

Challenges and Defenses II

Claims and Responses to Common Challenges and Defenses in Driving While Impaired Cases



U.S. Department
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**National Highway
Traffic Safety
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INTRODUCTION

DUI cases have become some of the most complex in the criminal justice system. As a result, defense challenges are being raised more frequently and are more procedural and scientific in nature. These challenges range from the initial law enforcement stop of the vehicle to the testing procedures used to determine alcohol concentration in blood, breath, and urine samples to possible alternative explanations for those results. This monograph was developed to assist prosecutors and law enforcement in understanding the nature of these challenges. It will assist prosecutors in formulating effective responses to these newer challenges and defenses and include drugged driving, alternative explanations to breath test results, blood draws and testing, scientific uncertainty, and computer source code discovery requests.

The National Traffic Law Center previously published *Overcoming Impaired Driving Defenses*, thanks to a contribution from a charitable foundation, discussing such defense challenges as invalid traffic stops, arrests and Miranda issues, as well as common trial tactics of attacking the investigation, such as driving observations, personal contact, field sobriety tests and breath testing. That monograph may be downloaded from the National District Attorneys Association Web site at www.ndaa.org.

The terms DUI (driving under the influence), DWI (driving while intoxicated or impaired) and OUI (operating under the influence) are considered interchangeable for the purposes of this publication.

Confronting Defense Issues in Prescription or Over-the-Counter Drug DUIs

When the topic of “drugged driving” comes up, most people think almost exclusively of the use of illicit or controlled substances by someone operating a motor vehicle. However, prescription or over-the-counter (OTC) drugs also impair a person’s ability to operate a motor vehicle in a safe and prudent manner. Both prescription and OTC drugs are known to cause mental and physical impairment, especially when multiple drugs are used in combination or drugs are mixed with alcohol.

CLAIM: The defendant is not guilty because he was using an over-the-counter or lawfully prescribed drug.

RESPONSE: Entitlement is not a legally recognized defense.

An entitlement defense encompasses the *mens rea* of “I didn’t do anything wrong, or at least I didn’t know that I was doing anything wrong.” It amounts to the defendant offering a seemingly valid excuse for his behavior. An entitlement defense occurs when the defendant presents a valid prescription or OTC purchase to the jury as justification for the medications found in his system. In doing so, the defendant asserts to the jury that he has done nothing unlawful by consuming the medicine and driving. Dissected: the defendant focuses the jury’s attention on the reason for the impairment and not on his decision to drive. He can justify the impairment but the prosecutor needs to point out that the defendant still can’t justify the decision to drive while impaired.

How a defendant came to be impaired is not an element of proof in a DUI case. However, the prosecutor should make strategic and tactical efforts to satisfy a jury’s curiosity of how impairment occurred. The prosecutor must also educate the jury that they must decide whether the defendant was impaired at the time of driving and not how he became impaired. It matters not that the defendant had a prescription or bought the medication over the counter. By so doing, this will negate the entitlement defense.

If the defendant alleges he possessed a prescription for the drug found in his system, the prosecutor may be able to request the defendant’s prescription records as part of pretrial discovery. If this type of discovery is allowed in the jurisdiction, the prosecutor should request the names and contact information of all doctors writing prescriptions for the defendant and a record of all the filled prescriptions at the time of the crime. The prosecution should actively counter any claim of doctor-patient confidentiality and HIPAA privacy by pointing out the appropriate HIPAA exception statutes (see 45CFR164.512) and the fact that the defendant’s intent to present such a defense creates an implied waiver of medical confidentiality. This information may help the prosecutor in answering the following questions:

- What was the length and depth of the defendant’s experience with the drugs found in his system at the time of arrest?
- Was the medicine being used in conjunction with other medicines?

- Did the defendant follow the directives of his doctor in taking the medication (dosage, timing, accompaniment, etc.)?
- Did the quantity of the medicine and its metabolites in the defendant's system correlate to a proper dosage of the medicine in agreement with the defendant's prescription(s)?
- Did the medicine come with explicit warning labels?
- Did the defendant receive any warnings from the doctor(s) or the pharmacist?
- Was the defendant's long-term consumption pattern consistent, and did it keep pace with the doctor's directives and prescription quantities?
- Did the defendant receive prescriptions from more than one health care provider? If so, were the providers aware of each other?

CLAIM: The defendant was mistakenly or involuntarily intoxicated.

RESPONSE: The defendant drove impaired.

The entitlement defense borrows from and mixes elements of the defenses of mistake and involuntary intoxication. By asserting a privilege to take the medicine, the defendant implies that the impairment occurred unintentionally - that it was a mistake. It also implies a lack of knowledge as to the impairing nature of the substance - that the intoxication was involuntary: "I didn't mean to do it" and "I didn't know it would do that to me."

To prevail on a mistake defense, the defendant must convince the jury that his belief that he was not impaired was reasonable. The defendant's mistaken belief that a prescription entitled him to drive while under the influence is not the fact in question. Nor is the defendant's mistaken belief that he wasn't violating the law. He must be mistaken as to the fact of his impaired state and his belief has to be both actual and reasonable. True, impaired people often believe that they are okay to drive. However, most jurors, when presented with the facts and observed behavior of the defendant by law enforcement officers, often find such beliefs to be unreasonable. One need only analogize this to an alcohol DUI to see how rigorous a burden the defendant faces in this type of defense.

Similarly, in drugged driving cases, the defense of involuntary intoxication contains two key flaws: (1) the crime of DUI does not require proof that the defendant intended to become intoxicated, and (2) involuntary refers to the act of consuming the intoxicant, not the outcome of the consumption.

A person voluntarily consuming a substance with knowledge that it can impair does not give rise to the defense of involuntary intoxication. Involuntary intoxication arises when a person unknowingly consumes an intoxicant, usually as a result of fraud, trickery, or deceit. Defendants may be hard pressed to present credible evidence that the drug procured over the counter or as a result of visiting a healthcare practitioner and then a pharmacy was subsequently consumed involuntarily.

Some defendants seek to preserve the viability of the involuntary intoxication defense by asserting ignorance as to the intoxicating properties of the drug. This type of defense is often presented in argument without any testimony from the defendant. Unless the defendant testifies personally as to their subjective belief, the defense attorney should not be permitted to argue this defense at any point in the case.

If the defendant does testify, the prosecutor should be prepared to confront the reasonableness of the defendant's ignorance. The prosecutor should gather as much evidence as possible pertaining to the medical reason for the prescription (pain relief, muscle relaxation, insomnia, etc.) or OTC medicine, any warnings that accompany the medicine (packaging, inserts, doctor's statements, pharmacist advisements, etc.) as well as the defendant's past experience with the medicine.

CLAIM: The quantitative levels of the drug are below the therapeutic dose and therefore not capable of causing impairment.

RESPONSE: Therapeutic doses of medication may equate to impairment.

Typically, this defense arises when the defendant introduces evidence that the amount of the drug found in their system would not produce impairment. The defense is raised almost exclusively where the quantitative level of the drug measures near or below the minimum therapeutic dosage level. Many jurors may be under the misconception that taking a prescription or OTC drug as part of a medical regime will make a person "all better" or normal. The concept that these drugs might cause impairment may be outside their daily understanding of drugs and how they work.

To effectively combat this defense and jurors' lack of understanding, a prosecutor needs a working knowledge of the drug and its effects. A drug handbook, the Physician Desk Reference (PDR) or a similar publication can be a good source for this information. Likewise, procure any available pharmacy literature, inserts and packaging that come with a prescription or OTC drugs.

If available, speak with a toxicologist about the effects of the drug, what the quantitative amount means and what the lab protocols were for testing. Review with the toxicologist whether the therapeutic or even lower dosage of the drug could have an impairing effect and what those effects may be. Then review the test results specific to the defendant and what, if any, impairing effect that amount may have. Some drugs, by their very nature and even when taken properly, can cause impairment for driving. For example, sleep aids taken at a therapeutic level cause sleep.

If possible, involve a drug recognition expert (DRE) in the case. A DRE's ability to describe drug impairment and driving behavior may significantly assist in the presentation of the prosecutor's case. The information obtained from the toxicologist can be tied together with the DRE assessment and signs of impairment observed by the law enforcement officers and others.

CLAIM: The defendant was unconscious or cannot remember what happened due to the effects of Ambien and therefore not legally responsible for his actions.

RESPONSE: Amnesia by the defendant is not unconsciousness and is not a legal defense.

