The Limits of Science in On-The-Job Drug Screening

by Morris J. Panner and Nicholas A. Christakis

Screening to obtain information about medical problems such as cervical cancer or hypertension is widely used and recommended within the medical community.[1] Increasingly, however, biomedical tests are being used in a way that reveals social and personal information. Scientific tests now offer the possibility of knowledge not only about an individual's health, but also about such things as his or her sexual, drug, or alcohol history.

The use of tests in this way is spreading. The armed services have already instituted mass screening for antibodies to the Human Immunodeficiency Virus (HIV), which causes AIDS. Screening is moving into the private sector as well; many insurance companies are testing for HIV antibodies before providing health or life insurance.[2] Moreover, the Centers for Disease Control (CDC) recently recommended that counseling and voluntary testing be offered on a routine basis to all people at increased risk of being exposed to HIV.[3]

Biomedical tests are also being used in an effort to decrease drug and alcohol abuse. Part of the effort to decrease drunk driving has involved stopping people at roadblocks and elsewhere and subjecting them to blood or breath alcohol determinations.[4] And, as the consequences of drug abuse have become apparent, random drug testing has been established in the military, athletic, and private sectors. For example, about 25 percent of the Fortune 500 companies, including Exxon, IBM, and AT&T, currently perform drug screening of some type, and this number is expected to rise by 20 percent within two years.[5]

When used in this way, biomedical tests are transposed, to some extent, from their medical context into a realm where test results assume social, political, and legal significance. Unlike the situation in clinical medicine, stigma and possible retribution are attached to testing positively for drug abuse or HIV antibodies. Thus, legal and ethical debate has begun to focus on the proper use of these tests and of their results.[6]

Mass drug screening offers a deceptively simple solution to the problem of drug use among workers. Even a very effective test is subject to error. In any given group of tested individuals, some will unavoidably be falsely accused. Even though scientific tests appear to provide efficient solutions to social and legal problems, these tests should not be accepted unless they also meet our standards for fair dealing.

The case of screening for drug abuse illustrates some of the problems encountered when medical tests are used in a nonmedical context. Moreover, the issue of drug screening is especially pressing because the President's Commission on Organized Crime recently recommended that all U.S. companies test their employees for drug use. As an incentive, it urged that the federal government refuse to award contracts to companies that did not comply with this policy. In addition, the Commission recommended that the government test all of its own employees.[7]

Mass drug screening offers a deceptively simple solution to the problem of drug use among workers. Administering a straightforward scientific test and thus determining someone's guilt or innocence has a dangerous allure: a person who tests positively for morphine use must be a morphine user, the misguided reasoning goes. Such reasoning is founded on a misunderstanding of the scientific method. In any given group of tested employees, athletes, prisoners, or soldiers, some individuals will unavoidably be falsely accused. This is not to say that the tests are grossly inaccurate; indeed, many represent highly refined bioscientific methods and are the best of which scientists are capable. However, even a very effective test is subject to error. And the existence of scientific error poses legal and ethical questions.

In discussing the effect of science on ethical choice, Robert M. Veatch notes the danger of such an excessive reliance on science. He warned that "we may become so infatuated with our technical abilities to accumulate data and tally scores that we run the risk of seriously misunderstanding the nature of the difficult decisions that must be made. We may succumb to what might be called the 'technical criteria fallacy.'"[8]

The Predictive Value Model

The tests employed in screening programs have a significant error rate. The accuracy and reliability of screening tests, the extent of unavoidable error, may be understood with the help of the so-called "predictive value model."[9] This model assesses test performance by means of two standards: sensitivity and specificity.

