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The True Environmental Cost of Chlorofluorocarbon-Based Inhalers

To the Editor It was with apprehension that I read the interesting and sobering analysis by Jena et al¹ and commentaries^{2,3} on the health care and/or cost consequences of the decision of the US Food and Drug Administration (FDA) to ban chlorofluorocarbon (CFC)-based metered-dose inhalers (MDI) in order for the United States to comply fully with the Montreal Protocol. I participated as a panel member of the FDA advisory committee meeting in 2004 and chaired a follow-up meeting in 2005 convened to discuss the issues ahead of their final ruling later that year.

The panel members and I were quite concerned about the implications of placing the cost of this laudable environmental goal on the backs of economically disadvantaged Americans with little or no health insurance given the fractured and chaotic state of health care access in the United States and the anticipated higher price of alternative non-CFC MDIs. The goal of complete cessation of CFC use had become a high priority of the government (in particular, the US State Department and Environmental Protection Agency) and was strongly supported by those pharmaceutical manufacturers, which already had more expensive hydrofluorocarbon and other non-CFC propellant-driven MDIs on the market. The FDA was tasked with finding CFC alternatives unless 3 essential aspects were met: (1) that no technically feasible alternative existed, (2) a substantial health benefit was being met, and (3) the release of CFCs was small. No considerations of price, adverse health consequences, or an exact definition of "small" were included in the criteria. Other Western or first-world countries with more comprehensive health insurance coverage and cost controls could readily afford to switch to inhalers with non-CFC propellants, but we in the United States had to rely on the goodwill of the several pharmaceutical manufacturers who individually proposed that they would make their newer MDIs readily available and affordable to poor Americans through vouchers and rebates. These, however, would necessitate physicians and patients having to apply and seek this price relief, which is a difficult hurdle for busy physicians and poor patients. As a member of the advisory committee, I voted to support to phase out CFC MDIs where alternatives existed with the hope that access and affordability would not be problematic.

To gain a better perspective on the environmental consequence of such a small health-use exemption, I asked the following question to the experts at the meeting who claimed that it would take 50 years for the Austral ozone hole to completely close after all use of CFCs in refrigeration, air conditioning, and other industrial uses in the United States and elsewhere had been eliminated. "How much longer would it take if the quantitatively trivial use of CFCs in MDIs were continued until non-CFC generics might become available?"

The answer: roughly another week.

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Editorial Note: This letter was shown to the corresponding author of the original article, who declined to reply on behalf of the authors.

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LESS IS MORE

The Lariat for Left Atrial Appendage Closure: Rehash of Known Literature or a True Analysis?

To the Editor We read with great interest the recent review of a small body of literature in *JAMA Internal Medicine* by Chatterjee et al.¹

The implication by Chatterjee et al that somehow the US Food and Drug Administration (FDA) was lax in their approval of 510(k) class II status for the Lariat snare device (SentreHeart Inc) is perplexing. It is not unusual for device manufacturers to obtain marketing authorization for one use and then seek additional indications for a different use based on clinical need. Clinical scenarios often force physicians to make choices using clinical tools based on medical necessity. Those of us who have seen devastating bleeding complications from oral anticoagulation or strokes from failed anticoagulation strategies have chosen to close the left atrial appendage (LAA) with a device that is capable of doing the job with a high rate of complete closure.² Many patients we have ligated with a Lariat had no choice other than open heart surgery or to stop their anticoagulation, which would leave them vulnerable to an atrial fibrillation (AF)-related stroke. Most cases where the Lariat is used off-label are "compassionate" cases that have no other FDA-approved alternative.

Pulmonary vein isolation had similar issues when AF ablation started with 20% to 30% complications related to a radiofrequency ablation catheter that had not been approved for AF ablation at the time. Angioplasty endured decades of trials and tribulations to advance to where it is today. New data have been reported at major meetings demonstrating the merits of LAA ligation and stroke prevention in AF patients with contraindications to oral anticoagulation therapy.³⁻⁵ Additionally, the merits of LAA ligation to improve catheter ablation in treating persistent AF has been reported. Based on this growing body of beneficial evidence of LAA ligation, engagement with the FDA to initiate pivotal clinical trials to warrant labeling of the device beyond the soft tissue closure of the LAA are currently being undertaken.

As with any new technology, there is a learning curve time period when the periprocedural difficulties get worked out. Improvements in techniques, micropuncture needles for access, and postprocedure management have markedly improved outcomes.⁶