

# “Franken-Pharma”: The Compounding Pharmacy industry

By David N. Brown

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Lee Silsby, sponsor of Age of Autism, is only one representative of an entire (sub)industry known collectively as compounding pharmacies. The wares of a compound pharmacy are comparable to “hot rod” automobiles, “wild cat” ammunition (direct inspiration for the Eliminator in *Worlds of Naughtenny Moore*), or for that matter to Frankenstein's monster: The creator begins with an existing product, and modifies them for improvement or for a significantly different purpose. For the compounding pharmacy, this means buying others' health products, and mixing, modifying and/or relabeling them for a new function. At one time, most prescriptions were “compounded” to a certain extent, and today compounding remains a small but perfectly legitimate practice. However, it has long been a source of concern for regulators, doctors and consumer-protection groups. In this essay, I will outline major areas of particular concern:

## Regulation

So far, compounding pharmacies are substantially unregulated, at least on a national level. The FDA does not define compounding pharmacies as “manufacturers” or their products as original medications, and so has no basis for regulating them with anywhere near the thoroughness applied to commercial pharmaceutical manufacturers. A significant attempt at regulation, which would in all likelihood have shut down compounding pharmacies as a discrete industry, was a 1997 FDA Modernization Act, which in its original form would have banned the advertising of compounded medications; this provision was struck down in court. (An interesting retelling of this affair on Lee Silsby's site neglects to mention this.) For now, what regulation there is is in the hands of state agencies, which in the age of the internet are powerless to limit the distribution of a poorly-run or unethical business. This also gives such operators the option of survival by migration. If regulators in one state crack down on their activities, they can simply move their center of operations elsewhere, and then resume distribution on a national (or international) scale. For that matter, it's likely that quite a few of such individuals and organizations started out conducting equally marginal operations in different industries, particularly “nutritional supplements”, and moved on to become “compounding pharmacies” when increasing government regulation, media scrutiny and industry self-monitoring began putting too much pressure on them.

## Quality

The quality of compounded pharmaceuticals would appear to be uncertain at best. It would be all too easy for an unethical, incompetent and/or underequipped pharmacist to introduced major contaminants to the final product. But that is only part of the problem. The other, much greater part is where he gets his materials. Even where a compounding pharmacist works with a well-tested, medically and commercially successful product, there is a wide range of sources he might turn to for the base medication. He might buy the name-brand product from the original manufacturer. He might buy an approved, domestic “generic” equivalent, or one produced outside the US. (Unfortunate jingoistic overtones easily creep in at this point. I would say counter to this that foreign pharmaceuticals, especially by when made by a well-established and successful company, should be accepted as legitimate commercial competition. But, differences between regulations in the US and the nation of origin should be carefully considered.) Or, in what would be cause for the greatest concern, he might

turn to entirely “shady” sources: fly-by-night operations (foreign or domestic!) with reverse-engineered, bootlegged, black market, or simply fake pills. (He may also take the “outsourcing” route and buy most or all of his product from other pharmacists.) Obviously, it is crucial for any truly legitimate compounding pharmacist to be honest and transparent about his suppliers. Yet, even that may be enough: The pharmacist himself may, due to haste, naivete or indifference, be as much in the dark about the ultimate origins and quality of his drugs as his customers.

### Testing

The potential problems with compounded pharmaceuticals are multiplied when even the base product is subject to unknowns (if not pervasive criticism!) in fundamental areas like appropriate manufacturing methods, safety and side effects, and (especially) usefulness for a particular purpose. It appears to be not uncommon for compounding pharmacies to market a product for a very specific purpose based on *at most* a single professional publication. This amounts to a bypass of virtually the *entire testing process* dictated by both regulation and orthodox scientific peer review. Fortunately, this is the one area where they are directly accountable to the FDA. Unfortunately, discipline consists primarily of “cease and desist” letters ordering them not to make an “unevaluated” or false claim when marketing a product. Of course, this only occurs after the claim in question has been made publicly, and all too likely after large quantities of the product have already been sold and used for the questionable purpose (and also after imitators start making the same claims for their products). This is easy enough to bypass. The most well-documented dodge, seen with chelation therapy (see “Lethal Fraud”), is for physicians, not improbably encouraged by compounding pharmacists, to make a false diagnosis that would justify a treatment, while intending it for a use which regulators and others expressly disapprove of. The most drastic response (well-known for frauds of all types) is to dismantle the current operation, set up a whole new company, possibly under a new assumed identity, and market the same product for the same purpose until the FDA catches up with them again.

### Organizational transparency

For regulators, customers and investors to evaluate a business's products and practices, it is important for the business to be forthcoming about itself, including its income and internal organization. Lee Silsby is a problematic case, particularly since there is no page on their site about subsidiaries, suppliers, or even sales and earnings. The self-declared “leader” of the compounded pharmaceuticals business, ApotheCure, Inc, presents a considerably murkier profile. Court documents indicate that ApotheCure, Inc. is actually one of six “sister corporations”, the others being ApotheCure Pharmacy, ApotheCure Injectables, Spectrapharm, Lotejas Laboratories, and the Texas Institute of Functional Medicine, all of whom have somehow managed to operate out of Suite 100 of 4001 McEwen Road in Dallas, Texas. (I have determined that this is an office, not a PO or safe deposit box- a sign of a high-end operation!) Apart from the potentially risky concentration at a single address, this is an ideal setup for minimizing visits and if necessary slowing down inquiries by regulators, court officers and less-than-pleased former customers. In all likelihood, most or all compounding and “research” conducted by ApotheCure, Inc. etc. takes place at less easily-determined locations. If anyone reading this is in Dallas, pay a visit to Suite 100.