Ambien is zolpidem tartrate,¹ which is marketed as both Ambien and Ambien CR. Both promote the rapid onset of sleep (usually within 20 to 30 minutes of consumption). Ambien CR (controlled release) is designed to assist a person to fall asleep and stay asleep. Ambien CR is designed to wear off within six or seven hours and thereby permit the person to awaken normally.

Understanding the Ambien Defense

The crux of the Ambien defense is that the defendant was unconscious, and thus unable to make a conscious decision, at the time he chose to drive. Unconsciousness negates the *mens rea* element required in almost all crimes.

The manufacturer's prescription inserts for Ambien CR states:

Complex behaviors such as "sleep-driving" (i.e., driving while not fully awake after ingestion of a sedative-hypnotic, with amnesia for the event) have been reported with sedative-hypnotics, including [z]olpidem. These events can occur in sedative-hypnotic-naïve as well as in sedative-hypnotic-experienced persons. Although behaviors such as "sleep-driving" may occur with Ambien alone at therapeutic doses, the use of alcohol and other CNS depressants with Ambien appears to increase the risk of such behaviors, as does the use of Ambien at doses exceeding the maximum recommended dose.

As noted in the insert, complex behaviors may occur when Ambien is used appropriately; however, such behaviors increase when it is used improperly. Therefore, the prosecutor needs to watch for evidence indicating the improper use of Ambien whenever the defense is raised. Any improper use negates an otherwise legitimate defense; that the person took the drug as prescribed and did not consume any alcohol or other CNS depressants.

¹ Ambien and Ambien CR are registered trademarks of Sanofi-Aventis U.S. LLC.

The defense may claim that a defendant's lack of memory is a result of unconsciousness. The defense, however, often overlooks the distinction between unconsciousness and amnesia. According to *Black's Law Dictionary*, unconsciousness is defined as "being without awareness; not conscious. A person who commits a criminal act while unconscious may be relieved from liability for the act."² In other words, the person is unaware that he is performing an action. Amnesia, on the other hand, is defined in the *Merriam-Webster's Medical Dictionary* as "a loss of memory sometimes including the memory of personal identity due to brain injury, shock, fatigue, repression, or illness or sometimes induced by anesthesia. It may also be a gap in one's memory."³ Unconsciousness may be a legal defense; amnesia may not.

The prosecution bears the burden of proving consciousness. Fortunately consciousness can be proven rather easily. The arresting officer should be able to give the following information as it pertains to the defendant's actions and responses:

- Was the defendant aware of his surroundings?
- Was he capable of answering questions in a cogent and logical manner or was he confused and unresponsive?
- Was the defendant able to identify himself and provide pertinent and accurate personal information?
- Was the defendant able to follow directions?

Upon a showing of consciousness by the prosecution, the defense bears the burden of producing evidence suggesting unconsciousness. Often, the defense offers little more than the self-serving declarations of the defendant claiming to have taken Ambien and being unable to recall anything else afterwards. The defendant's claim of no recollection is amnesia, not unconsciousness. If the defense fails to put forth sufficient proof of unconsciousness, then no unconsciousness defense should be presented to the jury for consideration.

Should the defense succeed in making a showing of unconsciousness, most States would require the defendant's unconsciousness be the result of involuntary intoxication. Recall that involuntary relates to the consumption of the intoxicant, not to the consequences that result from the consumption. The prosecutor should point out that the defendant went to a doctor, received a prescription, had it filled at a pharmacy, may have had the opportunity to speak directly with a pharmacist, and then consumed the drug for the expressed purpose of sleeping. That information could negate a defense claim that he did not know that it could make him perform acts while asleep.

The law generally does not recognize voluntarily intoxication to the point of unconscious as a defense. If it did, then every instance in which a person consumed alcohol to the point of blacking out and then got behind the wheel would be perfectly defensible.

² Black's Law Dictionary, 8th Edition.

³ See, Merriam-Webster's Medical Dictionary, 2012

Additional information that the prosecutor should examine if an Ambien defense is raised includes the following:

- Did the defendant take the Ambien in combination with other drugs or with alcohol?
- When did the defendant take the Ambien in relation to the time of operation of the vehicle?
- Has the defendant had prior episodes of somnambulism (sleepwalking) while on Ambien?
- Has the defendant consumed Ambien in excess of the designated dosage?

ISSUE: Jurors may empathize with the defendant about the use of a legal drug.

RESPONSE: Address the issue of “Identification Bias” during voir dire.

Cases involving drivers impaired by “legal” or licit drugs present some of the most difficult jury and proof issues a prosecutor may ever face. The multitude of factors found in many licit drugged driving cases provide the defense with ample opportunity to conduct an appeal to the jurors’ hearts and minds and to derogate the prosecution’s evidence. Addressing the identification bias commonly found in licit drug DUI cases exposes any entitlement defense and eliminates any technical defenses. The prosecutor has the opportunity to enlighten and empower the finder of fact to recognize and reject the defense’s strategies in an objective, rational, and principled manner.

Driving and legal drug use are near universal in our society. As such, jurors have an instant commonality with the defendant that brings with it both conscious and subconscious self-identification influences. Jurors who empathize with a defendant may go to great lengths to acquit. When a juror can envision himself ending up in the defendant’s chair or thinks “there but for the grace of God go I,” the prosecutor has an identification bias issue that must be confronted.

The defense does not need to explicitly raise the identification bias in favor of the defendant. While most jurors cannot identify with other criminal behavior, they may have little difficulty identifying and empathizing with an otherwise law-abiding citizen who finds himself accused of driving under the influence. However, few potential jurors may feel a kinship with people accused of driving under the influence of illicit drugs like heroin, cocaine or methamphetamine. But, in cases involving OTC and commonly prescribed drugs, the biases can be particularly strong and easily exploited by the defense. The presence of a doctor’s prescription often weights the balance heavily in favor of the defense.

Long-running campaigns to create and increase public awareness of the dangers of drunk driving have been successful. These campaigns have created a mindset in most

people that reflexively equates drinking and driving with “bad behavior.” As a result, many jurors may consciously or subconsciously separate themselves from the accused sitting before them when the accusation is drunk driving. Few public awareness campaigns currently exist to educate the public about the dangers of drugged driving. There is no readily recognizable licit drugged driving message that a prosecutor can invoke to mentally distance the jurors from the defendant. As a result the prosecutor must attempt to show these behavioral differences between the jurors and the defendant.

Prosecutors use voir dire ostensibly to eliminate from the jury panel those individuals who are unable, for whatever reason, to serve as fair and impartial jurors. In licit drug DUIs, the prosecutor must use voir dire to uncover conscious and subconscious biases for the defendant. For example, the prosecutor might ask potential jurors if they take prescription and OTC medicines, and if they operate motor vehicles after taking such medications. This line of questioning identifies those jurors who may have possible conscious and subconscious biases.

Subsequently, the prosecutor may inquire if the jurors are aware that DUI is a crime of personal responsibility. For example, it is legal to drink and drive and a person of legal age does not need a prescription to drink alcohol. What is illegal is driving while impaired. It does not matter if the impairment is caused by alcohol, legal drugs, or illegal drugs. What matters is the decision on the part of the person to get behind the wheel of an automobile while impaired. That decision is fundamental to all DUIs.

Impaired drivers often contend that they thought that they were okay to drive. This mindset forms the core of the entitlement defense. The law does not recognize “I thought I was okay to drive” as a legitimate defense. Yet, it gets put before the jury in a great many drug DUI cases. Whether the defendant thought he was okay to drive or was even aware of the true magnitude of his impairment is not one of the facts that the jury is asked to decide. Often jurors will reject the notion of whether a person thinks he or she is okay to drive as a deciding factor in a DUI case. Many jurors will respond with statements such as “he should have known better” and “he was just fooling himself.” Those expressions of thought and belief play up the personal responsibility theme and aid in neutralizing the identification bias inherent in drug DUIs.

Breath Testing Results: Defense Alternative Explanations

Diabetes

A classic defense in impaired driving cases is to claim the officer mistakenly attributed signs of alcohol impairment to that of a diabetic reaction. Although a common medical condition, diabetes is often misunderstood and misrepresented by the defense. Understanding the disease and its effects on the body will allow prosecutors to dispel the notion diabetics are being wrongfully convicted in DUI cases.

Type 1 Diabetes versus Type 2 Diabetes

Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone made by the pancreas and its function is to convert the food a person eats into energy needed to sustain daily life. There are two main types of diabetes: Type 1 and Type 2.