The sensitivity of a test is an index of how well it picks up true positives for a given disease or condition (such as morphine use) from a popula-

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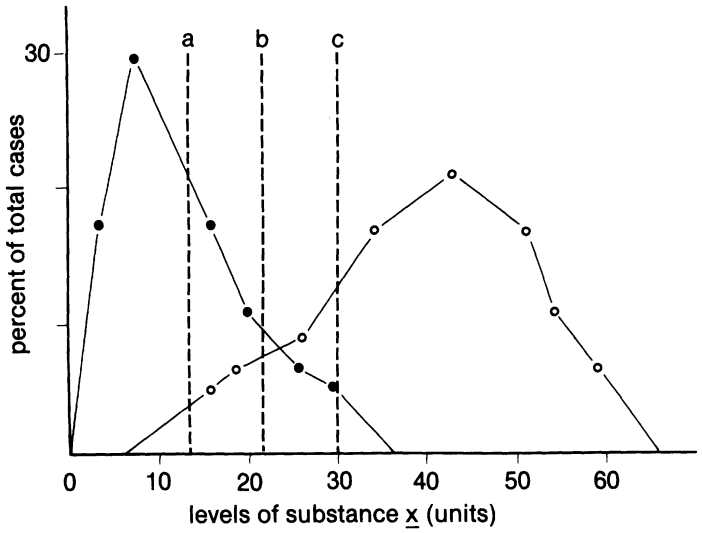
tion sample. It is a measure of how well the test does what it is supposed to do—namely, identify affected individuals. Stated more precisely, sensitivity is the frequency of positive test results in people who truly have a particular disease or condition. The higher the sensitivity, the fewer the false negatives, that is, people who test negatively but actually have the condition.

The specificity of a test is an index of how well it identifies true negatives. It is the frequency of a negative test result in people without a given condition. Alternatively, specificity may be viewed as a measure of the frequency of false positives. The higher the specificity, the fewer the false positives.

The difference between these two concepts may be best appreciated by looking at Figure 1. Let us assume that substance *x* in the blood or urine of a given individual is felt to be a good marker for condition *y*. The graph in Figure 1 has two independent curves co-plotted. The curve to the left shows the distribution of levels of *x* in individuals *without* condition *y*. For various levels of *x* on the *x*-axis, the percent of people having this level is indicated on the *y*-axis. As with virtually all biological phenomena, the curve is "bell-shaped," with a distribution of normal values. That is, there is a range of values, with most people having a value around the central average and some at either extreme of high or low.

Now we expect people *with* condition *y* to have greater values of *x* than unafflicted individuals—this is why levels of *x* are a marker in the first place. Generally speaking, this is, in fact, the case. That is, a test is chosen as such because the measured levels of given substance in an afflicted individual (such as drug levels in a drug user) *on average* are greater than the levels in unafflicted individuals *on average*. The values for afflicted individuals are thus graphed on the curve to the right.

The key feature of these curves, however, is that they overlap. A test with a cutoff, or upper limit of normal, at point *c* would be very specific: virtually all positively testing individuals would in fact have condition *y*; there would be virtually no false positives. A test with a cutoff at point *c* would be very sensitive: it would pick up virtually all the true positives in the population (but, unavoidably, also some false positives). A test with a "reference value" at point *b* would have intermediate sensitivity and specificity.



Distributions of test results in populations afflicted and unafflicted with condition *y*. Closed circles indicate true negatives, individuals unafflicted with condition *y*. Open circles indicate true positives, individuals afflicted with *y*. The average unafflicted individual has a level of *x* that is approximately 10 units, as compared with the average afflicted individual, who has a value of approximately 40 units. There is a distribution of values in the populations, however, and the distributions overlap. Selection of a cut-off value at points *a, b,* or *c* will determine the sensitivity and specificity of the test and hence the number of false positives and false negatives. Level *a* corresponds to a very sensitive test, level *c* to a very specific test; level *b* is of intermediate sensitivity and specificity. See text.

Predictive value theory thus dictates that as sensitivity increases, specificity decreases, and conversely. As we design a test with fewer false positives, we will perforce have more false negatives, and vice-versa. Thus, in the model described above, it will be *impossible* to avoid creating inaccurately typed parties (either false negatives or false positives). If an employer or other tester opted for a relatively specific test, he could be more certain that a positive test did in fact indicate drug use. But other problems would arise with this approach. A high false negative rate means that the test is not identifying all drug users. In practice, therefore, screening tests tend to be relatively sensitive.

