

IN THE SUPREME COURT OF FLORIDA

CASE NO. SC16-1752

JOHN GOODMAN,

Petitioner,

v.

L.T. CASE NOS.

4D14-3263

Div. Admin. Hearing No. 14-1918RX

FLORIDA DEPARTMENT OF
LAW ENFORCEMENT,

Respondent.

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RECEIVED, 12/05/2016 04:38:26 PM, Clerk, Supreme Court

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PREFACE

Petitioner, John Goodman, seeks review of the decision of the Fourth District, affirming a final order of the Division of Administrative Hearings, denying his rule challenges. The respondent is the Florida Department of Law Enforcement (“FDLE”).¹

The Fourth District certified two questions of great public importance:

(1) ARE THE CURRENT RULES OF THE FLORIDA DEPARTMENT OF LAW ENFORCEMENT (FDLE) INADEQUATE UNDER *STATE v. MILES*, 775 So. 2d 950 (Fla. 2000), FOR PURPORTEDLY FAILING TO SUFFICIENTLY REGULATE PROPER BLOOD DRAW PROCEDURES, AS WELL AS THE HOMOGENIZATION PROCESS TO “CURE” A CLOTTED BLOOD SAMPLE?

(2) ARE THE PRESENT RULES SIMILARLY INADEQUATE FOR FAILING TO SPECIFICALLY REGULATE THE WORK OF ANALYSTS IN SCREENING BLOOD SAMPLES, DOCUMENTING IRREGULARITIES, AND REJECTING UNFIT SAMPLES?

(A:10-11). This Court has jurisdiction to review the certified questions under Article V, section 3(b)(4), Florida Constitution.

¹ All emphasis is supplied unless otherwise indicated. The symbol “R:[page]” refers to the record on appeal. The transcript is contained at volumes IV and V of the record. All record and transcript references are to the .pdf page of the record. The symbol “A:[.pdf page]” refers to the Appendix to Initial Brief.

Goodman challenged rules 11D-8.012 and 11D-8.013 of the Florida Administrative Code. Goodman argued that rule 11D-8.012 is invalid because it does not set forth sufficient rules for proper blood collection, which are necessary to ensure reliable blood samples. Rule 11D-8.013, which governs blood analysis, is insufficient because it does not require blood analysts to screen blood samples, document any irregularities, and reject compromised samples. Because of these insufficiencies, the rules do not ensure scientifically reliable results for use in criminal proceedings.

STATEMENT OF THE CASE AND FACTS

A. Background

Goodman was involved in a motor vehicle accident in February 2010, and was charged with DUI Manslaughter/Failed to Render Aid and Vehicular Homicide/Failed to Give Information or Render Aid (R:10, 319).² Goodman's blood was drawn after the accident for blood alcohol testing, pursuant to Florida's implied consent statutes (R:10). *See* §§ 316.1932, 316.1933, 316.1934, Fla. Stat. (2016). In his criminal case, Goodman moved to exclude the blood alcohol test results from evidence based, in part, upon the improper method used to collect his blood for testing (R:10-11). Goodman asserted that the nurse who collected his

² Goodman has since been convicted and sentenced. His appeal from his criminal convictions is pending in the Fourth District, Case No. 4D14-4479.

blood used a different needle—a 25-gauge butterfly needle—than the needle contained in the law enforcement blood collection kit—a larger, 21-gauge needle (R:11). A 25-gauge butterfly needle has tubing that connects the needle to the blood collection tube, so the blood flows from the person, through the needle, through the tubing, and then into the collection tube (R:647-48). A butterfly needle is commonly used to draw blood from infants (R:11). Law enforcement blood collection kits contain straight needles, not butterfly needles (R:539, 542, 591-92). Straight needles draw blood directly from the person into the collection tube with no attached tubing (R:645). Goodman argued that the nurse’s decision to deviate from the needle in the blood collection kit resulted in a blood sample that was unfit for testing (R:11).

The trial court in the criminal case ruled that Goodman’s challenge was an attack on the sufficiency of the rules of the Florida Administrative Code governing the collection and labeling of blood for testing under the implied consent laws (R:11-12, 114-15). That court deferred action on the sufficiency of these rules to the Division of Administrative Hearings (“DOAH”) and reserved ruling on Goodman’s motion to exclude the blood alcohol test results pending resolution of Goodman’s rule challenge by DOAH (R:11-12, 115).

