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SUFFOCATED BY RED TAPE: HOW AN EPA AND FDA PROPOSAL WILL LEAVE ASTHMATICS GASPING FOR BREATH

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INTRODUCTION

One of the stated missions of both the U.S. Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) is the protection of public health. But can either agency fulfill this mission when it puts in place regulations that cause more harm than good? Increasingly, federal regulatory agencies are imposing ineffective, costly, and often dangerous regulations that not only do not protect public health or save lives, but in fact may endanger life. This may be the suffocating reality for an estimated 30 million Americans who suffer from asthma, cystic fibrosis, and chronic obstructive pulmonary disease, thanks to a recent proposal from the FDA and EPA.

Risking Lives for No Environmental Benefit

On March 6, 1997, the FDA issued an advance notice of proposed rulemaking (ANPRM)—which was developed in collaboration with the EPA—to remove from the market all metered dose inhalers (MDIs) that contain chlorofluorocarbons (CFCs).[1] The FDA's proposal is designed to bring the United States into compliance with the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer.[2] Under this protocol, production of CFCs will be terminated because they are thought to be ozone-depleting substances.

1 *Federal Register*, Vol. 62, No. 44 (March 6, 1997), p. 10242.
2 S. Treaty Doc. No. 10, 100th Cong., 1st Sess., 26 I.L.M. 1541 (1987), signed September 16, 1987.

Despite what the EPA and FDA proposed rulemaking might imply about the dangers of CFCs, CFC-powered inhalers used by Americans who have asthma and other chronic lung diseases account for only 4,000 tons of CFCs[3]—which is less than 1 percent of the total available chlorine in the atmosphere. What does that mean in everyday terms? By the EPA's own estimates, about 100,000 tons of CFCs continue to circulate in the air conditioners of 100 million vehicles, and 65,000 tons of CFCs circulate in 153 million domestic and commercial chillers and refrigerators. The impact of inhalers seems insignificant by comparison. One might wonder, then, whether federal regulators think it would be easier to take inhalers from asthmatic sufferers than to take cars, air conditioners, and refrigerators away from the American public for no good reason.

The lives of asthmatics depend on the availability of inhalers to treat a wide range of serious conditions. For this reason alone, the FDA's decision lacks any rational basis. But beyond this, it makes little sense to limit the number of inhalers on the market so dramatically when, according to the American Lung Association, the number of deaths from asthmatic attacks is on the rise. In addition, the Montreal Protocol has given developing countries around the world an exemption from the strict standards for reducing CFC emissions that the United States must follow.

The FDA–EPA proposal to ban CFC-MDIs will jeopardize the lives of millions of asthmatic children and adults in the United States needlessly. Their concern was recently demonstrated by the nearly 10,000 public comments sent to the FDA in direct response to its ANPRM proposal.[4] It is time for Members of Congress to have the courage to bring a stop to such regulatory insanity. Currently, three bills are before Congress that address this issue.

THE MONTREAL PROTOCOL: GLOBAL CFC INEQUALITY

The pressure on the FDA by the EPA to issue an ANPRM is due in part to the 1987 Montreal Protocol signed by more than 140 countries. The signatories agreed to phase out CFCs because of their presumed impact on the atmosphere's ozone layer. In accordance with the protocol, the United States and other developed countries banned the production of CFCs for use in refrigerators, air conditioners, all hair sprays, and cosmetics after January 1, 1996.[5] Developing countries, however, may continue to produce and use CFCs until 2010.[6]

What is most significant about the protocol is that the signatories also recognized that certain uses of CFCs can generate tremendous heath and safety benefits, and that these uses should be given a temporary "essential use" exemption from the treaty's restrictions.[7] One such use of CFCs is in the manufacturing of MDIs for asthmatics; the CFCs enable the inhaler to deliver a specific dose of medication to the lungs of the asthmatic immediately.

Despite this exemption, the FDA has decided to accelerate the phasing out of CFC-propelled inhalers in the United States. Unless the FDA modifies or delays its proposal, asthma patients in the United States will be prevented from using dependable and effective asthma medication propellants even as consumers in China and Indonesia continue using CFC-based products like hair sprays, cosmetics, and asthma inhalers.

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3 EPA figures provided by facsimile from the office of Representative Mark Foley.

