DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

DRUG TESTING ADVISORY BOARD

August 19-20, 2008

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The Drug Testing Advisory Board (DTAB) meeting was convened at 8:30 a.m. on August 19, 2008 in the SAMHSA Building (Sugarloaf and Seneca Conference Rooms), 1 Choke Cherry Road, Rockville, Maryland 20857

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on August 19 from 8:30 a.m. to 4:35 p.m. and on August 20 from 8:30 a.m. to 4:30 p.m.

Board members present:

Robert Stephenson II, Chairman
Dr. Jennifer Collins
Dr. Estela Estape
Ann Marie Gordon
Dr. Alberto Gutierrez
Dr. David Kuntz
Lisa Tarnai-Moak
Dr. Henry Nipper
Pat Pizzo
Dr. Robert Turk

Others present for all or a portion of the meeting were:

Dr. Donna Bush, DWP, CSAP
Charles LoDico, DWP, CSAP
Ronald Flegel, DWP, CSAP
Dr. Sean Belouin, DWP, CSAP
Dr. Janine Cook, DWP, CSAP
Dr. John Mitchell, RTI International
Dr. Michael Baylor, RTI International
Jim Swart, DOT
Dr. Yale Caplan, DOT Consultant
Tim McCune, NRC
COL Ron Shippee, DoD
Dr. Michael Walsh, The Walsh Group
William Sowers, DWP, CSAP
Dr. Deborah Galvin, DWP, CSAP

Dr. Larry Bowers
Barbara Spencer, ONDCP
Patrice Kelly, ODAPC
Charlotte Sisson, ONDCP
Mike Cala, ONDCP
Bob Schoening, USCG
Kaye Kirby, FMCSA, DOT
Maggi Gunnels, FMCSA, DOT
Ellison Wittels, FMCSA, DOT
Martha Bunting, FBI
Linda Zeiler, DOL, MSHA
Cynthia Atkinson, DoD
Matt Hall, USCG
Linda Shreet, FBI
Dr. Hina Mehta, FDA
Lisa Teems, HHS, FOH
Nicholas Lomangino, FAA, DOT
Thomas Fencht, SAMHSA
Bernard Arseneall, FRA, DOT
Tresa Grosshans, TSA, DHS
James Watson, ONDCP
Mary Warren, BEP
Elena Carr, DOL
Dennis Romero, OPS, SAMHSA
Leslie Cooper, DOL
Nevine Gahed, SAMHSA
Robert Hendricks, SAMHSA
Karen Drumgold, BEP
Toian Vaughn, OPBB, SAMHSA
Kelley Smith, OAS, SAMHSA
Gregory Goldstein, OPHS, HHS
Dr. Bertha Madras, ONDCP
James Valentine, OSHI, FDA
Dr. Al Bronstein
Dr. Anthony Campbell, DAT, CSAT
Dr. Westley Clark, CSAT, SAMHSA
Frances Harding, CSAP, SAMHSA
Dr. Edward Cone
Dr. Charlene Lewis, OAS, SAMHSA
Bradford Stone, OAS, SAMHSA
Dr. James Ferguson
Dr. Courtney Harper, FDA
DeMia Peters, DEA
Dr. Paul Starr
Dr. Gordon Smith
Dr. Donna Smith
Dr. R. H. Barry Sample
Dr. Robert Swotinsky
LTC Dr. Timothy Lyons, DoD

TOPICS DISCUSSED IN OPEN SESSION

Note: The transcript for the open session is available on the Internet at: http://workplace.samhsa.gov.

Opening Remarks

Dr. Donna Bush, as the Designated Federal Official, called the Board meeting to order at 8:30 a.m. on August 19, 2008.

Mr. Bob Stephenson, as Chair of the Board, welcomed all participants and provided opening remarks regarding the special topic of this two day Board meeting: Exploring the Science and Experience of Testing for Prescription Drugs in the Non-Regulated Workplace.

The Board members, as well as our Federal partners in attendance, introduced themselves.

Ms. Frances Harding, the new Director of CSAP, emphasized the importance of addressing the prescription drug use and abuse in the workplace, community, and the home. There is a rise in prescription drug misuse on our college campuses, our communities, and our schools. The misuse of prescription drugs creates many dysfunctional issues in both the workplace and in our homes and contributes to increased accident and death rates. The focus over these two days was on four major issues and possible outcomes: what we know about the incidence, prevalence, and trends of the prescription drug problem in general; what can be tested for; what the drug test results can tell us; and what we'll learn from the experience of others who are currently using expanded drug testing in the professional setting.

Dr. Bertha Madras is the Deputy Director for Demand Reduction in the Office of National Drug Control Policy (ONDCP). She presented the Federal Government perspective on the magnitude of the prescription drug abuse problem in the United States and the efforts being made to combat it. She outlined the strategies that ONDCP, in partnership with other Federal agencies, has designed to address the prescription drug issue.

There has been a 24 percent reduction in youth drug use in our nation since 2001. And yet, prescription drug abuse is a growing problem; prescription drugs are America's second most abused drugs as measured by prevalence, with marijuana being first. For the past three years, using SAMHSA-generated National Survey on Drug Use and Health (NSDUH) data, the numbers of new initiates into prescription drug abuse as compared to marijuana have numerically been higher. Among the 18 to 25-year-olds entering the workplace, prescription drug abuse rose 19 percent from 2002 to 2006. Most of this increase was driven by non-medical use of opiate analgesics. 70 percent of our population acquires prescription drugs from friends and family. Between 2004-2005, the number of people seeking treatment for prescription pain medication increased nine percent to more than 64,000 admissions, with a slight decline in people seeking treatment for heroin and an increase in those seeking treatment for opioid analgesics. In the past 10 years, the number of teens going into treatment for addiction to prescription pain relievers has increased by more than 870 percent. Children who start using drugs before the age of 14 are 6 times more likely to become addicted than if drug use is initiated past the age of 18. There is an escalating rate of death due to prescription drugs, primarily opioid analgesics.

This complex drug abuse problem has consequences to every sector of society, including the workplace, academic institutions, families, and the criminal justice system. Some of the strategies to deal with this involve law enforcement, legislation, and education of the public, including parents, students, people in the workplace, the elderly, and healthcare professionals, including doctors, dentists, pharmacists, nurses, and social workers. Another strategy is testing, whether verbal or biometric, followed by appropriate interventions. The challenge associated with selecting testing is to differentiate between illicit and licit use of prescription drugs and to detect intoxicating or

impairing drug concentrations.

Federal Drug Testing Updates

HHS Update

Bob Stephenson noted that the Proposed Final Notice for Revisions to the Mandatory Guidelines have been cleared through the Department of Health and Human Services and were delivered to the Office of Management and Budget for internal review on August 1, 2008.

DOT Update

Jim Swart

Jim Swart (DOT) is now the official Director of the Office of Drug and Alcohol Policy and Compliance (ODAPC).

In the interim final rule of Regulation Part 40 that was published on June 13, 2008, employers and third party administrators for owner/operators are permitted to report to state licensing agencies those individuals who have tested drug positive, in an effort to curtain “job hoppers”, who go from one position after testing positive to another without benefit of the required treatment and evaluation process.

As stated in the final rule, effective August 25, 2008, all DOT specimens will be tested for specimen validity, adulteration products, and substitution products using HHS protocols and certified laboratories. These HHS-certified laboratories must submit to DOT on a semiannual basis their DOT testing results. The results reporting process, especially for invalid results, will hopefully become more streamlined and straightforward to remove ambiguity about result disposition by medical review officers (MRO), laboratories, and employers. Also, a new, direct observation procedure for urine drug test collection will be implemented to stop cheating at collection sites and the numerous attempts to beat the urine drug test.

The collection and staff guidelines, as well as the employer handbook that contains links to appropriate regulations and HHS documents, have been updated. All the updated documents are available on DOT’s website.

On July 31, 2008, DOT issued an interpretive question and answer document addressing collection sites, alcohol testing, and MRO procedures for evaluating specimen results in the pH 9.0-9.5 range. This document prompts MROs to take into consideration temperature and time since collection in making a decision as to whether an individual with an invalid result related to pH does indeed have a legitimate medical reason.

DOT is very supportive of the five recommendations, two for DOT and three for Congress, received from the Government Accountability Office (GAO) in May 2008. In doing so, DOT will be more cooperative with its safety audits, share information, and rate and rank its service agents. DOT is supportive of Congress' activities to make those products designed to cheat the drug test illegal for manufacture or sale and to expand its civil penalty authority. In addition, DOT encourages the States to suspend and revoke those licenses of drivers who tested positive or refused a drug test.
The staff at ODAPC includes Bob Ashby, Chief Counsel; Patrice Kelly, Acting Deputy Director for Policy; Mark Snider, Acting Deputy Director for Administration; Bohdan Baczara, Policy Advisor, and Vicki Bellet and Maria Lofton, administrative and budget personnel.

DoD Update

COL Ronald Shippee

DoD funds and manages the six military laboratories, including the Army facilities at Fort Meade and Tripler, Hawaii; the Navy facilities at Great Lakes, San Diego, and Jacksonville; and the Air Force facility at Brooks. The Great Lakes laboratory handles both the military accession and MEPS (Military Entrance Processing Station) testing, which totals about 350,000 annually. Fort Meade is the only dual certified, both by DoD and the National Laboratory Certification Program (NLCP), forensic drug testing laboratory in the nation. DoD laboratories perform about 4.5 million military and about 135,000 civilian tests a year.

Standardization across these laboratories has produced a true joint testing program. In a Navy study assessing the impact to laboratories affected by Defense Base Closure and Realignment (BRAC), the preliminary report from an unbiased independent contractor stated that DoD saved about $21 million through in-house drug testing. The report concluded that the joint testing program is very successful and recommended that laboratory standardization continue.

