Denture Cream Myelopathy Claims Found Toothless

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If there's a better place for filing Daubert motions than in the Eleventh Circuit, we don't know of it. Of course, we're biased – we had great success with them ourselves in the Seroquel litigation and in the Ephedra litigation before that. Building on the Eleventh Circuit's landmark decision in McClain v. Metabolife, International, Inc., 401 F.3d 1233 (11th Cir. 2005), defendants have had a lot of success fighting "junk science" peddlers in Eleventh Circuit courts.

And so it was with yesterday's decision in In re Denture Cream Products Liability Litigation, No. 09-2051-MD-Altonaga, slip op. (S.D. Fla. June 16, 2011). The product is (surprise) a denture cream, Fixodent. The alleged defect is failure to warn that zinc compounds allegedly reduce the amount of copper in the blood, which in turn purportedly cause something called "copper deficiency myelopathy" (called a lot of other things, too, see slip op. at 2 n.3) – which we'll call "CDM" for short. The very existence of such a thing as CDM is controversial. The court in Denture Cream found that the claims didn't pass Daubert scrutiny.

The Denture Cream defense team went after this MDL pretty much using the Seroquel model – that is, take the MDL plaintiffs' best case and beat it on Daubert grounds. The test plaintiff in Denture Cream claimed numbness in her hands and feet (a description suspiciously like diabetic neuropathy) leading to loss of function in her arms and legs, along with various blood abnormalities. Slip op. at 2-3.

These symptoms appeared after the test plaintiff allegedly used Fixodent – a lot of Fixodent.

How much Fixodent?

From the Denture Cream opinion: The test plaintiff supposedly "use[d . . .] two to four 68-gram tubes of Fixodent denture adhesive every week for eight years to hold her dentures in place." Slip op. at 3.

Say what? That's between two and four toothpaste-tube-sized tubes of Fixodent a week, just to hold dentures in place.

For eight years.

We did the math. Using an average of three tubes a week, that's 68 X 3 X 52 X 8 = 84,864 grams of

Fixodent over eight years. Thus, according to plaintiffs, then, the test plaintiff consumed over **187 pounds** of the stuff. That works out to three fifths of a pound a week. Slip op. at 9 n.15.

Anyway, the basis of the defendant's motion wasn't the credibility of the test plaintiff's claimed consumption. So we'd have to say that, from an exposure standpoint, this test plaintiff has to rank as the Denture Cream plaintiffs' best case. She was literally worth her weight in Fixodent (give or take a few pounds).

The Denture Cream MDL has attracted the usual flock of plaintiff's experts willing to say anything if paid enough. It was a case of garbage in, garbage out. As the court observed, they relied "predominately [on] case studies" to claim that exposure to "very large" (we'll say) amounts of Fixodent caused CDM. Slip op. at 6. Reliance on case studies is an immediate red flag. That's scraping the bottom of the scientific barrel. It's doubly suspicious when the claimed condition itself is questionable. In short, "there is no reliable basis to conclude either Fixodent or zinc can cause copper deficiency myelopathy." Id. at 7.

Why?

Well for one thing, the experts' data – to use a technical term – stank. The court posed five questions: (1) was there a dose-response relationship, (2) was there supporting epidemiology, (3) what was the background risk of this type of injury, (4) was there a plausible physiological mechanism, and (5) what type of clinical studies and tests supported the claimed diagnosis? Slip op. at 8. Briefly, and without the jargon, here's what the Denture Cream court found when it drained this particular litigation swamp:

- Plaintiffs proved no dose-response relationship at all. They didn't establish how much for how long caused the claimed CDM. They had one wildly unusual plaintiff . . . and then, nothing – neither an estimate for how much zinc causes the purported reduction in copper, nor how much reduction in copper is needed for how long to cause the alleged injury. Apparently, the experts didn't even study the right chemical, looking at zinc acetate rather than the zinc compound actually in Fixodent. Slip op. at 9-12.
- There was no analytical epidemiology, only descriptive case reports. Plaintiffs didn't meet the gold standard, or even the zinc standard, but rather a bilge standard of the lowest form of medical "evidence." Here is where good Eleventh Circuit law comes in, since case reports can only be supportive and not sufficient. Slip op. at 12-14.
- Plaintiffs' experts admitted "they did not know the background risk of [CDM]." Slip op. at 14-15. Not only that, they didn't know the background risk of myelopathy generally. Id. at 15. As the

court observed, "[t]his is not even good lay reasoning, much less reliable scientific reasoning." Id. at 17. Simply deciding to study something isn't evidence of causation.

