

Pointless, Useless and Dangerous: The “cures” of Lee Silsby

By David N. Brown

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“Lee Silsby's products, aimed at helping physical symptoms of autism, have not permanently damaged or hurt one single patient.” “Kim”, Age of Autism blog comment

As I have previously pointed out (see “Age of Hypocrisy”), Age of Autism is sponsored by Lee Silsby Pharmaceuticals, which sells chelating chemicals and numerous other items for the stated purpose of treating autism. Since chelation therapy was proposed for autism on the theory that autism is caused by vaccines, Lee Silsby stands to profit from Age of Autism's continuing promotion of this view. I posted two comments on this at Age of Autism. One of the responses (above) was to defend the quality and safety of Lee Silsby's products. This essay is written to evaluate that claim.

EDTA (calcium) chelation products: These products are of most interest, as they may be the most widely used autism “treatment” and are used as such based primarily on the (debunked) theory that vaccines cause autism. The use of calcium EDTA is undoubtedly a response to the Nadama tragedy (see “Lethal Fraud”): The standard response of chelation advocates to this scandal has been that if a different chelator had been used, Tariq Nadama's death would have been prevented. However, calcium EDTA is clearly problematic in its own right. While it does not cause hypocalcemia, it does remove some calcium, can seriously deplete important minerals, such as iron and zinc, as well as vitamins C and E. Furthermore, it is a known anticoagulant (meaning it will impede the healing of a fresh wound), and may cause liver and kidney damage. Then there are variants offered by Lee Silsby, “transdermals”, “capsules” and “suppositories”. At least two of these are counterindicated in a significant study of chelators (as used in cosmetics) by Lanigan and Yamarik.¹ They reported “no absorption of EDTA salt through the skin,” which strongly suggests that EDTA administered through a skin cream would not even enter the body. As for the oral version, the study reports, “oral exposures... produce adverse reproductive and developmental effects in animals.” Finally, at least one study has made the devastating finding that administering chelators without prior heavy metal poisoning can produce the same long-term health problems as actual poisoning.² In summary, even where precautions are taken against the obvious harm seen in the Nadama case, chelation therapy can still cause significant harm, and even it did not, it would still have no known or plausible value in treating autism. *Any ongoing sale of any chelator for the stated purpose of treating autism constitutes **fraud**.*

DMPS chelators: Other chelation products sold by Lee Silsby are DMPA and DMPS chelators. As far as efficacy for autism, little can be added to what has been said above. One of the most significant But DMPS is a tale in itself, particularly for the complete absence of government approval for its use for ANY purpose in the US. A safety trial not only failed to lead to FDA approval, but was itself subject of a 2000 FDA complaint, which cited the manufacturer, Heyltex, for reasons including “failure to

1 Lanigan RS, Yamarik TA. Final report on the safety assessment of EDTA, calcium disodium EDTA, diammonium EDTA, dipotassium EDTA, disodium EDTA, TEA-EDTA, tetrasodium EDTA, tripotassium EDTA, trisodium EDTA, HEDTA, and trisodium HEDTA. Int J Toxicol. 2002;21 Suppl 2:95-142.

2 Stangle DE, Smith DR, Beaudin SA, Strawderman MS, Levitsky DA, Strupp BJ. Succimer Chelation Improves Learning, Attention, and Arousal Regulation in Lead-Exposed Rats but Produces Lasting Cognitive Impairment in the Absence of Lead Exposure. Environ Health Perspect. 2007 February; 115(2): 201–209.

notify FDA of serious unexpected adverse experiences... to review safety information as it is obtained ... to list subjects who died during participation in the study and the cause of death..."³ In 2004, Heyltex itself issued a letter urging "caution" in filling prescriptions for it.⁴ At some point, it appears Heyltex stopped DMPS production in the US, forcing those who do sell it in the US to import their stock from Germany, where Heyltex still manufactures it, or from Russia and China.⁵ In theory, DMPS can still be sold legally in the US *IF* it is prescribed and administered by a licensed physician. Whether Lee Silsby's distribution of the product would satisfy this slender standard of legality is uncertain at best.

Amphotericin: After DMPS, this is (if looked up elsewhere) the *most obviously dangerous* product listed on Lee Silsby's site. (It is part of a list headed "Other Compounded Medications often used to treat ASD", with no information given about why they are being recommended.) Its only use is in treating fungal infection. Its recommendation for autism is almost certainly based on the theory that autism is caused or aggravated by excessive yeast in the digestive system. It is well-known for causing life-threatening seizures. It may also cause damage to the heart, liver and kidneys. It can be added that this and all other anti-fungal agents may cause digestive problems by depleting beneficial gut flora.

N-Acetylcysteine transdermal cream: *Another dangerous product* (also on the "other" list). This is described elsewhere as a treatment for pneumonia, TB and other respiratory diseases. Reported side effects include damage to the heart and lungs. Usage is presumably justified only against the most extreme and life-threatening infections. No legitimate application for autism treatment is conceivable.

Enhansa (curcumin supplement): This is the most prominently featured product on Lee Silsby's page, and by all indications is an innocuous and plausibly beneficial product. Curcumin as a basic substance is indisputably safe and useful, being derived from an edible plant widely used in India for thousands of years, and there is credible evidence of medical benefits. But, there are some subtle problems with how the product is presented by Lee Silsby. Most seriously (as is pervasive on the site), no information is provided on the source of their material. It is also not made clear whether all the claimed effects of the supplement are attributable to curcumin alone. I, personally, had to look up curcumin elsewhere before being satisfied that this was the case, and without this information, one might easily think that the curcumin was, at least possibly, mixed with other substances. One of the claims is that it "chelates lead and cadmium", a claim which is substantiated by scientific studies. This is transparently appealing to the falsified theory that autism is caused by heavy metal poisoning. Worse, it is not mentioned that it is also known to remove iron (to my knowledge the only significant adverse effect reported so far). Another claim is that their product is "7 - 8 More Absorbed Than Standard Curcumin Extracts". Such a specific and dramatic claim, if challenged and found unjustified, would qualify as false advertising (and also libel against competitors). More importantly, if it is true it would be cause for concern. Such an increase in potency would be cause for a new round of safety testing for previously unknown side effects. There is no indication that Lee Silsby or others have done so.

