



Are There Fakes and Frauds in Your Nebulizer?

As patient advocates and educators, Allergy & Asthma Network Mothers of Asthmatics is concerned with the safety and quality of respiratory medications in our country. To address the issue, we formed CHASM, the Consumer Health Alliance for Safe Medication. This is the first in a series of articles looking at this topic.



Nebulized breathing treatments deliver moist, medicated mist to the airways – critical for many people young and old with asthma, COPD (chronic obstructive pulmonary disease), cystic fibrosis and other respiratory conditions.

Nebulizers convert liquid medication into an aerosol mist that floats deep into your airways as you inhale. Breathing the mist over a period of minutes can relax bronchial muscles, soothe raw airways, help loosen thick mucus and make coughing more productive.

There are many different nebulizer systems and medications. You and your medical care provider will select the best combination for your needs. However, when the prescription is filled, will you get what the doctor ordered?

The answer may surprise you. Increasingly, prescriptions for FDA-approved nebulizer medications are swapped out with unapproved products. Think it can't happen to you?

Take the AANMA Challenge. Learn ways to spot the imposters and what to do if you find one lurking in your medicine cabinet.

The Real Thing...



Expiration date embossed onto vial



Medication lot number embossed onto vial



Medication name and dosage embossed onto vial



Pharmaceutical manufacturer name embossed onto vial

When we take a prescription for a nebulizer medication to the pharmacy or hand it to a home health-care representative, we trust we'll receive the medication prescribed by the physician.

We take for granted that the medication is Food and Drug Administration (FDA) approved. We assume it is manufactured and packaged under sterile conditions at FDA-licensed facilities; that it is labeled clearly with an expiration date, medication lot number, medication name, dosage and pharmaceutical manufacturer (see left).

And we expect to be notified if the pharmacist cannot fill the prescription as written so that we can discuss the best alternatives with our physician.

Because that's the way it *should* be.

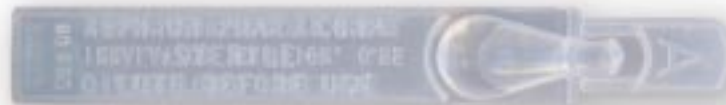
Disguised and Dangerous

However, an alarming trend is eroding America's trust in the quality and safety of respiratory medications. Operating under the guise of legitimate pharmacy compounding, some pharmacies are flouting the law at the expense of unsuspecting patients and physicians. They are making and dispensing substandard medications.

Legitimate pharmacy compounding occurs when a patient needs a medication that is not otherwise commercially available. The physician writes a specific prescription after discussing the need for a compounded medication with the patient, and the pharmacist makes the medication for that individual patient. All three parties speak directly to each other and discuss the risks and benefits

FDA-Approved Brand-Name and Generic Unit-Dose Medications

albuterol sulfate - Nephron Pharmaceuticals



Xopenex® - Sepracor Inc.



albuterol sulfate - Warrick Pharmaceuticals



DuoNeb™ - Dey, L.P.



Pulmicort Respules® - AstraZeneca



This is just a sampling of FDA-licensed medications. The clear vials are embossed on both sides, making photography difficult. Be sure to examine both sides of a vial to evaluate markings.

Not FDA Approved

Imposters come in all shapes and sizes. The plastic “wings” and paper labels are clues to question the safety, source, potency, sterility and inactive ingredients.



associated with the compounded medication.

According to Leslie Hendeles, PharmD, professor of pharmacy and pediatrics at the University of Florida, “There is no clinical reason to compound any nebulizer medication for any patient with asthma or COPD. There are FDA-approved, safe and effective medications available.”

Legitimate compounded medications are not sold on the Internet. They are not mass marketed. But maybe you’ve seen the ads: “Quality drugs at cheaper prices – the prices you deserve.” According to advertising, they’ll deliver products and equipment to your door and you’ll never see a bill; the company files claims for you. What could be simpler?

The problem: It’s not obvious when your prescription is filled with

an imitation. Furthermore, you and/or your medical care provider may unknowingly sign an official document allowing the substitution.

