

The Role of Physicians as Medical Review Officers in Workplace Drug Testing Programs In Pursuit of the Last Nanogram

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In discussing the role of physicians in workplace drug testing programs, I focus on the recent Department of Transportation regulations that require drug testing in such regulated industries as interstate trucking, air transportation, mass transit, and the railroads. These regulations require that applicable drug testing programs employ physicians as medical review officers to evaluate positive tests that have been screened and confirmed by different techniques to determine if there is a legal medical explanation for the result. The drug testing program tests for the presence of amphetamine, cocaine, tetrahydrocannabinol, opiates, and phencyclidine. If an employee testing positive has an acceptable medical explanation, the result is to be reported as negative. Little practical advice exists for medical review officers, and they must be aware of key elements of the regulations and potential trouble spots.

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In the past four years, there has been increased pressure for employers to test their employees for drug use in the workplace.¹ This pressure has come from employers themselves.^{2,3} Many have come to believe that despite the lack of accurate data documenting the magnitude of illness, disability, and monetary consequences of drug abuse in the workplace, the possible risks are enough to warrant drug testing.⁴ Substantial pressure has also come from the federal government.⁵ Finally, the public has expressed its support for urine testing of employees, especially those in safety-sensitive positions. Some believe, however, that our nation's preoccupation with the "war on drugs" is being used to tolerate unreasonable encroachments on basic constitutional rights to privacy and against unreasonable search and seizure.⁶ Others argue that the ethical basis for drug testing is unsound.⁷

The apparent controversy about drug testing in the workplace stems more from the use of preemployment, scheduled, and random drug testing than from for-cause testing. Obviously, for-cause testing is directed at persons who are either involved in workplace accidents or who behave in a "suspicious" way. On the other hand, preemployment, scheduled, and random urine testing are directed more at preventing and deterring drug abuse.^{8,9} Routine testing screens blindly, casting a net among the users of illicit drugs and nonusers alike. As a result, those who are not so concerned about the ethical and legal issues usually become concerned about the process of drug testing, wanting reassurances that they will not become unwitting victims of the war on drugs.

A major concern of many is the question of whether laboratories know what they are doing.^{10,11} To pursue both a national policy against psychoactive drug use in America and an industrial policy of no such drug use in the workplace, it

has become necessary to recognize that drug testing must be treated as a forensic process, complete with documentation, chain of custody, quality control, and the proper interpretation of results.¹² Indeed, professionals involved with laboratories and clinical toxicology have debated the prerequisites for adequate drug testing processes and procedures in the academic and clinical literature. The objective of this debate was to ensure, where possible, that no person be falsely accused of using illicit drugs as a result of inadequate or poorly conducted drug tests.¹³ Thus, a substantial number of papers have addressed the issues that inhere in the collection of urine and its subsequent testing.^{4,11,12,14-17}

A second major concern is privacy. While there are a number of components to the issue of privacy, one basic issue often unstated by proponents of urine testing is the direct observation of urination. Some experts do not hesitate to recommend the direct observation of urination for the purpose of producing a specimen for drug testing.^{8,18} In situations like the military where individual rights are understood to be subservient to a larger mission, direct observation can be done with impunity.⁹ For many people, however, bodily functions are private functions; the thought of strangers observing these functions, even in pursuit of a higher ideal such as a drug-free workplace, is unthinkable and unacceptable.⁶ This view is even more understandable when the majority of workers are not using illicit drugs.

Policymakers have turned for advice to the drug testing industry and to experts who have clinical familiarity with the urine collection and testing process. Many who have experience with the drug testing process acquired their experience from such programs as methadone maintenance or other drug treatment programs; in these situations, the clinicians are often involved in a cat-and-mouse game with career sub-

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ABBREVIATIONS USED IN TEXT

DOT = US Department of Transportation
 GC-MS = gas chromatography-mass spectrometry
 MRO = medical review officer
 NIDA = National Institute on Drug Abuse
 THC = tetrahydrocannabinol

stance abusers who themselves have developed skills to match those of their clinicians. Thus, those who are testing are often matching wits with those who are being tested. For example, several researchers have investigated additives claimed by addicts to produce false-negative tests and found some merit to these claims; such common substances as table salt, household vinegar, liquid bleach, concentrated lemon juice, liquid hand soap, tetrahydrozoline hydrochloride (Viasine) eye drops, and goldenseal (*Hydrastis canadensis*) tea have been used by addicts to alter their urine specimens.¹⁸⁻²⁰

In this vein, at least one laboratory specialist was reported to say that people would find creative ways to get around urine screening and that the technology of evading drug tests will parallel the technology of detection.²¹ Indeed, there are publications available for the public informing them about urine tests ("The Dope on Urine Tests," *San Francisco Bay Guardian*, 1990; 24:8, contained a brief "alert" informing readers that they could get a booklet that would help them pass urine tests. The booklet, "Conquering the Urine Drug Tests," can be purchased from Byrd Laboratories, 225 Congress #40, Austin, TX 70701). Because it is not clear how many casual users of drugs have developed the sophistication at deception found in career drug users, it can safely be said that a policy that encourages deception and evasion among casual drug users, rather than deterrence and prevention, is undesirable.

Drug testing experts are more likely to recommend the strict processes that appear to work for career drug users.⁸ Consequently, such recommended precautions as random testing, the direct observation of urination by same-sex observers, the use of bluing agents in toilet bowls, observing the urine color, and the measuring of urine temperature, pH, and specific gravity are a product of this experience. The following is an example of the diligence recommended by substance abuse experts in collecting the urine specimens:

The collector must watch the client urinate. To obtain the best view of the female's urethra [sic] meatus, the collector can ask her to bend over and view the process from behind her. It is important to view the urine actually coming from the meatus and into the empty collection container, for both men and women.^{22(p25)}

This type of procedure was recommended because skilled substance abusers have been known to strap bags of urine under their arms with tubing leading down their hands, making it difficult to distinguish whether the urine specimen is coming from the urethral meatus or the small tube.²² Although few can argue about the use of bluing agents and the measuring of the physical properties of urine, the issue of the direct observation of urination is appropriately controversial. Is the war on drugs worth the kind of familiarity that the procedure recommended by Andersen and co-workers breeds? That is a question the policymakers will have to answer.

