

IN THE COURT OF COMMON PLEAS, FRANKLIN COUNTY, OHIO

JOHNSON,	:	
	:	
Appellant,	:	
	:	
v.	:	CASE NO. 08 CVF-01-986
	:	
STATE MEDICAL BOARD OF OHIO,	:	
	:	
Appellee.	:	June 13, 2008

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Collis, Smiles & Collis, L.L.C., and Elizabeth Y. Collis, for appellant.

Nancy H. Rogers, Attorney General, and Karen A. Unver, Assistant  
Attorney General, for appellee.

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RICHARD A. FRYE, Judge.

**I. Introduction**

{¶ 1} Cynthia J. Johnson is a physician's assistant, subject to licensure and regulation by the State Medical Board of Ohio. Roughly six years ago, Johnson was diagnosed with alcohol dependence/abuse. Thereafter, the Medical Board supervised her through inpatient treatment, aftercare, and a multiyear probationary period. Johnson brings this appeal to contest the decision of the board in December 2007 that notwithstanding four years of sobriety demonstrated through negative alcohol screens and direct monitoring by multiple physicians and the Ohio Physicians Health Program, Inc., she relapsed

in her recovery. A suspension from practice was ordered, along with extension of supervised probation that would otherwise have now expired.

{¶ 2} In deciding this case, the board relied heavily upon a single positive ethyl glucuronide (“EtG”) test result, plus several ambiguous oral statements by Johnson made prior to her administrative hearing, in which she suggested possible explanations for her unexpected EtG test result.

{¶ 3} The EtG test is one of several recently available direct biomarker tests intended to detect drinking through the presence of minor alcohol metabolites formed when a person’s body breaks down alcohol. While recognized as admissible scientific evidence under the *Daubert* line of cases by the Medical Board and mentioned in a handful of court decisions from around the country (several of which concern medical board proceedings in other states), EtG testing remains at the cutting edge of forensic toxicology. *Daubert v. Merrill Dow Pharmaceuticals, Inc.* (1993), 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469. Clinical study and analysis in peer-reviewed literature continue due to recognized concern that the EtG test may give false positive results and is not fully understood. Indeed, in September 2006, such concerns prompted the Substance Abuse and Mental Health Services Administration of the United States Department of Health and Human Services to issue a formal advisory bulletin cautioning against using EtG testing in connection with “[l]egal or disciplinary action[s]” as “primary or sole evidence” because it is currently only a “potentially valuable clinical tool” whose “use in forensic settings is premature.”

{¶ 4} Doctors specializing in the treatment of alcohol abuse and other addictive behavior personally monitored Johnson, but none observed Johnson

drink, smell of alcohol, or fail to perform well at work. No random test for alcohol was positive prior to December 2006, or since then. Accordingly, the court must evaluate the entire administrative record to determine whether the findings by the Medical Board were based upon reliable, probative, and substantial evidence and whether that decision is otherwise in accordance with law.

## **II. *Procedural Background***

{¶ 5} The administrative hearing was held in September 2007. The hearing examiner prepared a 28-page report and recommendation. On December 12, 2007, the board met, heard short arguments from counsel and a brief statement by Johnson, discussed the issues, voted to adopt the findings of fact and conclusions of law of the hearing examiner, and issued an order (actually mailed January 4, 2008) finding that appellant had relapsed and violated her probation. The final order approved by the board reduced somewhat the hearing examiner's recommended sanctions but nevertheless suspended Johnson's certificate to practice for an indefinite period of not less than 30 days and extended her probation for at least one year.

{¶ 6} This appeal was timely filed on January 18, 2008. Following a hearing, this court stayed the suspension of appellant's certificate to practice until briefing was completed and a final decision could be issued. Nine enumerated conditions were imposed in the stay order. Among them were requirements for continued participation in alcohol-avoidance programs no less than three times per week, plus random urine screens at Johnson's expense, including periodic testing using EtG methodology. So far as the record reflects, Johnson has

remained fully compliant with all conditions of the stay, and no test result reflecting alcohol use has been brought to the court's attention.

### **III. *The Factual Record***

#### **A. *Essentially uncontested background***

{¶ 7} After working for some years as a medical technologist, Johnson graduated from a physician-assistant training program in 1999 and became licensed by the board. However, between 1999 and 2001, Johnson was convicted of misdemeanor-level crimes of disorderly conduct and criminal trespass. She acknowledged that those crimes were attributable to excessive alcohol consumption, secondary to the upset in her life from her divorce. In the course of renewal of her physician-assistant certificate, those criminal matters were voluntarily disclosed to the board.

{¶ 8} Johnson was formally diagnosed in 2002 with alcohol dependency/abuse and major depression. She completed a 28-day residential treatment program. Thereafter, she became involved in aftercare, and in November 2002 entered into an advocacy contract with the Ohio Physicians Health Program, Inc. ("OPHP"). OPHP serves as her "supervising physician" for the purpose of formal consent agreements between appellant and the board made in 2001 and 2003.

{¶ 9} In 2002, three physicians reported to the board that Johnson remained capable of practicing as a physician's assistant according to acceptable and prevailing standards of care, so long as treatment and monitoring continued. Accordingly, a Step II consent agreement was made between Johnson and the Medical Board effective in January 2003, and Johnson's certificate was

reinstated for a five-year probationary period. Among the terms of that consent agreement and appellant's separate contract with OPHP were requirements that Johnson abstain completely from use or possession of alcohol.

{¶ 10} The hearing examiner found that between January 2003 and December 2006, Johnson was "largely compliant" with her probationary terms. In fact, as discussed below in more detail, Johnson was not observed drinking or impaired and provided no clinical test prior to December 2006 that was determined to be positive for alcohol.

