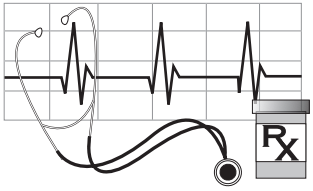


Health Awareness

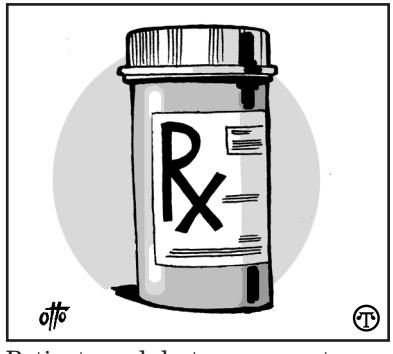
Compounded Drugs Need Closer Scrutiny

(NAPSA)—Thousands of Americans may not realize that some of their prescription medicines have not been approved by the Food and Drug Administration (FDA), the federal agency charged with ensuring the safety of the nation's drug supply. While the dangers of imported drugs have received much attention, increasingly more medicine is being manufactured domestically by pharmacists without FDA oversight.

For decades, pharmacists have customized prescription medicines to meet the specific medical needs of individual patients. For example, small children or elderly patients may require medicine as liquids rather than as tablets, or doctors may prescribe medicine that is not commercially available. Tailoring medicine this way, known as "pharmacy compounding," provides needed medicine that pharmaceutical manufacturers can't supply. This type of compounding is legal.

Recently, however, public health officials, patient advocacy groups and doctors have been increasingly alarmed that some compounding pharmacists mass manufacture drugs without FDA oversight and the normal checks on quality and safety required for regular drug manufacturers. Such pharmacies are typically small independent pharmacies or those owned by home health care companies.

Patients who use these drugs of unknown quality, purity, sterility and potency are not protected by the safety net the FDA has built to safeguard the nation's drug supply.



Patients and doctors may not even be aware that the pharmacy has dispensed a compounded drug instead of the prescribed, FDA-approved one. "Right now, consumers have more information about their breakfast cereals than they do about their drugs," says Nancy Sander, President of Allergy & Asthma Network Mothers of Asthmatics (AANMA).

Compounding pharmacists have a strong financial incentive to manufacture large quantities of copies of FDA-approved drugs. For example, producing nebulized drugs for asthma, emphysema, COPD and other respiratory diseases—some of the most frequently compounded—can be very lucrative. "Compounding allows pharmacies to realize profit margins of almost 75 percent from compounded drugs, because insurance companies and Medicare pay reimbursements that are significantly higher than the pharmacies' costs for making the drug," says Sarah Sellers, an independent FDA consultant on the pharmacy compounding industry.

While the FDA oversees pharmaceutical manufacturers, individual states regulate pharmacies. In most states, pharmacies are not required to check their compounded drugs for potency or sterility. Compounded drugs may be made in unsanitary conditions, and rarely include proper instructions or warnings. Independent testing of compounded drugs by the FDA has found bacterial contamination and significant variation in potency, both of which can be very dangerous for patients. In some cases, they have been deadly. Uncovering safety issues is difficult because most states do not require compounding pharmacies to report problems.

A new coalition of patients, doctors and nurses, the Consumer Health Alliance for Safe Medication (CHASM), is working to raise awareness of the public health threat from unregulated manufacturing that masquerades as pharmacy compounding. "It is terrifying that compounders would knowingly manufacture medicine that exposes children with asthma and fragile elderly patients with severe lung disease to possibly unsterile and substandard drugs," says Sander. To ensure patients receive safe, effective respiratory medicines and are protected from unnecessary risks, CHASM has petitioned the FDA to force compounding pharmacists to inform patients and doctors about drugs' contents and risks. To learn more, visit breatherville.org or call (800) 878-4403.