Rational drug testing programs attempt to balance the need for accuracy of the process with the need to preserve the rights and dignity of the people being tested. The federal government's approach to drug testing is basically consistent

with this concept. As an example, the US Department of Transportation (DOT) regulations prescribe the specifics of how urine specimens are to be collected, the informing of the specimen donor of the process to which he or she will be subjected, and the certification of laboratories by the National Institute on Drug Abuse (NIDA); these specifics are an effort to assure that each collection site and each laboratory testing the urine of employees adhere to certain basic standards of quality control.

The Role of the Physician in Urine Testing

The federal government approach, in an effort to avoid wrongly accusing an employee of illicit drug use, relies on a policy that includes placing a physician between the drug testing laboratory and the employer.²³ The physician functioning in this role, called a medical review officer (MRO), must be a licensed physician who has knowledge of substance abuse disorders and who has appropriate medical training to interpret and evaluate positive test results.²³ The medical review officer reviews positive urine drug tests that have been subjected to both screening and confirmation tests with the objective of determining whether there could have been a possible alternate medical explanation. The DOT regulations require that regulated industries conducting drug testing programs use a medical review officer. Consequently, many physicians will be asked by local companies, transit authorities, or governmental agencies to play a role in their drug testing programs. For some, this will be a familiar role, but others will find it unfamiliar. Given the primary forensic function of the medical review officer, many physicians may wonder if it is even appropriate for physicians to function in this capacity.

Some physicians will have ethical qualms about the MRO function, believing it does not constitute a true clinical function for a physician. A clinical rationale for physician participation might be that rehabilitation of the drug abuser would result. As McNeely points out, however, many drug testing programs are not linked to drug rehabilitation and are designed only to search for illicit drug use.⁷ Hence, it could be argued that the MRO function is a police function rather than a clinical one. Yet, the thrust of the federal policy, as articulated by DOT regulations, appears to be to use a physician as a safeguard against wrongfully accusing a person of drug use. The DOT regulations that spell out the MRO function were chosen because the regulated employers are both private and public; the effective date was January 2, 1990. More than 4 million employees and 200,000 entities are affected by the DOT regulations. Six Department of Transportation agencies have promulgated regulations on drug testing programs: Federal Aviation Administration, Federal Highway Administration, Federal Railroad Administration, United States Coast Guard, Urban Mass Transportation Administration, and Research and Special Programs Administration.²³ Furthermore, regulated entities will be conducting preemployment, periodic, postaccident, reasonable cause, random, and return-to-duty drug testing. Thus, many physicians will be approached to serve as MROs, either in their capacities as employees of a regulated industry or as a contract employee.²⁴

An MRO is not supposed to rubber-stamp the confirmed positive test reported by a laboratory. If an employee has a legitimate medical explanation for a confirmed positive drug test, the test will be reported to the employer as negative;

thus, the employee does not have to suffer the indignity of being accused of having used illicit substances.²⁵ An example of a situation where a laboratory reports a confirmed positive and the MRO reports a negative is with the use of topical cocaine by either a dentist, oral surgeon, or ophthalmologist; an employee unaware of the use of cocaine by the specialist provides a urine specimen for testing as requested and vehemently denies the use of cocaine when the urine tests positive.²⁶ (It is important to note that this is not an example of a false-positive on the part of the laboratory. Indeed, the employee has had exposure to cocaine but in a medically appropriate manner.) Without the appropriate inquiry into the circumstances of cocaine use by someone with medical knowledge, the employee's denial of such use would be met with knowing contempt, as many people who are confronted with evidence of drug use deny that use. All the MRO need do is to verify that indeed the visit to the specialist occurred and that the drug cocaine was used during the procedure at a time sufficiently close to the provision of the urine specimen to account for the confirmed positive drug test; thus, the result is reported to the employer as negative.

If an employee has a confirmed positive test and does not have a legitimate medical explanation, the test is reported to the employer as positive. This verified positive test means that an employee has had an opportunity to explore with the MRO possible explanations for the laboratory-confirmed results. An example of the MRO's role here would be wherein an employee tested positive for opiates and denied their use; the MRO on exploring drug use might elicit from the employee the taking of his or her spouse's prescription of Tylox for bursitis. The MRO would verify the laboratory's confirmed positive but would provide the employee with the information that Tylox contains oxycodone hydrochloride, a synthetic opiate. The verification occurs even if the employee denies knowledge of the content of the preparation and can establish that the spouse had a legally acquired prescription, since this was not the employee's prescription.

The conceptual role of the MRO is important. There may be physicians who envision their role as broad and sweeping; such physicians may identify too closely with the war on drugs, adopting a police posture rather than a more narrow review and interpretive posture. A role more broadly conceived than is prescribed by the regulations should be discouraged. The activities of the MRO conducted under DOT regulations must conform with the requirements of those regulations. Activities by physicians not explicitly sanctioned by the regulations will leave the physician vulnerable to negligence lawsuits for invasion of privacy and breach of confidentiality; the contracting or employing employer may also be subject to claims for hiring an MRO who acts beyond the permitted regulatory boundaries. For example, it is possible for an employee to test positive for morphine as a result of poppy-seed consumption. Here there is no prescription; should the MRO believe the employee? If the MRO does not believe the employee, and there is no rational basis for the belief such as track marks or acute behavioral changes, the MRO still must report the result as negative. If the MRO goes ahead and reports the confirmed positive as positive, this action is beyond the regulatory boundary.

On the other hand, physicians must take great care not to advocate for the patient in this situation. Implicit in the MRO function is a highly technical, almost neutral role. Again, the basic task of the MRO is to determine if there is a legitimate

medical explanation for the confirmed positive urine test result. Therefore, assuming that the documentation is all in order and there is no suggestion of scientific insufficiency, the MRO can only base an opinion on existing medical knowledge at the time of the interpretation of the confirmed positive urine test collected and conducted according to the principles delineated in the regulations. As stated in the Tylox example, the fact that an employee claims to have used his or her spouse's medication for even a time-limited condition cannot sway the MRO from the primary task. The test is confirmed positive for opioids; the specimen donor has no prescription; therefore, the test is verified positive. Some physicians may object to this hard-and-fast procedure, but for an MRO to be effective in the long run, clear-cut procedures should be followed.

Peat points out that the drug testing of urine for nonclinical purposes is different in that it is not used in conjunction with other medical tests to assist in diagnosis.¹² Thus, a physician functioning as a medical review officer does not have the clinical support that normally attends the diagnostic process. In addition, the physician is not usually diagnosing a status or condition such as delirium or intoxication in the drug testing process, unless the MRO is the same physician by whom an employee is being seen for clinical assessment as a part of a for-cause assessment. The federal regulations limit the MRO to the one specimen tested, permitting at the most a retest of the same specimen by a different NIDA-certified laboratory.