The laboratory management system (LMS) for the DoD laboratories was developed 12 years ago and is currently still in use. This software allows for efficient data handling and transmission of testing results from the laboratory to the Brigade Commander in a timely manner, wherever he/she may be located in the world. The LMS data is now merged with the Defense Manpower Data Center (DMDC), permitting unique data analyses of drug results by specific demographic variables. In addition, this data system merger gives DoD access to MRO-verified results. The MRO unknown category decreased to only 11 percent of the 21,000 positives in 2007. This system merger permits the creation of deployment reports for Congress in an expeditious manner.

DoD foresaw the prescription drug issue through its prevalence data. There has been a huge increase in pain medication, antidepressant, and benzodiazepine use in the military related to combat action.

Because of its large drug testing volume, DoD can leverage the in-vitro diagnostics (IVD) industry to manufacture new drug testing kits, such as for ecstasy and heroin.

DoD is in the unique position of having the flexibility to alter its drug panel within 30-60 days to address those drugs that are currently being abused by service personnel. DoD laboratories screen certain drugs at 100%, including heroin, amphetamine and its isomers, methamphetamine and its isomers, ecstasy, THC, and cocaine. Lysergic acid diethylamide (LSD) and barbiturates were recently removed from DoD's routine drug test panels. DoD also performs pulse screening in which a much smaller percentage of specimens are screened for specific drugs, including codeine, morphine, phencyclidine (PCP), oxycodone, and oxymorphone. In fiscal year 2007, overall, there was a 1.2 percent overall positivity rate (21,000) in active duty Guard Reserve personnel compared with the DoD-set two percent maximum positive goal, which was codified this year. Between fiscal years 2003 to 2007, the cocaine positivity rate rose from 19 percent to 39 percent. Marijuana use stayed constant at about 46 percent. The ecstasy positivity rate, which was seven percent in 2002, decreased to three percent in 2007 with a peak occurring in 2000. With oxymorphone, the data is limited because it is derived from pulse testing of only 20 percent of all laboratory specimens. The MRO-verified positivity rate for oxymorphone is 1.4 percent, implying illicit drug use. To identify drug-use trends, DoD is considering providing sub-cutoff drug results to the services by unit, which would permit identification of drug use trends within service unit.

The new DoD website is available at http://www.tricare.mil\DDRP.

NRC Update

Timothy McCune

The NRC (Nuclear Regulatory Commission) has updated its 10 C.F.R. Part 26 Fitness for Duty (FFD) program regulation. The drug, alcohol, and specimen validity provisions have been strengthened to detect tampering, dilution, and substitution. The cut-off for marijuana was changed to 50 ng/mL. An innovative process for detecting alcohol use hours after beginning a shift was developed, which involves a sliding scale to determine blood alcohol positive results. All workers in the FFD program will receive training at the supervisory level. In addition, the supervisors will be trained in behavioral observation and the detection of substance abuse, including prescription drug abuse.

In Part 26, Section 26.27, licensees are required to develop policies to mitigate the effects of drug and alcohol abuse, including prescription and over-the-counter drug abuse as determined by MROs and substance abuse experts who have received mandatory training in substance abuse detection. These substance abuse experts can make a determination of fitness when an individual may be impaired by alcohol, prescription drugs, or over-the-counter drugs. A determination of fitness must be made when there is acceptable medical explanation for a positive result, but there is a basis

for believing that the individual could be impaired while on duty.

Sanctions for attempting to subvert the testing process or for refusal to test have been made more stringent. If an NRC licensee subject to Part 26 is caught attempting to subvert the testing process or refusing a test, he/she will never work in the nuclear industry again. If an individual resigns to avoid removal for an FFD violation or has a second confirmed positive, there is also a five-year denial. A permanent denial is for any FFD violation following a five-year denial. Also, the requirements for reauthorizing an individual terminated unfavorably for FFD reasons were strengthened.

For the protection of worker rights, the opiate cut-off was raised to 2000 ng/mL to mitigate positives and as part of our strategy for addressing prescription drug use. The requirements for independence of the MRO from the licensee management were strengthened to insure MRO impartiality. The option for blood alcohol tests was removed, and saliva devices are permitted instead of breath for alcohol testing. Though under the current rule licensees may depart from the HHS panel and cut-offs, results must be certified by a certified forensic toxicologist. The inspection guidance has been revised, and training programs have been developed for inspectors. Finally, within the next year, online reporting of testing results from the licensees is expected. Licensees are required to report their FFD testing performance data once every year.

The rule has three implementation periods. Industry is developing the guidance documents, which will undergo public scrutiny, public review, and public meetings. The inspection guidance in the NRC was revised. The inspections are primarily conducted at our four regions, and training programs for our regional inspectors were developed.

The NRC's web address is http:\\www.nrc.gov.

Exploring the Science and Experience of Testing for Prescription Drugs in the Non-Regulated Workplace

The summaries of the day's presentations on prescription drugs follow below.

Smart Rx

Brad Stone, Office of Communications, SAMHSA

Because of the increasing use of prescription drugs for non-medical uses, the Office of Communications developed the Smart Rx program, which was implemented last year in conjunction with the marketing firm, Catalina Health Resource. This program provided printed material to targeted patients who were picking up prescriptions for select hydrocodones, benzodiazepines, sleeps aids, and Oxycontin. The Smart Rx message addressed the availability of these drugs as well as how these drugs are maintained, stored, and disposed of. This six-month, cost-efficient program was launched in 26 states, occurred in about 6300 pharmacies, distributed about 15 million leaflets, and

reached over 7 million people. A follow-up survey determined that 85% of those who received the SAMHSA material along with their prescriptions had read the information. Of those who read the information, 80% found the content useful, 48 percent kept the materials for future reference, and 26 percent of those who kept the materials shared the content of the leaflet with at least one other person. The information in the leaflet was perceived as very credible, ranking just below information received directly from either a physician or a pharmacist. Because of the success of this program, ONDCP has contracted with Catalina to expand the program.

Prescribing Trends for Opioids, Benzodiazepines, Amphetamines, and Barbiturates from 1998-2007

LCDR Sean Belouin, Pharm.D., Division of Workplace Programs, CSAP, SAMHSA

This presentation summarized the prescribing trends for 15 commonly prescribed scheduled controlled drugs (oxycodone, hydrocodone, methadone, Fentanyl, codeine, propoxyphene, alprazolam, lorazepam, diazepam, clonazepam, temazepam, amphetamine, methamphetamine, butalbital, and phenobarbital) that fell within the following pharmacologic classes: opioid analgesics; benzodiazepines; stimulants; and barbiturates. These 15 drugs were chosen based on their use relative to all other prescribed controlled drugs, potential for abuse, and potential for diversion from the individuals for whom the prescriptions were intended. Using data derived from Surveillance Data, Inc.,(SDI) Vector One National Database and IMS Health, IMS National Sales Perspectives: Retail and Non-Retail Database, FDA extracted the following information: the total number of prescriptions dispensed for each drug, for each year, over the last 10 years from 1998 through 2007, by drug strength; the gender and age demographics of individuals receiving the prescriptions; and the number of extended units (total number of tablets, capsules, patches, mL, etc.) dispensed.

From 1998 to 2007, the following changes in the total number of prescriptions dispensed were seen: hydrocodone prescriptions increased by about 59.7 million, an increase of 94%; oxycodone prescriptions increased by about 26.3 million, an increase of 166%; alprazolam prescriptions increased by about 17.6 million, an increase of 71%; amphetamine prescriptions increased by about 11.7 million, an increase of 463%; clonazepam prescriptions increased by about 10.9 million, an increase of 114%; Fentanyl prescriptions increased by about 4.4 million, an increase of 409%; lorazepam prescriptions increased by about 4.2 million, an increase of 24%; methadone prescriptions increased by about 3.7 million, an increase of 800%; diazepam prescriptions increased by about 1.9 million, an increase of 30%; phenobarbital

prescriptions decreased by about 900 thousand, a decrease of 22%; methamphetamine prescriptions decreased by about 36 thousand, a decrease of 65%; butalbital prescriptions decreased by about 381 thousand, a decrease of 61%; codeine prescriptions decreased by about 11.6 million, a decrease of 36.5%; and propoxyphene prescriptions decreased by about 8.4 million, a decrease of 27%;

The most widely prescribed drug in this group is hydrocodone. Hydrocodone units dispensed increased 172% from 2.68 billion units in 1998 to 7.28 billion units in 2007. This represents over 4.6 billion more units dispensed in 2007 than in 1998.

Out of approximately 7500 drugs on the U.S. market, all but 4 of the drugs discussed rank within the top 200 most dispensed drugs by prescription volume; methadone is close to the top 200 at a ranking of 203. As a perspective, the combination product, hydrocodone with acetaminophen, ranks number one at 117 million prescriptions, which is followed by lisinopril, a high blood pressure medication, in the number 2 position, at 61.7 million prescriptions, and Lipitor in the #3 position at 55.1 million prescriptions. In 2007, there were over 55 million more prescriptions of hydrocodone with acetaminophen than there were prescriptions for lisinopril and 62 million more than Lipitor.

National Forensic Laboratory Information System (NFLIS)

DeMia Peters, M.S., DEA Office of Diversion Control

The National Forensic Laboratory Information System (NFLIS) collects drug analysis results from 276 of our nation's 320 state (95%) and local (86%) laboratories, which represent approximately 91 percent of all laboratory cases. The NFLIS database consists of about 8 million cases and drug items that date back to 1998.

The primary purpose of the NFLIS system is to take chemically-verified data from law enforcement cases and seizures and compare them with and supplement the information from other databases, such as the Drug Abuse Warning Network (DAWN), NSDUH, and DEA STRIDE (System to Retrieve Information from Drug Evidence). This correlated data is used to support Federal, state, local, and international drug regulations. NFLIS provides drug trafficking information to state and local authorities, identifies changing distribution levels geographically and over time, and identifies emerging drug trends.