{¶ 11} Beyond her supervision by OPHP, Johnson was also monitored by Christina M. Delos Reyes, M.D. Dr. Delos Reyes is board-certified in both adult psychiatry and addiction psychiatry. In addition to her strong training and experience in addiction medicine, for which she "received numerous honors and awards," Dr. Delos Reyes has presented and published professional work. Given her professional stature, Dr. Delos Reyes's observation that since 2002, Johnson "had never missed an appointment with her, never had a positive urine screen previously, and had been compliant with all Board requirements, including in-person meetings" was entitled to substantial weight. In addition to that, from time to time Johnson was under the care of other mental-health professionals and attended many Alcoholics Anonymous recovery meetings.

{¶ 12} To monitor her abstinence and deter a relapse, Johnson was subject to random, unannounced screens with a limited time between notification and testing. On December 27, 2006, Johnson was contacted by Dr. Delos Reyes and directed to provide a urine specimen within six hours. Her specimen was collected by Dr. Delos Reyes and sent off for testing to the Bendiner &

Schlesinger, Inc. laboratory in Brooklyn, New York. Ordinarily such samples arrived within four or five days, but for some unknown reason this particular sample took 22 days to be received (that is, on January 18, 2007).

{¶ 13} The standard urine-alcohol test of the December 27 specimen was negative. The hearing examiner understood that tests of the specific gravity and the creatinine level in that sample were low, suggesting the specimen had been diluted. The examiner was mistaken as to the first test. The laboratory report shows on its face that the specific gravity level was *not* below the cutoff level at which this particular laboratory concludes that a sample “may indicate dilution.” Further, at the administrative hearing, Dr. Sateren of OPHP testified that the “specific gravity is fine.” Nevertheless, at least one member of the Medical Board also misunderstood that Johnson’s urine was “diluted to such a point” that “he doesn’t buy” her explanation that she did not relapse. Board minutes, Dec. 12, 2007, at 17186. The creatinine level of 9.6 was below the normal range of 95 percent of the population (which falls between 20 and 350 mg/dl), but Dr. Closson, who heads the Brooklyn laboratory, testified at the hearing (by telephone) that some normal people predictably test outside that so-called normal range. Further, “there’s no way you can say they have got a creatinine level [sic] that a person has done something intentionally to their body to affect the results of a drug test. Its just an indicator to the status of the dilutional nature of the sample itself.” In fact, as the hearing examiner found, of the 15 additional urine specimens collected from Johnson following mid-January 2007, her creatinine level bounced from a low of 13.9 to a high of 170.2. No evidence in the

record suggested that those values reflected anything more than her own body's normal variation.

{¶ 14} Stanley G. Sateren, M.D., is currently the president and medical director of OPHP. OPHP works at arm's length with the Medical Board to supervise some licensees. Dr. Sateren is a fellow in the American Society of Addiction Medicine, in addition to being board-certified in internal medicine. Dr. Sateren reviewed the initial test results for appellant's December 27 sample on January 24. Dr. Sateren concluded that because the creatinine level was reported at only 9.6, it was advisable to request another test on the same specimen, using ethyl glucuronide ("EtG") methodology.<sup>1</sup>

{¶ 15} The laboratory in Brooklyn did not conduct the EtG test. Instead, it forwarded the urine specimen to National Medical Services in Willow Grove, Pennsylvania. That laboratory concluded that Johnson had consumed alcohol, because her EtG test result was 1,800 nanograms/milliliter, well above the laboratory's cutoff level of 250 ng/ml. The State Medical Board of Ohio has adopted no formal administrative rule establishing a specific cutoff standard for judging EtG test results. In this case, it applied a standard of 250 ng/ml based upon the laboratory's cutoff point, which, in turn, was said to be based on a standard used by the United States Department of Transportation. The various cutoff levels used around the United States and evidence pertinent to the reliability of EtG testing are reviewed below.

**B. *The hearing examiner's conclusions***

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<sup>1</sup> Another recently developed direct biomarker test for the presence of alcohol, also usually measured in urine, is the ethyl sulfate ("EtS") test. EtS was not used in this case.

{¶ 16} The hearing examiner concluded that Johnson had used or consumed alcohol and thereby demonstrated that she was impaired in her practice. Appellant's consumption of alcohol was found to have violated conditions previously placed by the board on her certificate to practice, justifying further sanctions.

{¶ 17} The board's hearing examiner placed great emphasis upon two pieces of evidence, namely the EtG test result and statements by Johnson speculating about possible causes of that positive EtG test. The examiner specifically found that "[t]he EtG test showed the presence of the EtG metabolite of Alcohol" and that it "will only be present from use/consumption of ethyl alcohol." She also concluded "the EtG test is highly reliable."

{¶ 18} The examiner explicitly relied upon alleged admissions made by Johnson, months before her hearing, to the effect that "she had consumed communion wine during a church service a few days prior to submitting the December 27, 2006 urine specimen," even though during the administrative hearing Johnson "denied drinking communal wine at that time." The witness to whom Johnson allegedly made the admission was Danielle Bickers, the Medical Board's "compliance supervisor." The hearing officer also attached significance to the fact that "[e]arlier in 2006, Board staff had questioned Ms. Johnson's commitment to the recovery process." However, the sole member of board staff to raise any such question – on only one instance that was promptly corrected by Johnson – was compliance supervisor Bickers.

{¶ 19} Finally, under the subtitle "Conclusions of Law," the hearing examiner again emphasized that Johnson "admitted, in a February 2007

conversation with Ms. Bickers, that she had consumed communal wine shortly prior to December 27, 2006,” and that “[t]aken together, the EtG test result and Ms. Johnson’s admission to Ms. Bickers are reliable, probative, and substantial evidence which demonstrates that Ms. Johnson used/consumed alcohol” in violation of her obligations to the Medical Board. Emphasizing the importance of the alleged factual admission, the hearing examiner stated a few sentences later that “Ms. Johnson’s own testimony suggests that she did not abstain completely from the use of alcohol” and beyond that “provided a number of varying statements \*\*\* regarding her activities at church in late December 2006.”

