I suggest the following simple ten ways to avoid malpractice in litigation:

DRUG, DEVICE AND BIOTECHNOLOGY

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Reliability and Admissibility of Forensic Toxicology Testing in Civil Cases

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The American public has long been fascinated with crime investigation dramas, from *Quincy, M.E.* in the 1970s to *CSI* today. Perhaps this fascination explains why jurors assign such importance to scientific evidence, including forensic toxicology evidence. Evidence of toxicology testing results has long been important in criminal cases, but the importance of this evidence in civil cases – including pharmaceutical product liability cases – should not be overlooked. An obvious example for use of toxicology testing results in these cases might be to prove whether or not a drug caused or contributed to a particular injury. In more unusual circumstances, toxicology testing results might be used to prove that a pharmaceutical product was defective. See, e.g., *Acree v. Watson Pharmaceuticals, Inc.*, 2012 WL 5306296, *7* (N.D. Ill. 2012) (describing the plaintiff’s argument that an elevated postmortem fentanyl level provided circumstantial evidence of fentanyl patch malfunction).

Like other forms of scientific evidence, forensic toxicology testing results present unique issues of admissibility. At a basic level, toxicology testing results will be admissible only if reliable. But what are the standards for determining whether toxicology testing results are reliable? And what type of information will be necessary to demonstrate or challenge the reliability of toxicology testing results? This article provides practitioners with a general overview of forensic toxicology testing so that they can answer these questions and anticipate the admissibility issues that may arise with this evidence at trial.

### Establishing the Standards Applicable to Forensic Toxicology Laboratories

Broadly speaking, toxicology is the study of the nature, effects, and detection of chemical substances. Each of these areas are fertile ground for reliability challenges in legal cases, but this article focuses on assessing the reliability of tests used to detect chemical substances in the body. Urine and blood are the two most common body fluids used for drug testing, although other fluids (vitreous, cerebrospinal) and body tissues (heart, brain, liver) can also be used for toxicology testing.

In the United States, there is no uniform mandatory certification procedure for forensic toxicology laboratories. As a result, considerable variation in competence can exist amongst the laboratories that perform forensic toxicology testing. Since 1996, however, the American Board of Forensic Toxicology (ABFT) has offered a voluntary accreditation program for toxicology laboratories based on guidelines jointly drafted by the Society of Forensic Toxicologists (SOFT) and the Toxicology Section of the American Academy of Forensic Sciences (AAFS). Originally drafted in 1991, these guidelines have been revised a number of times, the latest of which occurred in 2006. Currently, a working group formed by these three organizations is working on developing a best practices document for forensic toxicology laboratories based in large part on the guidelines.

The SOFT/AAFS Guidelines outline general laboratory procedures that should be followed to help ensure the consistency and reliability of forensic toxicology
results. To date, there are no reported cases expressly adopting the SOFT-AAFS Guidelines as the standard governing reliability of forensic toxicology results. Nevertheless, the Guidelines were designed to reflect the general consensus of the forensic toxicology community on accepted toxicology practices. Thus, practitioners should consider the Guidelines as establishing the minimum standard for toxicology laboratories, although additional standards may apply depending on the drug being tested for and the testing method being used. Few (if any) toxicologists will disagree with the basic principles outlined in the Guidelines, so it should be possible to establish them as the appropriate standard through deposition questioning of the laboratory’s witnesses. Any variance from the Guidelines should be considered as potential grounds for challenging the reliability of toxicology results.

**General Principles of Toxicology Testing and Practice Pointers**

The Guidelines describe best practices for the many steps between the forensic toxicology laboratory’s receipt of a specimen and its reporting of drug test results, including storage of specimens, chain of custody, screening for the presence of drugs, and quantification of drug concentrations. Theoretically, a reliability challenge could result from any protocol deviation that occurs during these steps. Most frequently, however, reliability challenges will arise during the drug quantification (or confirmatory testing) phase.

Drug quantification is separate from drug screening; basically, screening identifies whether a substance is present and quantification identifies how much of the substance is present. Immunoassays and chromatography are common screening tests that appear in toxicology reports. Many toxicology laboratories only quantitate drugs that have been detected during the screening process. But some drugs (e.g., oxycodone) cannot be detected by certain screening methods (i.e., false negatives). Thus, depending on the screening method, the fact that a drug was not reported in the toxicology report does not necessarily mean that the drug was not present. Other drugs, or classes of drugs, may be “detected” during the screening process because the screening method is cross-reactive to multiple drugs (i.e., false positives). Amphetamines and opioids are two significant classes of drugs that can result in false positives depending on the screening method used. This fact may explain why a drug may be reported as present during screening but absent during quantification.
established by running calibrators of 1, 2.5, 5, 7.5, and 10 ng/mL through the GC/MS; the calibration curve is then validated if it accurately calculates the negative and positive controls included in that batch.

Toxicology laboratories typically prepare a summary report of their findings for the case at issue. It is good practice, however, to review the batch results to confirm that all test results are reflected in the summary report. For example, many laboratories will exclude from their summary report the results of repeat testing, testing that was not specifically requested by the referring agency, or testing that failed quality control (i.e., validation). These unreported results may be important to your case, for example, if the laboratory failed to report the presence of a drug that could have impacted the cause of death determination. These results may also suggest problems with the laboratory’s testing.

Receipt of the toxicology laboratory’s entire case file will be necessary to make or defend reliability challenges to toxicology testing results. Most discovery requests directed to toxicology laboratories ask for production of the “litigation packet” for the particular case. While the Guidelines describe the materials that should be included with a “litigation packet,” in practice there is great variability in what laboratories produce in response to requests for these packets. The most commonly missing materials are Standard Operating Procedures, which can be critical in determining whether a laboratory was applying an otherwise acceptable testing procedure in a reliable fashion. Standard Operating Procedures also commonly describe which substances can (and by implication cannot) be detected by the testing method and the minimum concentrations at which they will be detected. Thus, when requesting the litigation packet, a “belt and suspenders” approach is suggested: ask for the “litigation packet” but also include in the request a description of the specific materials expected. See, e.g., Guidelines, Section 11.10. Upon receipt, follow up with your expert to see whether there are any relevant materials missing.

Conclusion

Reliability challenges to toxicology results can arise from the manner in which the testing was performed, and while prudent practice dictates retention of an appropriate expert, practitioners should not ignore their role in preparing these issues. Ultimately, it will be the practitioner who must convince judge or jury whether or not the toxicology results are reliable. Further, your toxicology expert will look to you to provide all available testing documentation and communicate expectations for his or her review. Thus, it is imperative that practitioners familiarize themselves with the standards applicable to reputable toxicology laboratories.

1 For commercially available tests – for example, many of the screening tests – this information will not be in the Standard Operating Procedures but instead in the Product Information accompanying the test materials. Many laboratories keep this information for the tests they use, and thus this information should be separately described when requesting the litigation packet.