

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MICHELE FECHO, et al.,
Plaintiffs,

v.

CIVIL ACTION NO.
11-10152-MBB

ELI LILLY AND COMPANY, et al.,
Defendants.

MEMORANDUM AND ORDER

January 20, 2012

BOWLER, U.S.M.J.

For the convenience of the parties, this opinion reduces to writing the oral ruling on the motions in limine (Docket Entry # 181-184, 185-191, 193-194 and 199) made in open court on January 19, 2012. The ruling is as follows:

First, I want to thank all counsel for presenting more than ten days of highly technical and complex testimony and argument in such a very skilled and professional fashion. In order to expedite this matter given the age and health of plaintiffs and given the delays in concluding the testimony, it is my preference to give you an oral ruling which allows for a more prompt and efficient resolution rather than a written opinion, which will require an additional period of time.

First, I find that the experts plaintiff proposes satisfy the requirements of providing opinions that will assist the trier

of fact. I also find and reiterate that they are all qualified as experts in their fields. However, I found Ms. Retha Newbold to be the weakest in terms of qualifications and testimony by a significant margin.

Federal Rule of Evidence 702 further dictates that a witness qualified as an expert may offer scientific testimony if "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Rule 702, F.R.E. Overall, this court performs "a gate-keeping function" under Rule 702 "to ensure that an expert's testimony 'both rests on a reliable foundation and is relevant to the task at hand.'" U.S. v. Mooney, 315 F.3d 54, 62 (1st Cir. 2002) (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597 (1993)).

I have considered the reliability as well as the relevance of the opinions and the testimony of each of plaintiff's experts. Recognizing that an observed association between a disease, in this instance breast cancer, and in utero exposure to DES does not, without more, create causation, as discussed in Milward v. Acuity Specialty Products Group, Inc., 639 F.3d 11 (1st Cir. 2011), at pages 17 to 19, I have also considered the Bradford Hill viewpoints that counsel have so competently brought out during the testimony.

Plaintiff presented the following experts: Dr. Hans-Olov Adami; Dr. Paul I. Roda; Dr. David Sassoon; Dr. Robin Fischer; Ms. Retha R. Newbold; and Dr. Leena Hilakivi-Clarke. I have not included the specific academic degrees of the aforementioned experts. They are set forth in the experts' CVs which are part of the record pursuant to a stipulation which appears in the record at Docket Entry 236. I find that their methodology in arriving at their opinions rests on a reliable foundation and, as previously stated, their testimony will assist the trier of fact. Defendant Eli Lilly's motion to exclude plaintiffs' experts (Docket Entry # 181) is therefore **DENIED** except for the admissibility of the testimony of Dr. Arnold Schwartz, M.D., Ph.D., which I find moot at this point in time. The same ruling applies to the motions to exclude brought by the other defendants, including the motion to exclude filed by defendant Bristol Meyers Squibb Company. For the record, these motions are Docket Entries 182 through 191, 193, 194 and 199.

I would simply add that the facts of this case are somewhat unique. We have a relatively defined cohort of women inasmuch as no scientist today is going to give pregnant women DES today along with a control group and assess the development in their offspring of breast cancer years later. It is therefore difficult, if not impossible, to conduct human studies to test the consistency of the association between the environmental

exposure to DES in utero and the subsequent development of breast cancer. The temporal relationship between the exposure and the development of the disease, however, tracks the natural age at which breast cancer typically appears and breast cancer is not a rare disease.

Each of plaintiff's experts, however, considered a range of plausible explanations in the context of his or her field of expertise both in their testimony and in rendering their opinions. A number of them testified about relevant published studies. Dr. Adami in particular plausibly explained the merits of the Palmer 2006 study along with the confidence intervals therein and addressed the reliability of her findings and methodology, including her finding of a statistically significant increased risk of developing breast cancer in the subset of women over 40 after she controlled for confounding factors. I recognize the dangers and deficiencies in slicing data into subgroups that could be characterized as too thin.

That said, we now have a second human study in Hoover 2011, which I note arrived at a slightly smaller hazard ratio than Palmer 2006. Recognizing that there were five additional breast cancer cases in the over 40 subset, only one of which occurred in the DES exposed group, Dr. Adami explained that Hoover 2011 excluded the Horn cohort, which was present in Palmer 2006, due to an absence of information about vaginal epithelial changes in

the Horn cohort. Dr. Adami also evaluated the data, including the confidence intervals in Hoover 2011, discounted an excess risk calculation in preference for a proportionate hazards model and found that Hoover 2011 further strengthened the causal link.

It is also notable that the Hoover 2011 article was published in the New England Journal of Medicine which lends additional support for Dr. Adami's testimony. As testified to by Dr. Adami, the New England Journal of Medicine is a prestigious and esteemed journal which examines proposed articles in a most rigorous fashion with internal and external reviewers and independent statistical experts. Indeed, publication in this particular journal is recognition of a development that clinicians should take into consideration in the daily practice of medicine.

I am therefore ordering the parties to mediation with all due dispatch. Finally, with all that has been said, plaintiffs still face an uphill battle.

/s/ Marianne B. Bowler
MARIANNE B. BOWLER
United States Magistrate Judge