B. Goodman’s DOAH petition challenged rules 11D-8.012 and 11D-8.013

Goodman filed a DOAH petition to determine the invalidity of rules 11D-8.012 and 11D-8.013 (R:10-27).³ Goodman argued rule 11D-8.012 fails to prescribe the gauge and type of needle to be used in blood alcohol testing (R:18-21). Using the wrong needle, like the 25-gauge butterfly needle used to collect his blood, leads to irregularities in the blood sample that render the sample unreliable for testing (R:18-21).

Goodman also asserted that rule 11D-8.013, which governs the issuance of permits for blood analysts, fails to ensure that the standard operating procedures approved under the rule incorporate a process to identify and reject unreliable samples from the testing process (R:21-23). He alleged both rules are invalid because they fail to ensure scientifically reliable blood alcohol test results for use in criminal proceedings, i.e., that compromised blood samples are not tested (R:18-23).

C. Testimony at the final hearing

At the final hearing, Goodman presented testimony from four witnesses: (1)

³ A copy of chapter 11D-8 of the Florida Administrative Code, the “Implied Consent Program,” is contained at appendix pages A:12-20. This is the version of chapter 11D-8 that was in effect when the ALJ issued the final order in this case.

Patrick Murphy, Ph.D., the current manager of the Alcohol Testing Program for the FDLE (R:453-73); (2) Dr. Frederick Kiechle, an expert in clinical pathology and the medical director of Clinical Pathology Services for the Memorial Health System in South Broward County (R:474-518); (3) Laura Barfield, an expert in blood alcohol analysis and the former manager of the Alcohol Testing Program for the FDLE (R:520-611); and (4) George Souza, an expert in phlebotomy (blood collection) and the technical director of the Division of Pathology, Laboratory Support Services for Massachusetts General Hospital (R:618-93). Goodman also presented deposition testimony of two Palm Beach County Sheriff's Office ("PBSO") Crime Laboratory blood analysts who hold FDLE permits—Dustin Tate Yeatman (R:126-57) and Xiaoquin Shan, Ph.D. (R:126-210).

The FDLE presented testimony from two witnesses: (1) Bruce Goldberger, Ph.D., an expert in forensic toxicology, blood alcohol analysis, and laboratory practices, and a professor and director of toxicology at the University of Florida College of Medicine (R:702-88); and (2) Patrick Murphy, Ph.D. (R:789-823).⁴ The FDLE did not present an expert in blood collection. The testimony at the final hearing is summarized below.

⁴ Patrick Murphy's Ph.D. is in English (R:457, 790). He does not have a permit to analyze blood and is not an expert in blood alcohol analysis or blood collection (R:458-59, 464). Before he joined the FDLE in 2006, he had no formal education in toxicology; his education was in liberal arts (R:457).

1. Needles used in blood collection

Two different types of needles are used in blood collection—a straight needle and a butterfly needle (R:645-48). Needle gauge (size) and type are extremely important factors with blood collection (R:645). There is an inverse relationship between the gauge and the size of the needle (R:646). A smaller needle has a larger gauge, and vice versa (R:646).

The national standard for blood collection requires use of a 21 or 22-gauge straight needle (R:645). A straight needle attaches directly to the glass blood collection tube with no attached tubing (R:645). Law enforcement blood collection kits contain straight needles that are typically 21-gauge (R:539, 542, 591-92). They do not contain butterfly needles (R:539, 542, 748-49).

A butterfly needle gets its name from two little wings on the outside of the needle (R:647). A butterfly needle has tubing that connects the needle to the collection tube (R:647-48). The blood flows through the needle, then through tubing, and finally into the collection tube (R:647-48). Because of the tiny needle and the tubing, it takes blood longer to flow through a 25-gauge butterfly needle than a 21-gauge straight needle, leaving more time for clotting in the butterfly needle and its tubing (R:651, 666-69, 740-41). There is no anticoagulant in the

tubing of a butterfly needle (R:667, 742). Microclots that form in the tubing can pass into the collection tube (R:667).

25-gauge butterfly needles are used almost exclusively for pediatric blood collection (R:649). Outside of their pediatric use, 25-gauge butterfly needles can be used on patients whose veins have been severely damaged by long-term chemotherapy (R:649). Souza testified that use of a 25-gauge butterfly needle to draw blood from a healthy adult is below the standard of care (R:651, 675). He would notify the laboratory if he ever used a 25-gauge butterfly needle to collect blood because there would be some bias in the test result, which he would want the physician or analyst reading the test results to be aware of (R:649, 653).

2. Approved methods for blood alcohol testing under Florida’s implied consent laws require testing whole blood using the gas chromatography method.