{¶ 20} The examiner’s concluding remarks also referred critically to Johnson’s topical use of everyday products containing alcohol. “Despite the fact that Ms. Johnson is in recovery, she admitted to regularly using a number of different products that contain alcohol (*e.g.*, Lysol, hand sanitizers, and colognes), which can result in a positive urine test.”

#### **IV. *The Standard of Review***

{¶ 21} Under Ohio law, decisions of administrative agencies are subject to a “hybrid form of review” in which a common pleas court must give deference to the findings of an agency, but those findings are not conclusive. *Univ. of Cincinnati v. Conrad* (1980), 63 Ohio St.2d 108, 111, 407 N.E.2d 1265. Earlier this year in *Strausbaugh v. Dept. of Commerce, Div. of Real Estate & Professional Licensing*, 10th Dist. No. 07AP-870, 2008-Ohio-2456, ¶ 6, the Court of Appeals for Franklin County set forth more fully the standard of review under Ohio’s administrative procedure act as follows:

{¶ 22} “In an administrative appeal pursuant to R.C. 119.12, the trial court reviews an order to determine whether it is supported by reliable, probative and substantial evidence and is in accordance with the law. *Huffman v. Hair Surgeon, Inc.* (1985), 19 Ohio St.3d 83, 87, [487 N.E.2d 1248]; *Belcher v. Ohio State Racing Comm.*, Franklin App. No. 02AP-998, 2003-Ohio-2187, at ¶10. Reliable, probative and substantial evidence has been defined as follows:

\* \* \* (1) “Reliable’ evidence is dependable; that is, it can be confidently trusted. In order to be reliable, there must be a reasonable probability that the evidence is true. (2) “Probative” evidence is evidence that tends to prove the issue in question; it must be relevant in determining the issue. (3) “Substantial” evidence is evidence with some weight; it must have importance and value.

*Our Place, Inc. v. Ohio Liquor Control Comm.* (1992), 63 Ohio St.3d 570, 571.”

{¶ 23} In evaluating the weight of evidence and the credibility of witnesses in an administrative appeal, a common pleas court “has some limited discretion to exercise.” *Belcher v. Ohio State Racing Comm.*, 10<sup>th</sup> Dist. No. 03AP-786, 2004-Ohio-1278, at ¶7. “In an administrative appeal, the court of common pleas weighs the evidence in the record and uses the results of its weighing of the evidence to determine whether the administrative order is ‘unconstitutional, illegal, arbitrary, capricious, unreasonable, or unsupported by the preponderance of substantial, reliable, and probative evidence.’ *Henley v. Youngstown Bd. of Zoning Appeals* (2000), 90 Ohio St.3d 142, 147, 735 N.E.2d 433.” *Summit Cty. Bd. of Health v. Pearson*, 157 Ohio App.3d 105, 2004-Ohio-2251, 809 N.E.2d 80,

at ¶ 9. The Franklin County Court of Appeals has similarly recognized that this court's " 'review of the administrative record is neither a trial *de novo* nor an appeal on questions of law only, but a hybrid review in which the court "must appraise all the evidence as to the credibility of the witnesses, the probative character of the evidence, and the weight thereof" ' (Emphasis sic.) *Lies v. Veterinary Med. Bd.* (1981), 2 Ohio App.3d 204, 207, 2 OBR 223, 441 N.E.2d 584, quoting *Andrews v. Bd. of Liquor Control* (1955), 164 Ohio St. 275, 280, 58 O.O.51, 131 N.E.2d 390. Even though the common pleas court must give due deference to the administrative agency's resolution of evidentiary conflicts, the findings of the agency are not conclusive." *Graor v. State Med. Bd.*, 10th Dist. No. 04AP-72, 2004-Ohio-6529, at ¶20.

{¶ 24} Ohio administrative agencies may not rely upon evidence that is not genuinely probative and reliable, even though generally speaking "[a]dministrative agencies are not bound by the rules of evidence applied in courts." *Althof v. Ohio State Bd. of Psychology*, 10th Dist. No. 05AP-1169, 2007-Ohio-1010, at ¶73; *Pearson*, 157 Ohio App.3d 105, 2004-Ohio-2251, 809 N.E.2d 80, at ¶19; *Haley v. Ohio State Dental Bd.* (1982), 7 Ohio App.3d 1, 6. In determining when scientific evidence used to make an administrative decision is "reliable," the same considerations recognized for "good science" in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (1993), 509 U.S. 579, 125 L.Ed.2d 469, 113 S.Ct. 2786 are appropriately applied under Ohio law. *Belcher*, 2003-Ohio-2187, at ¶11.

## **V. Admissions or Contradictory Statements**

### ***Allegedly Made by Johnson***

{¶ 25} The board attached substantial weight to statements attributed to Johnson even though they were made months before her hearing. It gave relatively little weight to her testimony under oath at the hearing. The hearing examiner's view was that Johnson had admitted to the board's compliance supervisor Bickers that she consumed wine at communion just prior to her December 27, 2006 test, and from this corroboration was found for the EtG test result as reported in February 2007. Johnson's explanation for allegedly contradictory statements made around the time in February when she learned of the EtG result were seen as purely self-serving. Because the statements long before to the hearing were given such substantial weight, it is important to examine them with some care in the context in which these so-called admissions or contradictory statements were made.

{¶ 26} Under her Step II consent agreement, Johnson was closely monitored. During that time, she was obligated to submit specimens for analysis promptly upon request and without prior notice. A refusal to do so would result in a "minimum of one year of actual license suspension." Test specimens were collected by Dr. Delos Reyes, whose Cleveland office was a short distance from Johnson's place of employment. On December 27, Johnson walked to the office of Dr. Delos Reyes and gave the specimen well within the six-hour time window permitted. Dr. Delos Reyes testified that at that time in late 2006, Johnson was believed to be "stable in her recovery and carrying out all of the responsibilities of the Step II agreement; there were no signs that she was not doing well." Harris V. Taylor, M.D, shared these views. In early spring 2007, he wrote a letter to the

Medical Board relating that in his three and a half years of supervision of Johnson's work, he never smelled any alcohol on her breath or had other reason to suspect that she consumed alcohol. Similarly, a psychologist from North Coast Mental Health Associates, Inc. reported regularly to OPHP from January 2004 through June 2007. As of December 2006, North Coast found Johnson "compliant and faithful regarding her A.A. involvement" and "steadfast with her appointments with myself as well as any other requirements suggested by myself."

