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The Authors Respond

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facts derived from the best available aggregate data to make his medical assertions.[7] Today's judges are requiring nothing more. So, preference toward epidemiology is in no way against history; the history of any discipline is known only by the evolution of its ideas.

To address this issue via analogy: the FDA (and scientific community) requires clinical trials/epidemiological data in order to investigate drug efficacy without raising much critique. Why then should judges endure critique for requiring the same types of information when attributing etiology?

Epidemiology will not always be the dominant tool to assess causation, but in many situations it *is*. Many of the authors' critiques were directed towards situations where epidemiology *would* most likely be the preferred methodology to attribute etiology in the scientific community. For instance, they brought up examples of chemical structure analysis, in vitro studies, and in vivo studies supporting causation compared to "overwhelming epidemiological evidence" negating it, then critiqued the preference toward the epidemiological data. The simple reason the epidemiological analysis is given more weight is because it is an observational method analyzing *real* humans with *real* exposure often with *real* controls (though not required), whereas the other study designs are extrapolating from lab environments or non-representative samples. Epidemiology is not always the best methodology, although it is often preferred when attempting to understand etiology. This is accepted within the scientific community and should be the case within the legal community as well.

To clarify this situation we must also understand that epidemiology is intended to work in conjunction with other disciplines as indicated by the causal criteria of *coherence* with biological plausibility (inter-disciplinary plausibility).[8] It is common in the scientific process to conduct case studies, chemical structure analyses, and animal studies as precursors to massive epidemiological studies aimed at definitively attributing causation. Epidemiology is not divided from other disciplines; it is merely another tool used to assess the distribution and causes of disease in populations.

Bryant and Reinert specifically critiqued a district court's statement in a silicone breast implant case that said, "case reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls"(p. 16). There is absolutely nothing wrong with this statement in its context. Granted, some diseases may only be investigated by case studies (although I am unaware of any); this is not so for the elusive breast implant syndrome. The reason judges correctly required controls is because without a comparison group it is impossible to understand the effect of an exposure—there would be no way to know whether the morbidity/mortality experienced by the study participants occurred naturally, or as result of the exposure (silicone, in this case). The comparison with representative un-exposed controls allows a baseline morbidity/mortality rate from which an exposed group's morbidity/mortality can be measured. This was especially needed in the breast implant suits because the alleged symptoms were non-specific and common in those with *and* without exposure to silicone.

Courts are rightly interested in *attributable risk*, not the proportion of morbidity/mortality within a case series. The exposure of silicone gel was not rare and was readily assessable via epidemiological investigation—again justifying the court's request for research including controls. Even if the exposure had been rare, case control methodology would have been preferred over case-series when attributing causation, again because it implores controls. Case series are important research tools; however, they should be used to attribute causation only when it can be *explained* why other means of investigation are unavailable.

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Admittedly, isolated misuse of epidemiology has occurred in law (as referenced in Bryant and Reinert's article) and will undoubtedly occur again. On the other hand, "Structural misuse" of epidemiology in the courtroom is quite a claim, and I fail to see profound objective evidence in support of it. Also, analysis of epidemiology in the courtroom requires intricate knowledge of statistical terminology and methods of analysis; oversimplification/misinterpretation of these concepts could be potentially harmful to judges, further distorting the role of epidemiology in the courtroom.

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The authors respond

We welcome Mr. Korzeniewski's efforts at clarifying some of the epidemiological concepts included in our original paper. If anything, however, his critique only reinforces our fundamental point: that some courts, by applying inflexible rules of admissibility, are missing the complex and multi-disciplined dynamics underlying scientific assessments of causality. By so doing, these courts are preventing the factfinders from considering evidence that scientists would find relevant and even persuasive, thereby taking the legal system farther from rather than closer to the truth.

In this respect, Mr. Korzeniewski's

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7. Louis, *Researches on Phthisis- Anatomical Pathological and Therapeutical*, Walshe, ed. (London: The Sydenham Society, 1849); Louis and Trousseau, ANATOMICAL, PATHOLOGICAL AND THERAPEUTIC RESEARCHES ON THE YELLOW FEVER, WHICH PREVAILED IN GIBRALTAR IN 1828., Trans. by Shattuck. (Boston: Charles C. Little & James Brown, 1829); Morabia, *P.C.A. Louis and the Birth of Clinical Epidemiology*, 49 J. CLINICAL EPIDEMIOLOGY, 1327-1333 (1996).