4 Food and Drug Administration, Docket No. 97N–0023, 1997.

5 Cindy Skrzycki, "The CFC Exemptions Have 3M Pharmaceuticals Gasping," *The Washington Post,* October 11, 1996, p. F1.

6 Vincent Zulu, "Threat to World's Ozone Layer Leaves Many Zambian Consumers Cold," *The Worldpaper,* October 14, 1997.

7 *Federal Register*, Vol. 62, No. 44 (March 6, 1997), p. 10242..

THE ALARMING INCREASE IN THE NUMBER OF ASTHMATICS

An estimated 30 million Americans use MDIs for the treatment of asthma, cystic fibrosis, and chronic obstructive pulmonary disease.[8] Of these, 14.6 million suffer from asthma, including 4.8 million children under the age of 18.[9] These asthma sufferers rely on 42 different CFC-MDI medications already on the market with FDA approval as safe and effective products for the treatment of their medical conditions. Unfortunately, although such an extensive variety of asthma medications is readily available, asthma attacks caused a recorded 5,487 deaths in 1995 alone.[10]

Between 1982 and 1994, the prevalence rate (per thousand persons) of asthma in the United States rose from 34.8 to 56.1, an increase of 61.2 percent. The prevalence rate of pediatric asthma rose over the same period from 40.1 to 69.1—a 72.3 percent increase.[11] The American Lung Association also has found that asthma affects people of various races differently. Although African-Americans represent approximately 13 percent of the population of the United States, they account for 21.6 percent of the deaths from asthmatic attacks.[12] A 1994 Chicago study published in the *American Journal of Public Health* revealed that, although the asthma mortality rate remained stable among white Americans from 1968 through 1991, it had increased by 337 percent among African-Americans from 1976 through 1991.[13]

Asthma affects children differently as well. Childhood asthma in the United States has increased by 118 percent since 1980, making it the leading serious chronic illness of childhood and the leading cause of childhood hospital admissions.[14] Not only does asthma directly affect the health of American children, it also directly affects their education: Asthma is currently the number-one reason given for school absence.[15] This sizable impact on health and education should be enough to make officials in Washington, D.C., look for a better alternative than banning the use of MDIs just to prevent a presumed effect on ozone depletion. As asthma becomes an alarmingly prevalent health problem, the FDA should be more interested in implementing measures to ensure that the greatest number of safe, effective, and inexpensive medical treatment devices for asthmatics are available. Harming children and those who need help just to breathe—the very people the government claims its environmental standards on air quality will help—is unconscionable.

PUTTING A SEVERE LIMIT ON HEALTH CARE OPTIONS

MDIs are an extremely valuable tool in the treatment of patients with asthma and chronic obstructive pulmonary disease. The main challenge in treating asthma is determining the most appropriate medication regimen for each individual patient—a process that often requires months of trial prescriptions using different medications and inhalers. Before restricting such choices for asthmatic patients and doctors, the FDA should consider the fact that each patient is unique and will respond differently to medications; patients respond differently to different medications, and sometimes even to the same medication. The typical asthma patient routinely will use two to three different inhalers twice or even three times a day.[16] There also are significant differences among the various agents used within a class of MDIs for efficacy, side effects, and time to onset of action.

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8 "Let 'em Wheeze," *Investors Business Daily,* October 24, 1997, p. A34.
9 American Lung Association (ALA), "Lung Disease Data 1997," Washington, D.C., 1997, p. 4.
10 *Ibid.,* p. 7.
11 *Ibid.,* p. 4.
12 *Ibid.,* p. 7.
13 Paul V. Targonski, "Trends in Asthma Mortality Among African Americans and Whites in Chicago," *American Journal of Public Health,* Vol. 84, No. 11 (November 1994).
14 Wes Jones and Steve Wilcox, "Additional Protection Will Pay Off," *The News and Observer,* August 14, 1997.
15 ALA, "Lung Disease Data 1997," p. 5.

Because the effectiveness of MDIs varies for each person, it is important that physicians have as many MDI options available as possible so they can tailor treatment to the needs of each patient. Currently, the 42 MDIs on the market provide the safest and most effective medical means to deliver the specific doses of medication needed so that children and adults afflicted with asthma can breath easier and lead normal lives—and even to offset a potentially fatal attack of asthma.[17] Most of these inhalers[18] use only a tiny amount of CFC to deliver medication from the inhaler canister into the patient's lungs.