Of the top 25 2007 NFLIS drugs, 14 were pharmaceutical drugs. Narcotic analgesics are the major pharmaceuticals seized by law enforcement; of these, hydrocodone, the top prescription drug in the country, is number one, followed closely by oxycodone. Geographically, hydrocodone is more prevalent in the South, while oxycodone is more prevalent in the Midwest and the Northeast. Four prescription benzodiazepines were among the top 25 of the most seized and analyzed drugs identified by the NFLIS system, with the South again leading in prevalence.

Comparing illicit drugs with pharmaceutical drugs that are seized and analyzed in the forensic laboratories, the pharmaceutical drugs outweigh illicit drugs in volume.

The Department of Justice (DOJ) diversion website for NFLIS is at http://www.deadiversion.usdoj.gov/nflis.

Prescription Drug Misuse: Findings from SAMHSA's National Surveys

Charlene Lewis, Ph.D., Senior Advisor, Office of Applied Studies, SAMHSA

The Office of Applied Studies (OAS) supports three national surveys, which are continuous data collections based on the calendar year and differ in their sampled populations: the National Survey on Drug Use and Health (NSDUH), Treatment Episode Data Set (TEDS), and Drug Abuse Warning Network (DAWN). NSDUH is a nationally representative sample of people. It polls the civilian, non-institutionalized population aged 12 and older. The data are collected through an hour-long, confidential, computer-assisted face-to-face interview. Annually, about a quarter of a million homes are screened and about 67,000 respondents are selected for interviewing.

Based on data from the 2006 NSDUH survey, about 20 million people (20.4%) used illicit drugs in the last month, with marijuana being the most widely used illicit substance in the country. In 2006, about 6% of respondents admitted to use of marijuana within the last month, with about a 2.8% rate for psychotherapeutics and a 1.0% rate for cocaine. There has been a significant decline in illicit drug use since 2002 in the 12 to 17 age group with the 18 to 25 year age group being the primary illicit drug abusers. In 2006, about 22.6% of the survey respondents admitted to illicit drug and/or alcohol dependence or abuse, with alcohol being the most prevalent followed by marijuana.

About seven million people are misusing or abusing prescription drugs. The 18 to 25 age group showed a marked increase in their use of prescription pain relievers and tranquilizers. From 2004 to 2006, there was a statically significant increase in the number of psychotherapeutic drugs users.

Non-medical use of a prescription drug is defined as using a prescription intended for someone else or using a prescription drug just for the feeling or the sensation that it causes. There was a statistically significant increase from 2004 to 2006 in the percent of people who are current non-medical users of prescription pain relieving drugs, which was not the case with stimulants, sedatives, or tranquilizers. Past month non-medical use of prescription drugs was 2.1% for pain relievers, 0.5% for stimulants, 0.2% for sedatives, and 0.7% for tranquilizers. Over half (55.7%) of all people who are currently using prescription drugs non-medically obtain them, with or without permission, from a friend or a member of their family who predominately obtained the prescriptions from

legitimate physicians.

In 2006, there were more new users of prescription pain relievers than there were for marijuana. Adolescents tend to initiate their substance use with inhalants or marijuana, whereas 18 to 25 years is the initiate age for pain relievers, stimulants, tranquilizers, and sedatives.

The most commonly abused legal substance in the US is alcohol, with marijuana being the most abused illicit substance followed by cocaine. Pain relievers are now in third place as a common substance of abuse.

TEDS is client-level data on those who are admitted to publicly-funded specialty substance abuse treatment facilities. TEDS is a national database that includes about 80 percent of total US admissions, or about 1.8 million admissions annually, since 1992. The TEDS database includes the patient demographics; the patient's drug use history, including age at first use, frequency of use, and how that substance is being used; the planned treatment protocol; and three substances of abuse at admission. Most of the drug information is based on drug classes, though 16 states do obtain opioid name brands.

In 2006, the opioid analgesics accounted for four percent of all treatment admissions. Through TEDS, the entrance of certain new drugs into the marketplace can be traced. For instance, since OxyContin was introduced in 1996, there has been a steady increase in the number of treatment admissions that involve opioid analgesics since about 1999.

The increase in these prescription drug admissions to treatment are not related to an overall increase in treatment admissions. We've seen about a 12 percent increase in total admissions and a 4 percent increase for heroin, but a 367 percent increase for prescription drug abuse as a primary substance of abuse. Oxycodone is given as the number one substance bringing patients into treatment, whether as a primary, secondary, or tertiary substance of abuse. Oxycodone has shown a 1,500 percent increase in admissions with a 168 percent increase with opiate analgesics. Geographically, Maine, Massachusetts, Rhode Island, Delaware, and Maryland have the highest rates per 100,000 for treatment admissions for opioid analgesics. The highest admission rates occur in less urbanized areas. Prescription drug abuse, regardless of the route of administration, primarily occurs in the 19 to 25 age group. The age of the person entering into treatment has shifted dramatically; in 1997, only 20 percent of the people entering into treatment were under the age of 30; now it's closer to 50 percent. There is an upswing in the number of new users, and an increase in the number of people who are taking them through inhalation rather than orally or through injection.

The Drug Abuse Warning Network (DAWN) is a national probability sample of non-

Federal, short-stay, emergency department (ED) visits for drug-related incidents. Data for DAWN are derived from retrospective chart reviews of medical records. Annually, there are about 115 million visits to EDs across the country. Approximately 12 million of these records are sampled and charts reviewed. On average, three percent of cases are drug-related. From these, the national estimates are derived.

The prevalent demographics of those with non-medical use of pharmaceuticals are female and within the 18-24 age group. In 2006, there were 1.7 million emergency department visits related to drug misuse or abuse. There has been a tremendous increase between 2004 and 2006 in the number of emergency department visits which were attributable just to pharmaceuticals. Similarly, there has been a 36 percent increase the number of visits attributable to pharmaceuticals in combination with another illicit substance. Between 2005 and 2006, there was a 22 percent increase in visits attributable to pharmaceuticals and alcohol.

For patients entering EDs for drug-related causes, about half get sent home, go to jail, or they leave against medical advice. Around 45 to 46 percent receive some kind of follow-up care, including referral to a treatment program or admission into a detoxification unit. The percentage attributable to death is quite small.

National Poison Data System (NPDS): Real-time Documentation and Surveillance

Paul Starr, Pharm.D, C.S.P.I., Certified Poison Information Specialist, Poison Information, Maryland Poison Center, University of Maryland School of Pharmacy
Al Bronstein, M.D., FACMT, Toxicosurveillance Director, University of Colorado Health Sciences Center and Medical Director, Rocky Mountain Poison Center, Denver Health and Hospitals

NPDS derives its data from the general public as well as health professionals and hospitals calling into one of the 61 24/7 certified regional poison control centers, which are staffed by certified specialists in poison information, including pharmacists, nurses, toxicologists, educators, IT personnel, social workers, and consultants. Computerized data, recorded as medical records, include time and date of call, the call type, exposure duration, the cause of exposure, symptoms, severity, and course of action. The mission of poison control centers is to maintain and/or improve patient outcomes, prevent poison exposures, and reduce healthcare costs. For every million dollars spent on operational costs, poison control centers save seven million dollars in healthcare costs. These centers also provide treatment recommendations, triage information, and education to both the public and health professionals. In addition, the centers perform evidence-based research from retrospective and prospective studies of the NPDS data.

For example, the Maryland Poison Center received about 66,000 calls in 2007 with 35,000 being exposure-related. Other calls are for drug-information, drug identification,

and animal exposures. 80% of the human exposures were unintentional with only 15% being intentional. The majority of the calls (72%) originated from non-medical sites. In adults, analgesics rank first, sleep aids and antipsychotics second, and antidepressants third among the top ten drug classes included in exposures. Only in the 6 to 19 year age group did stimulants and street drugs fall into the top 10 drug classes that are included in exposures. Antidepressants rank fifth in the 6 to 19 age group but are third in the over 20 year age group. In the population exposures that include sleep medicines and antipsychotics, the ranking is fourth for the 6 to 19 year age group and second for the over 20 age group. Analgesics were ranked first in both the 6 to 19 and the over 20 age groups.

NPDS is a near real-time poison data system, which uploads data from the regional poison centers every 11 minutes. With this system, acute and chronic trends can be detected. The data are very periodical, with calls peaking during the summer months, decreasing around Christmas and New Year's, and increasing again. Data analyses allow for comparison of the real-time data with the historical database which dates back to 1983, looking for anomalies. Flags can be set to identify cases with certain characteristics, such as symptoms. Methods to survey the database include by call volume, clinical effects, and case-based definitions. The database is also useful for law enforcement personnel placing drug identification calls and using these data to determine street drug issues, including drug diversions and drug swapping. NPDS is valuable for identifying and tracking outbreaks, including contaminated water supplies, drugs, and food.

Nationally, there were 2.4 million exposure calls in 2006 and 2.6 million in 2007. There were over 13,000 oxycodone exposures in 2006 and slightly more last year, with about one percent of the calls from people in the workplace. NPDS also has some data on workplace drug exposures. In 2007, the workplace-related exposures were 2.1% for barbiturates and 1.3% for amphetamines.

Prescription Drugs in a Shock Trauma Setting

Gordon Smith, MD, MPH, National Study Center for Trauma and EMS, Shock Trauma Center, University of Maryland, Baltimore

National Study Center for Trauma is the research unit associated with the Shock Trauma Center in Baltimore, which receives about 7,500 admissions annually for trauma in the State of Maryland. Most admissions are motor vehicle crashes and work-related injuries.