Type 1 diabetes, previously known as juvenile diabetes, is usually diagnosed in children and young adults. In Type 1 diabetes, the body does not produce the hormone insulin that is needed to convert sugar (glucose), starches, and other food into energy. Only 5- to 10% of people with diabetes have this form of the disease. This fact is important to remember when we later talk about the substance “acetone.”

Type 2 diabetes, previously known as adult onset diabetes, is the most common form of diabetes and accounts for 90- to 95% of all cases. In Type 2 diabetes, the body either does not produce enough insulin or the cells simply ignore the insulin. When glucose builds up in the blood instead of entering the cells, it immediately starves the cells of energy and over time may damage the person’s eyes, kidneys, nerves, or heart.

Hypoglycemia versus Hyperglycemia

When the diabetes defense is raised, the most important distinction for the prosecutor to recognize is the difference between hypoglycemia and hyperglycemia. Either condition can happen to diabetics from time to time. However, the effects of hypoglycemia (low blood glucose) are much different than the effects of hyperglycemia (high blood glucose). The defense will try to intermingle the two conditions to create a story most advantageous to their client.

Hypoglycemia occurs when blood glucose (or blood sugar) concentrations fall below a level necessary to properly support the body’s need for energy throughout its cells. It is often referred to as an insulin reaction because the body either has too much insulin, meals and snacks are missed, or there is an increase of physical activity or exercise. Furthermore, hypoglycemia can occur if a diabetic injects too much insulin, resulting in insulin shock.

Some of the symptoms of hypoglycemia and alcohol impairment can be similar – slurred speech, dizziness, and disorientation. The onset of hypoglycemia is rapid. Left untreated, it can result in loss of consciousness and/or seizure activity. Unlike signs of alcohol impairment, the symptoms of hypoglycemia will not dissipate over time. Treatment is required for the person to get better. It should also be noted hypoglycemia does not produce a fruity smell to the breath and will not cause a false positive and/or elevate a breath alcohol test result.

Hyperglycemia occurs when blood glucose concentrations are high. This happens when the body has too little insulin or when the body cannot use insulin properly. The onset of hyperglycemia is slow. The signs of hyperglycemia include feeling thirsty, constant urination, and a dry mouth. Hyperglycemia will not cause impaired behavior that mimics intoxication in the same manner that hypoglycemia will.

If left untreated, hyperglycemia can lead to a condition called ketoacidosis. This is a serious condition that can lead to a diabetic coma or even death. Ketoacidosis develops when your body does not have enough insulin. Without insulin, the body is not able to use glucose and will begin to burn fat for energy, which produces ketones. Ketones are acids that build up in the blood and appear in the urine. This is a warning that the diabetes is out of control or the person is otherwise getting sick.

Ketoacidosis can produce a fruity acetone-like smell to the person's breath. It is a smell much different than the smell of beer, bourbon or other alcoholic drinks. It is claimed this fruity smell can be mistaken for alcohol, but most officers should be able to tell the difference. In fact, if the officer detects a fruity smell on the person's breath at roadside, it would be expected the person would appear to be very ill. The person could be vomiting and exhibiting signs of fatigue, difficulty breathing (shallow), and confusion. Ketoacidosis is a very serious condition.

Note: Ketosis may exist for conditions other than diabetes. Ketoacidosis is rare in people with Type 2 diabetes. It is most common in people with Type 1 diabetes who have taken too little insulin. Remember, only 5 to 10% of people with diabetes have Type 1 diabetes.

Comparison of Manifestations of Hypoglycemia and Hyperglycemia⁴

| Characteristic | Hypoglycemia | Hyperglycemia |
|---|--|--|
| Onset | Rapid (minutes) | Gradual (days) |
| Mood | Labile, irritable, nervous, weepy, combative | Lethargic |
| Mental status | Difficulty concentrating, speaking, focusing, coordinating | Dulled sensorium, confused |
| Inward feeling | Shaking feeling, hunger, headache, dizziness | Thirst, weakness, nausea/vomiting, abdominal pain |
| Skin | Pallor, sweating | Flushed, signs of dehydration |
| Mucus membranes | Normal | Dry, crusty |
| Respiration | Shallow | Deep, rapid (Kussmaul) |
| Pulse | Tachycardia | Less rapid, weak |
| Breath odor | Normal | Fruity, acetone |
| Neurologic | Tremors late: hyperreflexia, dilated pupils, convulsion | Paresthesia |
| Ominous signs | Shock, coma | Acidosis, coma |
| Blood Glucose Ketones Osmolarity pH Hema- tocrit HCO ₃ | Low: below 70 mg/dl Negative/trace Normal Normal Normal Normal | High: 240 mg/dl or more High/large (only if DKA) High Low (7.25 or less) High Less than 15eEq/L |
| Urine: Output Sugar Acetone | Normal Negative Negative/trace | Polyuria to oliguria High High |

⁴ Chart constructed from information provided by the American Diabetes Association. For more information, please visit www.diabetes.org

What Does This Mean for the Impaired Driving Investigation?

An impaired driving investigation does not occur in a vacuum. Officers gather various facts and observations before making the arrest. The prosecutor reviews these facts before proceeding with the charge. The totality of the evidence is likely to reveal a diabetes defense is without merit. In most instances, the defense either unwittingly or deceptively mixes hypoglycemia with hyperglycemia. Either way, the issue here is the presence of acetone (ketones).

CLAIM: Defendant has diabetes:

Diabetes caused signs and symptoms that mimic intoxication.
Diabetes caused inaccurate breath test readings.

RESPONSE:

Hypoglycemia (low blood glucose) will not affect the results of a breath test for alcohol. If a defendant claims they appeared intoxicated due to low blood sugar, they cannot then claim a false positive or elevated breath alcohol test. Any potential false positive would have to come from high blood sugar (hyperglycemia).

The prosecutor should present all evidence which indicates the defendant was not suffering a diabetic emergency. For example, a person suffering a hypoglycemic (low blood glucose) reaction would not exhibit horizontal gaze nystagmus (HGN). A diabetic with poorly controlled glucose may experience a paralysis of one of the muscles that control the movement of the eye, but this would result in a lack of equal tracking which is different than the horizontal gaze nystagmus.

If a defendant claims the officer's smelling of an odor of an alcoholic beverage was actually a fruity acetone smell on the defendant's breath, this would not be the result of low blood sugar. The defense should not be able to produce enough acetone in his breath to register on today's breath testing instruments. NHTSA conducts acetone tests (with high and low levels of acetone) on all evidence breath test instruments. If an instrument detects acetone, it must be able to flag it as an interfering substance and not use it in the alcohol result, or respond to acetone presence. Devices that respond to acetone, without flagging it are not listed on the conforming products list. The defense will often argue there are thousands of substances in human breath besides alcohol that will read on breath testing instruments, specifically those using infrared spectrometry. In the case of a diabetic they will claim acetone provided a false result on the instrument. Harding provided a review of the literature and determined endogenous (naturally occurring) compounds in human breath do not significantly affect breath alcohol testing instruments.⁵ Furthermore, he reports even though acetone is the only compound to appear in sufficient concentrations to be considered a potential interferent, it has "no deleterious effect on current breath alcohol testing instruments."⁶ Prosecutors are encouraged to review this report as it provides

⁵ Harding, P. (1999, February 15). Report of the Subcommittee on Alcohol: Technology, Pharmacology and Toxicology. Report delivered to the Committee on Alcohol and Other Drugs, National Safety Council, Orlando, FL.

⁶ Id.

a literature summary and reference list of 50 articles. Note: Acetone is not an interferent with breath testing instruments using fuel cell technology.

Strategies to Consider

1. Consider filing a motion *in limine* to prohibit the defendant from raising this defense during cross-examination of the prosecution witnesses and then never introducing any evidence to establish they actually have a diabetes diagnosis.
2. Whether before trial or during trial, the diabetic defense should not be raised unless the defendant has actually been diagnosed with the disease. Request to be provided with (1) the date of diagnosis; (2) whether it is Type 1 or Type 2; (3) the current treating physician; (3) any blood glucose testing records; (4) the defendant's eating patterns; (5) the time of the last insulin injection and the amount prior to the officer contacting the defendant; (6) time of the last meal/snack prior to the officer's contact, to include type of food, portion size, and so forth. The earlier in the discovery process you can obtain this type of information, the better.
3. Contact the National Traffic Law Center to obtain the latest research and information on the diabetes defense.