{¶ 27} Once the EtG test result was reported, Dr. Delos Reyes testified, "she was very surprised and 'about fell out of her chair' when she learned that the December 27 specimen tested positive." Likewise, North Coast Mental Health Associates' written report in March 2007 found that she "remains compliant with program requirements and regimen as dictated by the Board" but on her most recent visit "she was quite distraught regarding the results of the EtG test. This has me greatly perplexed. It is not my intention to discuss the myriad of debates regarding this [EtG] test; however, it is my intention to reinforce that there have been no signs of relapse." For her part, as observed by others, Johnson was "very shocked, and she didn't know how it could have been positive, and she was very upset." In passing, it should be noted that nothing in the record suggests that Johnson had ever been tested using the EtG method prior to this incident using the December 27 specimen.

{¶ 28} The conversations that unfolded on February 7 and 8 when the EtG result was learned are not genuinely supportive of the conclusion that Johnson was dissembling about a relapse, much less concealing that she was impaired in

her ability to practice according to acceptable and prevailing standards of care. Her conduct and statements do not support an inference of awareness of being caught or engaging in a cover-up. Instead, they are completely consistent with the conduct one would expect from a person who had been serious about recovery and truly was perplexed and distraught.<sup>2</sup> Initially, on February 7, an OPHP employee notified Johnson of her EtG test result. Johnson then personally informed Dr. Delos Reyes and Dr. Sateren at OPHP. She did so the same day she learned of the test. In the administrative hearing, the witnesses related that it was observed that Johnson “was very surprised, and denied that she had drank any alcohol,” which Dr. Sateren took to mean that “she had not relapsed, and that she had not been drinking, you know, beer, mixed drinks, knowingly relapsed.” Dr. Sateren simply “instructed her to review the events around the time the specimen was collected and to ‘investigate hand sanitizer used at work’.”

{¶ 29} The following day Johnson spoke with Danielle Bickers, the compliance supervisor of the Medical Board. Bickers oversees monitoring of licensees by the board. This may have been the first conversation that Bickers and Johnson ever had, according to Bickers. Her initial description of their conversation was that Johnson called “to report that she had been notified she had a positive alcohol or EtG – excuse me, EtG result, and she denied use, denied alcohol use. And, we talked about possible reasons. Ms. Johnson offered some explanations as to where the result may have come from.” Bickers proceeded to

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<sup>2</sup> The September 2006 SAMSHA advisory discussed below recognized that an EtG “biomarker that is positive because of exposure or unintentional consumption, which results in an allegation of use or misuse [of alcohol], casts a cloud on the recovery process. False allegations provide incentive to disregard the intent of abstinence monitoring and may even provide the incentives to use because the individual has ‘nothing to lose.’ ” Id at 7.

file a complaint against Johnson “based on the [one] positive [EtG] screen.” She did not do any further investigation into the positive screening.<sup>3</sup> Johnson was the first person the Medical Board ever sought to discipline for having a positive EtG test with no other positive test results, so far as Bickers recalled.<sup>4</sup>

{¶ 30} The hearing examiner reviewed Johnson’s recollection of what she told Bickers and found that she had admitted she “may have had communion wine” at Christmas Mass and furthermore that during their February 8 conversation appellant “stated she had had punch at a family gathering and that, possibly, it had alcohol in it. She also recalled that she had speculated with Ms. Bickers about other possible sources of alcohol” including a hand sanitizer that she used repeatedly. The hearing examiner also noted that Johnson might have said to Bickers “that she may have gotten complacent in her recovery.” Bickers’s recall of the telephone conversation with appellant on February 8 was understood to be, “very clearly, that she had actually consumed communal wine at Mass on December 25, 2006.” The hearing examiner quoted verbatim the following testimony: “And I had even questioned her as to how much wine. Being Catholic myself, I know how much wine you consume while you’re standing there. And we had a conversation about how it’s a sip of wine, and two days later still testing positive. So we had quite the discussion based on the communal wine.”

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<sup>3</sup> Johnson was also subjected to additional screening, performed at the Mayo Medical Laboratory in Rochester, Minnesota using a sample collected in Cleveland on February 12. This was specifically tested for “investigation or follow-up of alcoholism.” Mayo Laboratory reported on February 20, 2007 that they had a normal test for glycosylated transferring isoforms resembling those found in congenital disorders of glycosylation (CDG). This test report was admitted at the administrative hearing as Respondent’s Ex. 1 (under seal).

<sup>4</sup> The only evidence in the record of any other legal proceeding in Ohio in which EtG evidence has been used was a case before the Medical Board in late 2004. In that matter, a hearing examiner relied upon one EtG test result of 460 ng/ml, and testimony of Gregory E. Skipper, M.D., who also testified in this case. That 2004 case was substantially different from this one, in that the physician had a documented history of drug abuse, dating back some 20 years, and a number of documented relapses.

{¶ 31} Bickers’s role as an enforcement agent for the board may have made her somewhat less than disinterested in the outcome of this case that she had initiated. Keeping in mind the surprise if not shock that everyone (other than perhaps Bickers) expressed when Johnson was thought to have had a positive EtG test, the February telephone conversation (related seven months later during the administrative hearing) was not entitled to significant weight. Largely it reflected speculation by appellant about what might have triggered a positive test result. Indeed, the testimony of several witnesses including even Bickers reflects some ambiguity about what constitutes a relapse and whether ingestion of a small amount of wine at a public religious service genuinely violated the consent agreement or other expectations reasonably placed upon Johnson. To be sure, Paragraph 7 of the Step II consent agreement stated that “Ms. Johnson shall abstain completely from the use of alcohol,” and Dr. Sateren of OPHP noted that the board’s expectation for someone in recovery is “to be totally abstinent.” But he also recognized that from a “clinical perspective, it’s more complex \*\*\* [and entails] looking at the whole picture of the individual of return of [bad] behaviors, not going to meetings, taking back control, not meeting with a sponsor, not working the steps, reemergence of the kinds of behavior that were present when the diagnosis was made, and what recovery and treatment should be causing the change.”