Nationally, shock trauma centers have collected much information over the years on alcohol and its dose response relationship with injury risk. Shock Trauma Baltimore has an aggressive alcohol testing program, which includes verbal screening questionnaires for alcoholism and brief interventions to prevent the recurring injury. Unfortunately, with illicit and prescription drugs, prevalence data are the only information currently

available. The incidence of patients with substance abuse disorders admitted into Shock Trauma is 24 percent for 18 to 20-year-olds who have of a lifetime dependence rate of 24 percent and a current dependence rate of 19 percent. Though Shock Trauma in Baltimore performs blood alcohol testing on 98% of its patients, urine drug screens are performed on only 60%. For instance, alcohol and opiates are found in about 27% of trauma patients with unintentional injuries while cocaine is found in about 9%.

The National Study Center for Trauma and EMS collaborated with The Walsh Group to evaluate the feasibility of using a rapid point-of-collection (POCT) urine drug test device in the trauma setting. Urine, collected for clinical purposes, was screened for THC, cocaine, methamphetamine, MDMA, opiates, and benzodiazepines using the POCT device. In 34% of trauma patients, no evidence of drugs or alcohol was found. 15% of patients had alcohol only, 26% had evidence of one drug in their system, while 12% were positive for alcohol and one drug. Marijuana positivity rates varied by age with the highest rate found in those in the 16-20 year age group (50%). Because performance impairment cannot be assessed using urine drug concentrations, culpability was determined using police accident reports. To estimate crash injury risk from drug use, test results for blood alcohol, urine cocaine, and urine marijuana were correlated with culpability. Drivers who were cocaine or alcohol positive were significantly more likely to be culpable than those who tested negative.

Prescription Opioids for Pain and Addiction

Westley Clark, MD, JD, MPH, CAS, FASAM, Director, CSAT, SAMHSA

At the policy level, SAMHSA works to ensure that science, rather than ideology or anecdote, forms the foundation of our nation's addiction treatment system.

There are 57 million people, or 23 percent of the population, who admit to binge drinking, which is five or more drinks on a single occasion, and 17 million people who are heavy drinkers, having five or more drinks on a single occasion in the past 30 days. Alcohol, when combined with benzodiazepines or opiates, can be fatal.

Psychotherapeutic, principally pain, medications are the second most commonly abused substances behind marijuana. Non-medical use of pain relievers began to increase over other substances around 1995 and has increased quite rapidly since. In 2006, 2.1 percent of the population, age 12 and over, misused pain relievers for non-therapeutic use. Each year, millions of Americans are treated for medical problems related to prescription medication use, including non-medical use. Emergency Departments are reporting increased number of visits related to prescription drug misuse and abuse, and poisoning deaths due to prescription drugs, especially methadone, are increasing. Of the US population age 12 and over, 4.8 percent misused pain relievers non-therapeutically; 57.7 percent of those abused hydrocodone and 21.7 percent abused oxycodone products. Interesting, 55.7% of abusers got their pain relievers from the medicine cabinets of relatives and friends. The majority of these

diverted prescriptions were originally obtained from one doctor; the internet and doctor shopping are minor sources. One reason for diversion is lack of physician access. Another is the financial barriers that prevent people from obtaining prescriptions from their physicians, the same financial barriers that are militating toward writing prescriptions that are larger than necessary. Since 1991, stimulant prescriptions have increased seven-fold and opioid prescriptions four-fold.

There are regional variations in the prevalence rates of pain medication use, which raises the issues of community culture and healthcare disparity.

The practice of medicine is changing; medications are as an integral part of treatment. Physicians, who treat roughly 191 million Americans at least once every two years, are in a unique position to personally address the prescription drug issue.

SAMHSA is addressing the following issues in the arena of prescription drugs: methadone-associated mortalities, accreditation of methadone treatment programs, the disposing and safeguarding of prescription medications, Fentanyl-related overdoses and deaths, “cheese” heroin, medical school and physician education on proper prescribing practices, and buprenorphine prescriber training. The Federal Government is considering restricting drugs, using either FDA laws or the Controlled Substances Act. In addition, they want restrictions placed on practitioners through Federal laws and regulations in addition to state law regulations.

Pharmacogenomics of Addiction

Courtney Harper, Ph.D., Office of In Vitro Diagnostic Device Evaluation and Safety, CDRH, FDA

Pharmacogenomics is the application of genomes with the person’s genetic information, be it DNA, RNA, or the protein product, to the study of the variability in drug response. Pharmacogenetics refers to the effect of a person's own DNA sequence on how he/she responds to drugs, including drug disposition, safety, drug tolerance, and drug efficacy.

Individual differences in the genes that encode the proteins and enzymes affect drug absorption, drug disposition, and drug action. Through pharmacogenomic testing, the physician can detect inter-individual genomic variations in drug response. Most important are the family of proteins called the cytochrome P450 enzymes that perform most of the hepatic drug metabolism. There are 57 different active genes in this group and 17 different families of genes. Each of these cytochrome P450 genes has overlapping specificity for certain drugs, but they also have individual responsibility for being primary metabolizers for clinically important drugs.

Polymorphic variation in the genes that code for drug transporters; drug metabolizing enzymes, especially the cytochrome P450 enzymes; and drug cellular receptors may effect drug efficacy. Genetic polymorphisms produce different phenotypes with respect

to drug metabolism. These phenotypes are classified as extensive (normal) metabolizers, poor metabolizers, intermediate metabolizers, and ultra-rapid metabolizers. Depending on the phenotype of the individual and whether the parent or its metabolite is biologically active determine the drug's effect. An extensive metabolizer with normal enzyme function, for instance, metabolizes a drug via a primary metabolic pathway to produce the major drug metabolites. A poor metabolizer who has little to no functioning enzyme has build-up of the parent drug and metabolism of the drug by an alternate pathway not involving that enzyme which may produce different drug metabolites. An intermediate metabolizer has one functional and one nonfunctional gene and thus will metabolize the drug at a slower rate. The ultra-rapid metabolizers have duplications of the genes in their genome and will metabolize the drug very quickly.

Drug efficacy can be determined, knowing the metabolizer status of the patient and whether the parent drug or its metabolite is biologically active. The metabolizer phenotype of the patient can affect drug clearance rate, making it difficult to determine user status. Metabolizer phenotype also determines the effective therapeutic dose, which is related to the dose required to cause addiction or create the desired effect by the user. Moreover, the metabolizer phenotype of the patient determines the metabolite pattern seen upon drug testing and thus the interpretation.

Drug-drug interactions and drug inhibitors can mimic a poor metabolizer phenotype in an individual who is an extensive metabolizer. Personalized medicine takes into account an individual's phenotype to help the clinician select the right drug in the right dose for the right person.

Laboratory Testing in Pain Management: Approaches and Issues

Yale Caplan, Ph.D., National Scientific Services

Pain management drug testing is relatively new, even though it uses existing technologies. For laboratory testing of pain management patients, different questions need answering than for forensic drug testing. For instance, is the patient compliant, are they taking the medications they're prescribed, is the patient using medications that are not prescribed or not authorized, is the patient diverting these, are they taking licit and illicit drugs;, are they becoming addicted, and are they at risk for toxicity or overdose? Because of the risk for overdose and drug-drug interactions, pain treatment physicians have liability issues.

Pain management testing is also different in that other specimen types besides urine can be used, point of collection (POCT) devices are frequently utilized, other analytical techniques besides immunoassay and gas chromatography (GC)-mass spectrometry (MS) may be employed, the drug panel is more extensive (10-30 substances) than the HHS five, testing is non-regulated and more clinical in nature, cutoffs are much lower, screening results may not necessarily be confirmed, unique metabolites that are not

expected or suspected are found because of mega dosing, normalization of urine drug results with specific gravity or creatinine may be performed, and patients are expected to test positive for compliance reasons, producing very high positivity rates. Thus, a whole different paradigm must be applied.

POCT is inexpensive, can be performed quickly in an office setting, serves as a deterrent, and provides immediate feedback to the physician on the patient's compliancy. Unfortunately, POCT technology, test panels, quality control, specimen collection, qualitative results, and training are limitations. Misinterpretation of POCT screening-only results can occur. Physician education about the capabilities and limitations of POCT is important.

Alternate fluid types, such plasma, serum, whole blood, oral fluid, and hair, may dictate whether the parent drug or a specific metabolite is monitored. Drug detection windows are fluid-specific. Blood and oral fluid have detection time frames of generally less than a day, urine for a longer period of time, while hair has the longest detection window. Urine is the most standardized and widely used specimen. For blood, oral fluid, and hair testing greater analytical sensitivity is needed, which is generally achieved with the use of liquid chromatography (LC)-MS-MS. Unfortunately, there is the perception that test results from different specimen types have to agree, and they don't.

Comprehensive drug testing is important in pain management. What drugs remain undetected are those drugs that never screened positive. That's a very important point because there are some drugs, no matter what testing is performed, will never be identified.

The knowledge base of the average clinician for how to correctly use these drug test results is limited. Because the physician must interpret the laboratory report to determine patient compliance, the reports are simplified for ease of understanding yet contain sufficient technical details. Because the questions are different in the pain management arena, the physician must consider the drug, its dosage, the route of administration, time since drug administration, pattern of use, drug interactions, drug metabolism, patient impairment, and the laboratory test results to render the proper interpretation. Unfortunately, the laboratory is not able to provide the most needed information, which includes the frequency of drug use and the amount of drug used. Other laboratory tests, such as drug concentration, drug metabolites, parent drug/metabolite ratios, isomeric ratios, biomarkers, and creatinine and specific gravity may help with the interpretation. Normalization also allows for better interpretation of drug compliance. In interpreting an unexpected laboratory result, the physician needs to consider alternate sources, major and minor drug metabolic pathways, dilute urine specimens, consistency between the dose and urine drug concentration, drug interactions, cross-reactivities, adulteration/substitution, and patient metabolism.