Rule 11D-8.002(14) of the Florida Administrative Code defines “blood” as “whole blood.” (A:13). “Whole blood” is blood as it flows from the body and contains all of its constituents—white blood cells, red blood cells, platelets, and all of the unformed elements that are dissolved in the blood plasma (such as proteins and enzymes) (R:459-60, 486, 642, 711). Under Florida’s implied consent laws, only whole blood may be tested for blood alcohol analysis (R:533-34, 711; A:13).

See Fla. Admin. Code R. 11D-8.002.

The only approved blood testing method is the gas chromatography method (R:711-12).⁵ The headspace gas chromatography method measures the alcohol in the gas above the blood sample, which is called the headspace gas (R:557-58). Under this method of testing, a sub-sample of blood is drawn from the collection tube and mixed with an “internal standard” (R:556, 713). The internal standard is a liquid that dilutes the blood and makes the blood alcohol results quantifiable (R:562-63, 579, 713).

After the internal standard is added to the sub-sample, the blood is heated and pressurized, causing the alcohol in the blood sample to equilibrate into the headspace above the sample (R:557-58). A sample of the headspace gas (which contains the vaporized alcohol) is pushed into a column in a machine called a gas chromatograph (R:558-59, 560-61). The gas interacts with a coating on the inside walls of the column, causing the individual components of the gas to separate (R:510-61). A detector is then used to measure the components and determine the amount of alcohol in the sample (R:561).

⁵ At the time of trial, a second method called the Alcohol Dehydrogenase (Enzymatic) method was also approved under the rules (R:765; A:17). During the appeal, the FDLE amended the rules to remove the enzymatic method. *See Fla. Admin. Code R. 11D-8.011* (amended July 29, 2015).

3. Improper blood collection techniques lead to compromised samples.

The testimony at the final hearing showed that using the wrong size and type of needle and improperly using the tourniquet can cause irregularities in blood samples. These irregularities include clotting and hemoconcentration. Using the right needle and properly using a tourniquet makes the irregularities highly unlikely (R:667-68). Souza would not expect clotting or hemoconcentration to occur during blood collection using a 21-gauge straight needle with proper tourniquet application (R:667-68).

a. Clotting

Clotting is the result of a biochemical reaction by which blood coagulates, changing from a liquid to a gel (R:665). When blood has completely clotted, the liquid portion that is separated from the clot is called serum (R:665). A blood clot changes the composition of the blood sample (R:185).

Using the wrong size and type of needle can cause blood to clot (R:666-69). Blood collected with a small (25-gauge) butterfly needle has a higher chance of clotting than blood collected with a 21-gauge straight needle (R:651, 666-69, 740-41). When using a butterfly needle, the blood is drawn through the needle and travels through tubing before going into the collection tube (R:647-48). Since it

takes longer for blood to flow through a 25-gauge butterfly needle and its tubing, as compared to a larger straight needle, clots can form in the tubing (R:602, 666-69, 740). The tubing does not contain any anticoagulant (R:667, 742). Microclots that form in the tubing can pass into the glass collection tube (R:602, 667, 669). The anticoagulant contained in the glass collection tube will not dissolve clots that have already formed; it is only meant to prevent new clots from forming (R:602, 766).

Clots occasionally form inside the glass blood collection tube, even when the tube contains an anticoagulant (R:599-601). Clotting inside the collection tube usually indicates a problem with the blood collection process (R:599-600). Removing a clot is against best practices and does not fix the problem with the sample (R:670-71).

Both parties' experts agreed that clotting can render blood alcohol analysis unreliable (R:569-70, 726, 728, 730, 767-78). Clotting artificially elevates the alcohol content in a blood sample because it changes the ratio of liquid to solid (R:569-70, 767-68). Alcohol follows water and other liquids, like plasma (R:570). When a sample contains more plasma than the "whole blood" flowing through the body, the alcohol content in the sample will be higher than the alcohol content in

the body (R:569-70, 573-75, 719, 730). In addition, clots can clog the pipette used to take a sub-sample of the blood for testing, rendering the sample unreliable for testing (R:568-69, 727-28). Clotting can occur as soon as the blood is taken if not properly mixed with an anticoagulant (R:769).

Dr. Goldberger, the FDLE's expert, stated that if a sample is clotted, and it is a legal blood sample, it should be rejected in the forensic setting (R:753-54). If the clot affects the ability to pipette the sample, it will affect the accuracy and reliability of the blood alcohol test (R:728). When this happens in his laboratory, he and his analysts note on the report that "the sample is not suitable for testing" (R:728). Dr. Goldberger characterized proper collection, selection and submission of specimens of "paramount importance" for analytic results to be accurate (R:744). He testified ensuring a clotted sample is not tested goes to the reliability of the sample for testing (R:768-69).