This increased level of sensitivity at the expense of specificity causes the greatest problems for the legal system. A very sensitive test, which would result in a larger number of false positive results, would lead to more false accusations.

False Positive Rates in Screening Tests

Even the best drug screening tests have a significant false positive rate. For example, sophisticated and widely used radioimmunoassay (RIA) screening of blood for drug abuse may yield false positive rates of 43 percent for cocaine, 21 percent for opiates, 51 percent for PCP, and 42 percent for barbiturates.[10] Another widely used and aggressively marketed urine screening methodology, "enzyme multiplied immunoassay technique" (EMIT), is also significantly unspecific and may have false positive rates estimated at 10 percent for cocaine, 5.6 percent for opiates, 5.1 percent for barbiturates, 12.5 percent for amphetamines, and 19 percent for tetrahydrocannabinol

(the active ingredient in marijuana).[11] By contrast, because of the high sensitivity of these tests, false negatives are few (on the order of 0.1-1.0 percent for the RIA procedure, for example).[12]

A urine drug screen can be falsely positive for many scientific reasons. Legally obtained and medically indicated drugs may cross-react in some testing protocols so that, for example, an individual taking over-the-counter codeine (in cough syrup) may test positively on EMIT-type urine screen for opiate abuse. There are many similar examples.[13] Alternatively, false positives can arise from a variety of operator errors such as equipment contamination or sample mislabeling. Still another factor leading to false positives is the presence of endogenous substances in the urine or serum that might confound the test.[14]

To detect true positives, positives on screening tests should be confirmed by an alternative analytic method that relies on different physicochemical properties of the substance in question. A variety of second-level confirmatory tests can be used following RIA or EMIT screening. The better (and more expensive) second-level tests increase the confidence in the positive result, that is, increase certainty that an individual who tests positively is in fact positive. The false-positive rate for this two-stage analysis using EMIT followed by thin-layer chromatography, for example, may realistically be expected to be on the order of 2-3 percent, depending on the drug and laboratory. For EMIT followed by gas chromatography/mass spectrometry (GC/MS), at an approximate cost of fifty dollars per sample, the false positive rate may realistically be expected to be on the order of 1 percent.[15] Unfortunately, however, as two toxicologists point out, "because of the high cost and need for specially trained operators, most laboratories either do not have or are not able to commit a GC/MS system to routine urinalysis."[16]

In practice, clinical labs apparently do not routinely conform even to these scientific standards, nor is it realistic to expect them to. For instance, a CDC study of marijuana testing noted that "because of the costs involved in confirmatory procedures, confirmatory tests have not always been conducted to verify presumed positive test results."[17] Even when multi-level testing is used, blind surveys of clinical labs across the nation, conducted by the CDC, have shown a false positive rate of up to 66 percent, depending on the drug and laboratory under consideration. Human error is presumably largely responsible. There is no reason to believe that the record will improve, since it has fluctuated but not shown a consistent upward trend since 1973 after the CDC initiated blind surveying.[18]

In sum, the problem of false positives in biomedical screening tests will not go away. Both practical expectations about laboratory function and—more important—theoretical considerations about test design dictate an inherent fallibility for urine drug tests.

Litigation over Drug Testing

Even prior to the extensive testing envisioned by the Commission, people have gone to court to fight test results. Suits to prevent or redress alleged wrongs arising from screening have been based on a variety of legal theories. For example, suits have claimed that drug and alcohol dependency can be considered a handicap protected under the federal Rehabilitation Act of 1973, that the tests violate common law privacy expectations, or that the tests violate state constitutional protections. The tests have also been fiercely contested by unions since the National Labor Relations Board considers drug tests a work condition that must be subject to collective bargaining.[19]