Professional Health Monitoring (PHM) Programs

Donna Smith, Ph.D., Regulatory Affairs and Program Development Officer, First Lab

Professional Health Monitoring (PHM) programs, administered through various state agencies, exist for health professionals, as well as social workers, attorneys, psychologists, et cetera, whose licenses are in jeopardy because of substance abuse. Participants are identified either through “self referral”, arm-twisting, administrative or criminal action for diverting drugs, abusing drugs or being chemically dependant on drugs, or other association with drugs and/or alcohol. This population is at extraordinarily high risk and prone to relapse, with over 80 percent of them having access to pharmaceuticals and other drugs on a regular basis. Each participant is assigned a case manager who is responsible for counseling as well as monitoring participant compliance. Less than half of all of the PHM programs use a third-party administrator or a medical review officer (MRO) as a service agent for administering their programs. The case manager designs several customized personal urine drug testing panels, which the participant must be subjected to at regular intervals and for which the participant assumes complete financial responsibility. 98% of the drug panels are performed on urine with a laboratory positivity rate of less than 12%; almost have of this population is positive for alcohol. Eighty-five percent of all laboratory-positive PHM drug tests are MRO-verified as authorized medical or legitimate use. These test panels range in scope from 5 to 32 drugs and/or metabolites per panel, including alcohol. The amphetamine class typically includes confirmation for d-amphetamine, methamphetamine, MDMA, et cetera. Five to seven different barbiturates are confirmed for the barbiturate class. For benzodiazepines, the range of confirmation for analytes or their metabolites is between 6 and 15. In the opioid class, upwards of 20 different metabolites or analytes are confirmed. Rarely is 6-acetylmorphine (6-AM) confirmation included. For the antidepressant, antihistamine, and stimulant classes, between five and eight analytes or metabolites per class are confirmed.

Because of a signed contract, the participant must enroll in a program, report all prescription and over-the counter medications in use, avoid contact with any food or drugs that could produce laboratory-positive results, initiate contact every day, and submit to random drug tests with a frequency ranging from three times a week to once a month. Each participant must call in every day by an assigned cutoff time to determine whether he/she must report for testing; thus, the case manager is provided with immediate feedback on the participant’s compliance status. As a deterrent for the full range of potential drug use, monitoring includes flex testing and specimen validity testing. The laboratories that perform this testing employ various methodologies and cut-off values for screening and confirmation. Typically, the cutoffs are much lower than seen in HHS programs. Review of laboratory results by a MRO is dictated by the PHM program and, in some instances, is at the request and expense of the participant.

Public Comments

N.B. Varlotta expressed her concerns with the specimen validity testing requirements and that due process protections do not appear to apply when an individual is accused of adulterating or substituting a urine specimen.

Richard Drake proposed a plan to remedy prescription drug diversions originating from the medicine cabinets of family and friends which involved returning unused prescriptions to the pharmacy for a refund.

Adjournment

The first day of this two-day meeting adjourned at 4:35 p.m. on August 19, 2008.

The Drug Testing Advisory Board (DTAB) meeting was reconvened at 8:31 a.m. on August 20, 2008 in the SAMHSA Building (Sugarloaf and Seneca Conference Rooms), 1 Choke Cherry Road, Rockville, Maryland 20857

Opening Remarks

Dr. Donna Bush, as the Designated Federal Official, called the Board meeting to order at 8:31 a.m. on August 20, 2008.

Bob Stephenson, as Chair of the Board, welcomed all participants and provided opening remarks regarding the special topic, Exploring the Science and Experience of Testing for Prescription Drugs in the Non-Regulated Workplace.

Exploring the Science and Experience of Testing for Prescription Drugs in the Non-Regulated Workplace

The summaries of the day's presentations on prescription drugs follow below.

Immunoassay as an Initial Test in Drug Testing

John Mitchell, Ph.D., Center for Forensic Sciences, RTI International

There are two major protocols that are used in testing for drugs in human matrices. The first is the one-test immunoassay protocol, which is most often used for medical purposes and the second is the two-test protocol, which has become the basis for workplace drug testing and forensic testing because of its high level of certainty. The two-test protocol usually utilizes a screening immunoassay to identify those specimens that may have drug present and is followed by a more specific confirmatory method.

An immunoassay is a biochemical test that measures the concentration of a substance in a liquid, such as blood, urine, oral fluid, or an extract of a biological specimen. Its basis is the reaction of antibodies, which are proteins known as immunoglobulins that are produced by the immune system in response to a foreign substance known as an antigen, with those antigens that are responsible for their production, which in the case of drug testing, is the drug. Immunoassays detect the binding of the drug to the antibody through tagged drug targets, which consist of an indicator tag, which could be an enzyme, a fluorophore, or a radioactive material, bound to the target drug. The detection is typically based upon competitive binding, whereby the antibody can either bind with the drug or with a drug target in the specimen. In an immunoassay procedure, antibody is first added to the specimen followed by an incubation in which the antibody binds to any drug that is present. The tagged drug target is added, and the signal is measured.

Analytical specificity, which is the affinity of the immunoassay for the targeted drug, affects the conclusions that are drawn from the results of an immunoassay. Specificity is

measured as cross reactivity, which is the response exhibited when an immunoassay reacts with a compound other than the target drug. In an immunoassay with low specificity, antibodies react with many different antigens or drugs that have structures similar to the target drug. A highly specific immunoassay will not react with structurally similar antigens or drugs. The specificity varies, depending on the manufacturer of the immunoassay reagent. This variable specificity is evident in the results submitted to the NLCP performance testing (PT) program and from data provided by immunoassay manufacturers.

A positive immunoassay screening result is only a presumptive positive. If an assay has low specificity, it may be positive for multiple compounds. If it is highly specific, there is a higher degree of certainty as to what it is reacting with. The drugs that are detected by the immunoassay are limited by the antibody specificity and the cutoff that is used.

Statistical Trends in Workplace Drug Testing: 2003-2007

R.H. Barry Sample, Ph.D., Director of Science and Technology, Employer Solutions, Quest Diagnostics, Inc.

This presentation discussed the Quest Diagnostics Drug Testing Index (DTI) workplace data, including the Federally-mandated safety-sensitive group and the general, private sector workforce, for the years 2003 to 2007.

Overall positivity or non-negative test results include non-negative drug results and/or failed specimen validity tests. The overall drug positivity was 13.8 percent in 1988 and decreased to 3.8 percent in 2007 in those workplaces that conduct drug testing. In 2007, overall positivity was 1.8 percent in the Federal group and 4.4 percent in the general workforce.

The pre-employment category positivity rate is slightly lower than the overall positivity rate. In the Federal group, the random testing positivity rate is lower than the overall and the pre-employment rates, whereas in the general workforce, the random positivity rate is higher than the overall and the pre-employment rates. There are slightly higher positivity rates in the Federal group for post-accident, and in the general workforce group, the post-accident positivity rate is 50 percent higher.

Between 2001 and 2007, 9.1 million Federal and 39 million general workforce specimens were analyzed. In the Federal group, there were about equal numbers of pre-employment and random tests with post-accident accounting for about four percent and the other testing reasons for seven percent. In contrast, in the general workforce, 78 percent of the tests were for pre-employment, only 10 percent were random, about 6 percent were for post-accident, while the other testing reasons were about 7 percent.

There was about a 44 percent increase in the amphetamine positivity rate between 2002 and 2003, followed by a decline, and a slight increase in 2007. There are higher

amphetamine positivity rates in the general workforce than in the Federal testing group. In the general workforce, positivity increased in 2003 and 2004, with both amphetamine and methamphetamine tracking together. There was a slight decrease in 2005; again, they tracked together. There was a continuing decrease in 2006, with methamphetamine dropping more than amphetamine, and in 2007, for the first time ever, those two drugs diverged with a big decrease in methamphetamine and a large increase in amphetamine.

Overall opiate positivity rates, which include codeine, morphine, and the expanded opiates, are about 0.3-0.35 percent in the general workforce and about 0.15 percent in the Federal group. Post-accident tests have two to three higher positivity rates for opiates than the pre-employment tests. Hydrocodone positivity increased from 0.57 percent in 2003 to 1.23 percent in 2007. The positivity rate for oxycodone was about 0.6 percent in 2005 and 0.85 percent in 2007. There were two to three times higher incidents of oxycodone positives in post accident testing versus pre-employment testing.

During this time period, barbiturate positivity was relatively constant at about 0.25 percent. Barbiturate positivity was about 50 percent higher in post accident testing versus pre-employment testing.

Benzodiazepines were also relatively flat during this time period with about a 50 percent higher positivity post accident versus pre-employment.

There was an initial increase in methadone positivity beginning in 2000 and 2001 that subsequently leveled off. In 2007, there were about 50 percent higher methadone positivity rates for the post accident versus the pre-employment test.

Positivity rates were relatively flat during this time period for propoxyphene. Differences between the post accident and pre-employment settings remained rather significant over that entire time period.

Urine Drug Testing of Pain Patients: Licit and Illicit Drug Patterns and Prevalence

Edward J. Cone, Ph.D., ConeChem Research

This study evaluated urine drug testing data on chronic pain patients to uncover the associated licit and illicit drug patterns. Chronic pain is highly prevalent, occurring in about 20 percent of all adult Americans. The primary therapeutic tools are opiates and opioids but patients typically receive other drugs as well. Pain patients may also become drug abusers and addicts, with addiction occurring in 3 to 20 percent. Monitoring pain patients is important to determine whether patients are taking the prescribed drugs appropriately and not taking drugs that were not prescribed.