All experts agreed that clotting increases blood alcohol levels under the gas chromatography testing method (R:569-70, 573-74, 726, 728, 730, 767-78). A clotted blood sample could overestimate the blood alcohol content by 15% (R:767-68, 719-21, 729-30). The two PBSO Crime Laboratory analysts agreed that clotting increases the blood alcohol content in the sample (R:143-45, 149-50, 186,

190).

b. Hemoconcentration

A second irregularity that occurs because of improper collection methods is hemoconcentration.⁶ Hemoconcentration allows more plasma to go through the needle into the blood sample than is contained in the blood circulating in the subject's body (R:573). Hemoconcentration increases the alcohol content in a blood sample because it raises the water content in the sample, and alcohol follows water (R:573-74, 656). Hemoconcentration can result from applying the tourniquet for too long or from using the wrong needle (R:573, 656, 777).

4. The FDLE's Alcohol Testing Program

Under the Alcohol Testing Program, the FDLE issues permits to blood analysts, conducts proficiency testing of blood analysts, and prescribes the approved methods of blood alcohol testing under the implied consent laws (R:461). The FDLE does not employ blood collection experts in the Alcohol Testing Program (R:465). Murphy testified that the FDLE does not regulate blood

⁶ Hemoconcentration is a loss of fluid to the tissues that results in an increase in the concentration of red blood cells. See www.merriam-webster.com/medical/hemoconcentration (last visited Dec. 1, 2016).

collection personnel and does not have the authority to prescribe blood collection practices (R:466-67, 471).

Blood analysts must apply to FDLE for a permit to test blood under the implied consent laws (R:462). *See* Fla. Admin. Code R. 11D-8.013(1). In addition to the applicant's qualifications, the application must include a complete description of the proposed analytical procedures⁷ that the analyst uses to test blood alcohol levels (R:462, 804-05). *See* Fla. Admin. Code R. 11D-8.013(1). The analyst must also demonstrate proficiency in blood alcohol analysis by satisfactorily determining the blood alcohol level in five samples provided by the FDLE (R:461-62, 804-08). *See* Fla. Admin. Code R. 11D-8.013(2). The FDLE's proficiency testing does not include compromised samples, such as samples containing clots (R:821-22).

Experts for both parties testified blood samples should be screened for irregularities and irregular samples excluded or at least documented in lab results (R:470, 566, 753). The FDLE rules have nothing in place to ensure an analyst or the lab is not testing clotted samples and reporting those results (R:768). The FDLE rules do not require that the analysts' standard operating procedures include

⁷ The laboratories' proposed analytical procedures were also called standard operating procedures and "SOPs" at the hearing (R:805).

screening blood samples for irregularities, such as clotting or hemoconcentration (R:463, 583, 820-21). Nor do the FDLE's rules require analysts to document irregularities and reject compromised samples (R:463, 820-21).

Murphy testified the FDLE rules are meant to be a minimum framework for blood analysts testing blood under the Implied Consent Program (R:804). Blood analysis must be performed in an accredited laboratory, in accordance with good laboratory practices, to produce accurate and reliable results (R:470-71). However, Murphy admitted that the FDLE rules do not require that the laboratories where analysts work be accredited (R:471). Nor do the rules require that testing be performed in accordance with good laboratory practices, besides those practices listed in the FDLE rules (R:470-71).

Murphy would expect an analyst to document a compromised sample in the laboratory record (R:470). However, he admitted that he would not reject an application for a blood alcohol testing permit on the basis that the standard operating procedures do not include documenting irregularities and rejecting compromised samples (R:463).

Laura Barfield testified that blood samples should be visually inspected by

an analyst before testing to look for clots and irregularities in color (R:565-67). Analysts should document abnormal findings during this examination because irregularities in the sample can render it unreliable (R:566-68). Rule 11D-8.013 does not require gross inspection of a blood sample before analysis or documentation of irregularities (R:568).

Dr. Goldberger admitted that standard operating procedures should include a written procedure for determining whether a blood sample is suitable for testing, and that analysts should document when a sample is not suitable for testing (R:753). It is important that every sample be analyzed with the same method (R:753). Dr. Goldberger also admitted that a blood sample that is clotted, or shows evidence of tampering, decomposition, or any signs indicating that the integrity of the sample has not been maintained, should be rejected for forensic blood alcohol testing (R:753-54). He agreed blood samples can change during and after collection, so good laboratory practices “require examination of biological specimens prior to analysis” (R:778). “Visual observations should be made, and recorded of [blood] specimens” and “presence of clots . . . should be especially noted” (R:778-79). Dr. Goldberger testified that the analyst’s ability to detect a clot depends on how well that analyst has been trained (R:785-86).