By and large, however, litigation and discussion have centered on the problems that drug screening poses for an individual's right to privacy. Instead of serving as a means to raise productivity and avoid workplace accidents, drug screening becomes a way for an employer or government to monitor a person's private activities. For example, an employee might well use some marijuana on a weekend night without suffering any impairment during the week. Such an employee, however, could test positively for drug use since metabolites triggering a positive test result may be excreted in the urine well beyond the time of intoxication and impairment. Marijuana, for example, may result in positive urine screen test results for up to twenty days, depending on the amount of drug used and on the cut-off value of the test.[20]

Because of this characteristic, critics see a blurring in the justification for screening. Dr. John P. Morgan of Mt. Sinai School of Medicine in New York City argues that "not only is [employer screening] a new phenomenon, but it places the drug-positive individual in the grim situation of proving his or her innocence—not of intoxicated dysfunction or malfeasance, but of immoral and undesirable behavior."[21] Testing becomes a way to achieve a degree of social control that normally might offend societal expectations of privacy. Moreover, these tests appear to be used most aggressively against behavior or persons looked down upon by society. This may explain why drug users in the workplace have recently received far more attention than alcohol users although there has been no reason to suspect that one group endangers productivity or safety more than the other.

The courts have similarly considered the issue of personal privacy. State governments, for example, have been involved in litigation over proposed testing programs for several years, and a primary issue has been whether the programs violated the expectation of privacy under the Fourth Amendment prohibition against unreasonable search and seizure. The courts have been asked to determine if probable cause is required under the Constitution to administer a urine drug screen. The courts have thus attempted a balancing test between the right to privacy and the presumed societal need for drug-free workers.

This line of thinking has met with mixed results. The courts' ambivalence about such balancing is well illustrated in a recent series of cases, argues John D. Feerick, Dean of Fordham University Law School.[22] In *McDonnell v. Hunter*, a U.S. District Court ruled that a prison could not require its guards to submit to

urinalysis tests without probable cause. The court held that a guard had a "reasonable and legitimate expectation of privacy in such personal information contained in his body fluids. Therefore, governmental taking of a urine specimen is a seizure within the meaning of the Fourth Amendment."[23] The court did not dismiss the state's contention that the drug screening was necessary for security, but instead it held that demanding probable cause for a drug test did not interfere with those concerns. The court held that the "possibility of discovering who might be using drugs and therefore might be more likely than others to smuggle drugs to prisons is far too attenuated to make seizure of body fluids constitutionally reasonable." In this case, the court's conception of the sphere of privacy was decisive in outweighing the state's special interest in conducting the search.

Courts, however, could easily come out the other way in the balancing test. In *Shoemaker v. Handel*, the U.S. District Court for the District of New Jersey held that the state's interest in a well-regulated race track industry outweighed that of the individual privacy right. Also, the court pointed to the special regulations that surrounded the industry in general and to the fact that the jockeys had given up certain expectations of privacy as a group.[24]

The very nature of the privacy debate has led to these inconsistent adjudications. Moreover, given the increasing emphasis on preventing drug abuse, courts may become more willing to allow more intrusive searches because of this perceived compelling state interest. The "balancing" test between privacy and state interest may increasingly shift in favor of allowing mass testing for drug use and, indeed, for other medical or behavioral attributes of individuals.

Beyond Privacy

But more is at stake here than privacy. The endorsement by the government of inherently fallible drug testing threatens to institutionalize a system that renders some nondrug users presumptively guilty of drug abuse. Moreover, once the federal government becomes involved in mass screening, due process considerations, which are akin to the presumption of innocence in a criminal trial, are endangered. It is essential here that it is the government that is proposing these tests—private industry does not operate under the same constitutional constraints.

