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The Role of the Scientist in Litigation
Involving Drug-Use Testing

by

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In recent years, inappropriate drug use has come to be considered a major public-health problem. Accordingly, drug-use testing¹ has expanded into the civilian sector of the U. S. workforce and spread to some other discrete populations, such as professional and college athletes. With few exceptions, drug-use testing in the workplace and comparable environments is not done for medical or clinical purposes, e.g., diagnosis or treatment of addictive disorders. Formal challenge of the reported test results and actions based upon them, and involvement of test results in litigation and other adversary proceedings such as arbitration, are expectable and predictable consequences of drug-use testing. Indeed, the frequency and intensity with which test results and actions based upon them are challenged and contested have increased in proportion to the expansion of drug-use testing. Drug-use testing for nonmedical purposes should be considered as a forensic toxicology activity,² and performed with due regard for that status and in accordance with all of its applicable principles, practices, and safeguards.

Four important factors contribute to the complexity of the current drug-use testing situation and to the frequency and intensity of challenges, and hence the need for expert forensic toxicology consultation.

First, the entire field has been, and remains, largely unregulated at both federal and state levels, especially with respect to its technological aspects and laboratory personnel. As of the end of calendar year 1987, proposed federal regulations for control of drug-use testing laboratories and of technical procedures (1, 2) had not yet been promulgated in final form. Laws controlling the scene and the practices were nonexistent (federal) or rudimentary (state and local).

Secondly, there exists only a relatively small body of persons experienced, qualified, and peer-approved in the

technology of drug-use testing. In part, that is so because, until very recently, large-scale drug-use testing was done only by the U. S. Armed Forces for their own military personnel and within internal military laboratories or a very small number of approved contract laboratories. The profession of forensic toxicology has typically been largely concerned with such matters as postmortem toxicology in coroner or medical examiner cases and drugs-and-driving prosecutions, and is accordingly small in numbers and limited in education programs and training opportunities. Its qualified practitioners are traditionally already overworked and overcommitted, and few of them were available to assume the burdens of massive drug-use testing activities. The inevitable consequence of these facts and the recent great and sudden surge in demand for drug-use testing was to divert drug-use testing almost exclusively into non-forensic laboratories, with attendant problems to be further discussed below.

Thirdly, drug-use testing readily lends itself to surreptitiousness, especially on urine specimens obtained with or without subterfuge in association with pre-employment or periodic post-employment medical examinations. Apart from its undoubted illegality under federal and state constitutional prohibitions against unreasonable searches and seizures, it is certainly unethical conduct for any person to be administratively or professionally involved in arranging for or conducting any clandestine or surreptitious drug-use testing. One major reason, among others, for that position is that deliberately concealed testing deprives the testee not only of guaranteed legal rights, but also of the opportunity for timely challenge of incorrect results and action based thereon. One such common action is denial of employment to otherwise qualified job applicants, without disclosure of the underlying test results.

Fourthly, in contrast to such other fields as clinical chemistry, there have been few, if any, established and widely recognized standards for drug-use testing. On the contrary, there is often lack of agreement even on such fundamental issues as the definition of "positive" and "negative" results, i.e., the so-called cutoff limits for the bright-line thresholds of impermissible concentrations of target analytes. Establishment of such recognized standards is a slow process. As an example, it took about five years to gain wide acceptance of the proposal that initial screening test results be independently and adequately confirmed by non-immunochemical methods different from those used in the initial presumptive testing (3-5).

The Forensic Scientist as a Consultant

The classical practice of forensic toxicology, like other forensic science activities, has traditionally been the exclusive domain of forensic scientists, who are familiar with the legal arena and prepared for involvement therein. In con-

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¹The term drug-use testing, as used in this article, means the systematic laboratory examination of biological specimens from humans to determine absence or presence of drugs that are illicit or have an abuse potential, and thus to establish inferentially whether the tested person is currently using such drugs or has recently done so.