At this time, there is no specific training for medical review officers for interpreting urine toxicology screens. Thus, there is no specific requirement for certification as an MRO. The federal regulations do not specify that the MRO should be an addiction medicine specialist, an occupational or industrial medicine specialist, a clinical toxicologist, a pharmacologist, or a laboratory medicine specialist. The regulations only require a medical license, a knowledge of substance abuse, and a knowledge of possible alternate medical explanations for a positive urine drug test result.

Medical Review Officers' Tasks

On receiving from an employer's drug testing laboratory the confirmed results of a positive urine drug test, the MRO must review and interpret the results. This interpretation is based on a medical interview and review of the employee's medical history, a review of any other relevant biomedical factors and all medical records, or both.²⁷ This review process must include all medical records made available by the tested person when a confirmed positive test could have resulted from legally prescribed medication²⁷; this means that for a drug such as phencyclidine, no medical records need be accepted from the employee because there is no known medical use for it. In addition, before making a final determination to verify the confirmed positive test, the MRO must give the tested employee an opportunity to discuss the test result.²⁸

US Department of Transportation regulations require special attention for the opioid class of drugs. Before an MRO verifies a test confirmed positive for opiates, he or she must determine if there is clinical evidence, in addition to the urine test, of an unauthorized use of any opium, opiate, or opium derivative. The DOT regulations provide for ignoring this regulation only if the employer's laboratory confirms the presence of 6-monoacetylmorphine, a heroin metabolite; thus, it is clear that clinical evidence is important when it

comes to the prospect of heroin users, unless a metabolite that can only come from heroin is present. This clinical evidence must reach beyond mere prescription and medical record verification.²⁹ Track marks are mentioned in the handbook that DOT provides for MROs.

The MRO's Knowledge

The MRO must also be knowledgeable about questions of accuracy and validity of a positive urine drug test. Under DOT regulations, only the MRO can authorize a retest of the specimen based on questions of accuracy and validity. Furthermore, the MRO must be able to determine if a confirmed positive is scientifically insufficient for further action, a conclusion that declares a test negative. For the MRO to declare a test specimen scientifically insufficient, the MRO must be able to assess inspection reports, quality control data, the results of multiple tests, and other pertinent conditions.³⁰

A medical review officer, then, must have some expertise and familiarity with the drug testing process and the literature associated with drug testing. The MRO must know the meaning of such concepts as screen positive, screen negative, confirmed positive, confirmed negative. The MRO should know what process is used to screen the urine specimens and what process is used to confirm the result. For instance, the DOT regulations permit immunoassay screening but require gas chromatography-mass spectrometry (GC-MS) confirmation.³¹

Furthermore, the MRO must know the meaning of the concept of cutoffs used by the laboratory to report the results of their tests. A laboratory reports a test as positive because the specimen contains an amount of drug equal to a certain threshold concentration. The threshold concentration, also known as the cutoff, differs from the concept of sensitivity or detection limits of the methods involved; thus, sensitivity refers to the lowest concentration of a drug that can be detected.³² The cutoff is usually higher than the detection limit because fewer errors will occur at the cutoff than at the detection limit, and fewer false-positives will result. The concept of cutoff for major urine screening programs has two basic applications: the lower limit of reliable testing based on the techniques involved in the testing and the lower limit of reliable testing based on the possibility of interference from medications, foodstuffs, environmental exposure, or endogenous processes. For example, the detection limit for cannabinoid radioimmunoassay is between 1 and 5 ng per ml, but the manufacturer's cutoff is set at 20 ng per ml.

Because a two-step process is required by the federal government in its urine testing programs and recommended by most authorities, the MRO must know that there are two sets of cutoffs involved in the urine drug testing process.²³ The DOT screening cutoff by immunoassay for marijuana metabolites is 100 ng per ml, but the confirmation cutoff by GC-MS is 15 ng per ml.¹³ The screening test for marijuana screens for multiple metabolites, but the confirmation test is specific for one metabolite. Using marijuana as an example again, GC-MS tests for Δ^9 -carboxytetrahydrocannabinol (THC); thus, despite the fact that there are 100 ng per ml of cannabinoid metabolites in a screening specimen, there must be at least 15 ng per ml of Δ^9 -carboxy-THC present before the laboratory can report a confirmed positive.

For the DOT regulations, there are those who think that certain cutoffs should be lower than they are, arguing for a screen-positive concentration of 20 ng per ml for marijuana

instead of 100 ng per ml, 500 ng per ml for amphetamines instead of 1,000 ng per ml, and 150 ng per ml for cocaine instead of 300 ng per ml. The rationale offered for the lowered levels is that more people using drugs would be caught.²³ The US Department of Transportation wisely chose a conservative route by maintaining the cutoffs as they are for two reasons: smaller quantities of metabolites are treated as negatives, avoiding the complications of cross-reactivity and interference by food products and passive exposure, and program costs are lower with the higher cutoffs. The MRO should know that these cutoffs are to some degree arbitrary and can be raised and lowered depending on new information and new technology (Table 1).

Urine specimens collected under the auspices of the DOT regulations will currently be tested for only five drugs: marijuana, cocaine, opiates, phencyclidine, and the amphetamines (including methamphetamine).³³ Thus, the MRO must be familiar with the properties, pharmacokinetics, metabolism, and legal uses of these drugs. Of the five drugs, only phencyclidine has no current medical use. There are those who would have the MRO test for a wider range of substances, adding to the list of five at least the following: alcohol, benzodiazepines, barbiturates, and methaqualone. Obviously, any MRO operating with this expanded list should have a substantive familiarity with these drugs. Only methaqualone on this additional list is clearly illegal; all other drugs may have legal uses.

NIDA and DOT Manuals

The National Institute on Drug Abuse and the US Department of Transportation have both published booklets to guide MROs.^{34,35} These booklets provide an overview of the perceived function of a medical review officer. The DOT manual does track, however, the DOT regulations, which gives MROs a specific approach to executing their function. The NIDA manual contains a graph of a decision tree that a physician would follow in decision making. Both manuals review the types of tests, the testing procedure, the assays that may be used, and an overview of the drugs that are prohibited.

