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Prioritize When Deposing Plaintiff 'FDA Experts'

Law360, New York (June 18, 2014, 10:15 PM ET) -- The proliferation of product liability mass torts has birthed the rise of the "regulatory expert" — someone who either worked for a regulatory body, like the U.S. Food and Drug Administration, National Highway Traffic Safety Administration or Consumer Product Safety Commission, or someone who has consulted for manufacturers seeking to navigate the regulatory field. But these are not traditional science-based product liability experts — there is no Ph.D. in "FDA Regulations," rather these are professionals who have made a living amidst the often contradictory and confusing promulgations of administrative bodies.

This sphere presents some challenges for drug and device manufacturers facing plaintiff FDA experts because plaintiffs have the upper hand when it comes to using these experts. First, it resonates with jurors if they can point to something the manufacturer did wrong or ambiguously under the regulations in question — the manufacturer did not follow the rules. Second, even if the manufacturer followed the rules, these "rules" are made by the federal government, and the federal government has lost credibility in the public eye. Plaintiffs' regulatory experts, therefore, use that distrust of government bureaucracy to their advantage to argue that the rules are just minimum standards established by industry cronyism or are not adequately enforced.

Manufacturing defendants face an uphill battle when it comes to attacking these experts, both in motion practice and in front of juries. These realities raise the importance of experts' depositions. By juggling the various and sometimes contradictory goals of a regulatory expert deposition, the manufacturer can put itself in the best position possible heading into motion practice and trial. The purpose of these depositions, aside from procedures followed by a few states like California, is not, as conventional wisdom dictates, "to find out all of their opinions" — those are in their (oftentimes excessively voluminous) reports; rather, it is to establish the bases and methodologies for their opinions and to obtain key admissions for cross-examination.

Preparation itself is paramount to a successful deposition of FDA experts. Read past testimony to make sure not to muddy any prior favorable quips, read any written opinions about the expert or the topic (e.g., if the expert is giving opinions about your client's adherence to the QSR regulations as a basis to avoid preemption) and prepare a malleable outline covering the waterfront. Given the current mass tort atmosphere in drug and device litigation, most of these depositions take place in large-scale litigation, covering multiple cases at a time. Under that

framework, the attorney taking the deposition is more likely to be on the trial team and not on the "legal briefing" team that will be crafting written motions. The deposing attorney should therefore work closely with whomever will be crafting that brief prior to the deposition to ensure that she asks the right questions to fit the themes of the motions.

To that end, motion practice considerations are three-fold: (1) summary judgment admissions (especially on preemption issues), (2) Daubert/Frye/Sargon support and (3) in limine/trial-related motions. For summary judgment admissions, pin down the expert with leading questions requiring short answers on subjects like preemption (e.g., "Isn't it true that Manufacturer X could not have changed this label without the FDA's consent?"). Allow the FDA expert to give her long answer, but always drill down on the inherent factual admissions that the evidence requires her to give; use the documents that will be exhibits to the summary judgment motion if at all possible.

While of course important from a preservation standpoint to assert the legal arguments, these motions also serve a practical point. Drug and device manufacturers should use these FDA experts' more outrageous opinions to prime the trial court on what the expert will attempt to tell the jury at trial (by way of an actual example, comparing a manufacturer's testing to Nazi experiments). Because they present themselves, essentially, as experts about regulations, FDA experts regularly cross the line between the province of the court and the jury. For evidence-related motions, long, narrative answers elicited by more open questioning may be preferred to clear-cut responses. The expert will often include in those answers their interpretations of the federal regulations, allegations of "violating" the regulations, "ultimate question" evidence, "state of mind" opinions and personal opinions about ethics and morality — all things that have been excluded by courts in drug and device cases.[1] At deposition, give the expert every chance to show the judge what to expect at trial. The defendant can then use that testimony to preemptively limit the FDA expert before she even takes the stand. Thus, even a "losing" motion can turn out to be a win for trial.

Obtaining fodder for cross-examination is the other main purpose of these depositions. Like the summary judgment admissions, proper impeachment fodder is crisp and requires tight, leading questions and answers. The trial attorneys cannot impeach the expert with one sentence in a three paragraph response. Too often attorneys unendingly focus on attempting to be "smarter" than an expert in their own field — to obtain a "gotcha" answer from them. But, generally jurors are not sufficiently interested in the bureaucracy and nuances of the FDA to follow, or even care about, such exchanges. A good cross-examination of these FDA experts, then, focuses on the more sensational topics of experience and bias, so the deposition should also include these areas.

Concerning experience, many of the plaintiffs' FDA experts either have no experience working at the agency or have no experience in the division or office that actually matters for the case at hand. For those experts who have never worked at the FDA but who may claim they "consulted" with the agency in various capacities, obtain exact admissions about how much time was spent per year on any certain topic. For former employees, an expert who spent 20 years in the Ear, Nose and Throat Branch in the Division of Ophthalmic, and Ear, Nose and Throat Devices for the Office of Device Evaluation is probably not qualified to testify about PMA compliance issues for an implantable cardiac device. To obtain these admissions, however, stick to the facts: Bring an organizational chart from the FDA (available on the agency's website), have the expert identify where she sat and which people are whom that were actually responsible for the issue at hand.

For bias issues, focus both on how lucrative testifying for plaintiffs has been for the expert as well as how often she has served as an expert across industry. On these topics, be sure that written requests have been served for all prior testimony (not just limited in years), invoices and total amounts of income derived from testifying for plaintiffs in personal injury cases. Attempt to boil down this information, much of which will be available ahead of time, for the jurors and to obtain it in clear, crisp form that the trial attorneys can use for impeachment. Do this by including concrete numbers and asking the expert to actually count, for example, the number of times she has testified in the past. Additionally, go beyond the typical "You testified against XYZ manufacturer, correct?"-type questions. Add in leading questions that establish that the expert had the same or similar criticisms of that other manufacturers' labeling or procedures (e.g., "For each of these manufacturers, you gave an opinion that they promoted their devices off-label, correct?"). This way, the jurors may note that, in the experts' opinion, no manufacturer ever follows the FDA's rules.

In similar fashion to the summary-judgment-related questions, attempt to obtain the factual admissions that fit with your regulatory story and thematic presentation of evidence. Depositions provide the perfect backdrop to attempt these admissions outside the presence of the jury and to try some creative things — leave the ego at the door and do not be afraid to do something a little different. While many of these experts are savvy testifiers, there may be a few points to make with them to shore up impeachment evidence at trial to help tell the corporate story during plaintiffs' presentation of their case. For example, in cases where plaintiffs' FDA expert uses the "FDA is overwhelmed" or "the agency does its best" theme, use the statutory mission statement of the agency, the framework for clearing or approving the drug or device or the time or staff involved.

As a final thought, leave the wilderness cleaner than you found it. Drug and device mass torts are still hot in today's product liability arena — manufacturers will face certain claims and similar experts for years to come. A great deposition transcript for defendant manufacturers (that may lead to favorable published opinions or verdicts) stays with that expert for many years. Deposing attorneys who are able to balance the competing interests at these depositions through careful preparation and active listening during the testimony can use these typically dreary witnesses to great reward for their clients.

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[1] See, e.g., In re Traysylol Prods. Liab. Litig., 709 F. Supp. 2d 1323 (S.D. Fla. 2010).

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