



**Before the Department of Health and Human Services Food and Drug Administration
Docket No. FDA-2009-N-0374
Public Workshop: Educating the Public about Removal of Essential-Use Designation
for Epinephrine**

Statement of the Asthma and Allergy Foundation of America

September 25, 2009

On behalf of the Asthma and Allergy Foundation of America (AAFA), I am pleased to make this statement. My name is Charlotte W. Collins, and I am Director of Public Policy & Advocacy. AAFA provides free information to the public, offers educational programs to consumers and health professionals, and advocates for supportive public policies.

FDA based its action to ban the epinephrine inhalers that are currently available over the counter on sound reasoning. It concluded that epinephrine inhalers do not provide a greater therapeutic benefit than similar adrenergic bronchodilators, and that its over-the-counter distribution does not provide an important public health benefit. Further, it expressed concerns about the risks of self-treatment by patients with over-the-counter (OTC) medications for asthma. Nevertheless, the transition from over-the-counter epinephrine metered dose inhaler products to therapeutic alternatives that do not contain ozone depleting substances is troublesome. As one of our scientific advisers put it:

Primatene is certainly inferior to newer, more selective SABAs (short-acting beta agonists). However, should the public be left without an OTC SABA necessitating that they see a licensed care giver to obtain an Rx for a rapid acting asthma reliever or visit an ER whenever they wheeze? Perhaps it is a good thing to require asthma patients to see a care giver for long term care, but will they comply?

After 2011, when asthma patients visit a pharmacy to buy an inhaler, they will discover that it is no longer on the shelves. We will not be able to point them to another product on the shelves. There are no over-the-counter comparable inhalers now and no prospect for any in the foreseeable future. What will be the effect on ER visits, hospitalizations and mortality rates? We do not know, yet we have to plan to support patients as they face this change.

Therefore, our strategy is to support patients by directing them to physician-level care using prescribed medications rather than transitioning them to another product. By exploring strategies to inform current users and direct them to find a medical provider for care, the FDA is exercising an unprecedented level of leadership in transitioning patients from CFC-based medications. For that, we applaud the agency.

The challenges of this transition are also unprecedented. We make assumptions about the users of OTC epinephrine products. We assume that they are not in a system of care for good reasons. They may not view these products as less safe and less effective long-term, or they may not have an asthma diagnosis. They use these products for convenience or because they lack access to medical care due to lack of medical insurance or inadequate prescription drug coverage.



The major issue before us is how FDA can help to transition people to an alternative that may not be readily available to them, and that FDA acting alone cannot make available to them.

- FDA can promote awareness through direct actions before December 31, 2011:
 1. Require that manufacturers place a prominent notice about the upcoming withdrawal on the label of the products.
 2. Require that pharmacies offer them behind the counter only.
 3. Offer a listing of medications slated for withdrawal on a web page, including dates and brand names.

While we see a role for FDA in direct action, we suggest that FDA can be much more effective in collaboration with others.

- FDA should collaborate with other agencies in the federal government that have ongoing outreach and programming aimed at consumers with asthma and other lung diseases.
 1. The Centers for Medicare and Medicaid Services is engaged in major outreach campaign to enroll children in the State Children's Health Insurance Program (CHIP), and information about the ban makes sense given the burden of asthma on children.
 2. The Social Security Administration is also undertaking outreach activities to enroll consumers into the Medicare Prescription Drug Part D benefits, targeting another group especially burdened by asthma - the elderly.
 3. NIH institutes identified potential grantees during the recent Challenge Grant Award process. FDA should link into that network to target communities.
 4. The Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA) and NIH agencies sponsor asthma programs.
- FDA can promote awareness education and sponsor mass communications, as it networks creatively with federal and non-traditional stakeholders:
 - AAFA works with Educational Support Groups (ESGs) all across the country to provide relevant information about asthma and allergies and offer emotional support. FDA should collaborate with AAFA to develop and disseminate information to these groups, and provide current information on AAFA's web site, Asthma PACT (AAFA's new online asthma adherence tool) and social networking sites like Facebook, MySpace and Care2.
 - Community health centers, supported by federal funding from the Health Resources Services Agency (HRSA) and organized as the National Association of Community Health Centers, are an important group of providers of care to low income individuals. FDA should include it in its communication network with outreach materials aimed at primary care providers, patients and parents of children with asthma.



- The EPA supported *Communities in Action for Asthma-Friendly Environments* represents another key link to asthma coalitions and programs in communities across the nation. It should be a primary target for FDA outreach.
- Some public health programs are working creatively to offer health screenings and education programs in barbershops and beauty salons, including asthma programs. Examples include the Harlem Children's Zone Asthma Initiative and the University of Pittsburgh's Lay Health Advocates' Training Program.
- FDA should provide flyers and online content to medical and public health trade associations like the American Association of Pediatricians and American Public Health Association as well as other organizations that support patients with lung diseases.
- FDA can also provide culturally diverse video and print content for popular social media websites, campaigns by volunteer health associations, religious and community groups, and popular media like YouTube.

I will close with this recommendation: FDA should identify funding to create a community outreach campaign and fund partners who can reach communities that we think will be impacted. There is still time for a robust campaign. This campaign can underscore ongoing initiatives to promote the NHLBI asthma diagnosis and management guidelines, as well as efforts to encourage adherence. Partners like AAFA are ready, willing and able, but need additional resources in order to be effective. Reaching existing users is going to be a challenge for all of us. We need to work together.

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