- While plaintiffs could show how zinc can reduce copper, they don't have any plausible biological model for either end of their causal equation. They couldn't explain either the bioavailability of zinc (how it does or doesn't get absorbed into the body), on the front end, or how low copper supposedly causes neurologic damage, on the back end. Slip op. at 18-19.
- Clinical studies? There ain't no clinical studies of zinc and CDM. Slip op. at 20-19. Plaintiffs claimed they'd be unethical, but the court held that certain useful studies could be run.

With this little valid data, then there isn't much there for any kind of scientific methodology to work with. Not surprisingly, the plaintiffs' methodology wasn't any more scientific than their data. First of all, the experts' causal syllogism – the process by which they reasoned from exposure to injury – skipped or assumed several essential logical steps. Denture Cream, slip op. at 20-23 (we'll skip the very case-specific details).

Second, they placed far more causal weight on case reports than such weak data could possibly support. The reports themselves did not claim causation. Slip op. at 29 ("[b]ecause the authors . . . do not conclude there is a causal relationship . . ., it is inappropriate for Plaintiffs' experts to draw that conclusion for them"). Not only are case reports inherently weak, but of the total universe of 21, only one (one!) involved only the precise product at issue. Id. at 25-26, 31. Nor is there any generally accepted definition of CDM, so plaintiffs couldn't show that the motley 21 case reports involved the same condition, or even any coherently classified illness at all. Id. at 26-28 (analyzing discrepancies in the case reports). Finally, some of the articles were just plain sloppy. Id. at 29-31, 31-32.

Third, plaintiffs' claims of "dechallenge" (that's medical jargon for "when you take the stuff away, the symptoms go away, too") weren't in fact accurate. Plenty of the patients in the case studies continued to have copper or zinc abnormalities in their blood after they stopped using denture creams containing zinc. Slip op. at 32. Ditto with the injury itself. Removal of the source of zinc exposure didn't reliably improve neurological condition in the case reports. Id.

Fourth, to the extent plaintiffs' experts relied on animal studies (whether they did at all was unclear), they didn't prove anything in humans. Slip op. at 32-33.

Fifth, an FDA notice didn't prove anything (except, we'd say, how plaintiff recruitment creates MDLs), because the FDA as an administrative agency can act on much less of a scientific basis than needed to

establish causation in a court of law. We blogged about this point at some length before, so you can add Denture Cream to our list:

"[R]egulatory agencies follow different standards than courts in toxic-tort cases. The risk-utility analysis involves a much lower standard than that which is demanded by a court of law. A regulatory agency such as the FDA may choose to err on the side of caution. Courts, however, are required under the Daubert trilogy to engage in an objective review of evidence to determine whether it has sufficient basis to be considered reliable. Accordingly, Plaintiffs' experts may not establish causation by reliance on the FDA Notice."
Slip op. at 33-34 (citation to McClain omitted).

Thus died plaintiffs' "general causation" (that is, in general, can this stuff ever cause that problem?) evidence.

Without ever proving general causation, it was probably unnecessary for Denture Cream even to consider plaintiffs' "specific causation" (that is, did the stuff cause the problem in this person?) evidence, but the court took a quick peek anyway. Plaintiffs offered the usual mush – a purported "differential diagnosis" – accompanied with the usual problems. First, the plaintiffs' experts couldn't legitimately "rule in" CDM, since they hadn't proven general causation:

"Without a reliable basis to infer Fixodent causes copper-deficiency myelopathy, a differential diagnosis reaching that conclusion is, in effect, a detailed, unpublished case report."
Slip op. at 35.

Beyond that, as is true with almost all litigation-generated claimed differential diagnoses, the plaintiffs' experts didn't rule out anywhere near all the other plausible causes of neurological injury. See Slip op. at 36 (listing a dozen things plaintiffs' experts didn't even consider). The possible causes that the purported differential diagnosis ignored were "far more common" myelopathies than CDM (assuming CDM exists at all). Id. Denture Cream involved a classic case of a doctor using a much looser methodology in litigation than s/he would dream of doing with a real patient. Id. at 37 ("failure to perform a test [the expert] considered reasonable before opining on the cause of [plaintiff's] disease shows a lack of methodological rigor in reaching the diagnosis").

That did it. What we have to think was the Denture Cream MDL's "best" (certainly the most thoroughly exposed) plaintiff couldn't produce scientifically sound evidence of causation. If not her, then who?

Now cometh the inevitable appeal.

Congrats to all defense counsel involved (we can't tell who did what), and thanks to Dave Walz of Carlton Fields for passing the decision along to us.