UNITED STATES OF AMERICA
DEPARTMENT OF TRANSPORTATION
UNITED STATES COAST GUARD

UNITED STATES OF AMERICA UNITED STATES COAST GUARD	)	Docket No. CG S&R 00-0342
	)	Coast Guard No. PA00 000406
v.	)	
JERRY M. PATTON Respondent.	)	

DECISION AND ORDER

This proceeding is brought pursuant to the authority contained in 46 USC § 7704; 5 USC §§ 551-559; 46 CFR Parts 5 and 16, and 49 CFR Part 40.

Respondent, Jerry M. Patton was charged by the Coast Guard with being a user of a dangerous drug having tested positive for Cannabinoids/Marijuana Metabolite, in connection with a pre-employment drug test.

Respondent has, by his representative, answered the complaint where he:
(1) admitted the jurisdictional allegations;
(2) admitted he took a pre-employment drug test on February 4, 2000;
(3) admitted the urine specimen was collected by S. Mallott of Virginia Mason Occupational Health Clinic, Seattle, Washington;
(4) admitted he signed a federal drug testing custody and control form;
(5) denied for lack of knowledge and information regarding the collection and analysis of the specimen by Quest Diagnostics of San Diego, California;
(6) denied the specimen tested positive because of lack of knowledge and information regarding chain of custody, lack of responsiveness of Greystone Health Sciences Corporation and the Medical Review Officer (MRO) of American Safety Inc's re-testing of the specimen by a referee laboratory;
(7) affirmatively asserted that he has, throughout his maritime career, tested negative for all substances including random drug tests;
(8) affirmatively asserted that the initial testing by Quest Diagnostics showed an extremely low level of metabolites suggesting a false positive.

A hearing on the complaint was commenced on October 11, 2000 in Seattle, Washington. At the conclusion of the hearing day, Respondent asked for time to present a rebuttal based on a challenge to the validity of laboratory testing. After some additional

adjournments due to Respondent's representative's illness and recovery, the hearing was reconvened on February 1, 2001.

Respondent holds a Merchant Mariners Document No. 453-43-2610 issued to him by the Coast Guard. It qualifies him to serve as a Fireman, Water-tender, Oiler, Pump-man, Steward's Department, and Able Bodied Seaman (AB). Jurisdiction is established in this matter by reason of Respondent's licensure and his admission of jurisdiction. See, 46 U.S.C. §7704(c); NTSB Order No. EM-31 (STUART); Commandant Appeal Decision, No. 2135 (Fossani).

PRELIMINARY DISCUSSION

In these cases the Coast Guard must prove its case against the mariner charged on the basis of reliable, probative and substantial evidence. 46 CFR § 5.63. This substantial evidence standard has been determined to be the equivalent of the preponderance of the evidence standard. See Commandant Decision on Appeal 2472 (Gardner) and *Steadman v. United States,* 450 US 91 (1981) which concluded that the preponderance of evidence standard shall be applied in administrative hearings governed by the Administrative Procedures Act, such as this hearing.

For some time now, the Coast Guard has brought cases charging use of a dangerous drug under 46 USC § 7704[c] based solely upon the results of chemical testing by urinalysis. 46 CFR § 16.201[b] provides that one who fails a chemical test for drugs under that part will be presumed to be a user of dangerous drugs. In turn, 46 CFR § 16.105 defines "fail a chemical test for dangerous drugs" to mean that a Medical Review Officer reports as "positive" the results of a chemical test conducted under 49 CFR § 40. In other words, 46 CFR § 16 establishes a regulatory presumption on which the Coast Guard may rely, provided the Coast Guard can satisfactorily show that a 49 CFR § 40 chemical test of a merchant mariner's sample or specimen was reported positive by a MRO. This presumption, however, does not dispense with the obligation to establish the presumption by the same standard of proof, *i.e.,* the elements of the case must be proven by a preponderance of the evidence. The elements of a case of presumptive use are as follows:

First, the Respondent was the person who was tested for dangerous drugs. Second, the Respondent failed the test. Third, the test was conducted in accordance with 46 CFR Part 16. Proof of these three elements establishes a *prima facie* case of use of a dangerous drug (*i.e.,* presumption of drug use) which then shifts the burden of going forward with the evidence to the Respondent to rebut the presumption. If the rebuttal fails then this Judge may find the charge proved solely on the basis of the presumption. See, Commandant Decision on Appeal 2592 (Mason) 2584 (Shakespeare); 2560 (Clifton).