²The American Board of Forensic Toxicology adopted the following position in November 1986: "It . . . is declared the policy of the American Board of Forensic Toxicology that drug (substance)-use testing activities by means of laboratory examinations be considered as encompassed within the scope of forensic toxicology when carried out under mandate of law, or under equivalent circumstances."

trast, drug-use testing is a relatively new forensic-toxicology activity for which the performance capability is broadly available and accessible. It is now largely performed in non-forensic laboratory settings such as independent clinical laboratories, hospital laboratories, correctional institutions, and industrial plants. The tasks are most often performed by personnel who are neither trained for nor experienced in forensic laboratory operations, nor sensitive to the latter's special characteristics and requirements. The typical clinical laboratory operation neither needs nor provides for challenge-proof specimen identification; chain-of-custody documentation; restricted and secure areas for specimens, facilities, and records; permanent documentation of laboratory methods, data, and results; and rigorous confirmation of findings. Consequently, if such enterprises enter the drug-use testing arena, they need to develop and implement a completely separate operation from that for routine clinical laboratory work, and generally they need suitably expert forensic science advice and assistance that is not usually available internally. Such consultation and assistance to the enterprises conducting the laboratory aspects of drug-use testing is an appropriate task for qualified forensic toxicologists.³

Consultation and advice is also needed by and available to the major non-laboratory participants in drug-use testing—the testers (i.e., the employer and other entities whose policies require drug-use testing of specified persons) and the testees (i.e., the job applicants, employees, sports participants, etc.) who are subjected to drug-use testing under authority of law or contractual arrangements. The former group generally needs expert advice on the following principal elements of drug-use testing:

- 1) selection and designation of the drugs and/or drug metabolites of interest and concern;
- 2) selection and collection of biofluid specimens;
- 3) identification, storage, preservation, and transport of the specimens;
- 4) the technology of and validity and reliability of the chemical analysis of the specimens, namely, the laboratory search for the designated analytes of interest;
- 5) reporting of the laboratory-generated analysis results; and
- 6) interpretation and use of those results.

Some cynical observers of the present scene would add a seventh element: litigation or other adversary proceedings because of the inherent potential for challenge.

The tested persons, usually through their personal attorneys or union representation, often need expert advice and consultation on the propriety and validity of the actual choices and execution of each of the foregoing six elements of drug-use testing; on alternative, "innocent" explanation for reported positive results; on independent re-analysis of reserve and remaining specimens; and on identification and challenge of improprieties in the drug-use testing process. The issues and hence the approach and responsibilities of the expert consultant necessarily vary considerably in so-

³ Two leading certifying bodies in relation to drug-use testing are the American Board of Forensic Toxicology (225 South Academy Blvd., Colorado Springs, CO 80910), which certifies qualified scientists in forensic toxicology; and the American Board of Clinical Chemistry (c/o Dr. W. H. Porter, Department of Pathology, University of Kentucky Medical Center, Lexington, KY 40536), which issues Certificates of Qualification in Toxicological Chemistry to qualified scientists.

called random testing situations from those involving "probable cause" or "reasonable suspicion" testing.

Some Commonly Contested Issues in Drug-Use Testing

Constraints of space and time prevent any in-depth discussion of the scientific and technical aspects of drug-use testing. Many of these matters have been recently addressed in the peer-reviewed literature (6, 7). Several aspects of drug-use testing commonly involved in litigation and other adversary proceedings will be considered briefly herein.

Analysis methodology is an obvious candidate for detailed scrutiny. Several special considerations apply. Many drug-use testing methods are subject to biological-matrix effects, and some commercial reagents are usable only for a particular kind of specimen such as urine. Any decision concerning the reliability of the testing procedure and validity of the test results must be based, in part, on evaluation of the following analytical method characteristics: (a) accuracy and precision; (b) sensitivity, detection limits, positive/negative cutoff value(s); (c) linearity of quantification over the concentration range of interest; and (d) specificity, selectivity, and interferences. It also cannot be overemphasized that initial (presumptive or screening) tests differ importantly from confirmatory analyses in the conclusiveness of the results yielded, and in other regards. Analysis methods are generally divided into those suitable for presumptive or screening tests and those recognized as suitable and adequate for confirmation. They are not interchangeable. Screening test methods are never acceptable for confirmation of initial test results; nor is repetition of a screening test an acceptable form of confirmation. In particular, immunochemical methods are not acceptable as confirmatory procedures. The pertinent principles are reflected in the policy statement on presumptive testing adopted in 1986 by the Toxicology Section of the American Academy of Forensic Sciences (4):