GERD

Gastroesophageal reflux disease (GERD) is a chronic digestive condition in which stomach contents leak upwards from the stomach into the esophagus, frequently causing heartburn. It occurs when the person's lower esophageal sphincter has either deteriorated or is weakened. Severe symptoms include regurgitation of food or sour liquid (acid reflux) into the upper portion of the esophagus.

Heartburn and acid reflux are common digestive conditions that many people experience from time to time. Doctors generally do not consider it to be GERD unless these signs and symptoms occur more than twice each week. GERD is a digestive condition in which lifestyle changes and/or over-the-counter medications do little more than offer temporary relief. However, studies report most people diagnosed with GERD suffer the symptoms intermittently (60%) while very few (7%) suffer from the symptoms every day.^{7, 8, 9}

CLAIM: Defendant has GERD, which created an artificially high reading or inaccurate result on the breath-testing instrument.

RESPONSE:

While GERD could possibly result in mouth alcohol contamination, the probability of this happening is remote. Furthermore, the standard operating procedures required by State breath testing programs have adequate safeguards in place to provide confidence in the forensic result, such as a valid deprivation period, working slope detector or sample agreement (where applicable). Prosecutors should be aware of the operating procedures approved in their State.

The GERD defense is highly improbable and studies support this contention.¹⁰ Kechagias et al. (1999) were the first to study the effects of GERD on breath testing. The people used in the study suffered from severe conditions of GERD (a fact prosecutors should cite when using this study). The study said, "We conclude that the risk of alcohol erupting from the stomach into the mouth owing to gastric reflux and falsely increasing the result of an evidential breath-alcohol test is highly improbable."¹¹ Gullberg conducted a subsequent study on a single subject with GERD. The study again demonstrated that people suffering from GERD are "capable of providing reliable, unbiased breath alcohol results."¹²

⁷ Locke, G. R., Talley, J. J., Fett, S.L., Zinsmeister, A.R., & Melton, L.J. Prevalence and clinical spectrum of gastroesophageal reflux: a population-based study in Olmstead County, Minnesota. *Gastroenterology* 1997;112:1448-56.

⁸ Nebel, O. T., Fornes, M. F., & Castell, D. O. Symptomatic gastroesophageal reflux: incidence and precipitating factors. *AM J Dig Dis* 1976;21:953-6.

⁹ Greenberger, N. J. Update in gastroenterology. *Ann Intern Med.* 1998;129:309-16.

¹⁰ Kechagias, S., Jonsson, K., Franzen, T., Andersson, L., & Jones, A. W. Reliability of breath-alcohol analysis in individuals with gastroesophageal reflux disease. *J Forensic Sci* 1999;44(4):814-8.

¹¹ Id. at 814.

¹² Gullberg, R. G. Breath alcohol analysis in one subject with gastroesophageal reflux disease. *J Forensic Sci* 2001;46(6):1498-1503.

What Does This Mean for the Impaired Driving Investigation?

Understanding the basic premise of GERD and having a working knowledge of the current studies provides everything a prosecutor needs to successfully combat this defense.

The defendant should have a diagnosis of GERD before the defense is even relevant. Without a diagnosis, all efforts should be taken to bar the defendant from raising this defense. The investigating officer can potentially block this defense by asking two simple questions during their investigation: (1) “Do you have acid reflux?” and (2) “Is it bothering you now?” If the suspect indicates they suffer from GERD, then additional insight can be gained by asking whether they take medication for the condition, how long they have had GERD, and how persistent it is. After the observation period the officer should ask, “Did you have any episodes of acid reflux while you were sitting here?”

There must be unabsorbed alcohol in the stomach for GERD to possibly be an issue. If the defendant is post-absorptive, GERD will have no effect on the breath test because there is no alcohol in the stomach to affect it. The absorption rate is quickest when the alcohol is consumed on an empty stomach. The defendant would have to be suffering an active bout of GERD immediately prior to the breath test for mouth alcohol to be a viable issue. This active bout requires actual material containing alcohol to be brought up from the stomach into the mouth cavity. Alcohol liquid regurgitated into the esophagus is not enough – it must reach the mouth cavity. If there is no alcohol in the stomach, even if liquid stomach contents are regurgitated in the mouth cavity, it will not negatively affect the breath test results.

Prosecutors should educate the fact finder of the impossibility to belch up stomach contents during a continuous exhalation of breath. An expert witness may or may not be necessary to introduce this evidence. The witness should be prepared to testify that the human body has a small flap of cartilage called the epiglottis that acts as a lid to keep solid food and liquid out of the respiratory tract. The throat contains both an air passage (the wind pipe) and a food passage (the esophagus) and if these passages were both open, air could enter the stomach and food could enter the lungs. The epiglottis actually closes over the esophagus when a person blows into the breath instrument, which would block stomach acid from being released into the mouth.

In addition, many people diagnosed with GERD do not suffer severe symptoms. It cannot be stressed enough that heartburn is not enough to potentially falsely elevate a breath-alcohol test. As stated above, it is estimated only 7% of people diagnosed with GERD suffer daily symptoms, and they are not necessarily bouts of bringing stomach contents into the mouth cavity.¹³ Finally, even if the defense is able to surmount all of the

¹³ Even studies using people with severe GERD, where the researchers even tried to provoke acid reflux by applying an abdominal compression belt, did not falsely elevate their breath-alcohol tests. In short, the research shows that people suffering even from severe GERD rarely bring up stomach contents into the mouth, even under extreme conditions. See, e.g., Kechagias, et al, Reliability of breath-alcohol analysis individuals with gastroesophageal reflux disease. *J Forensic Sci* 1999; 44(4): 814-818.

above hurdles, the GERD defense is still highly improbable if sound breath testing procedures are followed. These procedures may include a 15- or 20-minute deprivation/ observation period, duplicate breath testing, instrumental mouth alcohol detection systems, and the observations and fact-gathering conducted by a trained breath test operator. The GERD defense argument assumes none of these safeguards worked. Any one of them, on its own, is sufficient to support the evidentiary weight of the breath test result.

The following defense “expert” strategy is offered as an example of combating the defense through a concession-based cross-examination. Have the defense expert concede the following:

- The concern with GERD is only mouth alcohol.
- The purpose of the 15- or 20-minute deprivation/observation period is to rule out mouth alcohol.
- If there is no alcohol in the stomach (defendant is in the post-absorptive phase) then no alcohol would be brought to the mouth to negatively affect the reading.
- If there was any alcohol in the stomach it would need to be regurgitated into the mouth.
- If alcohol in the stomach were to be regurgitated into the mouth, it would dissipate quickly.
- No alcohol would still be in the mouth at the end of the deprivation/observation period.

In States having duplicate breath testing:

- The duplicate breath tests may rule out mouth alcohol.
- Because any mouth alcohol would cause the reading to spike dramatically and would then dissipate quickly, one of the two breath test readings would be significantly higher than the other.
- Therefore, the fact the breath test operator obtained two readings within 2- to 10 minutes apart and the reading were within a .02 agreement (or whatever your State requirements are) should rule out the possibility of mouth alcohol (GERD) impacting the breath test results.

Finally, remember that impaired driving cases most often have additional evidence of impairment. Do not get so focused on GERD (or any other defense) that you fail to support your case with the totality of the circumstances. Poor driving, defendant’s admissions, observations of the officers/witnesses, field sobriety tests and so forth are all corroborating evidence to support the breath test result.

Suggested Readings

1. Jones, A. W. (2007, January). Gastric reflux regurgitation and potential impact of mouth-alcohol on results of breath-alcohol testing. *Law & Science: DWI Journal* Vol. 22, No. 1.
2. Pehl, C., Wendl, B., Pfeiffer, A., Schmidt, T., & Kaess, H. (1993). Low-proof alcoholic beverages and gastroesophageal reflux, *Dig Dis Sci.*; 38:93-6.
3. Caddy, Gr., Sobell, M. B., Sobell, L. C. (1978). Alcohol breath-tests: criterion times for avoiding contamination by mouth alcohol. *Behav Res Meth Instrument*;10:814-8.

Challenges to Blood Draw and Test Results

Blood testing is an extremely reliable method of determining the alcohol concentration in an individual's system. Nonetheless, defendants frequently litigate their DUI cases and attempt to challenge blood test results. Taking the time to gain a familiarity with the methods and quality control standards employed by State forensic laboratories will greatly assist the practitioner to effectively address these issues. The prosecutor should work with the State forensic scientists to learn the science and better prepare for court. In general, when faced with defense experts, the prosecutor should question the scientific basis for the expert opinion and challenge the interpretation of the relied upon studies. Be prepared to demonstrate that the blood test results are reliable and that science does not support the defense challenge.

