In Reply: We analyzed the “inculpatory” potential of PCPA data—that is, the likelihood that such data may be used against physicians in malpractice litigation. Based on an analysis of the law of evidence, we concluded that this is unlikely. Dr Luft raises the possibility of “exculpatory” uses. Could physicians deploy their own PCPA data to defend against malpractice claims? For proponents of PCPA, particularly those working to overcome physician resistance to these measures, Luft’s notion is a hopeful one. However, the law is not on his side.

Physician clinical performance assessment highlights patterns of care for practitioners or groups of practitioners. Because PCPA is not directly connected to the particular issue in dispute, it constitutes “other act” evidence, akin to litigants’ past behavior or known character traits. Civil courts have generally ruled this type of evidence inadmissible irrespective of which side seeks to introduce it. The rationale is that indirect information “subtly permits the trier of fact to reward the good man and to punish the bad man because of their respective characters despite what the evidence in the case shows actually happened” on the particular occasion.1 As a result, while clinicians have tried to introduce evidence of exemplary behavior in previous similar circumstances to prove they acted appropriately in the case at hand, judges rarely find such evidence admissible.2

In evaluating legal rules, including rules of evidence, absolute statements are rarely accurate. Our Commentary outlined some unusual clinical circumstances in which physicians’ prior acts were admissible as inculpatory evidence. In these situations, the connection between past events and the care in dispute was so powerful that its probative value trumped its prejudicial potential. Such unusual circumstances may also arise in the exculpatory context.

For example, one rare situation where courts have admitted other act evidence is when it demonstrates an involuntary habit. In considering allegations that a nurse failed to respond to symptoms suggestive of a stroke, one court allowed the nurse to introduce evidence of her history of notifying physicians in such circumstances because she showed a pattern of behavior that was “semiautomatic, invariably regular, and not merely a tendency to act in a given manner.”3

By contrast, in Luft’s example of an allegedly missed diagnosis of breast cancer, it is unlikely that data showing the defendant had an average rate of mammogram use would qualify under the habit exception or otherwise have a tight enough connection with questions of causation and negligence in a particular case to be judged admissible. If it were admissible, the value a court would attach to it in disproving the allegations would be virtually nil.

Physician clinical performance assessment may have potential to improve quality of care. It also seems likely to remain a thorn in the side of some physicians. In debating the merits of PCPA, however, both promoters and critics would do best to leave malpractice litigation out of the equation.

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Financial Disclosures: None reported.

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Drug Safety Monitoring

To the Editor: The Commentary by Dr Strom1 points out several of the problems with the current drug safety monitoring system and offers several suggestions for improving the system. One recommendation calls for the use of independent and complementary nongovernmental organizations in the process of drug safety.

We believe that certified poison control centers (PCCs) fit this requirement and can significantly enhance postmarketing drug surveillance. Poison control centers are staffed with health care professionals trained to obtain detailed medication-related information and health histories, document calls, perform triage, assist in treating patients who are experiencing adverse drug reactions, follow up on outcomes, and perform surveillance. Acting as a focal point for the reporting of suspected adverse drug reactions would be consistent with the public health and surveillance activities currently performed by PCCs.

Data from individual PCCs are sent to the Toxic Exposure Surveillance System (TESS), a surveillance database coordinated by the American Association of Poison Control Centers.2,3 TESS data are already used by the pharmaceutical industry and regulatory agencies for postmarketing surveillance.3,4 The advantages of using the PCC system to collect medication safety data include it being nonpunitive, confidential, and independent; having a toll-free telephone number as a point of access; serving as a source for information regarding drug interactions; and providing immediate availability of reported data.4,5

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Financial Disclosures: None reported.

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In Reply: Dr Ruck and colleagues propose the use of PCCs and their national database, TESS, as a tool for postmarketing drug surveillance. I have long thought that PCCs are an underused resource for the study of dose-related adverse drug reactions.1 After all, what better way to study such reactions than in an overdose setting? However, it is important to place this in proper perspective.

First, TESS is not a comprehensive system for drug safety, but a data collection system. Second, TESS remains a surveillance system: it lacks the complete collection of data that would enable the conduct of formal hypothesis-testing epidemiologic studies. Thus, in many ways, this system resembles the MEDWATCH system maintained by the US Food and Drug Administration. Such systems generally can only be used to generate hypotheses, not test them.2 In contrast to MEDWATCH, TESS would be less able to study idiosyncratic reactions and more able to study dose-related reactions. However, it would remain one piece of a system intended for risk measurement, which then needs to be accompanied by risk assessment, benefit measurement, risk/benefit evaluation, and risk management.3,4

Nevertheless, I strongly agree that this is an underused but potentially very useful approach.

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Financial Disclosures: Dr Strom reports receiving funding from the National Institutes of Health, Agency for Healthcare Research and Quality (including Centers for Education & Research on Therapeutics (CERT) funding), DECIDE (Developing Evidence to Inform Decisions about Effectiveness) funding, and patient safety funding), having received grants and served as a consultant to most of the major pharmaceutical companies, and being a US Food and Drug Administration (FDA) Special Government Employee for serving on FDA advisory committees. He reports previously being a member of the FDA Drug Safety and Risk Management Advisory Committee and having served as a consultant to the Joint Commission on Prescription Drug Use, assisting in drafting its report. There was no funding/support for this letter reply.

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