

\$\$ Handoff to Brett Favre Worsens Pharmacy Fraud



By Lila Abassi — February 17, 2016



compounding pharmacy via [shutterstock](#) [1]

Here is another reason why the world should stop listening to celebrities who dispense medical wisdom because it s mostly a bunch of hogwash. And Brett Favre is no better qualified at making recommendations for treating stomach cramps than I am passing a football.

You may be wondering why I sound so angry. The retired NFL great and his ilk have contributed to the fleecing of Americans, by being paid big bucks to endorse phony products. The Federal Bureau of Investigation has launched an [inquiry](#) [2] into the shady practices of a compounding pharmacy, called World Health Industries, which does business as Aspire Rx (a division of Aspire Health). This company makes a compounded pain cream called Rx Pro, for which the celebrated former quarterback has been the commercial representative for three years.

What prompted the FBI probe is that these pharmacies had retained the services of marketing companies that cold-call beneficiaries of TRICARE, a healthcare program that covers 9.5 million members of the armed services and their families. TRICARE seems to be the victim of a large-scale scam, whereby phony prescriptions were generated simply by obtaining the beneficiaries' information and the names of their physicians. The prescriptions are for pain creams for which the insurance company can be billed upwards of \$15,000 for a single prescription.

In some instances, the doctors had not even met the patients for whom they were writing prescriptions and they received kickbacks from these compounding pharmacies to do so. The sum total of *\$1.75 billion* had been paid by TRICARE to compounding pharmacies that included coverage of these hack creams. It s like the supplement industry all over again, except the atrocious [DSHEA law](#) [3] gives some legal cover to those quacksters.

You may be wondering what [compounding pharmacies](#) [4] are exactly. Let me explain, first by saying that the name says it all.

They are pharmacies where a licensed pharmacist combines, mixes or alters ingredients to fill a prescription where the medication needs to be tailored to meet an individual's needs. For example that could be withholding a dye that a patient may be allergic to, or creating a liquid version of a medication that cannot be taken in pill form.

These pharmacies do help meet a crucial need, as many hospitals outsource sterile compounding to avoid the costs of having to build, staff and maintain their own clean rooms. Yet helpful as they may be, the compounded medications are not approved by the Food and Drug Administration meaning their quality, safety and effectiveness have not been verified. Compounded drugs are rarely approved or even tested by the FDA because it requires the pharmacist to mix a concoction of drugs that are unique for the individual patient so it is considered not feasible to test each mixture.

According to Ilisa Bernstein, Pharm.D., acting director of the FDA's Center for Drug Evaluation and Research (CDER) Office of Compliance, poor standards of compounding practice can result in contamination of medications that don't possess the strength, quality and purity required.

And because patients who use these compounded medications may have serious underlying health conditions," Dr. Bernstein said, "these flawed methods pose special risks.

One such example is [Eloise Soler](#) [5], a patient who had undergone heart surgery in Corpus Christi Medical Center in South Texas, who became septic after she received an infusion of calcium gluconate that was contaminated with a bacteria, *Rhodococcus equi*. The culprit of the infection was bad manufacturing at a compounding pharmacy called Specialty Compounding. By the time the drug was recalled, 15 people had fallen ill and two had died.

This is one small example of the countless injuries incurred at the hands of these specialty pharmacies because regulatory agencies fell asleep at the wheel. Here are some of the tragic outcomes of failures of oversight of compounding pharmacies:

- The 2012 outbreak of fungal meningitis caused by grossly contaminated injectable steroid killed 64, sickened 750
- The August 2011 outbreak of eye infections from Avastin resulting in complete loss of vision for some of the victims
- November 2011 April 2012, 33 eye surgery patients suffered rare fungal eye infection resulting in partial to severe vision loss

Because they are supposed to be operating at the level of traditional pharmacies, these compounding pharmacies have evaded regulation by the FDA.

Some aspects of these firms' operations appear more consistent with those of drug manufacturers than with those of traditional pharmacies," Dr. Bernstein said. "Some firms make large amounts of drugs that appear to be copies of FDA-approved, commercially available drugs when it does not appear that there is a medical need for an individual patient to receive a compounded version of the drug.

The U.S. Senate [introduced a bill](#) [6] that modified the Federal Food, Drug, and Cosmetic Act to grant the FDA more authority to regulate and monitor the manufacturing of compounding drugs.

The Drug Quality and Security Act was passed by the Senate on November 18, 2013 and signed into law by President Obama on November 27, 2013.

Nonetheless, the industry continues to be plagued by [safety problems](#) ^[5] that can potentially affect thousands of patients. Since the bill's passage, there has been an unprecedented crackdown on these compounding pharmacies, and according to federal documents more than 50 recalls have been issued in the past two years 20 percent of which were considered, dangerous or defective products that predictably could cause serious health problems.

Of the 150 inspections that occurred from the period October 2012 through September 2014, 90 percent were identified as having objectionable conditions having to do with safety and sanitary conditions, such as workers wearing soiled gloves, to visible growth of mold in injectable medications. Since October 2012, 30 warning letters were issued by the FDA to compounding pharmacies for serious deficiencies that if not corrected would lead to fines and prosecution.

The level of greed, corruption and blatant disregard for the safety and well-being of patients warrants a significant overhaul, once more, of how the government deals with compounding pharmacies. Sadly, celebrity hacks like Brett Favre are parasitizing the trust of the public to line their own pockets.

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