CLAIM: The swab used to cleanse the skin prior to the blood draw contained alcohol and contaminated the sample.

RESPONSE:

As a preface, this claim is potentially useful only in attacking DUI alcohol cases. Alcohol will not negatively affect the blood analysis in DUI drug cases.

Two things must occur for the swab to affect the test results. First, liquid from the swab would have to enter the needle and contaminate the sample as a result of the draw sight not being completely dry. Second, the substance on the swab would have to be measured by the blood testing instrument as ethyl alcohol.

In most cases, a swab containing no alcohol is used to cleanse the skin for a blood draw. The most common types of swab used in DUI cases contain benzalkonium chloride (BZK) and povidoneiodine (Betadine). Neither contains alcohol. Accordingly, the first response to this attack is to be proactive. When the swab does not contain alcohol, simply ask the person who drew the blood or the officer who observed the blood draw what type of swab was used to cleanse the skin during direct examination. Bring out that this type of swab is commonly used for blood draws in DUI cases and does not contain alcohol. This will often prevent the defense attorney from even raising the issue. If it does not, get the defense expert to concede the swab used was not a type that contains alcohol and would not negatively affect the test results.

In rare cases, isopropyl alcohol is used to cleanse the skin or it is unknown what type of swab was used and the defense argues it was an alcohol swab. The defense argument can still be defeated. The type of alcohol used to cleanse the skin for a blood draw is isopropyl alcohol. The type of alcohol one drinks and that is measured and reported in a blood test is ethyl alcohol. Most if not all State labs use gas chromatography to determine blood alcohol concentrations. Gas chromatography is a separation science. When used in blood alcohol testing, it detects and reports isopropyl alcohol separately from ethyl alcohol. Accordingly, only ethyl alcohol is reported even if isopropyl alcohol is present. Bring this out through the testimony of the analyst.¹⁴

¹⁴ See the section on contamination for more detail.

If possible, the prosecutor should elicit testimony establishing the person drawing the blood allowed the site to dry before inserting the needle. Even if ethyl alcohol had been used to clean the arm, contamination is unlikely if the alcohol evaporated prior to the draw. Finally, if vacutainer collection tubes were used, the person drawing the blood can testify that he/she removed each tube from the needle and holder before the needle was withdrawn from the arm. This phlebotomy protocol prevents any possible contamination from the skin when the needle is removed from the arm.

CLAIM: The presence of clots in the blood sample artificially increased the reported alcohol concentration.

RESPONSE:

In DUI alcohol cases, blood collection tubes with gray stoppers are commonly used because they contain both an anticoagulant and a preservative (stabilizer). These gray top tubes are specifically recommended for DUI blood draws. The anticoagulant is potassium oxalate and the preservative is sodium fluoride (NaF).

Be proactive. When applicable, elicit testimony the blood was collected in gray top tubes containing an anticoagulant. Have the person who drew the blood or the officer who observed the blood draw testify that a gray top tube was used and the tube contained a white powdery substance indicating the presence of an anticoagulant. The witness can testify that after the blood draw the tubes were inverted as recommended by the manufacturer to ensure the anticoagulant mixed with the blood. The analyst can also testify that inspection before testing verified that there was no undissolved powder and no clots present. These simple steps should provide the ammunition necessary to demonstrate clots are not an issue.

If an anticoagulant is not in the tube used to collect the blood, a whole blood sample will be clotted. While this will not affect the amount of alcohol in the blood sample it may affect the manner in which the alcohol content is reported. The lab can analyze the sample by either using a tissue grinder which breaks up the clots to produce a homogenous sample or it can use the centrifuge method where the sample is spun down and only the serum layer at the top is tested. If the grinder is used some alcohol may be lost through evaporation. Point out this would be to the defendant's benefit. If the centrifuge method is used the serum layer will produce results that report a higher alcohol concentration than that associated with whole blood. Accordingly, a conversion will need to be conducted by an expert.¹⁵

¹⁵ See the section on whole blood versus serum for conversion rates.

A variation of this claim is that the blood contained micro clots and these micro clots somehow make the sample non-homogeneous and artificially raise the reported alcohol concentration. It appears this idea has been extrapolated from situations using centrifuged samples where blood cells are packed at the bottom of the blood tube and the serum layer has a higher alcohol concentration than whole blood would. No peer reviewed, published studies support this claim. It is speculative at best to assume microscopic clots in whole blood could artificially raise the alcohol concentration reported. Experts commonly testify a clot that is big enough to affect the test results would need to be at least the size of a pencil eraser. It is standard practice for an analyst to look for, make note of and address any clots that could negatively affect the test results.

If faced with a defense expert who testifies to the theoretic possibility of this phenomenon, ask for the citation to any published literature confirming the claim. Ask the expert if he/she has seen any evidence of this in his/her own casework. Emphasize all of the measures noted above that guard against clots affecting the analysis.

CLAIM: Improper package and storage of the blood caused the development of yeast (*Candida albican*) artificially increasing the reported alcohol concentration (fermentation).

RESPONSE: Alcohol concentration does not increase during storage.

The studies generally relied on by the defense to support this attack used post-mortem blood specimens. Subsequent studies involving blood samples taken from live individuals indicate the alcohol concentration does not increase during storage after the blood draw even if the blood is not refrigerated and does not contain a preservative.¹⁶

The lack of refrigeration and preservative will likely result in the loss of alcohol concentration in the blood.¹⁷ This would be to the defendant's benefit. If the sample contains sodium fluoride and is refrigerated, the consensus is that no fermentation will occur.¹⁸ Heat should not affect the sodium fluoride. It is a highly stable inorganic salt with a melting temperature above 300 degrees F.

Defense experts will often rely on the Amick and Habben (1997) study to assert fermentation can occur in the blood of live subjects.¹⁹ This study can be easily distinguished from the average blood analysis. During the study, participants intentionally added yeast to blood samples, something that does not occur in DUI investigations. The inoculated samples that were not refrigerated and did not contain sodium fluoride produced small amounts of ethyl alcohol. However, the blood samples containing sodium fluoride did not produce ethyl alcohol even with heavy seeding of the yeast.

¹⁶ Glover, P. L. (2002). The Effect of Heat on Blood Samples Containing Alcohol. Raleigh, NC: Department of Health and Human Services; Winek, C. L., & Louette, J. P. (1983). Effect of Short-term Storage Conditions on Alcohol Concentrations in Blood from Living Human Subjects, *Clinical Chemistry* 11 29 (11): 1959-1960.

¹⁷ Brown, G. A., Neylan, D., Reynolds, W. J., and Smalldon, K. W. (1973). The Stability of Ethanol in Stored Blood, Part I, *Analytica Chimica Acta*, Vol. 66, pp. 271-283

¹⁸ See fn 16, 17.

¹⁹ Amick, G. D., & Habben, K. H. (1997). Inhibition of Ethanol Production by *Saccharomyces Cerevisiae* in Human Blood by Sodium Fluoride, *J Forensic Sci*, 42: 690 – 692.

While it is *theoretically possible* for yeast in blood samples to convert glucose into ethanol, it is not a realistic concern. In order for this type of fermentation to occur several things need to take place. The blood would have to be collected in a tube that did not contain sodium fluoride because sodium fluoride will starve yeast. Glucose would have to be present in the blood and the blood would need to be stored at greater than room temperatures. It is unlikely that each of these conditions would be present. Even if it were, yeast would also have to be present in the defendant's blood. An individual with *Candida albicans* in his/her blood would be very sick. Affected individuals are usually hospitalized and without rapid treatment may die.

CLAIM: The State has not demonstrated that the gray top blood tubes used to draw the blood contained the proper chemicals to ensure a valid analysis.

RESPONSE:

It is standard practice for the State's expert to inspect the blood tubes prior to analysis and report any unusual appearance or odor. If the analyst reports that the sample was not clotted, it can be assumed that the quantity of anticoagulant was sufficient. The manufactures of the blood kits introduce the anticoagulants and preservatives as a mix. Accordingly, the fact that the blood did not clot indicates that both the anticoagulant and preservative were present. As noted in the storage issues section, the lack of a preservative (stabilizer) should only result in the faster loss of blood alcohol concentration which would benefit the defendant. It will not lead to a situation where the results report an artificially high alcohol concentration. Admitting the manufacturer's certification for the type of tubes that were used may also assist with defending against this claim. Elicit testimony from the analyst regarding the lab's procedures for inspecting and analyzing the tubes and have the person who drew the blood, or officer who observed it, testify that the tubes contained a white powdery substance.

