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Are pharmacy compounded medications FDA approved?

Pharmacy compounded medications are not approved for any use by the FDA and are not produced in facilities meeting Good Manufacturing Practice (GMP) regulations.

What is a pharmacy compounded medication?

Before the evolution of the modern pharmaceutical industry, pharmacists prepared most medications from bulk ingredients according to a physician's prescription, or recipe. Traditional pharmacy compounding now involves taking an FDA-approved dosage form such as a tablet or capsule and preparing a solution or suspension for anyone who has difficulty swallowing. Any licensed pharmacist has the legal authority to prepare a compounded medication for an individual with a prescription from a licensed prescriber.

The preparation of final products by hospital pharmacies combining FDA-approved sterile medications according to agency-approved directions in the package insert is not pharmacy compounding. This activity is known as intravenous admixing.

All pharmacy compounded medications may be considered unapproved new drugs because they have not been tested for safety and effectiveness and are not produced in facilities meeting GMP regulations. The FDA decided not to take regulatory action in the past, believing most pharmacists prepared traditional pharmacy compounded products only when needed, in very small quantities, for individual patients.

Some pharmacists misused the FDA's trust and began to engage in the small-scale manufacture of drugs, or non-traditional pharmacy compounding, and claimed immunity from FDA oversight because the practice of pharmacy is regulated by state boards, not the federal government.

Non-traditional compounders may produce and sell thousands of dosage units of oral inhalation solutions used by patients with asthma or cystic fibrosis. These small-scale manufacturing pharmacies also produce products such as sterile injections, extended release capsules, and transdermal products which cannot be produced safely outside of FDA-regulated facilities. There are cases of non-traditional pharmacy compounders suspected of smuggling

bulk drug substances that were not FDA approved into the U.S.,or making products from bulk drug substances that have never been approved for sale in this country.

Non-traditional pharmacy compounding can be very lucrative, and the profit margin for these medications is substantial for two reasons. First, pharmacists do not invest in clinical trials to demonstrate that their products are safe and effective, and because clinical trials are very expensive to conduct, they save money otherwise spent on such testing. Second, pharmacists have not invested in the staff, technology, or facilities to meet GMP regulations to ensure that what they make and sell is pure, safe, and stable. Complying with GMP regulations requires a sizable commitment of resources over time, and that is very expensive.

Compounding pharmacists in the U.S. have created niche markets for a wide variety of unapproved, untested drugs. Many insurance companies will not cover pharmacy compounded medications because they are unapproved, untested, and are considered by these companies to be experimental treatments. This has made pharmacy compounded drugs a cash-and-carry business.

Do we need compounded medications?

In rare instances, there may be important reasons for using a compounded medication. For example, there is a family of heart drugs known as angiotensin converting enzyme (ACE) inhibitors that are available as tablets. This medication is sometimes necessary for infants and small children with heart problems, and sometimes these children may have difficulty swallowing tablets. There is no FDA-approved oral liquid ACE inhibitor on the market because the liquid form of this medication is not stable. In this case, a pharmacist making a liquid solution or suspension with traditional pharmacy compounding techniques provides a useful and necessary service.

Are the ingredients safe?

Since compounding pharmacists are not required to follow GMP regulations like FDA-regulated pharmaceutical firms, the answer to this question is unknown. Several companies in the U.S. sell bulk drug ingredients to compounding pharmacists; however, the origin of these bulk ingredients may be unknown.

The Internet has made it possible for compounding pharmacists to buy almost any drug in bulk as a powder. The producers of these bulk drugs may be anywhere in the world, and the drug may, or may not, be produced in an FDA-regulated facility meeting GMP regulations.

Are compounded products safe?

There have been an unknown number of injuries and deaths as a result of non-traditional pharmacy compounded products. The numbers are unknown because public awareness is dependent on local journalists who recognize that a number of individuals have died in a unique way in a short period of time. Compounding pharmacists are not required to report product problems to the FDA or any regulatory authority.

In 2001, a pharmacy compounded injectable steroid medication contaminated with bacteria resulted in 10 hospitalizations and three deaths from meningitis, an infection of the lining of the brain, in residents of Walnut Creek, CA. This injectable product was improperly made using equipment never intended to sterilize drugs that would ultimately be injected into spines of patients with back pain.

Three patients died in the Portland, OR, area in 2007 after being treated with injectable colchicine for severe back pain at the Center for Integrative Medicine. Injectable colchicine had never been shown to be safe and effective for this use. The drug was produced by a Texas compounding pharmacy and shipped to Oregon, but due to an error at the pharmacy, the colchicine was 10 times too strong.

A Fredericksburg, VA, hospital temporarily closed its cardiac surgery program after unusual infections developed in three patients. The hospital later determined at least 11 surgery patients were stricken over a period of 10 months, and at least three of these patients died. The cause of the infections was traced to a contaminated solution injected into the heart during surgery. The contaminated cardiac solution was made by a compounding pharmacy in Lanham, MD. The Virginia hospital had outsourced the cardiac solution to the Maryland pharmacy, but now makes its own heart solution.

The line is crossed when some pharmacists misuse their authority to conduct traditional compounding and instead engage in the small-scale manufacturing of large amounts of unapproved medications.

If you or your family members are prescribed a drug that must be compounded, ask your physician and/or pharmacist if there is an FDA-approved alternative available.

Our best advice for consumers is to avoid pharmacy compounded drugs.

Key messages

- ✓ The source of bulk chemicals used in pharmacy compounding may be unknown.
- ✓ Pharmacy compounded products are not produced under conditions that meet GMP guidelines.
- ✓ Additionally, they are not approved by the FDA for any use.
- ✓ In special circumstances, there is a role for compounded medications, but, in general, avoid pharmacy compounded drugs.