Resolution on the Use of Chlorofluorocarbons (CFC’s) and Metered Dose Inhalers (MDI’s)

WHEREAS, approximately thirty million (30,000,000) Americans currently suffer from respiratory diseases including asthma, chronic obstructive pulmonary disease (COPD) and cystic fibrosis, requiring treatment with use of metered dose inhaler;

WHEREAS, nearly five million (5,000,000) of those are under the age of 18 who suffer from asthma and each year more than five thousand (5,000) Americans die from asthma alone;

WHEREAS, for many patients suffering from asthma, COPD, or cystic fibrosis, the primary and often sole treatment for their disease is through the use of a metered dose inhaler (MDI);

WHEREAS, while MDI’s deliver medicines to open patient’s breathing passages, chlorofluorocarbons (CFC’s) are an essential part of the MDI delivery system and effectively carries medicines to the patient’s lungs;

WHEREAS, as many patients and their physicians have discovered, even with the same medicine, one type of MDI may work better for them than another;

WHEREAS, while these devices have been helpful to patients and been proven for over forty (40) years, CFC’s in large quantities are alleged by some to deplete the earth’s stratospheric ozone layer and in 1987 an international treaty referred to as the Montreal Treaty was thereby adopted;

WHEREAS, this treaty calls for an end to the production of ozone helping chemicals including CFC’s;

WHEREAS, the Environmental Protection Agency has the responsibility of implementing the protocol obligation in the United States except for exceptional cases in which a special permission – an Essential Use Exemption—is granted by the United States Food and Drug Administration;

WHEREAS, CFC used in metered dose inhalers is currently one exception. A principal reason for this is that pharmaceutical usage of CFC’s for inhalation aerosol accounts for less than 1 percent of the cumulative worldwide consumption of CFC’s. Potential benefits to the ozone layer from a premature product ban of CFC MDI’s are negligible compared to the greater risk in patient health;

WHEREAS, the FDA, however, has recently issued an Advanced Notice of Proposed Rulemaking (ANPR) for the purpose of rethinking the essential use designation for MDI’s;

WHEREAS, recognizing the medical necessity of some uses of CFC’s, the treaty deemed those used in MDI’s as an “essential use” and seeing a need to adopt a transition strategy to non-CFC MDI’s by the year 2005, and to assist ongoing market forces in achieving a seamless transition for patients to non-CFC MDI’s, the parties of the Montreal Protocol did adopt certain measures by which companies requesting CFC allowances must demonstrate their ongoing commitment. These measures are:

- Advancing research and development on non-CFC alternatives;
- Educating physicians and patients about transition;
- Conducting appropriate marketing of their CFC-free asthma treatments; and
- Minimizing CFC emissions during manufacture of MDI’s and proper returned or defective CFC metered dose inhalers;

WHEREAS, pharmaceutical companies serving this patient population have invested significant resources in a research and development effort to offer patients suitable non-CFC alternatives to its current therapies well within the time frame established by the Montreal Protocol.

THEREFORE, BE IT RESOLVED that until a broad range of satisfactory alternatives that meet governmental regulatory standards is developed for these pharmaceutical products, the (insert state legislative body) supports the continuation of the medical exception for CFC use.
Adopted by the Health and Human Services Task Force and approved by the ALEC Board of Directors in 1997.

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