Because of the small amount of CFCs used in the MDIs, however, the FDA has proposed a series of criteria for phasing out their use. The FDA under its proposed rule would ban the use of MDIs containing CFCs when three non-CFC alternative products (two of which must be MDIs) are available within each of the FDA-established therapeutic classes for the current CFC-propelled MDIs.[19] The proposed FDA criteria go on to specify that:

- Adequate supplies and production capacity must exist for the alternative products to meet the needs of the population indicated for the therapeutic class;
- At least one year of post-marketing use data for each product must be available; and
- There must be no persuasive evidence to rebut a presumption that all significant patient populations are served by the alternative products.[20]

A proposal that would force physicians and patients to switch from a regimen providing numerous medical alternatives to a regimen in which only a limited number of alternatives are available is not in the best interest of the patient. Even the chairman of the American Academy of Family Physicians, in a letter to the FDA, advised that an "accelerated phase-out of medical products that contribute to our patients' health and well being, without a reasonable range of non-CFC alternatives, is unwarranted." The removal of the current and available treatment options would impair the physician's ability to provide his patients with optimum symptom control. It should be up to asthma patients and their doctors—not the FDA—to decide when and if a change in medication and treatment is appropriate.

At a time in which doctors are striving to get asthma sufferers to maintain a prescribed treatment regimen, the FDA's proposed rule would interrupt the continuity of this treatment and throw treatment plans into disarray. To limit approved medical products before new ones are universally accessible and affordable is unreasonable and precariously risks the health of many children and adults who suffer from asthma.

The FDA proposal claims that the FDA will not ban a CFC-containing inhaler that serves a "significant patient sub-population." But who will determine what constitutes a "significant patient population"? Is a significant sub-population 1 person or 1,000 people; is it all children or just inner-city children; is it people under 60 years of age or those over 60? How will the FDA determine whose life is worth giving special access to the effective medication and whose life is not? These troubling questions highlight the fact that the FDA's proposal to revoke the use of CFC-propelled

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16 Peter A. Duhamel, M.D., Comments to the Food and Drug Administration, Docket Number 97N–0023, on behalf of the Michigan State Medical Society, May 5, 1997.

17 Information Management System, 1997, and the Physicians Desk Reference, 1997.

18 Only one metered dose inhaler on the market today does not use CFCs.

19 In addition, the FDA would ban the use of a CFC-MDI that is *not* in one of the rule's therapeutic classes and which the agency has not already determined is nonessential when one non-CFC alternative product containing the same active drug is available. Under this second condition, the same three criteria would apply. *Federal Register,* Vol. 62, No. 44 (March 6, 1997), p. 10244.

20 *Ibid.*

MDIs could have negative consequences, putting patients' health at risk and raising the cost of health care. Clearly, the "one-size-fits-all" approach of the FDA proposal will put the health of many current and future asthma sufferers at great risk.

The Costs of Limiting the Available Substitutes

Limiting the number of available substitutes for CFC-MDIs will make inhalers prohibitively expensive and increase the overall cost of health care. The simple economic rule of supply and demand should make it obvious that limiting the number of MDIs on the market will make the cost of *all* MDIs rise substantially. This increase in the cost of medicine and treatment for asthmatics would come at a time in which the average cost of MDIs has been declining due to an increase in competition among pharmaceutical companies and the entrance of generic products into the market. Thus, poorer families and children who are especially reliant on generic inhalers with CFC propellants—which can cost as much as one-eighth the price of newer brand-name products without CFCs—would be hit hardest by the FDA proposal.

Recent research suggests that poverty plays an important role in the rising rates of asthma. The American Thoracic Society stated in 1996 that "poverty may be the number one risk factor for asthma."[21] Other studies have suggested that morbidity and illness due to asthma in inner-city children are exacerbated by the living conditions of the poor.[22] By limiting the availability of treatment options, both the costs of medication and of health care would increase, becoming less accessible to those in low-income populations who need them most. The proposed FDA rule would limit market competition severely and have a devastating effect on Medicare patients as well as uninsured or inadequately insured individuals—patients who would not be able to afford the new, non-CFC MDIs.

Asthma currently accrues an estimated annual economic cost to Americans, in direct health care alone, of $9.8 billion.[23] Inadequate control of asthma symptoms would lead to an increased utilization of more costly forms of treatment and increased visits to physicians and emergency rooms. Thus, not only would the proposed rule have a potentially devastating effect on an asthmatic patient's health, it also would increase the national cost of health care overall.