8. Bhopal, *supra* n. 6.

that judges properly rely on their unanalyzed common sense, and most of his colleagues seem to concur. Grimm, though, offers an important caution. Agreeing with Badinter that political lassitude has transferred important dialogues from legislatures to courts, Grimm observes that the transfer involves a translation as well—from general political discourse into legal discourse—and that legal discourse is thinner than political discourse (p. 105).

Readers will evaluate the content of the conversations differently. Some will be troubled by the judges' acceptance of their own activism. Others will find the judges' willingness to intervene in the service of moral judgment admirable. All readers interested in today's constitutional courts will profit from eavesdropping on this conversation.

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comments on statistical significance are illustrative. First, we all apparently agree that courts should not exclude the testimony of an expert simply because it is informed, in part, by epidemiological studies that are not "statistically significant." Mr. Korzeniewski may disagree with our empirical assessment of what courts actually are doing, but we will not burden the reader with a further attempt to establish that point here.

More importantly, however, we think Mr. Korzeniewski misconceives our essential critique about the use of the term "statistical significance." We, along with many epidemiologists, find fault with it not because the information derived from significance testing is useless, but because the term is used as a black box that obscures the choices one makes in arriving at the final conclusion of significance/insignificance. In particular, it obscures the choice of which alpha level to use, and why to use, for instance, 0.05 as the cut off instead of 0.10 or 0.01.[1] Mr. Korzeniewski states that courts are correct to use 0.05 or 0.01 as an alpha level because that is what scientists have traditionally used, but this assertion is itself subject to dispute.[2] In any event, our point is simply that, whichever alpha level is chosen, it should be part of the analysis of whether evidence is admissible, and should not end the inquiry.

With respect to Mr. Korzeniewski's point regarding confidence intervals, the substance of our critique was not that confidence intervals *cannot* be used for significance testing, but that they should not be used *only* for significance testing. As Mr. Korzeniewski exhaustively illustrates, confidence intervals reveal much more about a potential causal relationship than simply the result of significance testing. It is precisely this "context," which Mr. Korzeniewski puts high value on, that is sacrificed when a court mechanically applies significance testing to scientific evidence. In the courts, it is not a question of whether some evidence should be given more weight than others; it is a question of whether some evidence will be heard at all if it does not meet arbitrary standards of admissibility.

Finally, we agree with Mr. Korzeniewski that epidemiological studies are remarkably powerful and useful means of evaluating causation. And to the extent that such studies are sound and relevant, they should be admissible, along with other relevant evidence. The question often faced by courts, however, is what to do when no such studies exist, or when such studies are in conflict with each other or with other sources of information. It is our contention that in these situations some courts increasingly have made choices that function to deprive the factfinder of data which scientists such as Mr. Korzeniewski would find relevant to the causal inquiry. In this respect, the critique's analogy to the FDA does not support its argument on balance. While there is some parallel between some courts' use of epidemiology and the FDA's requirement of clinical trials before new pharmaceuticals are introduced, it is well recognized that regulatory agencies like the FDA and EPA often make decisions about toxicity based on data that courts would consider unreliable to support causation. In fact, in toxic tort cases, plaintiffs sometimes seek to use the FDA or EPA's regulation of a particular substance as evidence of that substance's toxicity. This is often unsuccessful.[3] In this respect, Mr. Korzeniewski is simply wrong when he suggests that the approach used by courts is consistent with how the FDA makes decisions about causation.

To sum up, we agree with many of the critique's clarifications of the epidemiological concepts discussed in our original paper. And we agree with the critique's implicit argument that it is permissible for courts to value some evidence more highly than other evidence. However, courts should not, when evaluating the admissibility of evidence, deprive the factfinder of evidence that scientists would rely upon in making causal determinations. Nothing contained in Mr. Korzeniewski's critique undermines this fundamental point.

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1. To the extent that Mr. Korzeniewski suggests that a sentence of our original paper conflated the "p-value" and the alpha level, this was certainly unintentional, and we appreciate his clarification here. For the most part, however, we attempted to keep the two concepts analytically distinct, and saw no need to refer specifically to the alpha level by its technical term.

2. For an illustrative critique, see *Kadas v. MCI Systemhouse Corp.*, 255 F.3d 359, 362–63 (7th Cir. 2001) (Posner, J.).

3. *See, e.g., Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002) (noting that FDA's "risk-utility analysis involves a much lower standard than that which is demanded by a court of law").