On one level, this application of scientific testing might seem natural to a society accustomed to relying on science. For example, in the use of breathalyzers to identify drunk drivers, science figures prominently in criminal enforcement. If police officers can stop drivers at roadblocks to test their driving fitness, the argument might go, why shouldn't the government "stop" employees and test them for drug use that might compromise job competency? Indeed, sanctions against drug-abusing employees are generally not as severe as those against drunk driving: a positive drug test in the workplace would not necessarily, at present, entail criminal prosecution. In fact, many labor relations experts recommend treatment rather than sanctions after an initial positive test result.[25] And in the absence of criminal prosecution, a lower level of due process protection would apply. But, even if employee drug testing by the government necessitates less constitutional protection, some protection from government is nevertheless required.[26]

As a mechanism of social control, the move to administer mass drug testing represents a more intrusive use of science by the government than breathalyzers. Unlike a breathalyzer, which is used as a tool to investigate criminal behavior and is usually applied at a roadblock to a driver who manifests signs of intoxication, a mass drug screen would be applied to all employees. Hence in the process of mass screening, the government would unavoidably place a burden—even if it is only the humiliation of undergoing unnecessary therapy for alleged drug use—on some falsely positive, nondrug-abusing individuals who would otherwise never have confronted the power of the government.

In a few cases, the courts have considered the problems posed by false positives and the rulings have reflected an ambivalence about the danger of harming a group of innocent people. In *Shoemaker*, the court ruled that the state regulations for testing jockeys had established sufficient safeguards against the problem of false positives. The court noted that the tests would be administered with what in effect amounted to a high degree of specificity in order to avoid as many false positives as possible. But, for the few remaining cases of false positives that still inevitably arose, the court held that a jockey was sufficiently protected if he could "request a hearing to fight the test, [sic] test results." This is precisely the shift of burden that our system was designed to avoid. Courts should not cope with the inherent error in testing by relying on the possibility of a future appeal by the wronged party.

The burden placed upon innocent parties is more clearly portrayed in the military's mass testing program. Subject to some minor limitations, a positive drug test will seriously jeopardize a soldier's career.[27] Moreover, the military courts have not been very sensitive to the danger of false-positive results. One court ruled that a positive test result alone was sufficient to discharge a sailor for cocaine use.[28] This ruling came even after the substantial flaws in the test had been revealed and even though the court was aware that other soldiers and sailors had been seeking relief for actions made on the basis of false-positive test results.

The military's problems with its mass screening program have been widely publicized. An astounding 97 percent false-positive rate has been reported in one round of urine marijuana screening by the army.[29] This error rate was presumably due to a combination of human, mechanical, and design errors associated with the particular test system employed. Moreover, within the last two years, the Army has begun contacting 80,000 to 90,000 soldiers and veterans who may have been disciplined as a result of a false positive test result during the period from April 1982 to November 1983.[30] In light of the government's experience with

mass testing in the military, policy makers should have ample expectation that wholesale administration of screening tests will result in significant injustice.

Admittedly, this type of gross error will not occur in most well-administered programs. Yet, even with presumably better administered private tests, there have been problems. Aggrieved employees have brought suit against their employers and against the laboratories that performed the tests. In one such case, two women were denied jobs because of the results of a pre-employment screening test. The women sued the laboratory, alleging that the results of the test were false and that the company failed to confirm the results sufficiently well, if at all.[31]

Finally, even if it were possible to develop and use a perfect scientific test, the government would nevertheless be conducting an ongoing investigation and examination of employees in the absence of any reason to believe that particular employees were using drugs. This, too, would place a burden on individuals to establish their innocence of drug abuse. Even in the presence of important reasons for requiring a guarantee of fitness, here, as with imperfect tests, this guarantee would cost society a degree of freedom from unwarranted government intrusion and accusation.