WHAT CONGRESS CAN DO

The FDA received 9,595 public comments on its proposal between March 6, 1997, and May 5, 1997—a high number of comments for an ANPRM. These comments included the following:

- The American Osteopathic Association, which represents over 38,000 osteopathic physicians who see over 100 million patient visits a year, commented that

  > [W]e cannot support a plan which may be detrimental to the health of the patients treated by osteopathic physicians across the country. We believe that the already established transition period to CFC-free MDIs will allow completion of ongoing clinical studies to develop alternatives without disrupting the therapy of our patients.[24]

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21 American Thoracic Society, 1996 Conference Articles, cited in *Comments on the Proposed National Ambient Air Quality Standards for Ozone and Particulate Matter*, pp. iii–10.

22 For example, see David Rosenstreich, M.D., et al., "The Role of Cockroach Allergy and Exposure to Cockroach Allergen in Causing Morbidity Among Inner City Children with Asthma," *New England Journal of Medicine*, Vol. 336, No. 19 (May 8, 1997), pp. 1356–1384.

23 ALA, "Lung Disease Data 1997," p. 5.

24 John P. Sevastos, R.Rh., Comments to the Food and Drug Administration, Docket Number 97N–0023, on behalf

- The Michigan State Medical Society and its members

> strongly encourage the FDA to reconsider the necessity for this proposed rule. We feel any efforts to limit the medications and treatment options available to asthma patients and their physicians could potentially result in severe consequences for asthmatics and chronic obstructive pulmonary disease patients.[25]

Research and development on CFC-MDIs is ongoing throughout the pharmaceutical industry, and these industry efforts, along with the Montreal Protocol's decision, are likely to ensure the virtual elimination of CFCs from MDIs. Instead of proposing to ban CFC-containing MDIs, the FDA could choose to expedite review and approval for CFC-free MDI applications. In the words of Representative Mark Foley (R–FL), a former asthmatic,

> It seems incredible to me that a federal agency designed to protect us would propose something so harmful. I agree that we should do everything in our power to rid the atmosphere of CFCs and other threats to public health. But common sense must dictate the process. It defies comprehension that the EPA would propose a plan aimed at protecting asthmatic children in the long run that, in the short run, could well kill them.

Currently, two bills under consideration in the House and one in the Senate address this issue:

- On October 7, 1997, Representative Foley introduced H.R. 2627, the Asthma Inhaler Regulatory Relief Act, with co-sponsorship from 14 other Members of Congress. The bill would prohibit the EPA from barring the manufacture of CFC-propelled asthma inhalers until these agencies jointly can certify to Congress that the drugs replacing those pulled from the market are comparable in their effectiveness, retail availability, and cost.
- On July 22, 1997, Representatives Clifford Stearns (R–FL) and Christopher Smith (R–NJ) introduced H.R. 2221, with co-sponsorship from 33 other Members of Congress. This bill would require the secretary of the Department of Health and Human Services to take no further action on the FDA-proposed ban on CFC-containing MDIs.
- On October 22, 1997, Senator Tim Hutchinson (R–AR) with co-sponsorship from Senators Mike DeWine (R–OH), James Inhofe (R–OK), Christopher Bond (R–MO), Richard Shelby (R–AL), and Jeff Sessions (R–AL) introduced S. 1299, the Asthma Inhaler Regulatory Relief Act, in the Senate. S. 1299 is designed to stop the FDA and the EPA from banning the most common form of asthma inhalers until affordable, accessible, and effective alternatives become available.

CONCLUSION

Considering the tremendous need for metered dose inhalers throughout the country, the negligible amount of chlorofluorocarbons released by these inhalers, and that CFC-MDIs will be phased out voluntarily by the pharmaceutical industry within the next four or five years, the proposal by the Food and Drug Administration to pull these devices from the shelves clearly is not justified. Congress should take steps to ensure that the FDA proposal is not enacted.

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of the American Osteopathic Association, April 15, 1997.

25 Duhamel, Comments to FDA, Docket Number 97N–0023, *op. cit.*

This regulatory red tape threatens to suffocate asthmatics and is entirely without justification when one takes into consideration the internationally negotiated commitment to phase out CFC production and use, the competitive market forces already driving the development of alternative products within the pharmaceutical industry, and the apparent imbalance of the environmental benefit and the public health risk to asthma patients that underlies the FDA's planned proposal.