To rebut the presumption, Respondent may produce evidence (1) that calls into question any of the elements of the prima facie case, (2) that shows an alternative medical

explanation for the positive test result, (3) that demonstrates the use was not wrongful or knowing, or (4) that Respondent is not a *user* of dangerous drugs. If this evidence is sufficient to rebut the original presumption, then the burden of presenting evidence returns to the Coast Guard. The Coast Guard at all times retains the burden of proof. See, Commandant Decision on Appeal 2560 (Clifton).

FACTUAL FINDINGS

The first element is to show that the respondent was the person who was tested for dangerous drugs. This involves the proof of identity of the person providing the specimen. Also proof of a link between the Respondent and the sample number of Drug Testing Custody and Control number which is assigned to the sample, and which identifies the sample throughout the chain of custody and testing process, and proof of the testing of that sample.

Respondent admits he took a pre-employment drug test on February 4, 2000; that a urine specimen was collected from him by S. Mallott of Virginia Mason Occupational Health Clinic, Seattle, Washington an approved collection facility; and that he signed a federal drug testing custody and control form. Answer to Complaint.

The urine specimen was placed in an appropriate container and sealed with a tamper proof seal that bore Respondent's signature. TR 20, 23. Respondent also signed the customary custody and control form-showing specimen ID No. A-11736577 and assigned accession control number S.0149.3772.02. Answer to Complaint. He is the person tested for dangerous drugs.

The second element involves proof of the test results. The result of the initial screening showed positive for THC metabolites and that result is reported on the same custody and control form showing the same ID number and accession control number. The MRO verified and reported the results as positive. CG Exhibit 2. As noted above, the regulation only requires that the MRO certify the test result as positive for this element to be satisfied. Thus, the second element is proven.[1]

The third element is to show that the test was conducted in accordance with 46 CFR Part 16. This necessarily involves proof of the collection process, proof of the chain of custody, proof of how the specimen was handled and shipped to the testing facility, proof of the testing procedures, and proof of the qualification of the laboratory.

Ms. S. Mallott collected the specimen at the Virginia Mason Occupational Medicine Clinic in Seattle, Washington at 12:50 PM on February 4, 2000. Ms. Mallott took a sealed testing kit from a cupboard unwrapped it and gave the cup with a temperature measure to Respondent. Respondent provided a urine specimen, which was

[1] Respondent challenged the validity of the test conducted by Quest Diagnostics, Inc. As a result, ACL Laboratories, also an approved testing facility [CG Exhibit 12; 65 Fed. Reg. 500] conducted a second confirmatory test on the split specimen. That test was also positive for the marijuana metabolite tetrahydracannibinol or THC. CG Exhibit 9C.

then poured into a tamper proof container, sealed, and Respondent signed the seal. The packaged specimen was then sent express air courier to Quest Diagnostics Inc., San Diego, California for analysis. The laboratory is listed as one, which was then certified to meet standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing, programs [65 Fed. Reg. 501]; CG Exhibit 12.

Upon arrival at the Quest laboratory in San Diego, the specimen kits were taken directly to its high security accessioning room where authorized personnel inspected the package and sealed specimen containers for evidence of any tampering or prior opening. This was documented, and entered into the laboratory's computer system. From that point forward the Respondent's specimen was maintained in secure storage during testing. Access to the specimen were documented on chain of custody form.. CG Exhibit 3, 7.

Initial testing was conducted by Immunoassay and showed a result which exceeded the cutoff for this initial test. CG Exhibit 4. This positive result was later confirmed by Gas Chromatography/Mass Spectrometry (GC/MS). The initial test showed positive T5 at 149 (about three times greater than cut off of 50) and the confirmation GC/MS test was positive for cannabinoids as Carboxy THC (D-9) at a level of 27.02 nanograms per milliliter (ng/ml). The measured metabolite concentration was greater than 15 ng/ml, which is the minimum concentration required under the regulations.