A year's worth of data from Aegis Laboratory included almost 14,000 specimens collected from 31 pain clinics in 6 primarily Southern states. Of those, 10,922 specimens yielded 15,859 immunoassay-screened and GC-MS-confirmed positive results that were used for this study. The confirmation assays tested for 39 different analytes, of which 32 were detected. There were 8,996 opiate, 2,397 benzodiazepines, 1,209 methadone, 967 THC, and 310 cocaine positive results. The most prevalent opioids were hydrocodone, hydromorphone, dihydrocodeine, and oxycodone. About 85 percent used one, 12.5 percent used two, 1.2 percent used three, and 0.1 percent used four opioids. The most common combination of two opioids was hydrocodone and oxycodone followed by the hydrocodone and methadone combination. Frequently, chronic pain patients are prescribed a continuous release medication and a different medication for breakthrough pain.

There was evidence of significant illicit drug use. The most common illicit drugs used were cannabis, cocaine, methamphetamine, and ecstasy. About 8 to 10 percent of the pain population is using cannabis, most likely for self-medication.

Laboratory Perspective on Additional Drug Testing and Associated Costs

David J. Kuntz, Ph.D., Executive Director of Analytical Toxicology, Clinical Reference Laboratory

This presentation gave the laboratory perspective for drug testing in Clinical Reference Laboratory (CRL), a large, privately-held laboratory that performs drug testing in urine, oral fluids, and sweat patches. Screening is typically immunoassay-based with confirmation testing performed by GC-MS or LC-MS-MS.

Client drug panels pose a dilemma for laboratories because they are typically client-specific. Complexity is created when drugs are added and subtracted from panels because there are literally hundreds of possibilities for the panels produced. The most common drug panel is the SAMHSA 5, with common variations being the seven, nine, or ten drug panels, which typically include urine alcohol and expanded synthetic opiates. The larger panels are designed for testing medical professionals who have access to drugs, especially narcotics. The health professional groups insist on ethyl glucuronide and ethyl sulfate testing to detect alcohol consumption within the last two to three days. Because of positive results due to the use of mouthwash and so forth, the use of MRO services is appropriate for monitoring unless the donor is in a total abstinence program, where extensive rights are signed away. CRL has developed a requirement for ethyl glucuronide testing, with a 500 nanograms per milliliter cutoff for ethyl glucuronide (EtG) with an ethyl sulfate (EtS) at least at 100 nanograms per milliliter. In providing testing for the life insurance industry, pre-employment nicotine testing in urine and oral fluid specimens is performed to decrease healthcare costs and corporate premiums. Insurance companies are targeting medical staff for theft of drugs, for impairment in judgment, and for medical malpractice in an effort to decrease insurance costs. Drug testing is also performed to hold down workman's compensation costs.

CRL has a program to provide onsite devices to clients as a cost-savings measure. Specificity for these devices is not great, and the positive screens still need to be confirmed. The monitoring for specimen validity testing (SVT) can also be problematic.

Expanded drug panels cost more because the laboratory has the time investment in the data review and a financial investment in the instrumentation and reagents. Laboratory efficiency on the screening and confirmation methods is the cost driver for the price of a testing panel.

Laboratory Perspective on Additional Drug Testing and Associated Costs

Jennifer A. Collins, Ph.D., Laboratory Director, MedTox Laboratories, Inc.

This presentation provided the laboratory perspective on drug testing from MedTox, a clinical and forensic reference laboratory that provides drugs of abuse testing for both regulated and non-regulated workplaces, medical professionals, pain clinics, and criminal justice clients. Its workplace testing demographics are about 30 percent regulated and 70 percent non-regulated. In that non-regulated group, about 50 to 60 percent test for compounds beyond the standard 5 illicit drug panel, with the average panel size being 7 to 8 drugs. For the most commonly added compounds, excluding the opiates, the positivity rate is about 0.5 to 1 percent. For opiates, the confirmed positive rate is 0.4 percent. About 35 percent of non-regulated screens include expanded drug panels, with hydrocodone, hydromorphone, morphine, codeine, oxymorphone, and oxycodone being most frequently included.

What drug panels are created and how testing is performed depends the types of drugs requested by the clients. In non-regulated workplace testing, drug panels start with the standard 5 drug panel with additional tests added. Typical analytes include barbiturates, benzodiazepines, and opiates such as oxycodone, methadone, and propoxyphene. Also, methaqualone and alcohol testing is sometimes requested. Initial screening test results performed by automated homogenous immunoassay are confirmed by either GC-MS or LC-MS-MS. Testing drug panels for the impaired professional and the pain management patients usually involves the use of lower cutoffs on the initial screening test, if available. To test for opioids, LC-MS-MS is used because it significantly reduces the sample run times and increases overall laboratory productivity; however, equipment cost is increased, which increases overhead.

Added costs accompany additional tests. The additional cost associated with the initial immunoassay screen is minimal; the financial impact is associated with confirmation, including instrumentation cost, usage, and overhead. Many laboratories utilize more advanced instrumentation to minimize the amount of sample preparation and to reduce run times. For esoteric compounds, additional costs include labor and reagents. MedTox utilizes a tiered pricing approach. Tier 1, which includes a drug panel using standard testing on automated analyzers, is one level of pricing. For Tier 2, ELISA tests

are added, which cost 5 to 10 times more than homogeneous immunoassays. Tier 3 includes homogenous immunoassays, ELISA tests, and a chromatographic screen, the most expensive option.

Many of the ELISA tests used for the more esoteric compounds are not FDA cleared. Laboratory validation of these research use only kits requires more work and may result in laboratory-specific cutoffs based on validation data.

The major drug positives detected in the medical professional group are narcotic analgesics and benzodiazepines. For pain management patients, oxycodone and oxymorphone are the most prevalent, followed by benzodiazepines and acetaminophen. There is evidence of some illicit drug use in pain patients, specifically, marijuana. Antidepressants are also present in this pain population. For one criminal justice client, an onsite drugs of abuse screen is combined with a modified drug recognition exam (DRE). For this client, a comprehensive drug panel is tested when the results of the drugs of abuse screen are negative and the information from the DRE is inconclusive.

When additional compounds are added to a drug testing panel, the complexity of the testing process increases because of the use of multiple methodologies for the screen and the confirmation tests. The laboratories are going to incur added costs due to reagents, instrumentation, overhead, and labor. The magnitude of the cost increase depends on the make-up of the drug testing panel. Because of the cost associated with some of this instrumentation, not all laboratories can offer all of these tests. The interpretation of the MRO is vital to these expanded profiles.

Drug Testing in Sports

Larry D. Bowers, Ph.D., Senior Managing Director, U.S. Anti-Doping Agency

This presentation gives the extreme in drug testing which might represent the future of workplace drug testing. The unique features of drug testing in sports, which in some cases are mandated by specific law, lead to differences in the programs, such as in collection procedures and the result management process, including the development of new testing technologies. The testing program needs to fit the purpose, and in sports testing, it is deterrence. In sports testing, it is difficult dealing with those athletes who are trying to actively avoid detection and who have the assistance of health professionals and professional advisors who are knowledgeable about drug elimination, et cetera.

The World Anti-Doping Program includes the World Anti-Doping Agency (WADA) Code and four mandatory international standards. The WADA Code addresses the rights and responsibilities of stakeholders, defined as athletes, international sports federations, and governments. The WADA International Standard for Testing describes the procedure for collecting samples. The WADA International Standard for Laboratories describes the responsibilities and rights of laboratories, of which there are 33

laboratories in 29 countries. The WADA International Standard of Therapeutic Use Exemptions describes the application process for the use of prohibited substances, including some prescription drugs. The WADA List of Prohibited Substances and Methods, which defines what is tested for and the testing methods, is the annually-revised, published list of prohibited substances.

In the US, the Ted Stevens Amateur Sports Act mandates that any decision regarding athlete eligibility must be adjudicated by the American Arbitration Association (AAA) whose arbitrators must be members of the Court of Arbitration for Sport and have experience with sports and sports rules.

In the Anti-Doping Rules, there is a rule of strict liability, which means that there is no intent or no explanation for how a drug shouldn't have been in the body. A positive drug test results in a sanction unless it is a consequence of a pre-approved medically-testified therapeutic agent or was derived specifically from another substance. Additionally, the athlete is tracked down for specimen collection. About half of our samples are with no notice out of competition. If athletes are not available or they are not where they say they would be, this is a missed test. Three missed tests is considered equivalent to a positive drug test result. Athletes are required to inform us where they are almost 24/7, and they are held accountable.

One of WADA's most important jobs is to regulate the laboratories and to ensure that the laboratory results are harmonized and consistent. Every laboratory is required to be ISO 17025 accredited and to adhere to the WADA International Standard for Laboratories. WADA manages a proficiency testing program and is actively involved in the training of laboratory inspectors.

To be included in the published list of prohibited substances, two of these three criteria must be satisfied: medical evidence of enhanced performance, medical evidence of potential health risk, or violation of the spirit of sports. Items on the list are tested in and/or out of competition. The profited list is also an open list because different substances are available in different countries. When considering performance-enhancing substances to include on the prohibited substance list, it is important to think outside the scope of agents that just build bigger muscles. For example, stimulants, such as pseudoephedrine at high doses, give a euphoric feeling, improve focus and concentration, and alter the perception of fatigue, all of which could potentially help an athlete. It is difficult to verify the performance-enhancing ability of substances because of the inability to conduct the necessary research at the appropriate dosage and the combinations of materials due to IRB considerations. Thus, oftentimes, a substance is either proven to have performance enhancing effects or is logically extrapolated that it may possess performance-enhancing effects. What is important is the effect of a substance, not its source; a natural substance derived from plants can also be a prohibited substance.

One problem in sports testing is that some of prohibited compounds are present in the body as natural substances, resulting in not only testing issues for the laboratory but also producing programmatic philosophical issues. For example, if testosterone is both an endogenous substance and a prohibited substance, how will the laboratory determine if it was abused, and if so, how is it tracked? One way is the urinary testosterone to epitestosterone (T/E) ratio with each individual athlete's historical data used as a reference point. The WADA threshold T/E ratio is set at 4:1 to distinguish abnormal levels. Another example is erythropoietin (EPO) where the difference between endogenous and recombinant EPO is based on glycosylation. The laboratory can differentiate between natural and recombinant EPO based on total carbohydrate charges.