Excessive Reliance on Scientific Tests

Some have argued that the benefits from mass testing would outweigh the dangers. Peter Bensinger, former director of the Drug Enforcement Administration, endorsed the President's Commission proposal for mass drug testing "in the interest of safety, health, and increased productivity....Employers should not have to wait until an accident happens."[32] Many have felt that this argument is especially powerful for high-risk jobs where the cost of allowing a worker to show signs of drug use could be a serious accident. Mark A. Rothstein, a law professor at the University of Houston, maintains that this risk outweighs an employee's right to privacy. He argues that "a nursery school bus driver should not be under the influence of any drug, even if not *visibly* intoxicated. In such a situation, waiting until there is evidence of visible intoxication may be waiting too long."[33]

In allowing mass testing, these commentators dismiss the need for reasonable suspicion of drug abuse as a threshold for testing. We believe, however, that testing cannot be administered without some reason to initiate an inquiry. Although this safeguard has been proposed to answer privacy considerations, it serves an even more important function by limiting the impact that science can have upon government policy and process. By not insisting on probable cause to administer a test, policy makers are, in effect, using science to produce a decision seemingly divorced from the flaws of human judgment. We object to a system that answers an individual with a test result rather than a human decision.

In this expectation of probable cause to initiate an inquiry there is precedent: clinicians do not use clinical tests without judgment. Biomedical tests are ordinarily ordered by a physician when he or she suspects that the patient has a particular condition. However, when mass screening is used in the medical community (as in the screening of newborns for phenylketonuria or women for cervical cancer), there are two important differences from urine drug screens: (1) the results of the tests are used in a nonpunitive fashion to benefit the patient; and (2) screening tests are used to identify individuals for further work-up. Individuals testing positively are retested, subjected to other, more specific tests, or otherwise more rigorously examined.

In general, clinicians believe that test "results should complement the history, physical examination, and clinical evaluation, and [thus] help assure a correct diagnosis."[34] Scientists rely on tests to enhance their own critical powers rather than to replace them. When policy makers force medical methodology to function in a system for which it was not conceived, they risk using science as talisman rather than as tool.

Even though scientific tests appear to provide efficient solutions to social and legal problems, these tests should not be accepted unless they also meet our standards for fair dealing. Drug testing, like many other proposed shortcuts in our legal system, has been endorsed on the basis of convenience and public benefit.

We reject these appeals to greater efficiency. Instead, recognizing the utility of scientific tests, drug screens should be employed only with rigorous procedural safeguards. In summary, we believe that (1) tests should only be used after the employer is able to document a reasonable suspicion; (2) an employee should not be disciplined solely on the basis of a positive test result; (3) a test result should function as but one component in a larger case or investigation; and (4) employees should be guaranteed a hearing.[35]

Why is the level of error in scientific tests alone, a level of error that may be even less than that of the present American jury system, so disturbing? Unlike a case in which a government employer discharges an employee based on probable cause, an employee who has been inaccurately identified by mass testing cannot rely on proper conduct to avoid an accusation. When an employee has been unjustly accused by the employer, there has been an error on the part of the employer rather than an institutionalized and inevitable error in a system established by the government. In mass testing, even if all parties act properly and above reproach, there will still be false accusations due to government action.

It is here that the greatest danger of mass testing lies. The inherent error guarantees a Kafkaesque predicament for a few unlucky innocent individuals. These unfortunate people will not have shown any signs of wrongdoing. They will not, in fact, have done anything wrong. Yet still they will be accused. These employees will not confront a human accuser, but rather a faceless test result. The government will have set a precedent for using a system that imposes a known burden upon the innocent, a burden that cannot be eliminated even under the best of circumstances, a burden for which no person has to take responsibility.

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[33] Rothstein, p. 246.

[34] Craig Sutheimer, et al., "Clinical Application and Evaluation of the EMIT-st Drug Detection System," *American Journal of Clinical Pathology*, 77 (1982), 731-35, p. 734. Sutheimer et al. make this statement in the specific context of their evaluation of an EMIT test for ethanol, opiates, barbiturates, and benzodiazepines.

[35] In the case of a private employer since consititutional considerations do not apply, such safeguards would be binding only if enacted by federal, state, or local governments. For example, see *San Francisco Police Code*, Art. 33 (a), "Prohibition of Employer Interference with Employee Relationships and Activities and Regulation of Employer Drug Testing of Employees," 1985.