From the foregoing I must conclude that the Coast Guard has established each of the required three elements of a *prima facie* case, *i.e.,* the presumption that Respondent is a user of dangerous drugs.

RESPONDENT'S REBUTTAL

We start from the perspective that Coast Guard regulations require the initial positive immunoassay test must be verified by a second test, using a gas chromatography/mass spectrometry (GC/MS) technique. *See* 49 C.F.R. § 40.29(e) and (f). The Coast Guard and the Courts have ruled this test is ". . . the most sensitive and specific method of drug detection available. . . . This procedure is widely recognized as 'the state of the art' in drug detection." See CDOA 2584 (Shakespeare) quoting from *U.S. v. Arguello*, 29 M.J. 198 (C.M.A. 1989). See also *Transport Workers' Union of Phila., Local 234 v. Southeastern Pa. Transit Authority*, 670 F. Supp. 543 (E.D. Pa. 1988) (GC/MS [is] considered to be the most accurate [drug detection] technology available.)

Respondent seeks to rebut the regulatory presumption that Respondent is a dangerous drug *user* by showing there is a substantial doubt or error regarding the third element of the prima facie case. Essentially, Respondent challenges the so called state of the art GS/MS confirmation test conducted by Quest Diagnostics contending that the test of Respondent's specimen produced an invalid result.

Respondent supported this rebuttal by offering the testimony of W. James Woodford, Ph.D. Dr. Woodford was offered as an expert chemist with the education, knowledge and experience in Gas Chromatography and Mass Spectrometry in drug testing[2]. Dr. Woodford was qualified as an expert on the limited subject of GC/MS testing, but his opinions together with their bases and reasons would only be admitted in evidence if they were found to be reliable.[3]

Dr. Woodford opined that the GC/MS test was invalid. Tr. p. 162. He based his opinion on essentially two points.[4]

First, the chromatogram for Respondent's specimen[5], "was invalid from a visual consideration because of the humps and the total ion current." Tr. p. 162. He went on to explain that the graph is supposed to have a triangular shape with no humps. It is supposed to be a smooth sided triangle with only three sides. The graph in this case has five sides. See Tr. pp. 162-163. He suggested that the five-sided chromatogram in CG Exhibit 7, attachment 10 shows the existence of an unknown endogenous compound. .

Second, the type of GC/MS test performed by Quest Diagnostics was a *Selected Ion Monitoring* [SIM] technique, which is less precise or accurate than a broader or full scan detection

To support his theory that the five sided chromatogram revealed an endogenous substance and thus was unreliable to show a positive THC metabolite, Dr. Woodford points to a single page he claims comes from a National Institute on Drug Abuse Monograph 32.[6] The highlighted language reads:

> In spite of the high specificity of the selected ion monitoring technique, *particularly when ammonia chemical ionization is used,* ions from endogenous compounds will occasionally interfere. Usually a visual

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[2] The Coast Guard IO objected to Dr. Woodford as a expert contending that he was not a toxicologist. This judge determined that in order to qualify as an expert on the limited subject of Gas Chromatography/Mass Spectrometry, a doctorate in chemistry and substantial experience in running a quadrupole mass spectrometer in Selected Ion Monitoring mode would be satisfactory. This expert's testimony goes only to the reliability of the GC/MS test, nothing more.

[3] The Administrative Procedures Act mandates that no sanction may be imposed, or an order issued unless it is based on the whole record supported by *reliable*, probative and substantial evidence. 5 USC § 556(d). This reliability standard was asserted in a series of cases before the US Supreme Court, which determined when both scientific and other expert evidence can and cannot be admitted at trial. The four unanimous decisions are *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 US 579 (1993); *General Electric v. Joiner,* 522 US 136 (1997); *Kumho Tire Co. v. Carmichael,* 536 US 137 (1999); *Weisgram v. Marley Co.,* 120 S.Ct. 1001 (2000). The objective was to make sure the expert evidence was not only relevant but also reliable. See *Daubert* at p. 589.