Other ways to detect abuse of endogenous prohibited substances include the personalized reference interval, uniform standard deviation in reference change limit model, and Bayesian probability. These models predict an individual's next value based on his/her historical values.

One of the objectives of USADA is to change the perceptions of the next generation of athletes.

Analysis of Urine Drug Testing Results from a Medical Review Officer (MRO) Data Source, 2006-2007

Michael Baylor, Ph.D., RTI, International

This presentation is the Analysis of Urine Drug Testing Results from a Medical Review Officer Data Source covering calendar years 2006 and 2007. Drug testing indices, which are based only on laboratory-confirmed positive results, may not accurately represent illicit drug use rates because they inherently include blind quality control samples and also results that are later reversed after medical officer determination of valid medical explanations for the test results. This study evaluated the relationship between laboratory-reported positive drug test results and the MRO-verified results reported to employers in Federally-regulated and non-regulated workplaces. The data focus primarily on the expanded panel of prescription drugs, specifically synthetic opioids and benzodiazepines. This project involved the review of 2.52 million records, obtained from a large medical review officer database, of urine specimens collected from January 2006 through December 2007. Each record contained 254 data elements, including donor demographics, employer information, collection site information, laboratory results, and the MRO determinations. About 99 percent of the specimens were analyzed by SAMHSA-certified laboratories. All blind QC samples were excluded from the analysis.

For the two calendar years 2006 and 2007, the Federally-regulated laboratory-positive rates were approximately 1.38 percent and 1.43 percent, respectively, of which 85 to 90 percent were MRO-verified and approximately 9 to 15 percent were reversed by the

MRO. For the five drug classes, the percent MRO-verified rates for amphetamines were about 62 percent in 2006 and 41 percent in 2007. For cocaine and marijuana, over 99 percent were MRO-verified positive. PCP was 100 percent MRO-verified. Opiates were 30 percent verified positive in 2006 and decreased to 17 percent in 2007. The MRO reversal rates for amphetamines were about 38 percent in 2006 and 59 percent in 70 percent. The MRO reversal rates were 70 percent for opiates, which includes codeine, morphine, and 6-acetyl morphine, in 2006 and 82 percent in 2007.

In the non-regulated sector, the overall laboratory-positive rates were about 4.19 percent in 2006 and about 4.1 percent in 2007. The MRO-verified positives were 76 percent in 2006 and 73 percent in 2007, which gave reversal rates of 24 and 28 percent, respectively. The MRO reversal rates ranged from 0 percent reversal for PCP to 85.6 percent for hydrocodone laboratory-positive results. For amphetamines, the laboratory-positive rates were about 0.3 percent in 2006 and 0.4 percent in 2007 with MRO reversal rates of about 57 and 69 percent, respectively. Cocaine laboratory-positive percentages were 0.58 in 2006 and 0.47 in 2007 with over 99 percent MRO-verified. For marijuana, laboratory-positive rates were 2.1 percent with over 99 percent confirmed by the MRO. PCP also had over 99 percent MRO-verified.

In both the regulated and non-regulated sectors, the overwhelming majority of the marijuana laboratory-positives are MRO-verified positives. Next in order of prevalence of MRO-verified positives is cocaine, followed by methamphetamine, amphetamine, and opiates. PCP MRO-verified positives are almost nonexistent. Cocaine verified positives decreased over the two-year interval in both regulated and non-regulated industries.

For the remainder of the non-regulated testing, total opioids include codeine, morphine, 6-AM, hydrocodone, hydromorphone, oxycodone and oxymorphone. Overall, the laboratory-confirmed positive rate was approximately 0.5 percent with 27 percent in 2006 and 23 percent in 2007, verified by the MRO, producing reversal rates of 73 to 77 percent. For barbiturates as a class, about 0.3 percent was positive in both 2006 and 2007, and approximately 20 percent of those were MRO-verified positives, which gave a reversal rate of about 80 percent. Benzodiazepines were about 0.6 percent in 2006 and 0.7 percent in 2007, confirmed laboratory-positive. Approximately 30 percent in 2006 and 28 percent in 2007 were MRO-verified, which produced MRO reversal rates greater than 70 percent. For the synthetic opioids, the hydrocodone laboratory-positive rate was 0.31 percent in 2006 and 0.36 percent in 2007 with MRO-verified rates of approximately 20 percent and 15 percent, respectively, which yielded reversal rates greater than 80 percent. Hydromorphone was 0.17 and 0.21 percent laboratory-positive for years 2006 and 2007, with 21 and 17 percent, respectively, MRO-verified positives and reversal rates of 79 percent and 83 percent, respectively. Oxycodone laboratory-positive rates were 0.27 percent for 2006 and 0.34 percent for 2007 with 35 percent MRO-verified in 2006 and 27 percent in 2007, which produced reversal rates of 65 percent and 73 percent, respectively. Oxymorphone showed laboratory-positive rates of 0.3 in 2006 and 0.46 in 2007 with 34 percent and 32 percent, respectively, MRO-verified positive,

producing reversal rates greater than 65 percent. A significant number of the laboratory-reported positives are reversed with MRO verification.

For the percent of D-amphetamine results reversed by MROs in 2003 through 2007, the regulated reversal rate increased from 25 percent in 2003 to 66 percent in 2007 while the non-regulated reversal rate increased from 51 percent to 74 percent.

A Five-Year Analysis of Oral Fluid Drug Testing Results from a Medical Review Officer (MRO) Data Source 2003-2007

J. Michael Walsh, Ph.D., The Walsh Group

This presentation provides data on a five-year analysis of 650,000 oral fluid specimen unregulated workplace drug testing records from a single medical review officer database for the five-year period 2003 through 2007. The objectives of this particular project were to examine the frequency of laboratory positives in the various drug classes and to examine the relationship between the laboratory positives and MRO-verified positive results. Each record contains 254 data elements, including donor demographics, employer information, collection site information, laboratory results, and the MRO determinations. All blind QC samples were excluded from the data analysis.

Overall, there were 648,372 specimens tested. The overall laboratory-positive rate was 4.3 percent while the MRO-verified positive rate was almost 96 percent with a reversal rate of 4 percent. Most of the reversals were due to legitimate prescription use of opiates and amphetamines. The majority of the illegal MRO-verified positive drugs identified in oral fluid were marijuana at 60.4 percent followed by cocaine at 24.1 percent. The methamphetamine-verified positive rate was 6.4 percent while the amphetamine rate was 4.3 percent. The MRO-verified positive rate for opiates was 3.9 percent and for PCP was 0.5 percent.

For the overall MRO-verified positive reversal rate by drug, 4.3 percent were positive with a 96 percent MRO-verification rate. The percent MRO-verified positives ranged from 99 to 100 percent for methamphetamine, MDMA, cocaine, marijuana, and PCP. Most of the MRO reversals occurred in the amphetamine, at 47 percent, and opiate, at 57 percent, categories. In the last five years, the amphetamine reversal rate increased. The reversal rate in 2007 was close to 70 percent. Thus, the reversal rates for amphetamines in oral fluids parallel those seen in the urine data.

About 1.2 percent of the oral fluid specimens were rejected for testing. In the category of fatal flaws, 0.6 percent was rejected for volume not sufficient for testing, 0.4 percent was rejected because the seal was broken or showed signs of tampering, 0.07 percent had ID numbers on the bottle and the chain of custody that did not match, while 0.03 percent had no printed collector name or signature. For the uncorrected flaws, the majority was because the CCF (Custody and Control Form) was incomplete or never received by the laboratory. The second most frequent category is that the specimen

was not received or was destroyed in transit or at the laboratory.

About 0.08 percent of the oral fluid specimens were categorized as invalid with 79% of these having no detectable immunoglobulin G (IgG). Of those with invalids with no IgG detected, 5.8 percent were drug positive.

MRO Interpretation of Expanded Panel Laboratory Results

James Ferguson, DO, Chief Medical Review Officer, Verifications, Inc.

Regardless of the drug panel, specimen type, or reason for testing, the MRO asks the same questions. Is it the right specimen? Is the chain of custody intact? Is the laboratory report accurate and complete? And more importantly, is there some reason from the donor for the laboratory-confirmed positive results?

MROs should query employer decisions, such as what panels, what drugs, and why, because all criteria need defining. Both the MRO and the employer need to agree upon how to deal with issues, such as expired prescriptions, multiple prescriptions of the same drug, shared family prescriptions, prescription abuse potential, foreign prescriptions, Internet prescriptions, single or split specimens, reconfirmations, etc.

Workplace drug testing works best for illegal street drugs in a program that serves as a deterrent.

As drug panels expand in size, MRO reporting turnaround time also significantly increases, especially for prescription drugs where protocols are in place for verifying prescriptions. With more laboratory positives comes a higher MRO review rate, and for prescription drugs, many of these will be MRO-verified negatives. To be reported positive, there must be verifiable illegal use or an inability to verify that the medications were legally obtained. The most common form of verifiable illegal use is the use of somebody else's medication.

There is little to no Federal oversight for expanded panel testing, which adds mostly prescription drugs with differing cutoffs. DOT regulations do not apply, but there are many significant state regulations that must be considered both by employers and MROs.

MROs cannot verify abusive use of legal prescriptions. In certain specific situations in which very high urine drug concentrations are obtained, MROs can presume abusive use of legal prescriptions. MROs are not able to determine whether someone is fit for duty simply on the basis of a urine drug test result, thus, the fit for duty decision ultimately does not belong to the MRO. It is important for an MRO to talk with his/her client to understand what the employer is trying to do with an expanded panel. An employer without a fit for duty program should not be performing expanded panel

testing. Possible fit for duty program components include requirements for employees to divulge medications, fit for duty medical evaluations, light duty assignments, SAP/EAP availability, et cetera. Reasonable suspicion issues should be based on observable behaviors that are actually observed by the MRO to make an impairment decision.