TABLE 1.—US Department of Transportation Testing Requirements

Drug	Cutoff Level, ng/ml
Screening test (immunoassay)	
Marijuana metabolites	100
Cocaine metabolites	300
Opiate metabolites	300*
Phencyclidine	25
Amphetamines	1,000
Confirmatory test (GC-MS)	
Marijuana metabolite†	15
Cocaine metabolite‡	150
Opiates	
Morphine	300
Codeine	300
Phencyclidine	25
Amphetamines	
Amphetamine	500
Methamphetamine	500

GC-MS = gas chromatography-mass spectrometry

*25 ng/ml if immunoassay specific for free morphine.

† Δ^9 -Tetrahydrocannabinol-9-carboxylic acid.

‡Benzylecgonine.

Both manuals include a table that summarizes options in complex opioid-positive cases. The DOT manual has a specific section on the MRO review process and standard operating procedures that evolve from that process. The NIDA manual has a special section on proper prescriptions and on opiates.

The manuals, however, can be deceptive to an unsuspecting physician; their blind use projects an image of cookbook decision making in interpreting the confirmed positive results. Any physician who thinks that the process can be reduced to a simple chart is risking extreme liability. Furthermore, the manuals are only a guide; they do not substitute for the practice of medicine. In any event, there is at least one possible contradiction between the manuals and the response to the comments published with the final rule for DOT.

US Department of Transportation commentators and the DOT manual note that an MRO need only conduct a telephone interview with an employee who tested positive.^{23,35} Both the regulations themselves and the DOT manual, however, subsequently say that if a person tests positive for opiates, clinical evidence must be taken into consideration, unless the laboratory test involved tests for the presence of 6-monoacetylmorphine. Both the DOT and NIDA manuals point out that the clinical evidence includes recent needle tracks and behavioral signs of acute opiate intoxication or withdrawal; this clinical evidence is difficult to verify over the telephone. Medical review officers who are not prepared to actually examine opiate-positive persons can only guess at whether the positivity is from heroin or some other source. An enterprising addict replete with new track marks will simply state in a telephone interview that poppy-seed cake is the source of the positive result; without an actual examination, the MRO is forced to report the result as negative. If such an employee is subsequently involved in an accident, the MRO will be on record as having provided a negative report for someone who with a little diligence would have easily been verified as positive. Third parties will attempt to hold the MRO liable for any harm suffered by them based on the MRO decision not to examine an affected employee; this is especially applicable to operators of large vehicles such as trucks, buses, or trains.

MRO Standard Operating Procedure

Critical to the functioning of an MRO is an understanding of the authorizing regulations. (In situations where the urine testing is being conducted without the auspices of federal regulations, there must be clearly defined rules for the MRO and a clear understanding of what is expected of the MRO and to whom the MRO reports.) The DOT manual, under the section, "Standard Operating Procedure," summarizes the authorizing regulations succinctly. Ideally, an MRO should have a copy of both the DOT's manual and the authorizing regulations and be familiar with both. The MRO should develop his or her own set of standard operating procedures, especially if staff will be assisting in the process of contacting employees or in executing an initial medical history (a function permitted to medically licensed or certified staff).³⁶

The DOT manual prescribes a three-step process for carrying out the responsibilities of the MRO: the receipt of laboratory test reports, positive test report-verification process, and reporting of a verified positive test result. In each step, there are instructions for the MRO's conduct. The MRO should pay close attention to these instructions and follow the

process. The second and third steps offer the greatest potential for mischief and error; thus, they will be discussed further.

Immunoassay Negative Reports

The MRO's treatment of negative results is administrative. This means that the MRO or the MRO's staff must simply check the chain of custody documentation received from the laboratory and forward negative results to employers. The MRO also stores the documentation of these findings. Thus, the MRO is not concerned about false-negatives. If there are reasons to think that a person is using drugs, outside of self-admissions, that are unsubstantiated by a urine test, the MRO's function qua MRO is not to pursue further exploration of those reasons. Nothing in the DOT regulations precludes this activity per se, but the regulations do state: "The duties of the MRO with respect to negative results are purely administrative."³⁷ Thus, while an agent of the employer, the MRO's role is basically restricted to interpreting and reviewing positive test results.²⁷

Positive Test Report-Verification Process

The MRO must

- Review positive report documents
- Notify employees of positive test results
- Provide an employee an opportunity to discuss the test result
- Review medical records
- Review medical history and other biomedical factors
- Process employees' requests for retesting
- Authorize testing of a "split specimen" for drug metabolites.

The last two will not be discussed in this article, as they are technical and uncomplicated; the MRO should turn to the regulations or the MRO manuals to address these items.

While an MRO under DOT regulations receives both positive and negative results from laboratories, the primary and most important role for the MRO is in the area of positive test results. The physician must remember at all times that the MRO role is a forensic one. The physician should also understand that the MRO is an agent of the employer, not of the employee tested; for those whose clinical experience is limited to providing services directly to patients, with the patient being the focus of care, this role may produce conflict.

The Limits of Confidentiality

Before pursuing other aspects of the procedures that an MRO may use under the DOT regulations, the MRO must consider significant exceptions that appear in the regulations around the issue of confidentiality. The regulations proscribe disclosure of the specimen donor's medical information except for the following circumstances. The regulations permit the MRO to disclose medical information to the employer, a DOT agency or other federal safety agency, or the physician who determines the medical qualifications of the specimen donor under DOT regulations if

- An applicable DOT regulation permits or requires such disclosure;
- In the MRO's reasonable medical judgment, the information could result in the employee being determined to be medically unqualified under an applicable DOT agency rule; or

• In the MRO's reasonable medical judgment, in a situation in which there is no DOT agency rule establishing physical qualification standards applicable to the employee, the information indicates that continued performance by the employee of his or her safety-sensitive function could pose a major safety risk.³⁸

These exceptions to confidentiality create a special problem for MROs; they potentially broaden the MRO function beyond the mere role of reviewing and interpreting positive urine drug tests. Consequently, the MRO must weigh the implications of these exceptions before and during the primary medical reviewing task. The MRO should note that these exceptions are discretionary; by being discretionary, the MRO can choose not to disclose. With discretionary functions, however, the MRO will have to have a reasonable basis for disclosing or not disclosing, especially in the third exception. Note that the regulations apply to medical information, not just to a confirmed positive drug test.

