EXTENSIONS OF REMARKS

PRESERVING PATIENT ACCESS TO METERED DOSE INHALERS

HON. CHRISTOPHER H. SMITH

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Wednesday, July 9, 1997

Mr. SMITH of New Jersey. Mr. Speaker, today Mr. CLIFF STEARNS, my good friend from Florida, and I are introducing legislation aimed at helping those who suffer from respiratory conditions, particularly children with asthma, and preserve their access to medicines they rely upon to breath—metered dose inhalers (MDI's).

Our legislation calls upon the Food and Drug Administration [FDA] and the Environmental Protection Agency [EPA] to delay their plans to remove chlorofluorocarbon-based MDIs from the marketplace before 2005. The resolution implores the EDA to continue to allow these critically important medicines to remain on the market while environmentally safe alternatives are developed and manufactured.

As many of you know, nearly 30 million Americans suffer from respiratory diseases of one kind or another, including asthma, chronic obstructive pulmonary disease [COPD], and cystic fibrosis. When the symptoms of these diseases strike, patients reach for the safe, effective, and proven medication delivery systems that have kept them alive for years—metered dose inhalers. Quite literally, metered dose inhalers enable patients to breathe freely and often mean the difference between life and death.

These inhalers are generally powered by chlorofluorocarbon [CFC] propellants. Under the 1987 Montreal Protocol, CFC's are to be phased out globally because of the damage they are believed to cause to the ozone layer. I believe it is important to point out, however, that the signatories to this Protocol explicitly recognized that certain uses of CFC's—such as MDI's—pose relatively small environmental risk yet generate tremendous health and safety benefits, and consequently, MDIs were given a temporary Essential-Use exemption from the treaty.

Despite this global exemption and the internationally recognized health benefits of MDI's, the U.S. FDA has unilaterally decided to accelerate the phase-out of CFC containing metered dose inhalers. Under the proposed framework, CFC containing inhalers—used safely and regularly by millions of asthmatic children, adults, and senior citizens—would be banned and consumers would be forced to purchase alternative products, even if there was but a single alternative on the market. I believe that this proposal is outrageous and totally unwarranted at this time.

Although pharmaceutical companies are working diligently to develop CFC-free MDI's, the FDA proposal will force patients to abandon their existing medications and could place them at the mercy of a single supplier in certain cases. This is fatally flawed in two important respects: first, each patient is unique and responds differently to asthma medication—even to the same medication—so the one-size-fits-all approach that FDA is pursuing will harm many of these patients; and second, consumers will be charged higher prices due to the lack of competition in alternative MDI products.

Mr. Speaker, it is a well known fact that asthma is currently the No. 1 reason for school absences, and that roughly 5,000 Americans die each year from asthma-related complications. Furthermore, for millions of asthma sufferers, the single most important part of successful treatment is maintaining a steady medication routine. disrupting this routine, which is a certain byproduct of the FDA's proposal, will needlessly put the lives and health of our children and senior citizens at risk.

I am also dismayed that the FDA, by seeking to ban CFC MDI's even when only a single alternative MDI is on the market, is making the erroneous assumption that all significant patient subpopulations—such as children and the elderly—will be equally served by the alternative product. This assumption is not only incorrect, but it violates the FDA's very own procedures and rules. All products that wish to obtain a pediatric indication must be reviewed separately by the FDA to determine whether the effect of a drug on children is the same as an adult. Yet, in its zeal to phase out CFC products before the United States is even required to do so, the FDA is trampling on this principle.

An additionally egregious aspect of the FDA's proposed rule is that it is an answer in search of a problem. The United States is in absolutely no danger of missing the Montreal Protocol's compliance deadline (2005) for completely eliminating CFC's, and there is no need to abruptly ban MDI's that have been widely and safely used for years.

Furthermore, the amount of CFC's used in metered dose inhalers is so small—less than 0.025 kg per inhaler—that the marginal environmental improvement in the ozone layer that would result from the FDA plan would be virtually undetectable.

To put these amounts into perspective, consider that in 1996, transitional stockpiles of CFC's for use in air conditioners and refrigeration equipment totaled between 36,000 and 72,000 tons. The total production of CFC's used for MDI's that year was only 2,600 tons, and MDI's are responsible for less than 1 percent of the risk to the ozone layer, as measured by atmospheric chlorine levels.

In addition, while the United States and developing countries must eliminate all CFC's by 2005, developing nations can continue to produce CFC's until 2010. Unless the FDA drastically modifies or delays its plan, asthma patients in the United States will have their dependable and effective medications taken away from them while consumers in China and Inodonesia continue to use CFC's in hair spray and cosmetics.

It seems incomprehensible that anybody could support a proposal that secures negligible environmental benefits at a very steep cost to human lives and health. Notwithstanding, the FDA continues to move forward with its plan despite overwhelmingly negative public comments. I understand that the magnitude of the public reaction to the FDA's advance notice was among the greatest—in terms of the numbers of letters received—in recent history. This is even more remarkable considering that the ban on metered dose inhalers has received very little media coverage.

In conclusion, Mr. Speaker, let me say there is no doubt that pharmaceutical companies should be encouraged by the FDA to develop, test, and bring alternative products to market before 2005. However, it is absurd and downright dangerous to put asthma patients—including children whose very lives depend on adhering to familiar medical routines—at risk by pulling effective and safe products from our shelves in order to meet a self-imposed standard. There is absolutely no reason to disrupt the lives of asthma and cystic fibrosis patients in the manner FDA has proposed. That is why I have joined my friend Congressman STEARNS in introducing this resolution today.

The alternative approach that we suggest to the FDA is very straightforward: allow the existing products—proven safe and effective over years of use—to be used until 2005, and encourage the development and use of alternative [CFC-free] metered dose inhalers so that asthma patients can gradually become accustomed to the different medications without undue disruptions and risks. Rather than forcing patients to switch medications suddenly and involuntarily, our approach would allow environmentally safe products to flourish and attain widespread acceptance.

I call upon my colleagues on both sides of the aisle to reject the FDA's cold turkey policy—Australia has already rejected that strategy. The United States can achieve its goal of zeroing out CFR production in 2005 without the heavy-handed, one-size-fits-all approach that the FDA has proposed. The children and senior citizens who depend on metered dose inhalers to breathe and live normal lives surely deserve better than that.

TRIBUTE TO JACKIE O'CONNOR DOLLAR

HON. FRANK RIGGS

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, July 9, 1997

Mr. RIGGS. Mr. Speaker, I rise today to commend the activities of Jackie O'Connor Dollar, the director of the Head Start Program in Napa and Solano Counties, which I represent. Last week, Jackie was presented with the Head Start-Johnson & Johnson Excellence in Management Award for her outstanding work on behalf of Napa and Solano Counties' children.

In September 1995, the Napa and Solano County Head Start programs were consolidated into one. Although this merger increased her area of responsibility by 400 percent, Jackie handled the change in stride and