Finally, the forms of the supplement listed include a supply of powder. The only customers who would have a use for this are those who make their own capsules, most obviously *other pharmacies*. This raises a host of questions. If they are not only dispensing medication but also selling others the raw materials for doing so, can their business still be considered one of "compounding" only? Doesn't this take away their own control over the quality of their product as administered for human consumption? Do they compensate by controlling whom they sell the powder to? Any answers are nowhere in sight on Lee Silsby's public web page.

3 <http://www.dmpsbackfire.com/advocates/letter.htm>

4 <http://www.circare.org/foia2/heyfloener.pdf>

5 <http://onibasus.com/archives/am/129268.html>

Transdermal B-complex cream: In addition to conventional vitamin capsules, Lee Silsby sells this, a form of vitamin B, designed to be administered through the skin, in the same fashion as well-known vitamin B12 patches. It has been objected that the “patches” are useless because the vitamin in question cannot be absorbed through the skin, a criticism that ought to apply equally well to Lee Silsby's cream.

Folinic acid, methylcobalamin and hydroxocobalamin: These are mentioned here because of curiously differing effects. Folinic acid is important in the production of red blood cells, and is administered medically to treat anemia (possible effect of chelation), but has the side effect of causing or worsening vitamin B deficiency. Methylcobalamin is used to treat vitamin B deficiency, in fact being naturally produced by the body from vitamin B. Hydroxocobalamin is used to treat cyanide poisoning, which may result from excessive vitamin B! Thus, the only logical explanation why these would all be recommended, along with vitamin B supplements, is that folinic acid treats a side effect of chelation therapy, methylcobalamin plus vitamin B treat a side effect of folinic acid, and hydroxocobalamin to treat a side effect of vitamin B. Four drugs, all for no apparent purpose except to make up for the damage done by unnecessary and harmful chelation therapy, from which Lee Silsby also profits.

Naltrexone: There is nothing particularly dubious about this medication, which is FDA-approved and has side-effects warnings only for those with very specific pre-existing problems (including organ transplants), but its presentation on the Lee Silsby site is rather odd. The entry consists of a short article by Stephen M. Edelson, in which he reports that when given to the autistic “Naltrexone increased socialization, eye contact, and general happiness; normalized pain sensitivity; and a reduction in self-injury and stereotypic (self-stimulatory) behaviors.” All well and good (better than most of the products on sale!) But how does this justify Lee Silsby selling it commercially as an autism treatment? What Edelson describes is no better than a preliminary study, and even taken at face value argues only for more testing! And what has Lee Silsby's role in it been? Did they fund his work? Endorse it after he made the study independently? Or did he only test what Lee Silsby proposed? As usual, answers are not apparent Lee Silsby's online material.

Secretin: Another item from that “other” list, and in some ways more mind-boggling than the dangerous items mentioned above. Secretin, an artificial hormone with legitimate but limited applications, attracted intense interest as an autism treatment in the late 1990s. Orthodox science soon concluded that it had no real effectiveness, but not before it was widely sold at inflated prices for autism treatment. To just from retrospective accounts (eg. Offit's *Autism's False Prophets*), secretin would offer nothing to current “cure” efforts except an embarrassment to live down. But a web search will show that there are still at least a few defenders, such as Dr. Joseph Mercola, who give a better case than might be expected. But even these apologists are arguing for new tests, not commercial use as an autism “cure”. For Lee Silsby to sell it is unethical, irresponsible and ultimately foolhardy.

I could go on (though the additional material I have holds nothing as bad as the examples above), but I have surely made my point. Of eleven products under discussion, not one has been proven beneficial for the symptoms of autism in any manner that would be satisfactory to scientific or regulatory review. At least three are dangerous, and most have at least the potential for significant damage. The exceptions include a couple (transdermal vitamin B and EDTA) that are probably too worthless to have even adverse effects. So how can anyone accept or even seriously consider Lee Silsby as a legitimate source of pharmaceuticals, *especially* those who consider vaccines unacceptably dangerous? Undoubtedly because those people are not really attuned to “safety” as such. Instead, they are exquisitely sensitive to psychological suggestion and (sub)cultural prejudices, which tell them that because vaccines are “artificial”, produced by “Big Pharma” and directly promoted by “Big Government”, they *must* be untrustworthy. This predisposes them to interpret any known or alleged

problem with vaccines in the worst possible light, and scientists, public health officials and even many elected officials and businessmen are ill-equipped even to attempt a challenge to their virtually *a priori* judgments. But con men by nature and definition excel at adapting their message, appearance and behavior to satisfy the individual and the larger group (epitomized in the “affinity scam”). For health quacks seeking to exploit the anti-vaccine movement(s), this means affirming the evils vaccines while representing their own, objectively far more questionable enterprises as somehow antithetical to vaccination: “natural”, “non-profit”, “private”, etc. Once such quacks have entrenched themselves, there is almost nothing that can be done except either to wait for the group to implode or disintegrate of its own accord, or to prosecute the quacks with disproportionate force and accept the consequences of resistance, protest and negative public perception. When the quack in question is defrauding parents and risking harm to their children, how much choice can there be?

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