The danger: The source of ingredients in your nebulizer vial may be unknown – and untraceable. According to Stuart Stoloff, MD, “The vial may or may not contain a therapeutic dose of medication.” In addition, it may be contaminated with bacteria or contain preservatives and/or alcohol known to irritate the airways and cause coughing spasms.

“Preservatives or packaging contaminants may cause the same symptoms that are being treated, such as bronchospasm (constriction of the airways),” says Dr. Hendeles.

How frequently is this happening? No one knows for sure, but we do know that every time we write about this issue, more stories surface.

More Clues



Don’t assume a patent number applies to a medication. This one refers to the plastic vial.



Paper labels leach toxins into nebulizer solutions; all lack FDA-mandated information such as dose, expiration date and lot number

One mom who contacted AANMA said, “I feel like I’ve been kicked in the stomach. I’ve been giving my child a medication I thought my doctor prescribed and I was deceived.” Her son’s prescription for Pulmicort Respules® had been substituted with “generic budesonide” (pictured above). There is no FDA-approved generic for Pulmicort Respules, thus this product was counterfeit.

How can pharmacies get away with this? That’s a question that AANMA and other organizations are taking to the FDA, as well as state and federal lawmakers. Watch for updates on this important subject in upcoming issues of *Allergy & Asthma Today*. Don’t miss out – call us at 800.878.4403 to make sure that you’re on our mailing list.

And visit
www.breatherville.org/CHASM
for news links and legislation.

Call to Action

Do you think you have found an imposter nebulizer medication in your cabinet?

Notify your physician immediately. Show this article and a sample vial to your prescriber. Take steps to get the correct medication.

Tell your story to AANMA.

Call Sandra Fusco-Walker at 800.878.4403 x105, e-mail sfwalker@aanma.org, or write us at AANMA/CHASM, 2751 Prosperity Ave., Suite 150, Fairfax, VA 22031.

The FDA wants to hear from you at MedWatch.

Call 800.FDA.1088 or log on to www.fda.gov/medwatch/report.htm.

Do not discard imposter medications.

RED FLAG

■ Refuse any medication sold as a generic for Pulmicort Respules®, Xopenex® or DuoNeb®; there are no FDA-approved generics for these medications.

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WHAT'S IN A NAME?

When a pharmaceutical company launches a new medication, they give it a brand identity or name that will be easier to say, spell and remember than the chemical (generic) name. Once a brand name medication's patent expires, other licensed pharmaceutical manufacturers may produce generic versions, according to strict federal regulations.

In the chart below, we've listed some pharmaceutical manufacturers and the brand name medicines they make, along with licensed generic manufacturers who make a variety of respiratory medications.

Brand-Name Manufacturers of Medications for Nebulizers	
AstraZeneca	Pulmicort Respules® (budesonide) Suspension**
Boehringer Ingelheim	Alupent® (metaproterenol sulfate) Inhalation Solution
Dey, L.P.	AccuNeb® (albuterol sulfate) Inhalation Solution** DuoNeb® (albuterol sulfate and ipratropium bromide) Inhalation Solution**
King Pharmaceuticals	Intal® (cromolyn sodium) Inhalation Solution
Sepracor Inc.	Xopenex® (levalbuterol HCl) Inhalation Solution**

** No legal generic equivalent is available

Federally Licensed Generic Manufacturers of Medications for Nebulizers	
Activis MidAtlantic	Nephron Pharmaceuticals
Bausch and Lomb Pharmaceuticals	Novex
Dey, L.P.	QPharma
Hi-Tech Pharmacal	Respirare
Holopack International	Roxane Laboratories Inc.
IVAX Pharmaceuticals	RxElite
Morton Grove	Warrick Pharmaceuticals

Source: Electronic Orange Book, U.S. Food and Drug Administration, www.fda.gov/cder/lob, December 2006

Members of Consumer Health Alliance for Safe Medication (CHASM)



Baylor Martha Foster Lung Care Center - Baylor University Medical Center

National Association for Medical Direction of Respiratory Care