September 23, 2008
21 Raymond Road
Sudbury, MA 01776
978-337-4479

Mine Safety and Health Administration
Office of Standards, Regulations, and Variances
1100 Wilson Boulevard, Room 2350
Arlington, VA 22209-3939

RE: RIN 1219-AB41

To the Office of Standards, Regulations, and Variances:

I have reviewed the above-referenced Proposed Rule for drug and alcohol testing of miners. I offer comments as a physician with more than twenty years of practice as a medical review officer (MRO) and clinician who treats patients and prescribes controlled substances. I have written several text books for MROs, have helped write the Medical Review Officer Certification Council's exam, write a monthly newsletter for MROs, and teach in national training courses for MROs. I believe workplace testing programs can effectively deter illegal drug use and enhance safety. However I believe MSHA would be entering uncharted and potentially dangerous waters if it mandated workplace testing for prescription drugs. My comments follow:

Does MSHA Have Good Reason to Test for Prescription Drugs?

MSHA is planning to test for the federal 5-panel (which targets illegal drugs) and for unauthorized use of certain prescription drugs. MSHA states that it is testing for prescription drugs because they are widely abused in coal mining regions and because of a perceived safety risk. Because testing for prescription drugs puts employees at risk (as I will address later in my comments), it is important to consider why MSHA is doing this and whether its reasons outweigh the problems.

WIDESPREAD ABUSE

MSHA says it is adding certain prescription drugs to the test panel because they are widely abused. Twenty years ago, the federal government began testing for illegal drugs in the workplace. President Reagan's Executive Order 12564, which prompted the federal agency programs, cited the wide abuse of illegal

drugs among the reasons for mandatory workplace drug testing. This reason had merit, but it also had to be balanced against individual privacy rights. The federal programs prevailed because regulators developed standards and procedures that ensured fairness. They also prevailed because illegal drug use was clearly wrong.

SAFETY RISK

A number of court decisions have examined the government's right to mandate suspicionless drug testing in the workplace. The courts have typically supported that right only when there has been an overriding public safety interest. In its proposed rule, MSHA refers to a "widely recognized" consensus that misusing prescription drugs poses a safety risk in the mining environment. To illustrate this, MSHA cites incidents in which alcohol, drugs, or drug paraphernalia were found at the scene after mining accidents, and cases in which miners tested positive after accidents. But, almost all of these incidents involve illegal, not prescription, drugs. MSHA nevertheless assumes there is a significant safety risk from prescription drug misuse, is proposing to test for unauthorized use of certain prescription drugs, and is asking for public comment about banning *authorized* use of these same drugs. MSHA says the proposed rule would prevent accidents caused by drug-related impairment.

The "widely recognized" safety risk from use of prescription drugs is not based on epidemiologic or other scientific evidence. The few good studies on this subject do not establish an increased risk of work-related accidents from use of prescription drugs. For example, the Federal Motor Carrier Safety Administration (FMCSA) recently commissioned a review of the world's scientific literature to assess the risk from truck drivers using Schedule II drugs. The review found scant evidence of impairment from a single dose of the drugs and no evidence of risk from long term use of the drugs. [FMCSA. Medical Review Board Public Meeting; Washington, DC. January 10, 2007].

Prescription painkiller use does not necessarily make a miner impaired or pose a

safety risk. It may instead *enhance* safety by controlling pain so that the miner can better function and concentrate on the job. With the exception of the Federal Aviation Administration's approach to pilot certification, there are few job standards that categorically prohibit use of controlled substance prescription drugs. For example, FMCSA, which regulates commercial motor vehicle (CMV) drivers. allows drivers to operate CMVs while taking Schedule II drugs (other than methadone) with their physicians' permission.

For certain conditions, the worker's underlying medical condition may be disqualifying. To resolve this requires an individualized assessment by a trained physician who is familiar with the work environment. Some employers have a policy of requiring workers to self-report use of prescription medications (without revealing specific diagnoses or other details) so that the employer can refer the worker to its designated physician for a fitness for duty assessment.

MSHA has assumed that *un*authorized use of certain prescription drugs poses a safety risk, and authorized use may pose a risk, too. This reflects a widely held belief that use of controlled substances poses a safety risk. This belief is driven in part by manufacturers' warnings. Many package inserts carry broad warnings against driving or performing other safety-sensitive tasks after use of the medicines. More than 700 drugs in the *Physicians Desk Reference* carry such warnings. For example, consider the following warning:

> "When using this product do not use more than directed. Marked drowsiness may occur. Avoid alcoholic drinks. Alcohol, sedatives, and tranquilizers may increase drowsiness. Be careful when driving a motor vehicle or operating machinery. Excitability may occur, especially in children"

Should MSHA test for this drug, too? This warning is from the label of Robitussin Cough & Cold Long-Acting, an over-the-counter product.