{¶ 32} Bickers undertook this enforcement action notwithstanding the minuscule amount of alcohol that she recognized might reasonably be ingested at communion. She did so even though she never recalled telling Johnson, “Don’t drink any more communal wine,” or otherwise expressing immediate concern

that communion might violate Johnson's recovery obligations. In fact, Bickers was unclear whether she ever discussed the abstinence requirement of Johnson's probation with her at all. Given that this is the first case in which the Ohio board undertook enforcement on the basis of a single positive EtG test, other than the words "abstain completely," nothing in the record suggests that that language was actually intended to preclude someone from taking communion, using mouthwash containing alcohol, or otherwise absorbing molecules of alcohol through topical products, cooking, or daily activities. For her part, Johnson testified that in all her years of treatment and monitoring, no one ever advised that she should not take communion.

{¶ 33} Johnson's lack of clarity in recalling her conduct around Christmas 2006 was resolved by the time of her hearing. She explained, cogently in this court's view, that she had not taken wine at Mass. She further explained that there was always an option of taking wine during the ceremony in her Catholic church and that her understanding was that whether parishioners took wine had "really been sort of a controversial issue in the church as to \*\*\* whether a person will take the wine or not." That, she testified, was why she couldn't remember for certain at an earlier time when the subject first came up "in the chaos" of February 7 to 8. She explained in her testimony at the hearing that her recollection was aided "after recalling better and talking to my [adult] kids" about their attendance at the Mass.

{¶ 34} A key state witness concerning the EtG test was William Closson, Ph.D. He is a forensic toxicologist and the director of the Brooklyn laboratory where appellant's specimen was sent initially. Asked about the "amount of

alcohol [that] must be consumed for EtG to be detected,” he replied, “[N]ormally you would expect the minimum amount to be the amount in one drink.” Similarly, the SAMHSA advisory, discussed below, reported that EtG and EtS biomarker testing is intended to characterize “perhaps as little as a single drink” (as opposed to other available tests that might pick up only multiple drinks over a longer period of time). Four other relevant facts must also be kept in mind in gauging the weight fairly given to Johnson’s alleged admissions or contradictory statements upon learning of her EtG test result. First, her statements were made in the context of “close to five years of well-documented recovery with some good objective data to support that” as monitored by multiple doctors. (The quotation is from Dr. Sateren’s testimony. Report at 16, ¶ 38.) Second, the standard test for alcohol using Johnson’s December 27 sample was negative. Third, apart from that one EtG test result, “Dr. Sateren testified that OPHP had no other indications that Ms. Johnson had relapsed.” Finally, in the long interval between the December 27 urine test and her conversation on February 8 with Bickers, Johnson had submitted at least one additional test (administered on January 17, 2007), and there is no suggestion that it too was positive.<sup>5</sup>

{¶ 35} Viewed in context, Johnson cannot be faulted for lacking a clear recollection six weeks after Christmas about what alcohol-containing products, or communion wine, might have produced the EtG result from the December 27 specimen. Understandably, she was upset at learning that she had failed her first alcohol-detection test. Responding as one perplexed rather than as one

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<sup>5</sup> Dr. Sateren testified (in September 2007) that after February 7, 2007, all urine specimens provided by Johnson were tested for both alcohol and EtG, and all were negative.

admitting that one had been caught, Johnson talked openly to many people in the immediate aftermath of the EtG result becoming known. She explored various possibilities that might explain the test result. Her candor in doing so was not significant, probative evidence of drinking or of dissembling to obscure her relapse. The hearing examiner and the Medical Board were in error in concluding that Johnson's comments or lack of clarity with Bickers about possible de minimus consumption of wine at communion or other possible reasons for her test result were entitled to significant weight.

{¶ 36} A related point mentioned in the hearing examiner's report was likewise given undue emphasis. Viewed against the entire record, Bickers's mere "questioning [of] Ms. Johnson's commitment to the recovery process" in mid-2006 was entitled to no weight. No relapse was observed by any of the physicians reporting to the Medical Board. No test result was positive in mid-2006. No violation of Johnson's probationary conditions was asserted to exist in mid-2006 by personnel at the board, and no additional monitoring of Johnson was requested. The incident was trivial, and the hearing examiner was mistaken to suggest otherwise.

{¶ 37} Finally, the hearing examiner took a critical view of Johnson's apparently routine use of hospital hand-sanitizing products or household products containing alcohol. That too has no weight. Nothing in the evidence suggests that anyone ever warned Johnson that she would be subjected to highly sensitive EtG testing, much less that if she were tested, ordinary household products could produce a false positive EtG result. OPHP does not warn participants not to use hand sanitizers. Dr. Delos Reyes testified that it was not

until December 2006 or January 2007 that she even mentioned to Johnson the potential that innocent exposures to products containing alcohol could be problematic. The doctor was vague about when this occurred, and it is reasonable to infer that the conversation may well have occurred after everyone learned about Johnson's result on the December 27 test. Dr. Delos Reyes knew that Johnson used alcohol-based hand sanitizers "all the time, because in her research position, basically she was seeing patient after patient. And, particularly during the winter months, everybody is kind of carrying germs around \*\*\* so that would have been a time when she would more likely have been using that type of thing. And, actually \*\*\* most hospitals, they have them basically attached to the walls and you, basically, continuously wash your hands."

