

# Things you should know about **COMPOUNDED ANTI-OBESITY (AOM) MEDICATIONS**

## What Is Compounding?

Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Examples of customization could be a patient with an allergy to a certain dye and need for a medication to be made without it, or an elderly patient or child who needs a liquid formulation instead of a pill. Compounding does not include making copies of commercially available drug products, as this is not allowed by law. Patients should inquire about the source of the drug used in a compounded formulation. If the source ingredient is not from a Food and Drug Administration (FDA)-Approved drug manufacturer, the drug ingredient, quality, safety, and efficacy of the compound is unknown.



## What Are These Compounded AOM Injections?

The newest FDA-Approved medications to treat obesity mimic protein (peptide) gut hormones. They help to regulate blood sugar, slow the transit of food in the gastrointestinal tract, and decrease hunger sensation in the brain. Recently, compounding pharmacies, clinics, and medical spas have begun to advertise and distribute what they claim are generic forms of these medications. The injections these pharmacies are compounding are not the same as the FDA-Approved medications. Compounded AOM injections may not contain the same active ingredients as FDA-Approved AOMs. In reported cases, a modified version of the drug called a “salt form” or “acetate” is used. Products including these salt forms have not been shown to be safe or effective. In addition, the combination of these drugs with other ingredients such as Vitamin B12 or Vitamin B6 has not been tested and may affect the efficacy of the medications and the risk of potential adverse reactions. The FDA has expressed concerns regarding the sale forms of these products.

## Are Compounded AOM Injections Safe?

Compounded AOM injection medications are not regulated, tested, or monitored for quality, safety, and efficacy by the FDA. Compounding pharmacies are not required to manufacture these injections to the required standard of quality set forth by the FDA. Unsafe practices in making these sterile injections can lead to contamination, serious patient harm, and death. In 2012, the most serious outbreak of contaminated compounded injections led to more than 750 people in 20 states developing fungal infections with more than 60 patient deaths. The FDA has called into question the validity of compounding these injections since the ingredients may not be from an FDA-Approved manufacturer. The Boards of Pharmacy in several states have explicitly discouraged the use of these injections in their states.



[www.obesitymedicine.org](http://www.obesitymedicine.org)

*Written by:*

Michelle Look, MD, FAAFP, DABOM

Mike McClurken, MD, FACOG, DABOM, FOMA

Dana Trippi, DO, DABOM

## How AOMs Fit into a Comprehensive Obesity Treatment Plan

The specialty of obesity medicine has evidence-based guidelines to treat the chronic and relapsing disease of obesity. Obesity medicine clinicians provide care in a multidisciplinary and comprehensive approach; one that uses FDA-Approved AOMs, a healthy eating plan, physical activity, and behavior modification. FDA-Approved medications are supported by numerous clinical trials that determine their predictability and the dosage necessary to achieve the desired effect. The use of compounded drugs (i.e. peptides) lacks the basic components that are necessary to define a quality standard of care in the comprehensive management of obesity. For more information, please see the OMA's Position Statement on Compounding Peptide Medications here: <https://bit.ly/PeptideStatement>