CLAIM: Serum and plasma have higher alcohol contents than whole blood. Because BAC is measured in terms of whole blood, the serum and plasma results are misleading.

RESPONSE: Because they contain more water than whole blood, serum and plasma samples will each have a higher alcohol content than whole blood. Serum and plasma can be expected to have equivalent alcohol concentrations.

The ratio between the alcohol concentration of serum and that of whole blood depends on the water content of each sample and will vary among individuals. Serum to whole blood alcohol ratios appear to range from .91 to 1.31 with the extreme ranges being rare. The higher the ratio, the lower the blood alcohol reading will be after the conversion. Generally, expert testimony will be necessary to make the conversion. Most experts agree that if one has a serum sample, a reliable estimate of the whole blood alcohol content can be obtained by dividing the serum alcohol concentration by 1.14 to 1.16. Many State forensic scientists divide by the more conservative 1.20. This conversion method is unlikely to prejudice the defendant.

Example:

Assume serum alcohol concentration 0.200 g/dL

$$\frac{.200 \text{ g/dL}}{1.20} = 0.166 \text{ g/dL} = \text{average whole blood equivalent}$$

Blood alcohol testing in hospitals is often performed on serum or plasma. Accordingly, if the blood analysis was conducted at a hospital, it would be prudent to contact the hospital to determine if the test was conducted on whole blood or serum/plasma. The reported results may specify this. If serum/plasma was tested, a conversion will need to be conducted. The expert should be contacted to determine the conversion ratio he or she uses prior to court. This information should be disclosed to the defense.²⁰

CLAIM: The blood testing instrument measured and reported something other than ethyl alcohol and this artificially increased the reported BAC.

RESPONSE:

Gas chromatography is the method used by most, if not all, State labs to test alcohol in blood. It is a universally accepted separation science. When using this method, the instrument separates the sample in a column and measures the amount of the substances it tests for as they come out of the column at different, specific times. Because it separates volatile substances such as ethyl alcohol and isopropyl alcohol before analysis, gas chromatography is very specific. It does not allow interference by other substances.

Method validation has demonstrated gas chromatography's ability to differentiate other volatile substances from ethyl alcohol. This validation has been conducted extensively by the scientific community. The individual lab that conducted the analysis should also have conducted method validation and should be able to provide supporting testimony in court.

To ensure accuracy when testing blood for alcohol, State labs generally conduct duplicate tests on DUI blood samples. Duplicate testing analyzes a subject's blood twice using separate portions of the sample. Dual columns are also often used resulting in testing each portion of a duplicate test twice. Dual column gas chromatography is considered the "gold standard" in the scientific community for analyzing blood alcohol.

²⁰ For more information on this matter, see Alcohol Toxicology for Prosecutors, National District Attorneys Association, 2003, available at www.ndaa.org/publications.html.

If it is used, virtually any chance of co-elution of the sample will be eliminated because the nature of the material in the columns will cause different compounds to exit the column or elute at different times. In order for a substance other than ethyl alcohol to contaminate a blood alcohol result, another volatile compound must be present at a high enough concentration to be registered by the gas chromatograph. Few substances fit in this category. In addition, the substance would have to have the same retention time as ethyl alcohol on both columns of the chromatograph.

CLAIM: The tubes used to collect the blood were expired, so the results cannot be trusted.

RESPONSE:

The blood collection tubes that are used with the vacutainer system come with an expiration date. This is because as the tubes age, the vacuum in the vacutainer loses its effectiveness and will not pull blood into the tube as efficiently as new tubes. When the tubes do get old, vacuum loss is the only issue. The anticoagulants and preservatives that are contained in most tubes used for DUI blood draws do not expire or go bad with age. Both are inorganic salts that are highly stable. Because vacuum loss is the only issue, if the tube efficiently drew a full amount of blood this is a good indicator that sufficient vacuum was present.

If the tube does not fill completely due to the vacuum loss, there could be an excessive amount of air in the tube. This could result in the loss of alcohol in the sample and a lower reported alcohol concentration which of course would not prejudice the defendant. Another risk is that an expired tube will not draw enough blood for analysis. This is especially true in DUI drug cases because more blood is required to test for drugs than alcohol.

If the vacuum loss somehow affected the tube's seal, the most likely result would be the loss of alcohol concentration or other volatile substances such as inhalants.

CLAIM: Arterial blood is a much better indicator of actual BAC levels when compared to venous blood.

Defense experts will claim that because arterial blood is the blood flowing to your brain, it is the "impairing" blood. Some will also testify that the venous blood could be as much as .05 higher than the arterial blood. Because the blood drawn was venous blood, they assert the results do not reflect impairing blood or .05 should be subtracted from the State's blood test results.

RESPONSE:

As a preliminary matter, this entire line of testimony should be objected to as irrelevant. Generally, the defense uses this testimony to attack the blood test results in an attempt to try to get the reading below the State's *per se* limit. Most *per se* statutes prohibit a person from driving or physically controlling a vehicle if the person has "an alcohol concentration" of .08 g/dL or greater. Alcohol concentration is defined differently in different States. None of the definitions appear to contain even the suggestion that the

blood must be either arterial blood or venous blood. The statutes, therefore, permit a blood alcohol reading to establish the element of alcohol concentration/content without regard to the question of whether the blood is arterial blood or venous blood. Basically, because it is illegal to drive or physically control a vehicle if the blood alcohol reading exceeds the *per se* limit, it is irrelevant under the *per se* statutes whether the blood is arterial or venous. It is also irrelevant whether the reading from one might slightly differ from the other. Blood is blood and it is illegal to drive if anywhere in one's body the blood has an alcohol concentration above the *per se* limit. The State's toxicologist will establish that the result admitted at trial is an accurate measurement of the blood sample and is, therefore, an accurate measurement of the defendant's alcohol concentration at the time the blood was drawn.

Challenge the scientific support for this defense claim. A study on the topic by Jones, Norberg, and Hahn concluded that during the absorptive phase, arterial blood has a higher alcohol concentration averaging a maximum of .01, which rapidly diminishes to almost nothing once absorption stops.²¹ Once in the post absorptive phase, venous blood and arterial blood are almost exactly the same. The study found that the average difference between the two was about .001 to .002. (in terms of actual BAC level in gr/100 ml blood), not the .05 some defense experts put forward. Moreover, the study found that arterial-venous differences are at their most pronounced in body tissues with low blood flow to mass ratios such as skeletal muscle. In body tissues that are highly vascularized with high blood flow to mass ratios such as the brain and kidneys, the arterial-venous blood difference is negligible. Consequently, arterial-venous differences are negligible in the brain.

CLAIM: The gray top tubes used to collect the blood samples were not FDA-approved. Therefore, the jury and/or judge should not trust the results.

RESPONSE:

The manufacturers of the blood kits and tubes generally get FDA approval for their products. In some instances, the entire kit may be FDA-approved. Implicit in this is approval is the fact that the contents of the kits, including the tubes, are FDA-approved for collecting blood. Other companies have the tubes individually approved by the FDA. If asked, most companies will provide documentation of FDA approval.

²¹ Jones, A. W., Norberg, A., & Hahn, R. G. (1997). Concentration-Time Profiles of Ethanol in Arterial and Venous Blood and End-Expired Breath During and After Intravenous Infusion, *J Forensic Sci*, 42(6): 1088-1094.

Measurement Uncertainty

No measurement is absolutely perfect. Whether measuring breath alcohol or a length of wood, variation in measurement is always present.²² Unavoidable fluctuations in process result in minute variations in measurements. This is not to say that every measurement is flawed or unreliable. However, this does not prevent defense counsel from trying to amplify this measurement uncertainty into reasonable doubt in DUI cases involving breath test instruments or blood tests.