Confirmation of results is essential in forensic toxicology. Positive results of toxicological screening tests, regardless of the method used, and positive toxicological analysis results obtained by immunoassay methods should either be adequately confirmed before the results are used for forensic purposes, or be clearly designated as unconfirmed results.

Analysis methods used for attempted confirmation of presumptive results must be appropriately sensitive and specific or unequivocally selective for the analyte(s) in question, and must be based upon different chemical or physical principles than the initial analysis method(s).

Specimens for drug-use testing contribute their share of problems to contested practices and results. The biological specimens potentially usable for drug-use testing are blood, breath, hair, saliva, and urine. None is ideal in every circumstance and all possess inherent limitations. The choices, in practice, are controlled by the pharmacokinetics of the analytes of interest and the practicalities of specimen availability, accessibility, and collection. Urine has assumed, largely by default, the unwarranted status of the *de facto* pre-eminent specimen material for drug-use testing in the military establishment and in the civilian sector, despite material shortcomings for that purpose. In particular, the results of urine tests for drugs cannot be used to determine whether or not the specimen donor was impaired by drugs or their metabolites, was fit or unfit to undertake any given task or responsibility, or was subject to the systemic effects of the drug(s) of concern (8) at the time the specimen was collected or at any other given time. Positive urine drug-test

results cannot be used, by themselves, to establish what dose of a drug was administered or when, nor, in many instances, the actual parent or derivative form of the drug consumed, or the route of entry. Drug testing of urine has been the subject of two monographs issued by the federal government (9, 10), but still it remains widely misunderstood, especially with regard to its limitations.

Errors in drug-use testing, especially unrecognized or unacknowledged errors, are a serious and common source of concern. They include

Administrative errors:

- Incorrect specimen identification
- Incorrect result reporting

Technical errors:

- False-negative results
- False-positive results, including misidentification of drugs
- Incorrect quantification

Such errors are not easy to discover or to document, given the large scale of drug-use testing and the notorious reluctance of many drug-test laboratories to make full and complete disclosure of pertinent records, or even to provide adequate information concerning their analytical methods, raw test findings, quality-assurance procedures, personnel qualifications, and other relevant matters.

Under the demands of legal discovery proceedings by parties in litigation or arbitration, it is common for laboratories to provide so-called litigation or documentation packages, i.e., a compilation of copies of relevant records and documents. Unfortunately, these "packages" provided to the adverse party are almost universally assembled in a highly selective and nonforthcoming manner, and they consistently omit much pertinent or indispensable information. Further, the information actually furnished is often artfully camouflaged or buried among meaningless details. It thus requires suitably expert consultation and advice to the litigants and their legal counsel to delineate what information and records should be available within the responding entity and to itemize the data, data sources, records, and other information necessary for a complete and meaningful evaluation of reported drug-test results and findings. Appropriate checklists can assist in this regard.

However, there is no substitute for the simple principle governing such technical discovery: "If they need it, we need it." Every record or other form of information extant and all technical procedures used in the process of producing and reviewing the test results within the reporting laboratory must be disclosed promptly, fully, and in good faith. If the various procedures were accomplished and the records or files were compiled in the ordinary course of business by the testing entity, it must be presumed that they were considered necessary by that entity for the purpose of the drug-testing process, inclusive of establishing the validity of the reported results. Clearly, all of the same information is required by anyone charged with review and evaluation of the testing process on behalf of another party.