The first two optional exceptions to confidentiality require that an MRO have knowledge of the applicable DOT regulations that govern the disclosure of medical information, the medical qualification of regulated employees being tested, or both. Thus, MROs who serve a spectrum of industries might be required to be familiar with the medical qualifications of the aviation, motor carrier, railroad, maritime, mass transit, and pipeline industries. The second exception requires an MRO to make a reasonable medical judgment about whether the information that is discovered in the medical files or information that the employee submits for scrutiny would result in an employee being determined medically unqualified under applicable DOT regulations. An example of this second exception might be that in reviewing the medical records of a pilot with a first-class medical certificate who tested positive for codeine following the treatment of a bad cough by a local physician, the MRO finds references to chest pain that responded to the use of nitroglycerin. The Federal Aviation Administration-DOT regulations require that a holder of a first-class medical certificate have no established medical history or clinical diagnosis of myocardial infarction, angina pectoris, or either symptomatic or treated coronary artery disease.³⁹ By receiving all the medical records, the MRO now has to make a decision: to disclose or not to disclose.

It is in the third exception to the regulation governing confidentiality that the prospect of third-party liability is clearly established. In this exception, knowledge of the rules of DOT is irrelevant. If the MRO knows something about the specimen donor's job and discovers medical information that suggests that continued performance of a safety-sensitive job could pose a significant safety risk, the MRO has the option to disclose. Clearly that option here is really an obligation. The MRO would have to have an extremely solid reason for not disclosing, as the regulation requires the exercise of "reasonable medical judgment." Reasonable medical judgment becomes a standard in a negligence lawsuit against the MRO who fails to disclose information that a particular employee is a safety risk. Oddly enough, the original physician who actually examined and treated the affected employee may have no obligation to disclose the same information to the employer, any federal agency, or the employer's screening physician. In those situations where the primary physician may be held liable for a failure to warn a patient or failure to protect the public,⁴⁰ the MRO may simply become a backup defendant;

plaintiff's attorneys can use the "reasonable medical judgment" standard created by the regulations as a basis to convince a jury.

In any of the exceptions to confidentiality permitted by the regulations, decisions to disclose made without a face-to-face interview risk provoking the anger and rage of the employee. An employee may feel tricked and deceived by the MRO and the employer. If the drug testing program is perceived as a device to discover the medical records of an employee, the MRO and the employer may suffer subsequent litigation. More important, employees will view the drug testing program not as an effort to stop the use of drugs in the workplace but to probe into the private medical life of the employee; this view will encourage subversion of the drug testing program. The MRO, therefore, may choose to establish procedures that militate against the surprise of an employee who tests positive for a legally acquired drug but whose medical records may contain material that suggests the need to breach the employee's confidentiality.

Notice to Employees

First, before a medical review officer initiates contacting a specimen donor who has a confirmed positive specimen, there must be a clear understanding of legal issues in the DOT process. Before obtaining medical information from the employee as a part of the verification process, the MRO must notify the employee of the potential for the disclosure of medical information to third parties.⁴¹ This is required by regulation. Consequently, the MRO must have decided beforehand just who those third parties are to be. Furthermore, the MRO should inform the specimen donor that the medical information disclosed may not have anything to do with the confirmed positive urine test.

Second, the MRO may choose to tailor requests for medical information to the specific drugs for which the employee tested positive. Hence, the MRO could request that the employee have his or her prescribing physician send documentation of only the prescription involved or the medical procedure involved. By restricting the focus of the inquiry, the MRO decreases the chance of discovering other information that has nothing to do with drug testing. This may appear to some as an evasion of an obligation, but, as stated, the test-positive employee comes to the MRO only for the reason of the drug test, not for a routine physical examination and not for the assessment of a medical condition. The employee's workup could be incomplete, in progress, or in error. The MRO would have only the documents to guide the decision making, especially if the entire contact with the employee occurs over the phone and through the mails. Thus, the MRO would have to second-guess the primary practitioner to determine if the employee specimen donor were indeed a safety hazard or not medically qualified for his or her job.

Both the DOT and the NIDA manuals provide information about legitimate positive test results. The DOT manual states simply that there are four principal explanations for a legitimate positive test result: (1) Errors in the laboratory process, (2) errors in the "chain of custody," (3) legally prescribed or dispensed medications, and (4) legally acquired foodstuffs or other substances that produce the same metabolites as illegally acquired substances. Items 3 and 4 are most easily the major items that the MRO will be evaluating. While items 1 and 2 may occur, it is assumed that their frequency will be low. There is one situation, however, that

could be subsumed under item 1 in this paragraph that needs to be discussed, and that is the issue of Vicks nasal inhalers.

Vicks Inhaler contains the legal ingredient, desoxyephedrine, or *R*(-)-methamphetamine, which can test positive for methamphetamine on immunoassay and on GC-MS. Fitzgerald and colleagues showed that a person inhaling from a Vicks Inhaler every 20 minutes for six hours can test positive for the illegal *S*(+)-isomer.⁴² They used an EMIT and TDx, types of immunoassays, with a cutoff of 300 ng per ml, which is much less than the 1,000 ng per ml cutoff permitted by the DOT regulations; nevertheless, one subject had a peak urinary concentration of *R*(-)-methamphetamine of 6,000 ng per ml; this raises the prospect of a confirmed positive for a few persons who are heavy users of Vicks Inhaler either through abuse, through innocent misuse, or simply their idiosyncratic physiology. The only way to assess whether the confirmed positive is a true positive is for the laboratory to determine the optical isomers of the amphetamine; with the isometric composition of methamphetamine determined, the probable source of the drug may be determined. Thus, a medical review officer would be negligent to verify a confirmed positive for methamphetamine without having access to the optical isomers. Without the optical isomers, an employee with no prescription for methamphetamine but with a statement of using Vicks Inhaler would have to be determined to be negative.

The MRO relying only on the NIDA or DOT manuals (or both) would find no reference to the article by Fitzgerald and

associates. Nevertheless, the issue of a test that is false-positive for methamphetamine is real. Unless other researchers are able to challenge the findings of Fitzgerald and co-workers, their article must stand as the standard on the question of whether Vicks nasal inhalers can produce a false-positive result for methamphetamine. Without the MRO knowing that a repeat laboratory study is required to inquire about the question of optical isomers, great harm could come to the specimen donor. Furthermore, it is not clear that DOT regulations permit isomeric differentiation. In a lawsuit, the MRO would be more than embarrassed by an error caused by this ignorance. The MRO is supposed to have the knowledge and skills to interpret these tests—this is required by regulation. It would be a poor defense in a malpractice trial to assert that the question of Vicks nasal inhaler was not covered in either the NIDA or DOT guidebooks.

