



Carl C. Booberg
Executive Director
American Thoracic Society

Gary Ewart
Director
Government Relations

Fran DuMelle
Consultant
International Health

Washington Office
1150 18th Street, N.W.
Suite 900
Washington, DC 20036-3816
Phone: (202) 785-3355
Fax: (202) 452-1805
Internet: www.thoracic.org

National Headquarters
61 Broadway
New York, NY 10006-2747
Phone: (212) 315-8600
Fax: (212) 315-6498
Internet: www.thoracic.org

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President

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President-elect

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November 17, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Docket No. 2003P-0029
Use of Ozone-Depleting Substances; Removal of
Essential-Use Designations**

Dear Sir/Madam:

On behalf of the US STAKEHOLDERS GROUP ON MDI TRANSITION, we are pleased to submit the attached draft EDUCATION AND OUTREACH INITIATIVE for achieving a seamless transition to CFC-free MDIs in the U.S.

The US STAKEHOLDERS GROUP ON MDI TRANSITION is a consortium of nine leading patient and medical professional associations, representing more than 25 million Americans who suffer from asthma, chronic obstructive pulmonary disease (COPD), and other respiratory diseases. Since 1996, we have sought to ensure a transition to CFC-free MDIs that properly balances the threat to public health posed by stratospheric ozone depletion with the needs of patients who rely on inhaled therapies.

Since the formal comment period to the above-referenced rulemaking closed in August, both companies with approved HFA albuterol MDI products have publicly committed to having production capacity in place to meet demand for HFA albuterol by December 31, 2005. In addition, FDA recently (November 2004) approved a third HFA albuterol MDI product.

On the basis that it is technically possible for FDA to set an effective date as early as December 31, 2005, the US STAKEHOLDERS GROUP is beginning now, in advance of the Final Rule, to develop and refine its outreach and education initiative. Initiation of outreach and education need not wait until the precise end date FDA will choose for CFC albuterol is known. An early start gives patients added protection, and ensures that an adequate education plan will be in place, whatever effective date is chosen. Most importantly, to the extent the education campaign can improve disease management and treatment, beginning now only will serve to improve patient care.

From inception, the US STAKEHOLDERS GROUP has advocated a strong educational component to transition. Since the use of CFCs in MDIs was granted a temporary exemption from the worldwide ban on ozone-depleting chemicals, there have been various but uncoordinated efforts to communicate to patients and providers the message that CFC inhalers will be phased out. We will develop a unified message, create awareness, and implement an education program, beginning now with the albuterol transition. The STAKEHOLDERS also intend to monitor implementation

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until all patients are successfully switched to non-CFC containing products.

We hope the attached education plan assists FDA to meet its timetable for issuing a final rule on the essentiality of CFC albuterol MDIs. We look forward to working with the Agency, pharmaceutical manufacturers and other key healthcare organizations as we develop and implement outreach and education on the transition to CFC-free therapies.

Sincerely,



Fran Du Melle
Director, International Activities
202.785.3355 (x219)
frandumelle@lungusadc.org

ON BEHALF OF THE MEMBER ORGANIZATIONS

Allergy & Asthma Network Mothers of Asthma (AANMA)
American Academy of Allergy, Asthma and Immunology (AAAAI)
American Academy of Pediatrics (AAP)
American Association for Respiratory Care (AARC)
American College of Allergy, Asthma and Immunology (ACAAI)
American College of Chest Physicians (ACCP)
American Lung Association (ALA)
American Thoracic Society (ATS)
Asthma and Allergy Foundation of America (AAFA)

US STAKEHOLDERS GROUP ON MDI TRANSITION
PROPOSED OUTREACH AND EDUCATION INITIATIVE
ON THE TRANSITION TO CFC-FREE ALBUTEROL MDIs
November 2004

The Role of the US STAKEHOLDERS GROUP in Education and Outreach

Formed in 1996, the nine member organizations of the US STAKEHOLDERS GROUP ON MDI TRANSITION include the foremost medical specialty societies and patient organizations dedicated to the care of individuals with asthma and COPD. The physicians, respiratory therapists and other healthcare professionals represented by member organizations are recognized as leaders in their fields. More than 25 million patients and their families rely on the member organizations for education, advocacy and care.

Since its inception, the US STAKEHOLDERS GROUP has advocated a strong educational component to transition. This is because in the U.S., unlike other developed countries that have already successfully transitioned, there is not a single payer, some portion of medical treatment remains in the private sector, and there is a small, but significant population of low-income, uninsured individuals who lack access to regular medical care. Our combined expertise on patient and provider needs, our demonstrated outreach and coalition-building efforts on the transition and our history of work on this topic makes the STAKEHOLDERS GROUP uniquely suited to envision and execute outreach and education to effect a seamless transition to CFC-free MDIs in the U.S.