All states and the federal jurisdiction have elaborate statutory discovery codes. These generally provide for discovery of *any* matter, not privileged by statute, that is relevant to the subject matter involved in the pending action. Discoverable matters include the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things, and the identity and location of persons having knowledge of any discoverable matter. Discovery of facts known and opinions held by the

other parties' experts may also be had under stipulated conditions and by specified means, which include depositions. Protection from unwarranted or improper discovery can be obtained, for good cause, by protective orders issued by the courts. Obstinacy and open or covert obstruction and concealment by the parties legitimately subjected to discovery processes are not acceptable alternatives to protective orders; but they are unfortunate and common facts of life for litigators and their expert consultants.

Fortunately, recently enacted federal legislation enables federal employees subjected to drug-use testing to have full access to the relevant information. The pertinent provisions of P.L. 100-71 are (11):

Sec. 503(d). Any Federal employee who is the subject of a drug test under any program or plan shall, upon written request, have access to:

- (1) any records relating to such employee's drug test; and
- (2) any records relating to the results of any relevant certification, review, or revocation-of-certification review, as referred to in subsection (a)(1)(A)(ii)(III).

Problems of result interpretation are among the most difficult issues arising in litigation or arbitration. Accordingly, they require the greatest expertise in scientific consultants and expert witnesses. Interpretation of the results of drug-use testing is a multi-stage process; and requires at least the following elements: (a) verifying the actual laboratory findings; (b) establishing the validity or invalidity of the findings; (c) determining the significance of the findings; and (d) resolving inconsistent results or findings. One aspect of interpretation of particular importance is the interval during which the drug or its metabolites remain detectable in biological specimens after the last drug use. This is a very complex problem, which involves the nature and identity of the target drug and its metabolites and the concentrations of these analytes in the tested specimen. Those two variables, in turn, are the outcomes of all other biological, chemical and pharmacokinetic factors and events. However, in principle, three key variables are interrelated: (a) the drug concentration in the biological specimen; (b) the drug dose; and (c) the elapsed time between drug intake and specimen collection. Three additional confounding factors affecting the drug effect or impairment may also be present: tolerance, habituation, and drug interactions. Details of these matters are beyond the scope of this article but are covered elsewhere (6, 10, 12).

Proficiency testing is one of the elements of a complete quality-assurance and assessment program for drug-use testing laboratories. The military laboratories participate in their own proficiency-testing program for urine drug-testing, which involves both open and "blind" proficiency testing. There are several state-operated proficiency-testing programs available to civilian laboratories. In addition, two specialized laboratory-accreditation programs exist. They are administered, respectively, on behalf of the National Institute on Drug Abuse by a contractor (Research Triangle Institute, Research Triangle Park, NC) and in the private sector by the College of American Pathologists in collaboration with the American Association for Clinical Chemistry. Both programs include comprehensive periodic proficiency testing as part of the process of laboratory evaluation and accreditation. In litigation, the record of performance of the laboratory concerned, during the period in issue, in one or more proficiency-testing programs is important. Such quality assessment typically tends to document only the best performance of which a laboratory is capable. If the results

of proficiency testing have been unsatisfactory, routine testing is not likely to have been performed better during the interval under scrutiny. However, satisfactory performance in open proficiency testing—that is, the analysis of specimens clearly identified as proficiency test or quality control materials—does not in itself ensure that routine testing performance was equally acceptable.

For that reason, among others, a widely publicized one-time open proficiency test survey of 49 voluntarily participating laboratories conducted in 1986 by the American Association for Clinical Chemistry (13) has little, if any, bearing on how well or poorly routine drug-use testing is currently being carried out by private-sector laboratories.

The Forensic Scientist as an Expert Witness

A relatively small but growing number of contested civil matters involving drug-use testing ultimately proceed to litigation or to other formal adversary proceedings such as arbitration. These cases are especially important, because they tend to establish legal precedents with respect to the litigated issues and will in many instances control subsequent practices in drug-use testing. They are also usually more complex, in both legal and scientific aspects, than other contested drug-use cases, which are settled informally by mutual agreement of the opposing parties or, often, by default (e.g., failure to act at some stage) of one party or the other.