Review of Chain of Custody Documents

It is critical that the MRO review the chain of custody documents that are received from the laboratory. This function is important for both screening-negative and confirmed positive urine results. While the screening-negative specimens can be handled administratively, the MRO or staff must ascertain that the chain of custody documents are in order. This review of documentation is clearly important when an employee is to be informed that he or she has a confirmed positive test result. Standard procedures should be developed by the MRO for the staff to verify appropriate documentation

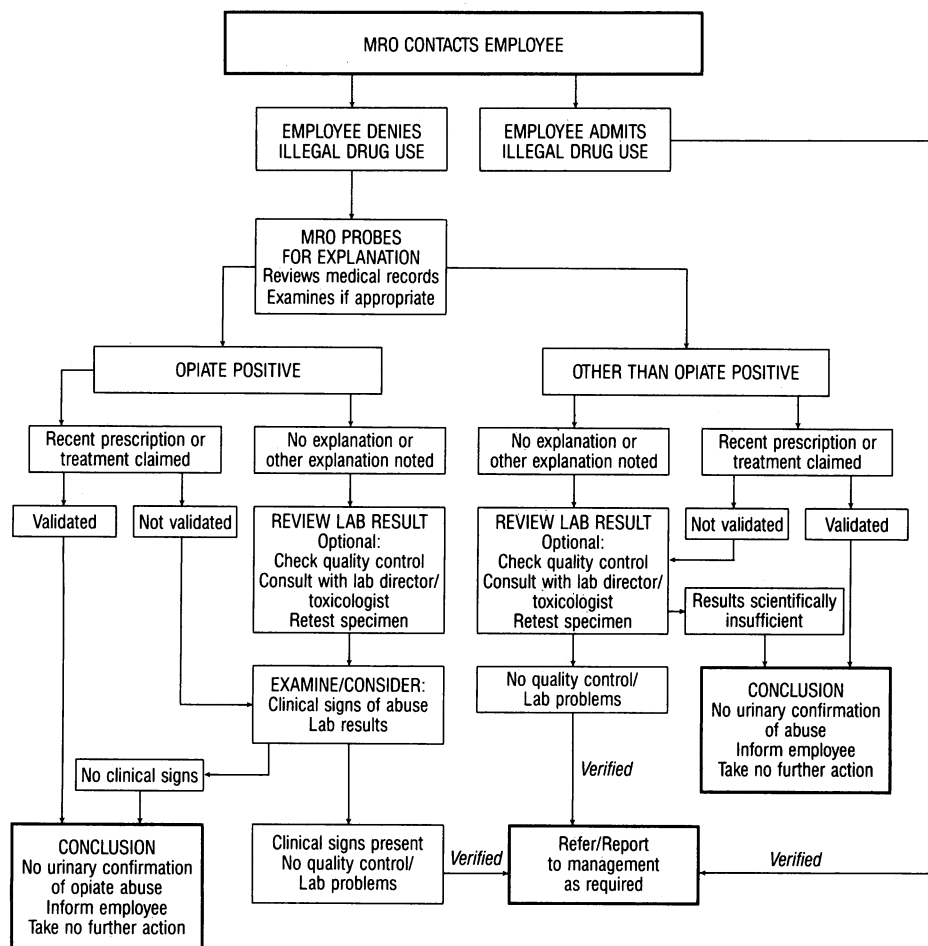


Figure 1.—A decision tree is shown for a medical review officer's (MRO) review and action for a urinalysis positive for drugs (from the National Institute on Drug Abuse).³⁴

that comes from the laboratory. Again, this should not be a significant source of error, but if there are errors, they will not be detected if the MRO has no systematic approach to this matter.

Legitimate Medical Explanations

As stated, legally prescribed or dispensed medications or foodstuffs that produce the same metabolites as illegally acquired substances constitute a principal basis for reporting a confirmed positive urine test as negative. The NIDA manual includes a decision tree for the MRO review and action (Figure 1). Both the NIDA and the DOT manuals include charts to assist in the conclusions in complex opioid cases (Table 2). These aids are useful for a physician who is formulating a standardized approach to decision making for confirmed positive urine tests.

As indicated, these decision trees and decision manuals are not a substitute for medical decision making. An absolute reliance on such material may lead to conflicts for employees tested, the employers, and the physician. An example of the limitations of standardized material would be the described case of a positive test for methamphetamine. The NIDA and the DOT manuals indicate that the screening tests cross-react for various amphetamine-related compounds; however, both manuals state that GC-MS confirmation distinguishes the cross-reacting compounds, assuring that final reports that are received by the MRO are not false-positives. Neither manual mentions the over-the-counter preparation Vicks Inhaler, however. In addition, the drug L-deprenyl (selegiline), a monoamine oxidase type B inhibitor used in the treatment of parkinsonism, is reported to produce isomers of amphetamine and methamphetamine that are excreted in the urine; these isomers are thought to be the R(-) type found in Vicks

Inhaler.⁴³ While it is not likely that more than a few employees will ever be taking this drug, mass screening of the working population may involve some of those on deprenyl therapy. In reality, all the permutations of drug testing and conflicting drugs have not been properly worked out. The MRO must keep abreast of the clinical and toxicology literature. As a result of a faulty MRO decision, a person may be denied a job, fired, or mandated into a treatment process that is unnecessary and undesired. As mentioned previously, the interpretations here, unlike other clinical settings, are primarily based on a single urine specimen.

The academic and clinical literature can help medical review officers understand the drug testing process. Four articles are recommended here to aid them in achieving an overview.^{13,15,17,32} Despite the fact that these articles are recommended, they are not definitive. Kelly's article, for example, reflects the contamination of science by the war on drugs policy; for instance, on the subject of the passive inhalation of marijuana smoke, she cites a study by Cone and associates, saying, "While several urine tests were positive for cannabinoid at the 20 ng/ml cutoff, the conditions were so extreme that the subjects had to wear goggles because of eye irritation."¹⁷ What Cone and co-workers actually wrote was

Our subjects were instructed to wear colored eye goggles throughout the smoke-exposure in order to prevent color discrimination between placebo and active marijuana cigarettes and to prevent eye irritation from smoke. Most subjects followed these instructions but some removed them for short periods of time while the cigarettes were burning. Based on their comments, it seems unlikely that exposure to the smoke of 16 marijuana cigarettes without eye goggles would have been tolerable for most subjects for extended periods of time.^{44(p95)}

Kelly, who works for the makers of the EMIT process, appears to have been distracted by Cone and colleagues' impressions. Because Kelly's article is a review, it should have