[4] Respondent speculated there was poor maintenance at the Quest laboratory resulting in a leaky septum in the GC/MS equipment. Because of the lack of any evidence to that effect that claim has been rejected as mere speculation.

[5] See CG Exhibit 7 at Attachment 10. Also see Respondent's Expert Report for Dr. Woodford at attachment EE(A).

[6] Dr. Woodford's Expert Witness Report at tab EE(E). Respondent's Exhibit EE(E)

> examination of the ion current profile plots will indicate when an analyte or internal standard peak contains a contribution from another compound: that is, the peak width will be broader than normal, or its retention time will be slightly altered. However, we have seen a few rare cases where an endogenous compound had an identical retention time and yielded ions at the same mass as either the analyte or the internal standard. When this situation occurs it can easily go undetected and result in erroneous data.[7] [emphasis added]

Essentially, Dr. Woodford's theories of invalidity, as I understand them, boil down to these. First, only a full scan GC/MS test is reliable enough to identify a target drug metabolite. Quest should have done a full scan. Second, the donor chromatogram demonstrates the presence of an endogenous substance, which invalidates the test result.

Turning to the opinion that only a full scan is reliable enough, the Coast Guard's certifying scientist, A. P. D'Addario, Ph.D. responded pointing out that Quest Diagnostics is a certified testing laboratory meeting the stringent standards of the National Laboratory Certification Program. See, CG Exhibit 12 [65 Fed. Reg.501]. He referred to the Guidance Document for Laboratories and Inspectors produced by the National Laboratory Certification Program, which was established by the Department of Health and Human Services. Tr. p. 214-216. The program is designed to certify laboratories that test specimens collected for Federal agency drug testing programs, including the Department of Transportation. The certification program includes a comprehensive performance testing and inspection program.[8] In particular the certification program emphasized that the SIM procedure is the "industry standard" to be used by certified laboratories. This program document discusses the inspection program and describes at p. J-10 the procedures used to identify an analyte and determine its concentration.

> Mass spectrometers (MS) create charged particles and separate them according to their mass-to-charge (m/z) ratios. A record of the ions formed and their relative abundance provides a unique mass spectrum that is used to identify the drug or metabolite. Mass spectrometers use either electron ionization (EI) or chemical ionization (CI) to generate the mass spectrum and are operated in either the full scan or selective ion monitoring (SIM) mode. In the

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[7] Dr. Woodford did not provide a full copy of the monograph, only the page attached to his report from which this quotation is taken. Moreover, there is no identification of the authors of this report. I cannot determine the reliability of this quotation given the absence of the authentication data. Stated otherwise, I am unable to determine whether the theories asserted here have actually been tested, whether this alleged monograph was subjected to peer review, the known or potential rates of error involved, and whether this theory has achieved "general acceptance" in the GC/MS scientific community. See, *Daubert,* supra at p. 592-594.

[8] This document is dated November, 2000 and carries OMB No. 0930-0158, expiration date of 6/30/03.

> full scan mode a full comparison of all ions can be made. When using SIM, only the monitored ions are acquired.
>
> Currently, most certified laboratories use quadrupole EI with the MS operated in the SIM (selected ion monitoring) mode to identify a substance. SIM techniques can significantly increase the sensitivity of the analysis without losing the ability to identify the substance. Because it has become the *industry standard*, certified laboratories must monitor a minimum of three ions and two ion ratios for each analyte. It is acceptable to monitor two ions and one ion ratio for the internal standard. It is preferred that the ions be prominent, derived from different fragments of the parent compound, and at m/z values that are relatively free of interference and relatively close in mass. Depending upon the selection of methods, it is sometimes difficult to identify three structurally important ions of sufficiently high molecular weight to protect against interference from common sources of contamination. Laboratories must carefully optimize their methods to avoid such problems (e.g., by using higher molecular weight derivatives or monitoring more unique ions).