#### ***VI. Evidence from the EtG Test***

{¶ 38} Based upon the hearing examiner's report and the discussion of the case reflected in the minutes of the Medical Board's December meeting, the other evidence heavily relied upon was the single positive EtG test. Despite the fact that the record contains very strong direct and circumstantial evidence casting doubt upon the board's reliance upon that single test and that current scientific knowledge teaches away from using EtG testing as primary evidence in legal proceedings, the board adopted the hearing examiner's view that this was strong evidence when coupled with the so-called admissions by Johnson.

{¶ 39} Placing primary reliance on an EtG test is inappropriate and scientifically unsupportable at this time. Recently the Center for Substance Abuse Treatment, within the Substance Abuse and Mental Health Services Administration ("SAMHSA") of the United States Department of Health and

Human Services, published a bulletin addressing EtG, EtS, and other biomarker tests. Advisory Vol. 5, Issue 4 (September 2006). The advisory was entitled “The Role of Biomarkers in the Treatment of Alcohol Use Disorders,” and it was admitted into evidence. According to that advisory, there remains an issue “whether exposure to alcohol or to the vapors of alcohol in many commercial products, such as personal care items, over-the-counter medications, cleaning products, desserts, wine vinegar, and the like, or combinations of these products may cause elevation in EtG or EtS that could appear to be a return to drinking.” Advisory at 6. Nevertheless, this is promising science. Alcohol biomarkers are physiological indicators of alcohol exposure or ingestion “and may reflect the presence of an alcohol use disorder.” Among the direct and indirect biomarkers of drinking are tests for ethyl glucuronide (EtG) and ethyl sulfate (EtS), both of which “may become positive shortly after even low-level exposure to alcohol and may remain detectable in urine for several days.” Advisory at 1.

{¶ 40} One witness at Johnson’s administrative hearing was Gregory E. Skipper, M.D. He began performing EtG tests in 2002 to monitor physicians for the medical board in Alabama and was one of the key people involved in publishing the federal advisory in 2006.<sup>6</sup>

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<sup>6</sup> Counsel for the board pointed out to Dr. Skipper, one of the 12 members of the committee responsible for the advisory, that the “fine print” at the end of it states that “[t]he content of this publication does not necessarily reflect the views or policies of SAMSHA or HHS.” Dr. Skipper was surprised and unaware of what that disclaimer meant. This court takes the advisory as significant evidence, comparable to a learned treatise that may be considered under Evid.R. 803(18). The advisory was presented formally by a federal agency acting within its defined field, has been widely distributed, and includes nearly a page of references to supporting scientific publications. The advisory has been cited at least once in medical literature addressing EtG, namely in a recent Swedish publication more fully referenced in footnote 7 below. Significant expert testimony in the record documents the importance of the advisory within the relevant scientific community. Accordingly, the disclaimer can mean only that this advisory has not been published in the Federal Register or otherwise been given legal or regulatory status by the government, not that the science reported in it is flawed.

{¶ 41} A recognized concern in using the EtG test is its high sensitivity to even inadvertent, low-level alcohol exposure, which can provide an unreliable result. The advisory reports, for instance, that “[b]ecause of the purported high sensitivity of these tests, exposure to alcohol that is present in many daily use products might also result in a positive laboratory test for these biomarkers.” Similarly, much testimony in the record addressed everyday products that may produce a false positive result, suggesting a relapse, when only benign exposure to everyday products at home or work is the actual cause.

{¶ 42} Dr. Skipper first became aware of the EtG test in 2001 at a World Health Organization conference in Italy. Dr. Skipper testified that since then scientific studies of EtG remain ongoing, including work not yet published. The court’s own modest research identified two very recent professional papers addressed to the reliability of EtG testing, one of which was not yet available at the time of the administrative hearing in this case.<sup>7</sup> While not considered because they are not formally part of the record, they illustrate what no one disputes: serious, peer-reviewed research remains underway because the science of EtG is not fully understood.

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<sup>7</sup> In January 2008 researchers from the Norwegian Institute of Public Health, Division of Forensic Toxicology and Drug Abuse, published a paper by Hoiseth et al., entitled “Comparison between the urinary alcohol markers EtG, EtS, and GTOL/5-HIAA in a controlled drinking experiment.” It was originally published online by Oxford University Press on behalf of the Medical Council on Alcohol. <http://alcalc.oxfordjournals.org/cgi/content/abstract/43/2/187> (last visited June 2, 2008). The sample size was ten men. Members of the Department of Clinical Neuroscience, Karolinska Institute and Karolinska University Hospital, in Stockholm, Sweden published a “technical brief” by Helander et al., entitled “Postcollection Synthesis of Ethyl Glucuronide by Bacteria in Urine May Cause False Identification of Alcohol Consumption” in *Clinical Chemistry* 53:1855-1857, (August 23, 2007) found at <http://www.clinchem.org/cgi/content/full/53/10/1855> (last visited June 2, 2008). In part, it concluded, “The presence of EtG in urine is not a unique indicator of recent drinking, but might originate from postcollection synthesis if specimens are infected with *E. coli* and contain ethanol.” Testimony of Dr. Sateren alluded to this research. The existence of these studies illustrates that concerns expressed by witnesses and within the advisory remain worthy of scientific study because EtG testing remains experimental. Advisory at 3.

{¶ 43} Dr. Sateren also testified that the EtG test has value but must be used with care. This test became commercially available only in 2003 or 2004, and Ohio started using it a year or so later. The state of Michigan does not use the test at all, and the Federation of State Physician Health Programs recognized concerns, prompting its Toxicology Committee to issue a position statement similar to the advisory. While the hearing examiner concluded that Dr. Sateren believes that ethyl alcohol is the only source for production of EtG, a review of his testimony shows that his views of EtG were nuanced due to the “ubiquitous nature of alcohol in our environment and society.”