In its proposed rule, MSHA acknowledges that there is scant information about the risk of prescription drug use in the workplace. MSHA hopes the expanded

testing panel will generate data that can be used to study this issue. This sounds good, but does it outweigh the problems inherent in testing for prescription drugs?

Most of the public concern over prescription drug abuse involves prescription opiates, especially hydrocodone and oxycodone. If MSHA is going to target prescription drugs, then these may be the best targets. But why is MSHA including barbiturates and benzodiazepines in its test panel? These drugs have relatively low abuse potential. Those who abuse them typically maintain their drug supply by getting prescriptions from their physicians, and thus would pass the MSHA drug tests. I discourage MSHA from including barbiturates and benzodiazepines in its test panel. Otherwise, MSHA will be testing for drugs that are widely used and uncommonly abused, many of the positive results will represent unconventional use without abuse. Unfortunately, some MROs will not accept those explanations and thus donors will have test violations and be fired for nonabusive use of prescription medication.

Collateral Damage From Tests for Prescription Drugs

Workplace drug testing that targets prescription drugs will cause unintended harm to workers who use the drugs in any but the most conventional manner. The proposed rule includes use of medical review officers (MROs) to evaluate medical explanations for certain drug test results. The proposed rule says the MRO would determine if "the miner has a valid prescription for the prohibited substance and is using it as prescribed." This is similar to other federal rules – i.e., the U.S. Department of Transportation (DOT) Part 40 rule and the Substance Abuse and Mental Health Services (SAMHSA) *Mandatory Guidelines* - except it adds the phrase "using it as prescribed."

The definition of "valid prescription" varies between MROs. The definition varies when applied to use of:

1. borrowed medication,
2. medication purchased over the Internet without a physician/patient relationship,
3. medication purchased abroad,
4. old medication,
5. medication taken for reasons other than prescribed, or
6. medication where the lab has reported a suspiciously high concentration
7. medication that has been self-prescribed

These situations occur when testing for prescription drugs. Except for item #7 (which may occur when testing physicians), these situations will occur often in MSHA-regulated testing that targets barbiturates, benzodiazepines, methadone, propoxyphene, and other prescription opiates. These situations may outnumber positives due to clear cut drug abuse. When employees test positive in situations like these, employers will fire them and deny their unemployment benefits. MSHA does not tell employers to do this, but they do so anyway. Under the proposed rule, employees who test positive would have to complete treatment recommended by substance abuse professionals. The rhetorical question is, What is the appropriate treatment for someone who tests positive from using a borrowed medicine (old medicine, medicine purchased abroad, etc.)?

MROs struggle with the ambiguous situations listed above. DOT has issued guidance about the first two situations listed above, which is essentially as follows:

- Borrowed medicine. If someone admits use of a borrowed medication that causes a positive drug test, DOT advises MROs to report the result as positive because the individual has admitted unauthorized use of a controlled substance.

- Internet prescriptions. The drug use is unacceptable if it was prescribed outside the context of an in-person physician/patient relationship.

DOT has issued no guidelines for situations 2-5 listed above. Federal regulators have hoped that MRO organizations would develop consensus statements about how to handle these situations. But this not happened, perhaps because no consensus exists, perhaps because the MRO organizations would prefer to leave this aspect of rule-making to the regulators. I do not expect MSHA has answers for these situations.

The specimen collection procedure can reliably link a drug test specimen to a donor. The laboratory analysis can reliably identify a positive result. But, if the donor used a prescription drug in an unconventional, nonabusive manner, the test's final outcome will depend on the MRO's opinion. In MRO training courses, when these situations are presented to audiences, perhaps one third of MROs say they would verify as positive, one third say they would downgrade to negative, and one third say they would cancel the test. Some MROs say they would check the employer's policy. But, as a practical manner, few employers have policies on these issues. The rare policy typically draws a hard line, e.g., declare borrowed medication unacceptable. But most employers who use MROs will defer to the MRO with regard to interpreting results. The test's final outcome then depends on the MRO's subjective opinion. This is unfair to the employee who ges an MRO who defines acceptable use narrowly.