Variations in measurement are categorized as either “systematic” or “random.” Systematic is simply a variation that repeats whenever the measurement device is used. An example is a bathroom scale that perpetually reads two pounds lighter than the true value. We can either adjust the scale to read “zero” before we stand on it, or we can add the two pounds to get the true result. In alcohol testing, there can be similar systematic variations occurring during the various calibration processes. A testing instrument can produce results that are repeatedly low or high by a slight amount. The instrument measures close to the known value of the reference solution, but it consistently reports slightly low or slightly high throughout the calibration testing. The instrument is deemed accurate because the variation from the known reference is within acceptable tolerances. However, the consistent high or low systematic error affects every future reading from the instrument. If the instrument reports 0.01 low during calibration, then we may safely assume that it will report 0.01 low during actual use in the field. Systematic error (also known as bias) can be corrected, and therefore does not constitute part of measurement uncertainty.

As the name suggests, random error is erratic. Metrologists, scientists who specialize in measurement science, characterize random variations in measurement as “uncertainty.” Uncertainty does not cast doubt upon the validity of the measurement. Quite the contrary, quantifying the uncertainty of a measurement gives added confidence to the measurement.²³ A bare measurement result provides no information about the quality of the underlying measurement process. If nothing is known about the laboratory or the process providing the test results, then no confidence can be placed in the results. They could be close or far from the true value.

²² Gullberg, R. G. (2006). Estimating the measurement uncertainty in forensic breath-alcohol analysis, *Accred Qual Assur* 11: 562–568.

²³ Eurachem/CITAC Working Group. (2004). §2.1.4., p. 4. In S. L. R. Ellison & A. Williams, (eds.), *Quantifying Uncertainty in Analytical Measurement*, 3rd Edition. (Eurachem/CITAC Guide CG4). Uppsala, Sweden: Eurachem.

Determining an Uncertainty Measurement

In a high quality testing process, an uncertainty measurement calculation yields a small range of possible random variation, also called a confidence interval. In a less rigorous program, an uncertainty calculation yields a much broader confidence interval (i.e. the range of possible values covers a larger range of values both below and above the stated value). A confidence interval is the range within which the true value should fall with a level of confidence stated in the form of a coverage factor (“K”), a percent confidence level or a variance range. (E.g. K=2; 95%; or +/- .01%). A measurement result is considered complete only when accompanied by a quantitative statement of its uncertainty.²⁴

CLAIM: The chemical test results without an accompanying uncertainty measurement value are not scientifically reliable.

RESPONSE:

Currently, no validated or generally accepted technique for determining uncertainty measurement value has evolved for either breath or blood alcohol testing. In fact, the use of measurement uncertainty in biological testing is relatively rare. Biological testing includes not only forensic toxicology but its much larger parent disciplines: Laboratory Medicine, Pathology, and Analytic Chemistry. Instead of measurement uncertainty, biological testing relies upon rigorous quality control systems to ensure a quality measurement result.²⁵ By controlling the quality standard of each process that contributes to the end product—we know the result is high quality. We describe a measurement result from a high quality lab as accurate. An accurate test is one that produces a result close to the estimated true value. Scientists, technicians, prosecutors and others confidently rely upon the biological testing program results because of the high quality standards inherent in the program. Biological test users recognize the results are not perfect; however, the results are still scientifically valid and very useful despite the absence of an uncertainty measurement. Consequently, demand for uncertainty measurement in medical and forensic laboratories remains scant.

At present, no breath test program in the United States provides measurement uncertainty for every breath test. Only a few programs in the United States provide uncertainty for alcohol in blood. However, breath and blood testing have been accepted in courts as scientifically reliable for decades. The prosecutor should highlight for the court that the testing processes are well established and accepted by the scientific community. The proponent of the motion to exclude the evidence bears the burden of proving there has been a change in the acceptance of the testing processes in the relevant scientific community.

²⁴ Taylor, B. N., & Kuyatt, C. E. (1994, September). Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results (NIST Technical Note 1297). § 2.1. . Gaithersburg, MD: National Institute of Standards and Technology. Available at <http://physics.nist.gov/Pubs/guidelines/TN1297/tn1297s.pdf>; Working Group 1 of the Joint Committee for Guides in Metrology, Bureau International des Poids et Mesures. (2008, September). Evaluation of measurement data -- Guide to the expression of uncertainty in measurement, First Edition. § 7.1.4. (Report No. JCGM 100:2008). Sèvres, France.

²⁵ Westgard, J. (2010). Managing Quality vs. Measuring Uncertainty. *Clin Chem Lab Med*; 48(1): 31-40.

This is not to say the failure of the forensic community to adopt uncertainty measurements has not gone unnoticed. In the 2009 National Academy of Sciences Report on Forensic Science, the committee stressed the need to incorporate uncertainty measurement in forensic laboratories.²⁶ Efforts at including uncertainty measurement had been made prior to the report's issuance. Since the 1980s, metrologists have worked to persuade organizations that uncertainty measurement should be utilized in test reporting. The International Standards Organization (ISO) has introduced uncertainty measurement concepts for testing and calibration laboratories. For forensic laboratories, the standard is ISO 17025. For medical laboratories, the standard is ISO 15189. These standards provide over 400 different program requirements ranging from laboratory organization to communication. One requirement is calculation of measurement uncertainty and the form of reporting it.²⁷ However, the proposed standards provided no direction up- on how to implement uncertainty measurement. They merely state the need to do so.

Laboratories seek recognized accreditation to demonstrate they follow good practices. The American Association of Laboratory Accreditation (A2LA) is the largest accrediting agency for medical laboratories, accrediting around 2,000 medical facilities (48% of all accredited labs). Likewise, the American Society of Crime Laboratory

Directors (ASCLD) accredits approximately 100 forensic laboratories in the United States. ASCLD has adopted the ISO standards. ASCLD makes accreditation conditional upon compliance with the ISO standards and failure to comply with the ISO standards may result in a loss of accreditation. However, neither ASCLD nor A2LA require compliance with uncertainty measurement to obtain or maintain accreditation. Both agencies explain that the introduction of uncertainty measurement is new to laboratories and their clients and is undergoing a pragmatic phasing in process.²⁸

Simply put: There has been no change in the relevant scientific community with regard to the continued acceptance and reliability of blood and breath alcohol testing. The science continues to progress and move forward. This includes aspiration of establishing an accepted methodology for determination and inclusion of uncertainty measurement. However, the failure to include an uncertainty measurement does not render results derived from a quality testing process scientifically unreliable.

CLAIM: The bare chemical test result without a confidence interval misleads the jury.

RESPONSE:

The chemical test result should and will be evaluated along with and in light of other evidence presented to the finder of fact at trial. This includes evidence such as the

²⁶ Committee on Identifying the Needs of the Forensic Sciences Community. (2009, August). Strengthening Forensic Science in the United States: A Path Forward. Pp. 195-97. Washington, DC: National Academies Press.

²⁷ ISO 17025, Test and calibration methods and method validation, § 5.4.1; Estimation of Uncertainty, § 5.4.6.

²⁸ ASCLD/LAB Inter'l, Updated approach to Uncertainty of Measurement Requirements, Sept. 14, 2008; A2LA, P103 – Policy on Estimating Measurement Uncertainty for Testing Laboratories, Nov. 6, 2009.

defendant's driving abilities (or lack thereof), emotional demeanor, physical appearance, and mental processing abilities. Whether or not evidence misleads the jury turns on the evidence presented in the case and not just the evidence being challenged by the defense. Testimony regarding an instrument's calibration-maintenance records and the federally mandated $\pm 5\%$ inaccuracy (95% accuracy) interval also conveys to the jury the message that no test is absolutely perfect.

There is often an erroneous assumption that the jury will only consider the test result in reaching a verdict. While a scientist in a lab setting may have only a test result and be forced to interpret it in a vacuum, jurors do not face the same dearth of information. The prosecution must demonstrate to the jury the scientific accuracy and reliability of a test result. This means providing much more than a bare result in isolation. The fact the prosecution could offer *more* about a chemical test by providing a statistical evaluation does not diminish the validity of the test actually provided. The prosecution's failure to provide more information does not mean the information provided was not scientific or reliable. The defense's argument that nothing may be offered except the most rigorous analysis possible is intentionally misguided. It is an argument the defense may make to the jury, and it may find merit there. However, it is not an evidentiary preclusion argument that the court should accept.

Whether or not the evidence is helpful and sufficient is a classic jury question. What weight to attribute to the scientific evidence produced at trial is a determination to be made solely by the finder of fact.

Challenges to the Source Code of Breath Testing Instruments

What is source code?

