In preparing this brochure, the groups involved agreed on important basic messages and information patients need. EPA is committed to continue working with these groups to correct any misinformation that may exist.

At the international level, we believe that all countries of the world share our commitment to fully protect patients. Every year, the Parties to the Montreal Protocol

decide to grant requests from each country for additional CFC production. All prior U.S. annual essential use exemption requests have been approved in their entirety based on medical need and our commitment to move forward. We do not anticipate a rejection of any future U.S. request, and clearly the responsible course for protecting the availability of the CFC-based medications still needed by U.S. asthmatics is to create the best-supported U.S. request possible. A crucial element of supporting that request is to continue to plan for the time when CFC-free alternatives are fully available.

The Montreal Protocol imposes no clear due date for the MDI transition on the U.S. or on any country. In 1996, the Technical and Economic Assessment Panel (TEAP), an expert advisory body to the Montreal Protocol Parties, suggested in its evaluation of the progress of transition in different countries that 2005 might be an appropriate date for transition. Some have suggested that this date should be adopted by the U.S., or that the Montreal Protocol already requires it. However, the TEAP is an advisory body only, and no action has yet been taken by the Parties to set any firm date by which the MDI transition must conclude.

The date that exists for the international process is January 31, 1999. By then, signatories requesting essential uses will share an initial draft plan with the Parties describing their country's strategy for managing the transition. The purpose of this requirement is to assure the Parties that countries continuing to request exemptions consider how best to move forward with a transition, and to facilitate the sharing of ideas and approaches among countries facing this issue. The requirement does not create any

international approval process for country-based strategies, nor does it compel a nation to implement any approach described in the initial strategy submitted. The U.S. has already shared the ANPRM with international colleagues informally prior to the decision requiring such submission in 1999. We believe the consultations and information sharing we have already done satisfies this requirement.

The U.S. by virtue of its draft transition strategy has shown leadership, but we are by no means alone in the process of reformulating important asthma therapies. Other countries are moving forward. IPAC estimates that by 2000 in the European Union (EU), 2 CFC-free albuterol substitutes will be available in each EU member state, compared to the single product approved in the U.S. Some of this more rapid progress by the EU is likely to be reflected in reductions in the amount of CFCs requested by these countries for use in future years.

Misinformation has given rise to a sense of urgency surrounding the ANPRM. Particular confusion surrounds EPA's role. A recent editorial in the Wall Street Journal summarizes key elements of this confusion, when it alleged that EPA would "announce a ban on...inhalers" at the Meeting of the Parties to the Montreal Protocol, held in Montreal in September 1997. EPA had no such intention, and no such announcement was made. The editorial stated that EPA would no longer "ask to exempt inhalers" from the CFC production ban. In fact, at that meeting EPA successfully argued for exemptions to produce CFCs for use in MDIs in the year 1999. I assure this Committee that EPA remains committed to supporting necessary exemptions until there are safe and effective

CFC-free medications available for all who need them. Finally, the Journal's editorial asserted that on September 19, 1997, the Clinton Administration proposed to "take away asthma inhalers from...children." No such proposal was issued on that date, or contemplated at any time.

The record of EPA's actions speaks very clearly. For the past five years, since the inception of the essential use process prior to the U.S. CFC phase out in 1996, EPA has worked with other federal agencies and pharmaceutical manufacturers to compile, substantiate and successfully defend annual essential use requests. Most recently, on January 16, 1998, Administrator Browner signed a final rule allocating "essential use allowances" for specific continued uses of CFCs, including as propellants in MDIs, for the year 1998. This final rule -- and the prior five years' of effort -- demonstrate EPA's tireless effort to assure that CFCs for asthma inhalers can continue to be produced until there are safe and effective alternatives for all who need them.

I recognize that reasonable and well-informed persons may disagree over specifics of the approaches laid out by the FDA in the ANPRM. That is appropriate given the importance of the issues involved. Many commenters have provided FDA with a wealth of fresh perspectives, which will no doubt be vital in FDA's effort to refine or redraft the existing approaches. EPA worked cooperatively to provide support on environmental aspects to FDA in the development of their transition strategy. Because we believe patients and other stakeholders deserve calm, accurate information about CFCs in MDIs,

we have worked with FDA to answer some of the questions raised by those affected by the MDI reformulation.

EPA's perspective remains guided by the need to assure continuing availability of lifesaving medications for asthmatics as we protect the ozone layer. While recovery of the ozone layer is expected, recent scientific data from satellites and balloons highlighted unusually low ozone levels in the Arctic, following a pattern previously only seen at the Antarctic ozone hole.

Skin cancer is rising in the U.S. at what the American Academy of Dermatology has called "epidemic" rates. For a child born today, the lifetime risk of skin cancer is much greater than it was twenty years ago. Protecting the ozone layer will reduce that risk, so future generations will be less likely to suffer dangerous and disfiguring skin cancers.

But continuing progress in ozone layer protection cannot come at the expense of other growing public health concerns, like asthma. In contrast to the rumor that a "ban" on inhalers is imminent, the reality is that EPA is committed to protect all MDI users. Over time the availability of substitutes will provide plenty of options for American asthmatics while protecting the ozone layer, so that as we preserve the best possible treatments for asthma, we also lower the incidence of skin cancer.

We must continue our leadership role by meeting our commitments as a Party to the Montreal Protocol, ensuring that we take the responsible road of decreasing skin cancer for our children and future generations, while preserving an unflinching

commitment to maintaining the high standard of care the U.S. has always enjoyed for asthma and other respiratory diseases. This is where sound policy leads, and I urge you to support us in this effort.

Thank you, Mr. Chairman, Members of the Committee, for your attention. I would be happy to answer any questions you may have.