It is too easy and cavalier to accept only prescription drug use of the most conventional type, i.e., taken directly after a visit to a doctor, taken for the reason it was prescribed, and taken in the correct dose. Many Americans have old prescriptions in their medicine cabinets. Many Americans share medicines. According to two recent studies from the Centers for Disease Control and Prevention [Peterson et al. *J Womens Health.* 2008;17:1-6] and North Carolina State University [Goldsworthy et al. *Amer J Public Health.* 2008;98:1115-21], about 30 percent of Americans admit to use of a borrowed prescription medication. Many Americans buy prescriptions over the Internet, bring them over the border from Canada and Mexico (where they are cheap and/or over-the-counter), take old medicines for new conditions, and/or take medicines in doses other than prescribed.

MROs Cannot Determine if Employees Are Taking Drugs as Prescribed

Verification of dosing and timing is difficult because urine drug/metabolite concentrations are not well correlated with dose and urine measures use over a period of several days. SAMHSA certified laboratories do not routinely report urine drug concentrations, anyway. They instead just report if the drug/metabolite was or was not present at or above the cufoff, i.e., positive/negative. SAMHSA is trying to limit the extent to which concentrations are (miss)interpreted, when in fact the program is pass/fail.

Verification of the reason for taking the drug is difficult because testing measures use but not intent. The MRO review does not examine why the donor is taking a particular drug, or what the dosing schedule is supposed to be. Instead, the MRO review focuses on whether the individual was administered or prescribed a drug that could account for the positive result. The MRO usually does not communicate with the prescribing physician and instead gets information about the drug from the pharmacy and/or directly from the donor, e.g., copies of labels or receipts.

Testing for Prescription Drugs Can be Technically Challenging

The metabolic pathways for some prescription drugs are complex. Many employers, MROs, and other drug testing service agents get confused about what opiates and benzodiazepines are covered by different panels. Laboratory analyses and MRO interpretation of benzodiazepine tests are likewise complex due to the widespread use of these drugs and the various metabolites. To illustrate this, I have enclosed with this letter figures that show metabolic pathways for common opiates and benzodiazepines. By contrast, the relevant metabolic pathways for marijuana, cocaine, methamphetamine, and heroin involve one or two arrows and one or two metabolites.

Addressing Prescription Drug (Ab)use

Prescription painkiller use has increased in America for multiple reasons. These include inappropriate patient demand and a consumer-based approach to healthcare delivery in which many physicians are apt to satisfy (or anticipate) their patients' desire for prescription narcotics. This is a societal problem. Perhaps regulators should make it more difficult to prescribe narcotics or large quantities of narcotics. I do not think workplace testing is the proper venue for addressing the problem. I do not think MSHA has evidence that prescription drug use poses a safety risk among its workers. Workplace testing is expensive, invasive, and unfair to people who use prescription drugs in any but the most conventional of ways. Physicians know the precept, "First do no harm." Prescription drug testing does harm, perhaps more harm than good.

Make Split Specimens Optional

Split specimen rarely (never?) fail to confirm the presence of a drug/metabolite detected in the primary sample. The great majority of split specimen failures to reconfirm involve failure to meet the narrowly defined specific gravity threshold for "substituted specimen," failure to collect an adequate split specimen (i.e., collector error), or failure to properly split a single sample and instead submitting A and B samples that represent different voids (i.e., another example of collector error). Split specimens do not help assure that results are reliable. Instead, they make drug testing more complex, expensive, and confusing. Because of split specimen tests, positive test results get cancelled because of mistakes unrelated to their reliability. The DOT added split specimen tests to its programs because Congress mandated it to do so in the Omnibus Employee Testing Act of 1991. This was a political decision based on perception. The great majority of laboratory directors, MROs, and other service agents recognize that split specimens do not make testing more reliable; if anything, they make it less reliable. SAMHSA and the Nuclear Regulatory Commission allow but do not require split specimen tests in the programs they regulate. MSHA should consider allowing, but not requiring, employers to conduct split specimen tests.

Please Extend the Comment Period

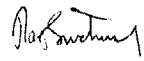
Much of the public learns about proposed federal rules through news articles and other secondary sources. For example, soon after MSHA published its proposed rule in the *Federal Register*, I wrote an article about it for *MRO Update*, a monthly newsletter. Readers will get that article in mid-October 2008, after the comment period has ended. The 30-day comment period for this proposed rule is too short and does the public a disservice.