As MROs verify prescriptions for expanded drug panels, they must be concerned about Health Insurance Portability and Accountability Act (HIPAA), because questions are being asked whose answers would normally be confidential. This has not been tested in court, thus the specter of HIPAA looms in these programs. Many pharmacists will not release prescription information because of HIPAA.

MRO'ing Prescription Drugs

Robert Swotinsky, MD, Chair, Occupational Medicine, Fallon Clinic

This presentation provided a perspective from an occupational medicine doctor who works at a clinic with five different locations in which non-DOT drug test panels, ranging in size from 5 to 10 drugs, and on-site testing are conducted. Most of the clients are small companies, typically less than 15 employees, whose employers are not savvy about drug testing. These employers believe that drug testing will yield better employees. They want flexible drug testing policies and do not want to address specific issues, such as what constitutes alternative medical explanations, familial prescription drug use, and foreign medicines. Ideally, these issues should be resolved by the employers, but in truth, the employers do not know and they do not care. So, they leave it up to the MRO. Unfortunately, MROs want specific rules by which to judge drug testing results rather than rely on individual opinion.

Employers believe that more is better when it comes to drug panels. If they ask for counsel, I explain that 5 drug panels are easy while 10 drug panels incorporating prescription drugs are tough. Likewise, I explain that pre-employment testing is easy while random testing is tough. I recommend that employers initially start with the five drug panel and pre-employment testing. Only after those programs are established should prescription drug testing be considered. If prescription drug testing is performed in the workplace, then testing is conducted without suspicion.

Also, employers treat all positive drug results the same. To them, a positive is a positive whether due to codeine, Xanax, or crystal methamphetamine.

In the Physician Desk Reference, more than 700 prescription drugs have warnings stating that use of this drug may affect performance. So, which drugs do you focus on? The Federal Motor Carrier Safety Panel studied the issue of drivers and their use of oxycodone and hydrocodone. There was no scientific evidence that long term use of these drugs caused a safety risk for truck driving. In the trucking regulations, it is acceptable for truck drivers to use prescription drugs, with the exception of methadone, with the prescribing doctor's permission.

An MRO must interpret positive drug results. To do so, drug metabolism must be understood. THC metabolism is straightforward while that of benzodiazepines and opioids are very complex. It is easy to interpret illegal drug results. Conversely, the interpretations of prescription drug results are much more complex because the knowledge base and experience for prescription drugs is scant. Prescription drug review produces more work for MROs and yield reversal rates of 70 to 80 percent.

As a substance abuse professional, I know what types of treatments are appropriate for cocaine and marijuana abusers. For the person who borrowed another's medication, I refer him/her to treatment and tell him/her do not do that again. I am not sure what the right treatment is for these people.

The prescription drug issue needs to be fixed by doctors and the way medicine is practiced. This is a prescribing issue and not necessarily a drug testing issue. If the Federal government adds prescription drug testing, MROs will need clear guidance on how to interpret these results.

DoD's Experience with Prescription Meds

LTC Timothy Lyons, Ph.D., US Army , Deputy Director, Forensic Toxicology, Office of the Armed Forces Medical Examiner, Armed Forces Institute of Pathology

This presentation discussed the random urine drug testing program of the Department of Defense (DoD) and the special testing performed at the Office of the Armed Forces Medical Examiner, which tests for prescription drugs and also provides data for investigative cases, postmortem cases, fitness for duty, et cetera.

DoD has routinely pulse tested for codeine and morphine since the mid to late 1980s and for oxycodone since late 2005. Prevalence testing is periodically performed for some of the prescription medications, including methadone and benzodiazepines. For 100 percent mandatory testing, the overall drug positivity rate must exceed 0.25 per cent in a prevalence study. In addition, DoD has special drug data from postmortem and investigative cases.

The pulse testing screening goal for codeine and morphine is 15 to 20 percent of the total specimens received at the laboratories at a cutoff of 2000 nanograms per milliliter with morphine used as the calibrator. In the first eight months of fiscal year 2008, the confirmed positive rates were 0.04 percent for morphine and 0.11 percent for codeine. The overall confirmation rate of positive screens confirmed by GC-MS was about 65 percent. 15 to 20 percent of specimens are screened for oxycodone and oxymorphone at 100 nanograms per milliliter with oxycodone as the calibrator. For the first eight months of this fiscal year, the confirmed positive rates were 0.34 percent for oxycodone and 0.5 percent for oxymorphone. The overall confirmation rate of positive screens

confirmed by GC-MS was about 85-90 percent. The majority, 90%, of these oxycodone and oxymorphone confirmed positive results are determined to be due to legitimate prescription use after medical review. For hydrocodone and hydromorphone, there has been no prevalence testing because of the unavailability of a commercial screening kit. From anecdotal data derived from postmortem and investigative cases, hydromorphone is definitely in the field. In a methadone prevalence study, the confirmed positive rate was 0.01 percent, with 50% due to legitimate prescriptions. In a benzodiazepine prevalence study, 0.55 percent confirmed positive. Since 2004, 100 percent screening testing for 6-AM has been done using a commercially available kit exhibiting a 50% confirmation rate. Heroin positive results have been increasing since 1999, with 89 6-AM positives in the first eight months of this fiscal year.

Because of the low confirmation rate for 6-AM, the nature of the cross-reactive substances were investigated by further testing those specimens that screened positive with the 6-AM kit but did not confirm. The majority of those specimens were morphine positive, with morphine concentrations above 10,000 nanograms per milliliter.

For many of the pain management drugs, no commercial screening kits are available. Since most testing for pain management drugs is performed by GC-MS, prevalence studies, routine testing, or random testing would be extremely difficult to perform from a production standpoint.

Review of E.O. 12564 and "Reasonableness"

Donna M. Bush, Ph.D., Drug Testing Team Leader, Division of Workplace Programs, CSAP, SAMHSA. HHS

Executive Order 12564, issued September 5, 1986 by President Regan, established a deterrent-based Federal Drug-Free Workplace program, which focused on demand reduction for illegal, illicit substances, including heroin, methamphetamine, THC, PCP, and cocaine. Per Section 7 in that Executive Order, an illegal drug is a controlled substance, included in Schedule I or II as defined by that section 802(6) of Title 21 of the United States Code, whose possession is unlawful under Chapter 13 of that title. The term "illegal drugs" does not mean the use of a controlled substance pursuant to a valid prescription or other uses authorized by law.

From the Fourth Amendment of the Constitution comes the concept of reasonableness: "…whether a particular search meets the reasonableness standards is judged by balancing its intrusion on the individual's Fourth Amendment interests against its promotion of legitimate government interests…" Collecting urine for a Federal employee workplace drug test is considered a search under the Fourth Amendment. Another aspect of evaluating reasonableness is the special needs doctrine, developed by the U.S. Supreme Court through a series of cases permitting suspicionless drug testing in certain situations. Under the special needs doctrine, the court identifies a special need, which makes impractical adherence to the warrant and probably cause requirements,

then balances the government's interest in conducting the particular search against the individual's privacy interests upon which the search intrudes.

We are digressing from our charter, which specifically addresses Schedule I or II illegal drugs, when considering prescription drugs which are not Schedule I and II drugs. Any changes to the Guidelines must be done in a systematic, scientific manner with laboratory-derived data, as was done to increase the opiate cutoff and include testing for 6-AM.

DTAB Panel Discussion

Testing Morphine/Codeine Only at 2000 ng/mL Cutoff versus Testing Expanded Opioid Panel at 300 ng/mL Cutoff

Pat Pizzo, Director of Toxicology, Substance Abuse Testing, Kroll Laboratory Specialists, Inc.

Because of concerns about safety and the abuse of hydrocodone and oxycodone on the job site, a union client requested an extended opiate panel, which included hydrocodone, hydromorphone, oxycodone, and oxymorphone at a 300 nanograms per milliliter cutoff. From January through September 2006 for this client, there were 707 total positive drug results of which five percent were positive for opioids, including codeine and morphine, at the 2000 nanograms per milliliter a cutoff level. With the 300 nanograms per milliliter cutoff expanded opiate panel, the positive ratio increased to 45 percent. The client had 200 confirmed and MRO-verified union members who were illegally using either hydrocodone or oxycodone. Even considering the 80 percent average MRO reversal rate for opiates, the union decided the additional cost was justified from a safety standpoint.

Public Questions

"Does it matter whether a substance is legal or illegal, therapeutic or not? Rather, isn't it the concern of whether or not it has impairing affects and hence creates an unacceptable safety risk?"

This program was established as a demand reduction for illegal drugs. It has nothing to do with impairment or safety risk at work in the context of therapeutic drugs.

"Although urine drug test results do not indicate or correlate with a level of impairment, is it scientifically feasible to associate results of chemical urine drug tests with levels of impairment in the same way that a blood or a breath alcohol level is associated with intoxication?"

No. Urine is a fluid that is stored in the bladder until a convenient time for

elimination. Though urine is still contained in the body, it reflects what happened in the past. Since urine is not in equilibrium with the CNS as is blood or breath for the purposes of ethyl alcohol testing, interpretation impairment cannot be assessed.

Adjournment

The second day of this two-day meeting adjourned at 4:30 p.m. on August 20, 2008.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

/SIGNED/

Donna M. Bush, Ph.D., D-ABFT
Designated Federal Official, DTAB

/SIGNED/

Robert L. Stephenson II, M.P.H.
Chair, DTAB

These minutes will be formally considered, amended, and approved by the Board using email.