Throughout the transition-setting effort in the United States, the STAKEHOLDERS GROUP has collaborated with a broad spectrum of health sector participants to ensure clarity of issues and obtain an inclusive perspective on the timing and mechanisms necessary to ensure a safe Transition for patients and healthcare providers. In addition to individual and group meetings with the key government agencies responsible for the U.S. adherence to the Montreal Protocol (FDA and EPA), the STAKEHOLDERS have sought the repeated input of industry representatives (IPAC), primary care physicians, allied health professionals, insurers, managed care organizations, consumer organizations and state-sponsored health care plans. The STAKEHOLDERS have consistently sought coordination of effort with the National Asthma Education and Prevention Program (NAEPP) of the National Heart, Lung and Blood Institute (NHLBI), and have, over the past eight years, initiated and produced education symposia and materials for physicians and patients introducing and updating them on transition in the U.S. and overseas.

As a result of this process, the STAKEHOLDERS have established a longstanding position as an objective arbiter of the needs of the patient and healthcare community regarding the transition in the U.S. We recognize that pharmaceutical manufacturers also will be conducting outreach and developing educational materials about transition. Their efforts will include among other things, education for their marketing personnel, direct education to physicians, and coordination with benefit managers, other drug purchasers, and retail-level distributors. Although we will maintain close collaboration with the private sector, FDA and other government agencies, our initiative is designed to draw upon the specific strengths of the STAKEHOLDERS' members, chief among these being direct communication with patients and their caregivers, including outreach via local associations and regional networks.

FDA's Proposed Rule on Albuterol Non-Essentiality

In its NPR on albuterol essentiality, FDA requested specific comments on how educational and assistance programs run by pharmaceutical manufacturers could ameliorate some of the

anticipated adverse impacts of price increases. Our comments in turn indicated intent to file supplemental comments, largely because it was expected that filings on the part of manufacturers would provide needed clarity on a chief determinant for setting the optimum date to end the sale of CFC albuterol MDIs: the capacity of manufacturers to meet the demand for HFA inhalers. As expected, comments by manufacturers 3M and Schering-Plough have provided FDA with clarity –it is now affirmed that there will be adequate HFA capacity in place by December 31, 2005.

On the basis that it is technically possible for FDA to set an effective date as early as December 31, 2005, the US STAKEHOLDERS GROUP is committed to begin now, in advance of the Final Rule, the refinement and implementation of its OUTREACH AND EDUCATION INITIATIVE. Our plan will create awareness, implement an education program, and monitor implementation to ensure a smooth transition to HFA albuterol as detailed herein.

Now that there is no longer any doubt about whether CFC albuterol will be phased out, we believe it is prudent to begin outreach and education. We see no problem with beginning our education initiative without a final end date in hand. If FDA meets its announced timeline for issuance of the Final Rule, the specific effective date for albuterol phaseout should be known by late spring 2005. The lack of a precise end date for CFC albuterol need not delay initiation of outreach and education – when the date is known, we will simply incorporate that specific information into any materials or messages already developed. Beginning six months or so in advance of the Final Rule gives patients added protection, and ensures that an adequate education plan will be in place, whatever effective date is chosen. Most importantly, to the extent the education campaign can improve disease management and treatment, beginning now only will serve to improve patient care.

With this in mind, three principles will underpin our outreach and communication initiative:

- 1) Using the opportunity of transition to improve patient outcomes;
- 2) Ensuring uninterrupted and affordable access to medication by the most vulnerable patient populations, including the underinsured, elderly, disabled and children;
- 3) Leveraging the value and reach of partnerships with customizable and redistributable materials.

Using the Opportunity of Transition to Improve Patient Outcomes

The STAKEHOLDERS believe that transition to HFA inhalers offers a unique opportunity for patient and physician education. First, albuterol is the only moiety used by patients with different types of asthma -- mild, moderate or severe – so any outreach associated with transition has the potential to reach the vast majority of people who suffer from respiratory disease. Second, if conducted at the physician rather than the pharmacy level, the switch from CFC to HFA albuterol can provide a specific occasion for doctors to review and improve asthma care plans for their patients. Given our sense that education more than anything improves patient adherence with treatment plans, transition offers the opportunity for doctors and other members of the healthcare team to educate patients about adhering to their disease treatment plan, including taking simple steps for minimizing exposure to their asthma triggers and the importance of utilizing their maintenance medications. Transition also presents an occasion for a greater number of patients to better appreciate the appropriate role of rescue medications in managing their asthma.

Additionally, we expect transition to provide an opportunity to increase usage and familiarity with treatment guidelines, especially among non-specialty physicians. There have been significant advancements in asthma therapy since the National Asthma Education and Prevention Program (NAEPP) first published treatment guidelines in 1991. (A third update is underway). The STAKEHOLDERS will work closely with the NAEPP, physician organizations and other key actors to leverage HFA product education with increased utilization of the guidelines for managing asthma.¹ This outreach should "refresh" the use of the guidelines for many, and provide stimulus for introduction and education about the guidelines to others unaware of this resource. For patients, we envision the need to meet with providers for a new prescription as a "teachable moment" to communicate the importance of having a current and up to date asthma management plan that reflects the patient's current health status and the NAEPP treatment guidelines. Patients in specialty and primary care settings alike will benefit from more up to date, informed care.

