

# Getting Past Gatekeeper: “No Shoes, No Shirt, No Service” re: Admissibility of Expert Opinions

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“No shoes, no shirt, no service.” How long has it been since you’ve seen a sign like that? Does it still ring true? Apparently so, when it comes to admissibility of expert opinions in federal court. A recent opinion in the numerous *Cymbalta* labeling cases proves in order to make it through the gate, your experts need to be dressed to impress.

## No Shoes

When testifying as an expert, one has big shoes to fill?literally. Not only must you testify to your ownknowledge and understanding of the issue, but you must also step into the shoes of the players involved and testify to their capacity as well. For instance, in the *Cymbalta* matter, one of the plaintiffs’ experts, Dr. Morris, a social scientist, was brought in to testify that *Cymbalta*’s label was inconsistent with **FDA** guidelines and was misleading to physicians. ***Hexum v. Eli Lilly & Co.***, No. 2, 2015, U.S. Dist. LEXIS 106153, (C.D. Cal. Aug. 10, 2015). Now, you could call Dr. Morris an FDA labeling guru. He had worked at the FDA for twenty years and held prominent positions such as Acting Director of the Division of Drug Advertising with responsibilities that focused specifically on evaluating consumer-oriented advertising materials. It would seem Dr. Morris was the quintessential person to speak on FDA labeling issues. But, let’s think on that for a moment. Dr. Morris was an expert in evaluating labels directed at *consumers*, yet one of the opinions he was offering was whether the label was misleading to *physicians*. The judge was quick to close the gate on this. Specifically, the court found Dr. Morris’ “lack of experience as a prescribing doctor” rendered him incapable of testifying as to a *doctor’s* interpretation of the label.

The lesson here: make sure your expert can fill the right shoes. Dr. Morris was clearly an expert in FDA labeling. He was not, however, a prescribing physician and that was the specific role he needed to fill to be able to testify as to a physician’s impressions. While someone may have significant expertise in an area?twenty years in the upper echelon of the regulating agency even?that will not allow him to step into and opine on a role in the process in which he has no experience or has not studied.

## No Shirt

If the goal is “dress to impress” you probably want your expert in a button-down. While imagining

your expert walking into court bare-chested probably makes you cringe, if he takes the stand with bare opinions that are void of sufficient support and reliable methodology, the impact to your case would likely be worse. In the Eli Lilly opinion, the judge prevented another of the plaintiffs' experts, Dr. Glenmullen, a clinical psychiatrist, from testifying that Eli Lilly obscured the results of its clinical trials by publishing them in a medical journal that was not widely read in the United States because the court found the opinion was completely bare. Dr. Glenmullen failed to cite any relevant authority or study to support these opinions. It was merely his stated assertion. An expert opinion must be buttoned down, *i.e.*, adequately supported by reliable data, research and methodologies.

While a completely "bare" opinion, void of scientific support, may be easy to spot and avoid, sometimes a supported opinion can be excluded if the methodology is not the right fit. For instance, the court additionally struck Dr. Morris' opinion that Eli Lilly could have altered its label to more accurately reflect information published in a 2005 medical journal because it found Dr. Morris failed to show the FDA typically reviews published articles summarizing raw data rather than the raw data itself. In other words, Dr. Morris' process did not match that of the FDA's which meant his methodology was ill-fitting.

### **No Service**

The judge in this case certainly stepped into his role as "gatekeeper" in excluding these ill-fitting, uncovered opinions. The lesson to be learned: if you want your expert to get through the gate, be sure he is dressed to impress. You should also take stock of opposing counsel's experts as well. Do the buttons on his shirt look like they are about to go?

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