As an expert witness at such trials or hearings, the forensic toxicologist can have one or more of four functions: (a) presentation of the results of drug-use testing if he or she was personally involved therein or if such testing was performed by others under his or her control, supervision, and direction; (b) interpretation of the results; (c) support and amplification of scientific evidence in issue or of other expert witness testimony; and (d) review and rebuttal of opposing evidence or expert testimony.

Expert witnesses called by the testing party usually testify with respect to the first three functions, those called by the tested party usually testify concerning the second and fourth, or only the fourth. The usual situation is for expert witnesses to be presented by the respective adverse parties. Rarely, courts or arbitrators will also appoint their own additional expert witness, usually from a panel nominated jointly by the contesting parties. The usual spheres of the expert witness are the functions mentioned immediately above, and the nature and validity of the reported laboratory findings, as well as the degree of certainty of the reported findings. In giving testimony, the expert witness needs to be aware of and conform to the general standards of proof applicable to litigation. Under the federal constitutional due-process clause (Amendment V), those standards of proof are (14):

- beyond reasonable doubt: criminal cases
- clear and convincing proof: civil actions where the interests at stake are more substantial than mere loss of money
- preponderance of the evidence: civil actions where society's concern with the outcome is minimal and the parties share, more or less equally, the risk of error

Litigation and other adversary proceedings that involve drug-use testing in the context of this article are civil matters, and only the last two of the foregoing standards are applicable. The last is by far the most common in individual proceedings.

Whatever may be the standards imposed upon the trier of fact, the standard imposed upon the expert witness is simple

and clear—truthfulness. Under current federal rules of evidence, an expert witness may testify in the form of an opinion or otherwise. Most states follow the same rule. In federal courts, an expert witness may also offer testimony in the form of an opinion or inference on the ultimate issue in contention; e.g., whether a tested person has used or been exposed to the drug(s) identified in a body-fluid specimen. Expert opinion testimony may generally be based on relevant information from at least three sources: the expert witness' personal knowledge; facts and information established by evidence in the trial record; and facts and information supplied to the expert outside of the trial (but discoverable from the expert by appropriate discovery). When an expert witness does not have direct personal knowledge of the relevant facts or information, as in a drug-use test performed by others without his or her participation, that relevant information is often supplied in the form of a hypothetical question. The latter, in essence, requires the expert witness to assume certain facts supported by evidence in the record or, occasionally, subject to those facts being properly introduced and admitted into evidence at a later time.

The probative value of proffered evidence is a matter of concern to the expert witness. Federal Rule of Evidence 401 concerns "Relevant Evidence" and defines it as follows: "Definition of 'Relevant Evidence.' 'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence" (15). Most state evidence codes have similar or identical statutory provisions. Jurisdictions differ in the particular procedures used to establish the probative value of scientific evidence, including opinion testimony by expert witnesses. The traditional expression of the standard, prior to adoption of the Federal Rules of Evidence, was "reasonable scientific probability" or "reasonable scientific certainty." In some jurisdictions that or a comparable phrase remains a required predicate to a response of an expert witness to questions by counsel. The intent of all such verbal formulae is to establish that the preponderance-of-evidence test has been met with respect to the fact, information, or opinion offered by the expert witness. The latter must, therefore, assess whether any given planned opinion does meet this "more probable than not" standard; that is, the statistical probability of the intended statement or response being true exceeds 50% ($P > 0.50$). Because jurisdictions differ in the nature and extent of establishing that the applicable burden of proof has been met, an expert witness should specifically inquire of counsel what the standard is in the action concerned, and what wording will be used when applicable. Normally, use of the applicable predicate phrase is the responsibility of the advocate; but both counsel and witness should understand and agree upon the significance of such statements and what they imply or infer about the probability of the opinion statement. In particular, the legal term "reasonable scientific certainty" in such usage does not carry the statistical connotation that $P = 1.0$.