In summary, my suggestions are:

1. Limit testing to the federal 5-panel and alcohol. Workplace testing for alcohol and illegal drugs is complex enough. Put these programs into place first, and explore prescription drug testing as a potential expansion of the program for implementation at a later time.

2. Remove the phrase "using it as prescribed" from §66.100(b)
3. Explore options for individualized medical assessment of workers on controlled substances, e.g., mandatory self-disclosure and referral to designated physician
4. Extend the comment period to at least 60 days
5. Make split specimens an option, not a requirement

Sincerely yours,

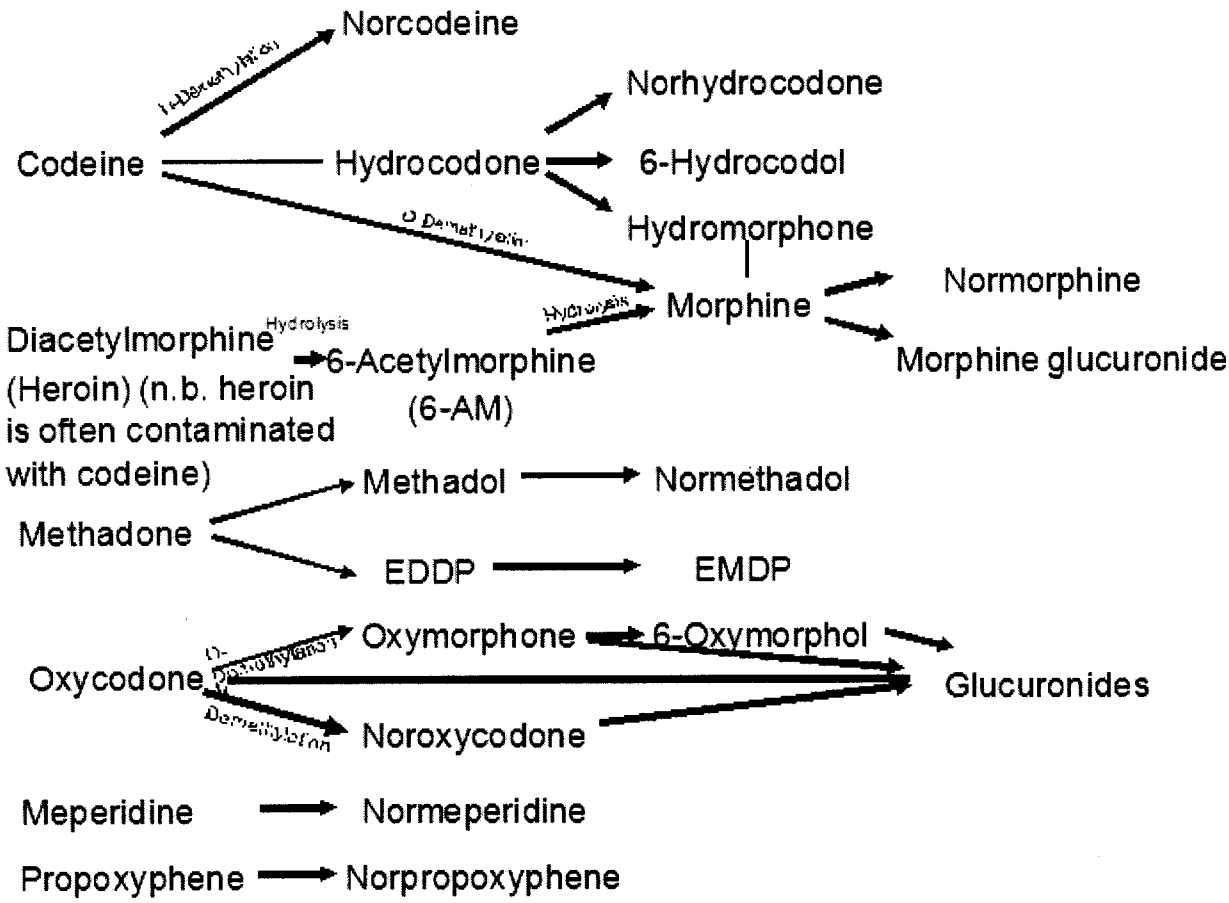


Robert Swotinsky MD

Enclosures: Opiate and Opioid Metabolism
Benzodiazepine Metabolism

Enclosure to comments by Robert Swotinsky MD, re: 1219-AB41

Opiate and Opioid Metabolism



Enclosure to comments by Robert Swotinsky MD, re: 1219-AB41

Benzodiazepine Metabolism