

The TRUTH About Illegally Manufactured Nebulizer Medications

Increasingly – and without their knowledge – patients are being exposed to health risks associated with illegally manufactured nebulizer medications. Furthermore, the businesses that make and sell these medications don't want you to know the truth.

You won't find it in their advertising or the forms they ask you and your physician to sign under the pretense that the forms are required for reimbursement purposes. But the truth is, illegally manufactured nebulizer medications:

- Are not FDA-approved for safety, efficacy or sterility
- May or may not contain therapeutic levels of the prescribed medication
- May contain known airway irritants such as preservatives or diluents such as ethanol (smells like alcohol)
- May contain pneumonia-causing bacteria
- May contain carcinogens leached from inks and glues used with paper labels
- Are not established as therapeutically equivalent to FDA-approved generic and branded nebulizer medications
- Are not manufactured in FDA-licensed facilities or according to federal current Good Manufacturing Practices (cGMP), a standard required to ensure safety, efficacy and sterility
- Usually are not packaged to ensure stability of the product over a specified period



- May or may not include identifying information such as the dose, lot number and name of the manufacturer and/or packager

Illegal manufacturers try to operate under state laws intended to protect patient access to pharmacy-compounded medications. These laws provide patients with rare medical conditions access to medications that are not otherwise commercially available. In these cases, the patient, physician and pharmacist discuss the goals of therapy and the risks and benefits of the product, then monitor the patient's progress. It is a relationship

in which all parties are communicating. But that's not what's happening with most illegal nebulizer medication manufacturing.

Asthma, chronic obstructive pulmonary disease (COPD), emphysema, bronchitis, pneumonia, cystic fibrosis and RSV are not rare diseases. These diseases are common and potentially life-threatening conditions for which numerous FDA-approved generic and branded nebulizer medications are currently available.

National and international treatment guidelines for these diseases do not endorse use of compounded or illegally manufactured nebulizer medications. Most physicians agree that there is no conceivable reason to expose a patient to known health risks associated with compounded or illegally manufactured nebulizer medications since FDA-approved nebulizer medications are abundantly available.

When illegally manufactured nebulizer medications are given to patients, there is no discussion of potential health risks. Nor is there any label warning the patient that symptoms associated with use of contaminated vials mimic the symptoms being treated. And almost certainly there is no warning that the product is not FDA-approved.

When Allergy & Asthma Network Mothers of Asthmatics (AANMA) first reported this story in "Are There Fakes and Frauds in Your Nebulizer?" (Fall 2004 *Allergy & Asthma Today*,

available online at www.breatherville.org/pdf/pu_fakes_frauds.pdf), many patients and physicians couldn't believe this was happening. Then they looked in their medicine cabinets.

Using the pictorial guide in the article, families across America were shocked and angered to discover they'd been using illegally manufactured nebulizer medications. These were people who were very sick, some whose symptoms worsened while using these products. Numerous physicians, nurses, patients and family members contacted AANMA to report their findings and ask for help.

AANMA shared their stories with the U.S. Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), state pharmacy boards and several pharmacy association groups and gave presentations at medical conferences across the nation.

AANMA also formed the Consumer Health Alliance for Safe Medication (CHASM), a working group of healthcare professional and patient organizations, to expose this illegal industry and to work with state and federal agencies to close policy gaps and financial incentives that make victims of us all.

CHASM has conducted national awareness campaigns exposing the strategies these companies employ. We are actively reporting cases to state and federal authorities and investigations are underway.

Two pharmacy businesses say that they are no longer making their own nebulizer medications and substituting them for FDA-approved products. CMS changed reimbursement codes for some nebulizer medications to help distinguish between those that are FDA-approved and those that are not.



AANMA and CHASM members will continue to advocate on behalf of patients and families. Meanwhile, vigilance is your best protection.

- Your written prescription is the only authorization any pharmacy needs to dispense medications. Be wary of companies that require your or your physician's signature on company forms before they can fill your prescription.

- Make sure the FDA-approved nebulizer medication name is written on your prescription and marked "no substitutions." Ask your doctor to add the phrase "Do Not Compound This Nebulizer Medication."

- Know your pharmacist. You should be able to trust that the medications you receive are exactly what you and your physician expected – that is, FDA-approved unless you have a rare condition that requires a pharmacy-compounded medication.

- When purchasing or renting a nebulizer from a company that offers to provide pharmacy services or home delivery of nebulizer medications, be sure the products you will receive are FDA-approved. Write on all forms "Do Not Compound This Nebulizer Medication."

These six words, "Do Not Compound This Nebulizer Medication," send a powerful and effective message that becomes part of your medical record: You want and expect to receive the FDA-approved nebulizer medication your physician prescribed. No substitutions will be accepted.

AANMA and CHASM member organizations are distributing self-inking, prescription pad "Do Not Compound This Nebulizer Medication" stamps to medical practices nationwide. Medical professionals can contact AANMA at 800.878.4403 to order stamps at \$6.00 each to cover shipping and handling costs.

Together, we can protect our access to FDA-approved nebulizer medications.

What We've Learned

Most cases of nebulizer medication substitution reported to AANMA began with or involved a nebulizer rental or purchase from a home healthcare agency linked with a national or local pharmacy.

In each case, patients had originally been using FDA-approved generic or branded nebulizer medications when, at some point, without explanation, their nebulizer vials changed.

Some patients thought or were told that the new vials were generics for the medication they used to take. Some were told that the new drug was better than their previous medications because the new drug was made in smaller batches or took less time to nebulize. Both of these claims are unproven.

If you believe you currently possess a nebulizer medication that is not FDA-approved, please contact AANMA right away at 800.878.4403. Do not discard or return the medication.

Join other families and medical care professionals who want to put a stop to illegal nebulizer medication manufacturing. Log onto www.breatherville.org and click on the CHASM logo to learn more about this issue and take action today.