{¶ 44} EtG testing is discussed in six recent court cases, two of which involved medical board proceedings like this one. *Bergin v. McCall* (D.Or.2007), case No. 06-6311-HO, 2007 U.S. Dist. LEXIS 60353, was a civil rights challenge to Oregon Medical Board proceeding. *Perez-Rocha v. Pennsylvania* (Commonwealth Court 2007), 933 A.2d 1102, was a direct appeal of a license suspension imposed by the Pennsylvania Medical Board. *New York v. Oehler* (Warren Cty.2006), 12 N.Y. Misc. 3d 1101, 821 N.Y.S.2d 380 addressed a probation violation proven by both an EtG test and observation of numerous empty and partially empty beer cans during an unannounced home visit. *Tauck v. Tauck* (Superior Ct. Middlesex), 2007 Conn. Super. LEXIS 2618 involved a divorce case in which one spouse was ordered to regularly provide EtG tests as a condition for sharing custody of her children. Two lawsuits filed recently against laboratories alleged that they were breaching a tort duty to use reasonable care to avoid erroneous EtG test results or that they established an arbitrary cutoff limit for EtG tests that resulted in scientifically unreliable results. *Garlick v. Quest*

*Diagnostics, Inc.* (D.N.J.), 2007 U.S. Dist. LEXIS 95160 (not for publication) (Rule 12(b)(6) motion granted in purported class action) (now on appeal to the Third Circuit); *Wilson v. Compass Vision, Inc.* (N.D. Cal.), 2007 U.S. Dist. LEXIS 95500 (Rule 12(b)(6) motion to dismiss denied.)

{¶ 45} The Ohio Medical Board’s decision to consider Johnson’s EtG test as admissible evidence is not challenged by appellant under the *Daubert* line of cases. In view of the advisory and testimony in the record, this court has no basis to disturb the board’s decision to admit it as evidence.

{¶ 46} Nevertheless, while reliable enough to be admissible, the EtG test must be used with caution. The specific warnings published in the advisory and the other credible concerns reviewed in the medical testimony in this case document serious scientific concern about overreliance upon this test as a primary indicator of relapse given the current state of knowledge. Overreliance is improper from both a legal and a scientific perspective. The scientific method in general and the *Daubert* line of cases in particular caution us to be aware of “whether the method has a known or potential error rate.” *Terry v. Caputo*, 115 Ohio St.3d 351, 2007-Ohio-5023, at ¶ 25 citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, supra, 509 U.S. at 593-594. Dr. David Goodstein’s article in the Federal Judicial Center’s Reference Manual on Scientific Evidence (2d Ed.2000) 82, entitled “How Science Works” points out that *Daubert* contemplates that “[t]here should be a known rate of error *that can be used in evaluating the results*” of scientific evidence. (Emphasis added.) That is merely another way of saying that one must consider any limitations on scientific reliability of evidence even *after* that evidence is admitted in legal proceedings.

Accordingly, despite the fact that the EtG test is increasingly used to monitor populations suspected of covert drinking, including probationers and recovering medical professionals, it is contrary to the rules of science and contrary to law to afford it much weight standing alone.

{¶ 47} The Medical Board gave too little consideration to the cautionary evidence in this record, most notably the paragraph placed prominently on page 1 of the advisory. It reads: “Currently, the use of an EtG test in determining abstinence lacks sufficient proven specificity for use as primary or sole evidence that an individual prohibited from drinking, in a criminal justice or a regulatory compliance context, has truly been drinking. Legal or disciplinary action based solely on a positive EtG, or other test discussed in this Advisory, is inappropriate and scientifically unsupportable at this time. These tests should currently be considered as potential valuable clinical tools, but their use in forensic settings is premature.”

{¶ 48} The body of the advisory published less than two years ago elaborated upon matters summarized in the warning. Referring to developmental testing of EtG as having occurred primarily in only one European laboratory, SAMSHA recommended that “it is prudent to await replication of results from another independent investigator.” Advisory at 3. Further, the advisory cautioned, “[u]ntil considerable more research has occurred, use of these markers should be considered experimental.” Id. “[A]s yet there has been little research on the new direct biomarkers, particularly on the very sensitive biomarkers, EtG and EtS. At issue is whether exposure to alcohol or to the vapors of alcohol in many commercial products, such as personal care items,

over-the-counter medications, cleaning products, desserts, wine vinegar, and the like or combinations of these products may cause elevation in EtG or EtS that could appear to be a return to drinking. Exposure to these products combined with possible influences of individual variables such as gender, age, and health status on alcohol biomarker responses has not been adequately studied to date.” Advisory at 6.

{¶ 49} The advisory and witnesses with genuine familiarity with the science involved in EtG testing who testified agree about the sensitivity of the test and the need for further research to refine it. Seeking to more accurately identify those who truly consumed alcohol, and to minimize false positive test results from unintended or innocent exposure, much consideration has been given to selection of a cutoff value or concentration level at which an EtG test should sensibly be considered positive. The advisory did not recommend any specific cutoff point for a positive EtG test result. Instead, it recommended factors to take into account in setting a cutoff value, among which should be “the base rate of problem drinking in the population being evaluated, [and] the individual’s likely exposure to products containing nonbeverage alcohol.” Advisory at. 6.

{¶ 50} Apparently more for convenience than out of some conclusion of scientific reliability, the Ohio Medical Board accepted a test result greater than 250 ng/ml as positive for alcohol consumption by Johnson simply because that is the standard otherwise employed by its testing laboratory. Dr. Sateren candidly acknowledged “we could choose 100, we could choose 250, we could choose 500” but “250 seems to be the majority of what state physician health programs are using.” In the discussion at the Medical Board hearing, the doctor who moved to

approve the hearing examiner's findings of fact "stated that she does not want the EtG test to be on trial here. The Board is not going to make a conclusion today, nor should it, about what the cutoff should be, that it is the absolute reliable test, or that it's not." Board minutes at 17184. Another physician likewise observed, "[T]he Board doesn't know the absolute cutoff number that should be used, [although Johnson's test at] 1800 does seem unlikely to be an incidental finding. When most states and experts are using levels significantly less than that, it's hard to ignore. \*\*\* [P]erhaps, the Board should only look at a negative as confirming abstinence, but not a positive as confirming a relapse." Minutes, p. 17185.