Ensuring Uninterrupted and Affordable Access to Treatment by the Most Vulnerable Patient Populations

From its inception, the STAKEHOLDERS have expressed concern about the potential impacts of transition on asthma and COPD patients who are low-income, uninsured or underinsured. Many of these patients already have impediments to accessing care. Transition to CFC-free albuterol, because of the increased cost of inhalers, may add yet another barrier to accessing care.

As FDA has stated, the promise by GlaxoSmithKline to distribute 2 million albuterol MDI samples annually has the *potential* to significantly ameliorate access problems faced by low-income, uninsured and underinsured patients. Whether the generous (close to 10% of GSK's annual sales) sampling will meet its stated objective will depend on samples being properly targeted and distributed to those patients who are most in need. Educational materials to be developed will help providers understand not only the need for an appropriate treatment plan, but also about the patient's ability to adhere to the plan given the increased cost of their inhaler.

To assist in the success of sampling programs, the STAKEHOLDERS will develop and expand mechanisms for identifying and reaching these patient populations. We will catalog and make public information about medication subsidy programs now in place in communities across the U.S. The list will serve to direct efforts by the pharmaceutical companies so as to provide maximum benefit to the population in need. Examples of such programs include donations of inhalers to schools, the MedBank subsidy program for low-income individuals in Maryland, Project Concern, and programs of individual STAKEHOLDER members such as programs run by local chapters of the Asthma and Allergy Foundation of America (AAFA).

Another important mechanism for ensuring access to treatment despite the higher cost of albuterol is the patient assistance programs administered by the individual pharmaceutical manufacturers. Our experience tells us that there are limitations to these programs, namely, that patients and their caregivers can be unaware of this resource, that each company has

¹ For example, through the American Lung Association, the STAKEHOLDERS developed a brochure, "Stepwise Approach to CFC-Free Management of Asthma." Available for download at www.inhalertransition.com (What Physicians Need to Know), the *CFC-Free Stepwise* brochure helps physicians and other caregivers identify specific CFC-free products for treating disease according to the NAEPP guidelines.

established its own application and qualifying process, and that many patients are intimidated by the complexity and personal exposure of the application process, including in some instances, the need to obtain referrals or statements of need from their treating physician. The STAKEHOLDERS will begin now to work with pharmaceutical manufacturers to improve outreach about these programs, and to assess, streamline and educate about participation requirements.

To improve the reach of both the sampling and patient assistance programs, we will consider a task force or other mechanism for collecting ideas about how to identify and target vulnerable populations, for assessing their specific needs, and for addressing them.

Leveraging the Value and Reach of Partnerships

Since the use of CFCs in MDIs was granted a temporary exemption from the worldwide ban on ozone-depleting chemicals, there have been various but uncoordinated efforts to communicate to patients and providers the message that CFC inhalers will be phased out. Now that the eventuality of the phaseout is clear – except for the specific date in the next year or years that it will happen -- the collective strength of the STAKEHOLDERS GROUP will be critical in developing and disseminating a unified message. Member organizations will begin now to develop and redistribute a unified message for use beginning now and until all patients are successfully transitioned. Our efforts will be focused on materials that can be customized – with messages that resonate to particular audiences – and redistributed with little additional effort or expense.

In addition to the special efforts described above to preserve access to treatment by low-income and underinsured populations, our educational efforts will include the following messages:

- *environmental and public health rationale for transition* (the effect of CFCs on the ozone layer, increased risk of skin cancers; worldwide phaseout of CFCs and the risk to U.S. patients of relying on chemicals slated for elimination)
- *proven safety and efficacy of HFA products* (design, use and care of HFA delivery system; HFA development process; FDA safety studies)
- *demonstrated patient acceptance of HFA products* (experience and use around the world).

Among the types of materials and tactics already under discussion are:

- talking points to be used in presentations, by call centers or hotlines such as those manned by American Lung Association, Asthma and Allergy Network/Mothers of Asthmatics, and Asthma and Allergy Foundation of America (AAFA)
- Q&A/FAQs
- articles for general circulation magazines and specialty medical publications
- public service announcements
- teleconferences for healthcare providers

The US STAKEHOLDERS GROUP ON MDI TRANSITION already is in discussions with NAEPP and pharmaceutical manufacturers in an attempt to outline the precise needs of patients during transition. As these collaborations continue, we will update FDA, manufacturers and the public on specific measures and materials under development.

THE US STAKEHOLDERS GROUP ON MDI TRANSITION is a consortium of leading patient and medical professional associations, representing more than 25 million Americans who suffer from asthma, chronic obstructive pulmonary disease (COPD), and other respiratory diseases. Since 1996, the STAKEHOLDERS have sought to ensure a transition to CFC-free MDIs that properly balances the threat to public health posed by stratospheric ozone depletion with the needs of patients who rely on inhaled therapies. For further information, visit www.inhalertransition.org.

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