The qualifications required of an acceptable expert are ordinarily within the exclusive discretion of the court or other formal proceedings authority. By action of the profession, the American Board of Forensic Toxicology (ABFT) was established (incorporated in the District of Columbia in 1976) to promulgate and apply appropriate standards, qualifications, and requirements for issuance of Certificates of Qualification in Forensic Toxicology to those voluntary

applicants who satisfy the Board's criteria. The Board and its certification program are supported by all cognizant professional organizations, and have been recognized by federal and state courts and executive agencies of government. Accordingly, valid current certification by ABFT, or documented possession of the qualifications required for that certification, should be the threshold qualification for expert witnesses in forensic toxicology. Persons holding valid current Certificates of Qualification in Toxicological Chemistry issued by the American Board of Clinical Chemistry who also possess adequate and appropriate experience in the forensic science aspects of toxicology should also be deemed qualified to provide such expert testimony.

Persons offering expert testimony in actions involving drug-use testing, or comparable matters, should keep in mind that the jury, judge, or other finder of facts in any given case will, in effect, have five questions:

- Is the expert witness competent?
- Is the expert witness honest?
- What did the expert witness say?
- What is the significance of the expert witness' testimony?
- What weight, if any, should be accorded to the expert witness' testimony?

The successful expert witness anticipates these unstated questions and makes the answers clear and obvious. In my view and experience, the following factors and practices contribute to personal serenity when preparing for and providing expert testimony:

Prior to the trial or hearing

- Clear understandings of the expert's role and responsibilities in the instant action
- Laboratory and other technical findings confirmed and validated by suitable measures
- Appropriately extensive and intensive preparation
- Adequate, timely pretrial conferences with the advocate(s)

At the trial or hearing

- Absolute truthfulness
- Keeping within strict boundaries of one's own expertise and competence

- Presentation of any limitations or defects of the evidence during the initial direct examination by own counsel.

- Willingness to say "I don't know" or "I do not remember" when that is true

References

1. Alcohol, Drug Abuse, and Mental Health Administration. Scientific and technical guidelines for federal drug testing programs. Fed Reg 52:30638-30643(14 August 1987).
2. Alcohol, Drug Abuse, and Mental Health Administration. Standards for certification of laboratories engaged in drug testing for federal agencies. Fed Reg 52:30643-30652(14 August 1987).
3. McBay AJ, Dubowaki KM, Finkle BS. Urine testing for marijuana use. J Am Med Assoc 1983;244:881.
4. Backer RI. Policy statement on presumptive testing. AAFS News and Views—a Forum for Forensic Toxicologists 1986;11:1.
5. Mohan K. Re drugs of abuse screening test devices. Letter to manufacturers from Food and Drug Administration, 21 July 1987.
6. Dubowaki KM. Drug-use testing: scientific perspectives. NOVA Law Rev 1987;11:415-552.
7. Dubowaki KM (ed.). Drug abuse in the workplace. Prevention and control. Proc 1987 Arnold O. Beckman Conference in Clin Chem. Clin Chem 1987;33(No. 11B):1B-112B.
8. Blanke R, Caplan Y, Chamberlain R, et al. Drug concentrations and driving impairment. J Am Med Assoc 1985;254:2618-21.
9. Catlin DH. A guide to urine testing for drugs of abuse. Washington, DC 20500: Executive Offices of the President, Special Action Office for Drug Abuse Prevention, 1973.
10. Hawks RL, Chiang CN (eds.). Urine testing for drugs of abuse. NIDA Res. Monograph 73. DHHS Publication No. (ADM)87-1481. Rockville, MD 20857: National Institute on Drug Abuse, 1986.
11. Public Law 100-71, 100th Congress. Supplemental Appropriations Act, 1987. Approved 11 July 1987.
12. Barnett G, Chiang CN (eds.). Pharmacokinetics and pharmacodynamics of psychoactive drugs. Foster City, CA 94404: Biomedical Publications, 1985.
13. Frings CS, White RM, Battaglia DJ. Status of drugs-of-abuse testing in urine: an AACC study. Clin Chem 1987;33:1683-6.
14. U. S. Supreme Court. Addington v. Texas. 99 Sup. Ct. 1804 (1979).
15. Federal civil procedure and rules as amended to May 1, 1986. St. Paul, MN 55164: West Publishing Co., 1986, p 268.