{¶ 51} The Alabama Physician Health Program and its medical board (in which Dr. Skipper is personally involved) use 100 ng/ml as the cutoff.<sup>8</sup> However, that level is used not as a conclusive value, but only as a place to start further investigation with the subject, with the subject's family or co-workers who might observe a relapse, or through additional chemical testing.

{¶ 52} While the 1800 ng/ml result reported for Johnson was unlikely to have resulted from incidental exposure, that explanation cannot be ruled out according to Dr. Skipper. He testified that with a relatively low cutoff point of 250, "you've got to be prepared to consider that you may be picking up incidental exposure." Further, while conceding that Johnson's test result at 1800 fell well outside the range of 300 to 800 typically seen from incidental exposure, Dr. Skipper testified that "we cannot definitively conclude with reasonable medical

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<sup>8</sup> As a point of reference, testimony indicated that heavy drinkers entering detox and undergoing withdrawal will test 50,000 to 100,000 ng/ml for EtG.

certainty from this value alone that alcohol beverages were intentionally consumed.” Given his training and experience with EtG, this court accords Dr. Skipper’s views substantial weight.

{¶ 53} Dr. Closson, director of the Brooklyn laboratory, testified that in his understanding, “[t]he level of 250, the cutoff, has been determined by most toxicologists and most researchers as the most reliable level to indicate somebody who has consumed alcohol.” However, in evaluating his views, it must be kept in mind that at the time Johnson’s EtG test was run in early 2007, the Brooklyn laboratory where Dr. Closson worked did not yet perform EtG testing. Moreover, like Dr. Skipper, the Dr. Closson recognized that, although unlikely, an incidental exposure to alcohol-containing products (other than consuming alcohol) could explain appellant’s test level of 1800 ng/ml and that “this explanation cannot be ruled out.”

{¶ 54} Dr. Sateren testified that Arizona uses a cutoff level of 2000 ng/ml, and he concluded that “[t]here’s a lot of variability across the country in terms of what cutoff to use, because of the extreme sensitivity of the test.”

{¶ 55} In deciding whether new scientific evidence such as DNA should be admissible, Ohio courts have rejected the method of mere “scientific nose-counting” in which the value of evidence turns upon how many other jurisdictions have come to accept similar evidence. That approach, known within the legal community as the *Frye* standard, based upon *Frye v. United States* (C.A.D.C.1923), 293 F. 1013, was discarded in *State v. Williams* (1983), 4 Ohio St.3d 53, 446 N.E.2d 444, and *State v. Pierce* (1992), 64 Ohio St.3d 490, 597 N.E.2d 107. Yet essentially informal nose-counting was used here by the Medical

Board when it came to setting a cutoff point for Johnson's EtG test result. That was contrary to law and sound science. Having acknowledged the absence of a well-accepted cutoff point grounded in good scientific research, the board was not free to act on an ad hoc basis or to embrace a particular test cutoff point merely because as a generality researchers in this experimental field currently think that a particular level is useful. Where a test is used in forensic settings without some recognized standard identified as reliable and supportable in published, peer-reviewed literature, and where no test standard is formally adopted by statute or administrative rule, the ad hoc approach taken here cannot be dispositive, or nearly so. It leaves those like Johnson at the whim of the decision-maker.

### **VII. *Conclusions***

{¶ 56} The Medical Board was required to address a challenging case, premised largely upon science that a federal agency recently described as still experimental. Very limited reliance upon Johnson's one EtG test result would have been permissible, but the board went far afield. In effect, the board disregarded the strong cautionary language in the advisory as well as the most probative testimony received at Johnson's hearing. In addition, the board disregarded the evidentiary value of Johnson's years of negative tests for alcohol and the strong testimony from trained professionals who supervised Johnson's probationary period. In short, the board acted contrary to the greater weight of the probative evidence in this record.

{¶ 57} Much energy in this case was devoted to debating whether 250 ng/ml is an appropriate cutoff point for a positive EtG test or whether some other

number is more appropriate. That is the wrong focus. As the advisory and Dr. Skipper plainly recognized, EtG testing remains at such an early stage that good science demands that no test result be given conclusive effect in legal proceedings. EtG testing must be only used with more traditional evidence – such as observations by those living and working with the person being monitored for alcoholism—whether it refutes or corroborates any single EtG test result. In the end, the Medical Board afforded dispositive weight to one positive EtG test coupled only with ambiguous statements by Johnson having little evidentiary value. The board’s decision was not supported by reliable, probative, and substantial evidence.

{¶ 58} Something should be said in closing about the musings of members of the board as they decided Johnson’s case. Just as Johnson’s own informal statements to Bickers speculating about how she might have given one positive EtG test cannot sensibly be given significant weight, so too there is a danger in attaching too much emphasis to statements by board members as they discussed this case and voted sanctions. Nevertheless, one should not ignore the fact that immediately before the board voted, the physician-member who discussed this case at more length than most, and who formally proposed the final sanctions that were then imposed upon Johnson, stated that “if it’s the Board’s conclusion that this is a relapse, she would be in favor of a suspension of less than 90 days [as recommended by the hearing examiner]. She stated that she would probably go for 30 days, the reason being that, if she [appellant] did relapse, this would be a minor one as the Board evaluates relapses. What the Board should do is watch Ms. Johnson a little longer.” Minutes at 17186. Respectfully, the board should

have done exactly that *before* voting sanctions. Watching Johnson a little longer and gathering and considering other up-to-date probative evidence (like the report from the Mayo Laboratory cited at fn. 3, *supra*) would have been very prudent, given the number of years of Johnson's apparent sobriety and the experimental nature of the EtG test. Further investigation would have reflected both good science and the fairness due Johnson under the law. The Medical Board's order entered December 12, 2007 is reversed.

So ordered.