Seriously, We Couldn't Make This Stuff Up

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We often go out of our way to infuse our posts with humor – or at least we try for a few chuckles. But sometimes, a case finds its way to us that doesn't need to be "punched up" with witticisms or amusing anecdotes because the facts themselves are comically simplistic and frankly, we're not sure we could make them any funnier (not that we won't try). So, with minimal elaboration, we bring you the case of Milton v. Robinson, 131 Conn. App. 760 (Conn. App. 2011).

We should start by saying this is not a typical product liability case. Rather, plaintiff filed suit against a university, hospital and manufacturer based on her involvement in a clinical trial. Plaintiff alleged that as a result of participating in the trial she suffered an adverse allergic reaction. Let's start there. What was this adverse reaction that warranted the filing of a lawsuit including claims by plaintiff's husband for loss of consortium and emotional distress? A rash! Milton, 131 Conn. App. at 767. Really? A lawsuit over what was described as a back full of mosquito bites? Id. We checked; Walgreen's carries Calamine lotion for $5.00 a bottle.

On a slightly more serious note, we should point out that when plaintiff discussed the risks of the trial with one of the investigators, the investigator specifically mentioned the possibility that plaintiff could suffer from "rashes and allergic reactions." Id. at 765. Rashes were also warned about in the informed consent form plaintiff signed. Id. So clearly, plaintiff didn't have a failure to warn claim.

But we haven't even scratched (sorry!) the surface of what makes this case so odd. How about the fact that plaintiff wasn't given the study drug, but rather -- *the placebo*! Id. at 767. By definition, a placebo is a substance containing no medication. So, what plaintiff had an allergic reaction to was one of the inactive ingredients -- polysorbate 80. Polysorbate 80 is commonly used as a solubilizing agent in intravenous medical preparations and an additive to tablets (more importantly it is also used as an emulsifier in foods, particularly in ice cream). In other words, we bet if you looked around your kitchen and bathroom, you are going to find some polysorbate 80.

So, when we first picked up this case, we thought the fact that it was about a placebo was going to be the punch line, but as we read further, we realized that as with most good comedies, this case had many layers. Ultimately, the case was dismissed because plaintiff did

not meet her burden of proof on standard of care – which needs to be proven through expert testimony. And, well, plaintiff's experts were simply a farce.

Expert No. 1 – Plaintiff's Husband: He was disclosed as an expert on, among other things: the risks of polysorbate 80; informed consent; failure to warn; FDA clinical study protocols; and design defect. Id. at 773-774. Wow – is he an epidemiologist, a clinical investigator, a pharmacologist? Nope. He's "an artist and film producer." Id. at 775. Told you we couldn't make this stuff up. Somehow, the court wasn't convinced that the fact that her husband "researched" polysorbate for the past . . .eight years," id. at 774, qualified him as an expert – at least as to anything relevant to his wife's lawsuit. Now, maybe if his wife was claiming to have been scarred by seeing the latest big screen adaptation of The Three Musketeers . . .

On to Expert No. 2 – The Allergist: He was proffered as an expert on the standard of care, the adequacy of the trial design and causation. Id. at 769. At least this one was a doctor, but let's take a closer look.

- His specialty is mold-related allergies;
- Prior to becoming involved in the case, he was completely unfamiliar with polysorbate 80;
- He had never designed nor acted as a clinical investigator in a phase III clinical trial;
- He was unfamiliar with FDA regulations concerning phase III clinical trials;

And our personal favorites:

- Before rendering his opinion, he had not reviewed plaintiff's medical records; and
- He had not read the study protocol which was the subject of his opinions.

Id. at 775-778. Not surprisingly, the appellate court found that the trial court "did not abuse its discretion in deciding that [the doctor] lacked the requisite knowledge or experience to assist the jury in determining the pertinent matters in issue." Id. at 778. An understatement to say the least.

To recap – plaintiff alleged that she got a rash from a placebo and she attempted to prove her claim with testimony from her artist-husband and a mold-specialist who hadn't read

her medical records or the clinical study at issue. Maybe you're tee-heeing a bit, maybe you're shaking your head in disbelief, maybe you're questioning why we even bothered with this – but what we bet you are all wondering is whether there is polysorbate 80 in Cherry Garcia?