### Conflict of interest

Conventional pharmacies acting within conventional medicine are, in theory, the party least subject to financial conflict of interest. This is most apparent in the implications of the failure of a drug. Researchers have to report that years of research and the costs thereof have no possibility of financial return. Manufacturers have to write off not only research expenses, but those of materials, manufacturing and marketing, and may additionally be left with holdings in specialized materials and

machinery that may have no other use. But the pharmacy has incurred none of these expenses. If a drug proves medically and/or commercially unviable, all they have to do is not buy it, or return it, or at worst throw out the remaining stock and eat the wholesale price. This gives pharmacists a high degree of “plausible deniability” for a particular medication; they can always say something like, “If people hadn't *already* want it, I wouldn't have stocked it.” A compounding pharmacy, however, is a substantially different animal. In particular, unlike a conventional pharmacist, the compounding pharmacist is effectively “manufacturer” of his own wares. This has positive and negative implications as far as his interest. On one hand, he has greater liability if a customer is not helped or actually injured, and so presumably more motivated to check that what he sells is safe, and also used in an appropriate manner. On the other hand, he will- to some extent by necessity- have to take a far more direct role in promoting his goods if he is to be successful.

### Influence on physicians

A significant consideration is how compounding pharmacies promote their products, to the public and especially to doctors. It is important at this point not to seem to say too much. In particular, it would be foolhardy to go very far in comparing actions by compounding pharmacies with those of “Big Pharma” (a trap I suppose I backed into in my own brief correspondences with AoA). Realistically, even if compounding pharmacies were able and willing to act as a unified and well-coordinated group (unlikely to say the least!), they could never match the resources that any one of the established “Pharma” corporations puts into promotions both to the public and the medical community. Where a compounding pharmacy may well surpass “Big Pharma” is in aggression, perhaps out of desperation at least as often as calculated greed. An especially problematic practice that has been noted is the distribution of information about a product's effects and appropriate use to doctors. Obviously, if this information is inaccurate at the source, the harm done will be multiplied. The role of uncritically circulated disinformation is blatant in the death of Tariq Nadama. The responsible physician, Roy Kerry, formally qualified as only an “Ear, Nose and Throat” doctor, apparently learned what he thought he knew about autism, mercury and chelation from ApotheCure. ApotheCure's source of its (dis)information was probably ultimately the American College for the Advancement of Medicine, an institution which has a linking on the chelation page of ApotheCure's website. ACAM is also reportedly linked to the PCCA and IACP, two Texas-based compounding pharmacists' organizations that provide instruction and other support for *thousands* of members.

### Ties to “Big Pharma”

A final and potentially decisive issue about compounding pharmacies is that they are NOT independent of mainstream “Big Pharma”. In fact, for better or worse, these disparate segments of the industry have every reason to *cooperate* with each other. Compounding pharmacies need established manufacturers, at the very least, to supply many if not most of the existing products which they modify to produce their own. If they can get discounts, assistance and even direct financial support, all the better for them. “Big Pharma” also has plenty to gain. A compounding pharmacist may discover a way to improve on an existing product, or a new application and thus a new market for it. The Lupron protocol (see “Even Worse”) appears to have started out as such a cooperative venture between a “mainstream” pharmaceutical company and “independent” medical researchers. Furthermore, the pharmacist may be able to do the job for less money, and, on the darker side, less legal and financial liability. The greatest potential for gain for the established company is in “salvage work”: If years and millions of dollars of research leaves them with reams of data or even large quantities of actual medication, but no commercially viable product in sight, handing it off to another business is the simplest way to cut one's losses and maybe turn the fortunes of the project around. Of course, this need only be suspicious or sinister if one is inclined to interpret it in that light. Ironically, it is groups like

Age of Autism, with characteristic skepticism toward orthodox medicine and outright hostility to corporations, that have the most reason to look askance at such behavior.

It is fitting to close, building on this last point, with further comment on Age of Autism's place in all this. I have never seriously doubted the sincerity of AoA, and I will admit that even the leaders of Lee Silsby *might* sincerely believe in their cause. Sincere or not, I suspect that their relationship to each other is something like a line I put into one of my own novels about the relationship of a warlock to a group of demons: "*He does only what is in his nature. So do we.*" If there were no Lee Silsby, I am sure the staff of AoA would still be pitching anti-vaccine rhetoric, and if there were no AoA, I suppose that Lee Silsby would still be hawking dubious nostrums for autism or whatever other real or imagined maladies were of concern to the public. But, their relationship as it is can only be unequal: AoA would probably not exist in its present form without the support of Lee Silsby (or some similar organization), whereas Lee Silsby could probably function perfectly well without AoA. And both would undoubtedly exist without their supposed "nemesis", "Big Pharma", and while representatives of AoA could easily be credited with believing otherwise, it is hard to imagine the Lee Silsby management entertaining such delusions. Ultimately, Age of Autism's place relative to compounded pharmaceuticals and the pharmaceutical industry as a whole is that of a King Zog to a Mussolini to a Hitler to a Stalin. And no matter how pervasive and intractable they seem to be in the autism and vaccination discussions, no matter how many people they misinform and mislead, that is almost certainly all they will ever be.

David N. Brown is a semipro author, diagnosed with Asperger's Syndrome as an adult. Previous works include the novels *The Worlds of Naughtenny Moore*, *Walking Dead* and *Aliens Vs Exotroopers*, and the nonfiction ebook *The Urban Legend of Vaccine-Caused Autism*. This and other articles related to autism are available free of charge at [evilpossum.weebly.com](http://evilpossum.weebly.com).