The first question most prosecutors and judges ask is “What is source code”? Source code is the bridge of communication between humans and computers. It is a collection of instructions from the programmer to the computer written in computer programming language. However, the computer is not able to read or understand the source code. Consequently, the source code is assembled by a compiler into machine language, which is sometimes referred to as object code. In the context of the source code issue and alcohol testing, every computer application has source code.²⁹

To respond to a motion for production of the source code, a prosecutor should start by reviewing the discovery rules and have a basic understanding about computer programming to be able to explain to the court why it is not subject to discovery. It is also helpful to review the State’s approval process and requirements for breath test instruments.

Like most things in today’s society, alcohol test instruments are run by computers. This has several advantages, including the elimination of human error and the elimination of discretion or manipulation by the test operator. Like every computer application, alcohol testing requires software, hence source code. This includes test instruments used to test blood and urine. In fact, virtually all of the instruments at a State crime lab are run by computers and have source code. The software for breath alcohol test instruments is contained on microchips installed in the computer of the test instrument.

CLAIM: The defense needs the source code in order to be assured of the accuracy of the breath test instrument and its results.

RESPONSE: The source code is not relevant because it is not necessary to ascertain the accuracy and reliability of the test result.

People use electronic devices every day without knowledge of the source code used to create them. Computers, cell phones, calculators, microwave ovens and even cars were created using source codes. A determination of a device’s accuracy and reliability can be made by examining its output, commonly referred to as black-box testing.

²⁹ One exception is the assembly languages, which are low level languages. In addition, the terms source code and object code are inapplicable for script languages.

The source code issue is not a *Frye* or *Daubert* issue. Infrared spectrometry follows the scientific method and is generally accepted in the scientific community. In the *Frye* or *Daubert* context, the burden is on the State to meet the appropriate legal standard, but there is no requirement that this burden be met with a particular method. With regard to the source code, the standard can be met through black box testing methods.

In the context of breath alcohol testing, pre-use validation/verification takes place at a variety of levels. Instruments must meet specific performance and accuracy requirements prior to being listed on the Conforming Products List published in the *Federal Register*. Individual States often conduct their own validation studies of instruments before certifying their use in that State. Often local laboratories or agencies will then conduct a validation study before approving an instrument for the field. This may include testing of live subjects with known alcohol levels, perhaps verified with a simultaneous blood test. It may have also included the use of simulator solutions or dry gas compounds.

Once the instrument is in the field, ongoing verifications are performed through various methods to insure continued accuracy. Prosecutors should become knowledgeable with the validation studies and procedures used in their jurisdiction.

In addition, the prosecution should solidify the validity of the instrument by enumerating for the Court the numerous self-diagnostic and automated safeguards built into the instrument, as well as the actual testing protocols employed in the field. The indicia of impairment observed by the arresting officer may further corroborate the test result.

The defense may claim that this type of black-box testing is not sufficient to ensure the accuracy of the instrument and still request the source code for examination by their own expert. Software testing methods are divided into three types: black-box testing, white-box testing, and grey-box testing. Black-box testing is when the tester does not have the source code or knowledge about the inner workings of the software. White-box testing is when the tester has access to the internal data structures and algorithms, including the source code. The newest type of software testing is grey-box testing, which is a combination of black-box and white-box testing. The software tester has knowledge of the internal data structures and algorithms to design test cases, but uses a black-box method.

The scientific experts in the alcohol breath testing community have long accepted black-box testing to establish the validity and accuracy of breath testing instruments. Black-box testing is recognized as having advantages over white-box testing. Notably, the black-box tester is an unaffiliated opinion with no ties, prejudices, or preconceived notions as to the software. Consequently, black-box testing often finds software problems that white-box testing does not.

It is the position of the National Safety Council Committee on Alcohol and Other Drugs that access to the Source Code of the software of an evidential breath-alcohol analyzer is not pertinent, required, or useful for examination or evaluation of the analyzer's accuracy, scientific reliability, forensic validity, or other relevant characteristics, or of the trustworthiness and reliability of analysis results produced by the analyzer. These matters can be and have been fully assessed and examined by multiple other well established and recognized methods and procedures in common use worldwide; and many other adequate and appropriate means exist to challenge evidential breath-alcohol analysis results. <http://www.nsc.org>

CLAIM: The defendant has a right to discovery of the source code and the prosecution must produce it.

RESPONSE: The source code is not in the possession, custody or control of the prosecutor or State.

Generally, rules of discovery apply only to items within the possession, custody, or control of the prosecution or State. The source code is in the possession, custody, and control of the manufacturer of the test instrument, who generally refuse to share it because of intellectual property interests. Several States have ruled that the source code is not subject to discovery because it is not in possession, custody or control of the prosecution and cannot be obtained.³⁰ The only State to rule that the source code is in the possession, custody, or control of the State is Minnesota.³¹

The source code is clearly not within the possession, custody, or control of the prosecution. Under the rules of discovery, the source code is not subject to discovery for that reason and the courts should require defendants to conduct their own investigation by obtaining the source code directly from the manufacturer, who may be willing to provide it conditioned on a non-disclosure agreement.

Practice Tips

One defense tactic may be to request disclosure of the source code but have never sought or retained the services of an expert. In the event the Court is inclined to still grant disclosure and depending upon your evidentiary and discovery rules, request the court to require the defense to make an offer of proof that the defense has retained experts to analyze the source code, including contract documentation, and to identify how the analysis will be done, and when it will be done.

³⁰ City of Fargo v. Levine, 747 N.W.2d 130 (N.D. Apr. 17, 2008); New York v. Robinson, 53 A.D.3d 63 (N.Y. App. June 10, 2008); Nebraska v. Kuhl, 741 N.W.2d 701 (Neb. Ct. App. November 6, 2007); Georgia v. Hills, 663 S.E.2d 265 (Ga. App. May 15, 2008); Arizona v. Bernini, 2009 WL 922471 (Ariz. App. Div. Apr. 7, 2009); Connecticut v. Burnell, 2007 WL 241230 (Conn. Super. Jan. 18, 2007).

³¹ Minnesota v. Underdahl/Brunner, 767 N.W.2d 677 (Minn. 2009); Minnesota v. Crane, 766 N.W.2d 68 (Minn. App. 2009).

Inquiry could also be made as to what format the defense attorney is requesting the source code be provided. Do not agree to a particular format for disclosure when the State does not have it and without consulting with the manufacturer. For example, it could be provided in a printed hard copy. Alternatively, there are various electronic formats. If an electronic format is requested, this raises questions about how this is to be accomplished in terms of hardware, software and location.

In the context of forensic alcohol testing, source code represents the intersection of two areas of expertise: software engineering and breath testing. This requires two layers of expert witness testimony. A prosecutor should challenge a defense witness' qualifications to testify about matters outside of the witnesses' area of expertise.

RESOURCES AND REFERENCES

National Highway Traffic Safety Administration

www.nhtsa.gov/impaired

www.stopimpaireddriving.org

www.nhtsa.gov/Research/Behavioral+Research

National District Attorneys Association

www.ndaa.org

National Traffic Law Center:

http://www.ndaa.org/ntlc_home.html

National Association of Prosecutor Coordinators www.napcsite.org

White House Office of National Drug Control Policy (ONDCP)

<http://www.whitehousedrugpolicy.gov/>

Federal Motor Carrier Safety Administration (FMCSA)

<http://www.fmcsa.dot.gov>

International Association Chiefs of Police

www.theiacp.org

National Sheriffs' Association

<http://www.sheriffs.org/>

Drug Evaluation and Classification Program

<http://www.decp.org>

National Transportation Safety Board (NTSB)

<http://www.nts.gov/>

National Safety Council

<http://www.nsc.org>

Other Publications Available From the National Traffic Law Center

The following publications were made possible by contributions from corporate foundations:

Basic Trial Techniques for Prosecutors

The Drug Evaluation and Classification Program

Breath Testing for Prosecutors Drug Toxicology for Prosecutors Alcohol Toxicology for Prosecutors

Prior Convictions in Impaired Driving Prosecutions Overcoming Impaired Driving Defenses Admissibility of Horizontal Gaze Nystagmus Crash Reconstruction Basics for Prosecutors Hardcore Drunk Driving Prosecutorial Guide

The following publications were made possible in cooperation with NHTSA:

Horizontal Gaze Nystagmus: The Science and the Law Children and Cars – A Potentially Lethal

Combination Traffic Safety Resource Prosecutor's Manual

The Criminal Justice System: A Guide for Law Enforcement Officers and Expert Witnesses in Impaired Driving Cases

DWI Prosecutor's Handbook

To obtain copies of any of these publications, contact the National Traffic Law Center, National District Attorneys Association.

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