Dr. D'Addario added, Quest as a certified laboratory has regularly used the SIM mode, *electron ionization*, which is the recognized industry standard in its Federal agency testing, and did so in this case. The relevant GC/MS documents (CG Exhibit 7, Attachment 10) show that Quest monitored for the parent drug ions 575, 515 and 413. And, for the deuterated internal standard they monitored ions 581 and 524. Tr. p. 210. Accordingly, Quest monitored five specific ions associated with the target metabolites.

Addressing Dr. Woodford's theory that something else is contributing to the area underneath the donor chromatogram curve, if that were true it would "kick the ion ratios out of range." Tr. p. 211. Thus, the lab also monitors ion ratios as an additional measure of the identity of the drug. Next he says that the chromatogram at issue here actually shows two substances neither of which is endogenous. Referring to the donor TIC chromatogram ". . . that simply consists of is the superimposition or placing of two separate chromatograms on top of one another." Tr. p. 206. One is due to the internal standard and the other is the drug metabolite. Tr. p. 206. Upon questioning by this judge, Dr. Woodford agreed there are two substances, but still insisted the second is endogenous. Tr. pp. 225-226.

From all of this I must conclude, the use of an industry standard of GC/MS in Selected Ion Monitoring mode and monitoring a minimum of three specific ions associated with the target analytes (here finding the THC metabolite) is a scientifically reliable testing methodology.

I must also reject Dr. Woodford's opinion that only a full scan is acceptable and reliable to determine the presence of the target analytes. I have not been presented any evidence that a GC/MS SIM mode electron ionization test for three analytes is inherently unreliable or produces such unreliable results that it must be rejected in favor of a full scan test. At most, the drug testing laboratory community has accepted a full scan as an alternative method of testing but it is not the only reliable method.

Second, Dr. Woodford's opinion that the donor chromatogram shows an endogenous substance such as to invalidate the GC/MS SIM test is also rejected. His opinion is based largely on the quoted language from what is claimed to be NIDA Monograph 32. Even if authenticated, that language points out that presence of endogenous substances arises principally when ammonia chemical ionization is used. Quest uses electron ionization and did so in this case. So-called Monograph 32 does not support Dr. Woodford's theory.

Third, Dr. Woodford's opinions are rejected for another equally significant reason. He says the bases and reasons for his opinions are his *knowledge, education, and experience.* In other words *believe me because I say so.* See. Respondent's Exhibit EE (Expert Report) at page 1. That is not enough. Such self-serving exclamations do not meet the requirements that an expert opinion be supported by reliable evidence. See *Kumho Tire Co. v. Carmichael,* 526 US 137 (1999).

Lastly, Respondent offered no opinion or evidence challenging the validity of the second test of Respondent's specimen. That test re-confirmed the original GC/MS positive test.

I must find that Respondent has failed to successfully rebut the *prima facie* case of the Coast Guard.

CONCLUSION

Because Respondent has failed to rebut the *prima facie* case of the Coast Guard, I find the charge proved solely on the basis of the presumption. See, Commandant Decision on Appeal 2592 (Mason) 2584 (Shakespeare); 2560 (Clifton).

SANCTION

46 USC § 7704 [c] provides if it is shown that a holder been a user of a dangerous drug, the merchant mariner's document of the holder shall be revoked. This judge has no discretion in the matter.

Respondent is directed to immediately hand over his document to the nearest Marine Safety Office of the United States Coast Guard.

Service of this Decision upon you serves to notify you of your right to appeal as set forth in 33 CFR Subpart J, §20.1001. (Attachment I)

Dated: April 26, 2001.

EDWIN M. BLADEN
Administrative Law Judge

Certificate of Service

I hereby certify that I have this day delivered foregoing Decision and Order upon the following parties and limited participants (or designated representatives) in this proceeding, at the address indicated as follows:

Marine Safety Office, Puget Sound
Attn: Ron Kinsey
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ALJ Docketing Center
(Telefax with Activity Report)

Dated at Seattle, WA this 26th day of April 2001.

MARY STRADFORD PURFEERST
Legal Assistant to
Administrative Law Judge