TABLE 2.—Medical Review Officer's (MRO) Conclusions in Complex Opioid Cases

Urinalysis Results	Employee			MRO's Conclusion of Probable Explanation
	Presents Prescription	Claims Poppy-Seed Eating	Signs of Abuse	
6-Monoacetylmorphine with or without other findings	NR	NR	NR	Urine test confirms heroin abuse
Morphine	Morphine sulfate	NR	NR	No urinary confirmation of opioid abuse
Morphine	None	Yes	Yes	Urine test confirms heroin or morphine abuse
Morphine predominates, some codeine	Morphine sulfate	NR	NR	No urinary confirmation of opioid abuse
Morphine predominates, some codeine	Codeine	No	Yes	Urine test confirms morphine or heroin abuse
Morphine predominates, some codeine	Codeine	Yes	NR	No urinary confirmation of opioid abuse
Codeine predominates, some morphine	Codeine	NR	NR	No urinary confirmation of opioid abuse
Codeine predominates, some morphine	None	Yes	Yes	Urine test confirms codeine abuse
Codeine predominates, some morphine	None	Yes	None	No urinary confirmation of opioid abuse
Negative	None	No	Yes, extreme	No urinary confirmation of opioid abuse
Hydromorphone HCl (Dilaudid)	None	Yes	None	Urine test confirms hydromorphone abuse
Methadone	Methadone HCl	No	Yes	No urinary confirmation of opioid abuse
Methadone and morphine	Methadone HCl	Yes	Yes	No urinary confirmation of morphine or heroin abuse
Methadone	None	Yes	NR	Urine test confirms methadone abuse

HCl = hydrochloride, NR = not relevant

noted that Cone and associates did not assess or measure the amount of smoke in the atmosphere of the room or the degree of irritation on the eyes of the subjects but based their conclusions only on the comments of a nondescript "some" of the seven subjects in the study population. Just how extreme the conditions would need to be before a person could not tolerate atmospheric marijuana smoke is not clear. Cone and co-workers could have used the smoke from tobacco cigarettes as a comparison or measure of eye irritation. In addition, their work did not address the question of what happens when both tobacco and marijuana cigarettes are being smoked in the same room. The issue of marijuana smoke is important because of the lingering question of passive inhalation. An MRO may be asked by an employer or employee assistance program person if an employee with a low titer of THC metabolite could have been a passive inhaler; this question is not answered by either Cone and associates' study or Kelly's review. This may seem a minor point, but it underscores the problem confronting MROs. Much of the literature is biased either for or against urine testing. This bias creates a credibility problem and a liability problem, given that most MROs will not have any actual research experience in urine drug testing. Nevertheless, the four articles mentioned, as well as the one by Cone and co-workers, are good background reading.

Standard of Care

Given the potentially grave consequences of faulty interpretation, enterprising attorneys undoubtedly will push for a stricter standard than the regular practice of internal medicine, occupational or industrial medicine, or family practice. Standards based on the expertise of specialists in pharmacology, toxicology, or addiction medicine would be demanded. Such standards would be justified, given the risks for specimen donors involved and given that the justifying regulations require a reasonable knowledge of information shared by those specialties.

How a medical review officer will keep abreast of changing toxicology and substance abuse issues is not currently clear. Subscribing to mainstream toxicology and clinical laboratory journals that carry research about the various methods, their potentials, and their limitations should be helpful. Addiction medicine literature and pharmacology literature will undoubtedly carry more information about the usefulness and pitfalls of urine testing. Attending periodic continuing education courses in the area of substance abuse and urine testing for drugs of abuse should also help. With the passage of time, there should be newsletters circulating to physician-MROs highlighting changes in the body of knowledge. Perhaps NIDA, DOT, or another federal agency will take the lead in creating a clearinghouse to keep subscribing MROs apprised of this information; this would be ideal, given that the urine testing regulations under which MROs are operating are federally promulgated, and NIDA, DOT, or both might publish more frequent updates of their manuals as clinicians in the field acquire more experience through the large-scale testing being conducted.

At least one DOT agency, the Federal Aviation Administration, has sponsored a seminar on the role of medical review officers. While tailored for the aviation MRO, the day-and-a-half seminar covers the regulations, the specimen collection procedures, pharmacologic aspects of the five drugs tested, laboratory and toxicology issues, and the duties

and responsibilities of an MRO. The agency also publishes its own MRO guide.⁴⁵ In addition, there is at least one proprietary course on the role of MROs (Employee Health Programs, 1825 Eye St, NW, Ste 400, Washington, DC 20006).

On Fees and Time

A physician functioning as an MRO must realize that stepping into the role of assessing the legitimacy of an employee's prescription or food consumption is not the same thing as doing a certifying physical examination for a license. The standard of care, then, must be that reasonable level of care that should be given in the situation. Because of cost considerations, many companies will pressure physician contractors to perform the MRO service at the lowest fee. Fees set too low, however, will encourage physicians to be too quick or careless in the assessment of a confirmed positive urine test. Flat fees, as in capitation, must take into consideration epidemiologic aspects of drug use in the employee population tested: a low prevalence of drug use permits a low capitation fee based only on the administrative costs; a high prevalence of drug use suggests a fee-for-service basis because of the uncertainties of how much time a given employee's case will require. Caution must be exercised not to deny an employee as much time as is required to establish whether a confirmed positive test should be verified. Thus, streamlining the interview process for the sole purpose of saving time and money should be discouraged.

Documentation and Records

Medical review officers must have careful documentation on each confirmed positive case reviewed. From the moment of contact to the moment of reporting, a written record should reveal the character and the content of each transaction. This documentation can be organized around a record flow chart or questionnaire set. However it is completed, the documentation should permit a plaintiff's attorney to understand the procedures employed and the reasoning used to make the decision. Using the chain-of-custody approach, the MRO should establish sign offs for each step. If a secretary or nurse first contacts the confirmed positive employee, the time and date should be recorded and the signature of the contacting staff person should be clearly legible. The MRO should also document his or her interactions with the person with a confirmed positive test: this includes time and date of interview, the substance of the interview, releases of information signed by the employee to talk with health care practitioners, a list and time of receipt of documents from corroborating health care practitioners, a summary of the decision-making process, and when the decision, either negative or verified positive, was sent to the employer or other agency. Each folder, then, should be a litigation package that should also serve as a memory jogger for the MRO in the event of litigation or arbitration.

Reporting a Verified Positive Test Result

Once a confirmed positive report has been verified by the MRO, the result must be reported to the employer. Employers may choose the policy that they want to follow, however. Some MROs may report to the employer's employee assistance program; others may require that the employee be directed to a designated rehabilitation program. Still others may simply request that the MRO report to a designated management official who would handle the management of

the employee's situation from that point on. Whatever the procedure, the policy should be clear and written so that the MRO does not disclose private information to the wrong person. In addition, the MRO must possess knowledge about the rehabilitation process and community resources.

Medical review officers should understand what options are available under the insurance plans offered by the employers for whom they work. They should also know which public programs exist in their community so that they can refer employees who are not insured to these facilities. Because the MRO may be required to review the urine specimens of employees who are reentering employment following a period of rehabilitation, he or she may prefer to recommend to the employer or to the employee assistance program that a formal monitoring and reentry program be involved. These programs routinely have participants produce urine specimens for drug testing and evaluate those specimens. In situations where no physician is available to interpret drug tests, the MRO may work with the monitoring and reentry program as a part of helping the employee return to duty.

Return-to-Work Recommendations

Work with rehabilitation counselors through monitoring and reentry programs is critical. As US Department of Transportation agency regulations may require a medical review officer to make a recommendation on when an applicant or employee may be hired or permitted to return to duty in a security or safety-sensitive position. The DOT manual points out that the MRO must obtain from the rehabilitation counselor an assessment that includes the nature and degree of a person's past substance abuse, progress in any rehabilitation effort, and the prognosis and recommendations concerning recommended aftercare services.³⁵ Upon reviewing the rehabilitation report, the MRO must also be satisfied that the employee complied with the conditions and requirements of the rehabilitation program in which he or she participated. In addition, the MRO must determine that a return-to-work urine specimen is drug-free, showing no evidence of any current drug use. Then the MRO makes a return-to-duty recommendation. If the MRO recommends that an employee return to work, he or she must also establish a schedule for random, unannounced drug tests based on the assessment and recommendation of the rehabilitation counselor.³⁵

It is clear, then, that the role of the MRO in return-to-duty recommendations requires a combination of skills: clinical pharmacology, laboratory medicine, addiction medicine, and occupational or industrial medicine. It is also clear that a physician undertaking MRO functions must exercise great care in making the appropriate determination. For instance, while the rehabilitation program may make recommendations, employers rely on the MRO's assessment to decide whether an employee returns to work. If the MRO is unfamiliar with drug treatment and recommends that an employee return to work prematurely, the liability cannot be shifted to the rehabilitation program. Concomitantly, if the MRO unreasonably prevents an employee from returning to work, challenges will occur in either arbitration or litigation.

Physicians With Several Roles

Some MROs may have more than one role in their relationship with employees subject to testing. Conceivably, the MRO may be the certifying physician who determines that

the employee is physically fit and the collection site physician who collects urine for the drug testing. In each of these roles, information is collected about the employee that requires record keeping. Although the MRO may be tempted to collocate the record of the employee into one central file, implicit in each role is a different set of responsibilities. Furthermore, the more roles that a physician has in a relationship with an employee subject to testing, the greater the potential for conflicts of interest and of loyalties. Physicians who are actual employees of a company are more easily identified as being the exclusive agent of the employer; physicians who are simply contracting with the employer may be confused by the employee as a more personal practitioner. Physicians who function as the MRO and in other capacities should take great care to avoid the appearance of conflict. The maintenance of function-specific records, kept and accessed separately, can serve to document the separate objectives of each function. Physicians with multiple roles should consult with attorneys conversant with the authorizing regulations and with the practicalities of their practice about the best method of record keeping; however, the employee subject to testing should have a clear understanding of the boundaries of each of the multiple roles.

Conclusion

A number of details about the role and function of medical review officers are unaddressed by this article. This is not meant to be a definitive encyclopedic review of the function of the physician as a medical review officer, but it should be clear to physicians interested in the role of MRO that great care must be exercised in executing this decidedly forensic function. While some commentators have noted that laboratories are making substantial monies from the war on drugs (M. Freudenheim, "Booming Business: Drug Use Tests," *New York Times*, Jan 3, 1990, p C1), it should be clear from the above material that physicians will probably earn no more than they would from seeing a regular patient. Physicians should always remember that great care must be exercised in the MRO function because the decision making has outcomes that are almost immediate. Jobs and reputations ride on the skill and deliberations of the physician MRO.

Malpractice carriers will obviously look closely at the experience of physicians functioning as MROs. More so than the normal practice of medicine, the role of the MRO invites litigation. The MRO reviews and evaluates positive drug tests. Therefore, either there is a legal medical alternative or an employee will be subject to treatment, termination, or not hired, if a job applicant. Given the possible desperation that the situation of a positive drug test creates, legal recourse will be an almost instant reaction. Consequently, any deviation from the prescribed procedures of the regulations will create a cause for legal challenge. Any failure on the part of the MRO to keep abreast of contemporary literature and research that results in denying an employee a deservedly verified negative report will invite legal challenges. As mentioned, the medical community is far from united on the issue of widespread testing for illicit drugs; this is particularly the case because such substances as alcohol and nicotine are responsible for billions of dollars of health care costs and large-scale morbidity and mortality. This lack of uniform support will encourage specialists who are willing to serve as expert witnesses in malpractice cases where breaches of the standard of care are alleged.

Even in those situations where a person acknowledges the use of proscribed substance, the MRO must take great care in decision making and documentation. The MRO must keep scrupulous records; the forensic nature of the MRO function requires clear evidence of decision making. The MRO must resist pressures for rapid and premature conclusions. If errors are ineluctable, they should not be errors that could have been avoided by adequately interviewing the employee or by keeping abreast of the research that shows that a given drug cross-reacts with a proscribed one or produces metabolites that are otherwise prohibited.

Once in possession of medical information other than that directly related to the confirmed positive test result, the MRO must take great care in deciding how to manage that information. The employee may be encumbered by the careless disclosure of information about his or her health. On the other hand, the public has a right to require those who hold security or safety-sensitive positions to be capable and vigilant while on the job.

The controversy around the issue of urine testing continues to rage. Undoubtedly, as more of the public is involuntarily subjected to this procedure, the conflict over urine testing will escalate. Physicians cannot avoid this controversy, either because of the role of MROs or because they are prescribing medications for their patients that may produce confirmed positive test results. For the many reasons stated and unstated, it is critical that physicians appreciate the advantages and disadvantages of the concerted pursuit of the last nanogram of proscribed substances in the urine of Americans.

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