Goodman presented two blood analysts from the PBSO Crime Laboratory who hold FDLE permits: Xiaoquin Shan, Ph.D. and Dustin Tate Yeatman (R:126-57, 159-210). Yeatman tested Goodman's blood in this case (R:161). Yeatman testified that the standard operating procedures of the PBSO Crime Laboratory do not require analysts to visually inspect samples or to document clotting or any other irregularity (R:172-73, 179-80, 182-83). However, he would document a clotted sample (R:170, 172-73, 185). Importantly, Yeatman acknowledged a clotted sample is not whole blood (R:185). And he agreed that clotting increases blood alcohol levels (R:186, 190). Yet, he admitted the PBSO Crime Laboratory tests clotted samples for blood alcohol content (R:185). Yeatman could not recall any sample being rejected by an analyst at his laboratory because of an irregularity in the sample (R:180).

Dr. Shan also tests clotted samples in the PBSO Crime Laboratory (R:143, 150). She first removes the clots and then analyzes the sample for blood alcohol level (R:143, 150). If the clot is small, Dr. Shan will report her results as whole blood analysis and consider the results to be accurate and reliable (R:143, 150). Dr. Shan will make a note of the clot on the lab report because clotting can elevate blood alcohol content (R:143-45, 150-51). Dr. Shan admitted that she cannot see every clot in a sample with her naked eye (R:142-43). Dr. Shan also admitted that

it is important to test blood that is as close to the blood in circulation as possible when the results will be used in a DUI case (R:144). Dr. Shan could not recall ever rejecting a blood sample because of irregularities in the sample (R:138).

Souza testified it is “against best practice” to open the tube, remove the clot, close the tube and submit it for testing (R:670). If the analyst sees a clot that big, the sample should be rejected (R:671).

D. The ALJ denied Goodman’s petition to invalidate rules 11D-8.012 and 11D-8.013.

The ALJ denied Goodman’s rule challenges, rejecting Goodman’s argument that rules 11D-8.012 and 11D-8.013 are invalid for failing to ensure that compromised samples are rejected (R:392-423; A:21-43).⁸ The ALJ recognized that clotting (which he called “coagulation”) can occur even in glass evacuation tubes containing a preservative and an anticoagulant (R:413; A:34). The ALJ found that deficiencies in the collection process, such as using an improper needle, or failing to mix the sample properly with the anticoagulant, can lead to clotting (R:413; A:34-35). Clotting alters the ratio of liquid to solid in the blood sample, which can increase the concentration of alcohol in the liquid portion of the sample (R:415, 419; A:35, 39). Nevertheless, the ALJ ruled that there was insufficient

⁸ A copy of the final order is contained in the appendix at pages A:21-43.

evidence to show that clotted samples **always** produce unreliable results, so it is not necessary to exclude clotted samples from testing (R:415, 420; A:35, 39). According to the ALJ, “The evidence fails to establish that the mere presence of coagulated blood in a sample **inevitably precludes** the withdrawal of an appropriate subsample.” (R:420; A:39).

The ALJ concluded by ruling that the omission of a requirement for needle gauge and tourniquet use “is of no material consequence” so there is no basis to invalidate rule 11D-8.012 (R:418; A:38). The ALJ also ruled that the omission of a requirement to exclude clotted samples from testing does not require invalidation of rule 11D-8.013 (R:419-20; A:39-40). The ALJ did not address hemoconcentration. Goodman appealed.

E. The Fourth District affirmed, but certified two questions of great public importance to this Court.

With regard to rule 11D-8.012, the Fourth District found that “there was sufficient evidence in the record to support the ALJ’s findings of fact as to the effect of clotting on the accuracy of blood testing.” (A:6). Referring to Dr. Goldberger’s testimony, the Fourth District found that clotting, even when increased by the use of a butterfly needle, does not render blood alcohol testing inaccurate because the sample can be homogenized—a “[v]ery easy” process,

“necessary only with larger clots.” (A:6-7). The Fourth District also found that “[r]egardless of the size of the clot, testimony also revealed that standard practice is to ‘mix[] the sample’ prior to testing, in order to avoid problems such as those created by clots.” (A:7). The Fourth District concluded that “‘a sample collected using a 25-gauge needle [is] valid for blood alcohol determination using headspace gas chromatography’ so long as proper procedures are followed.” (A:7). The Fourth District held that clotting is different from the lack of refrigeration at issue in *State v. Miles*, 775 So. 2d 950 (Fla. 2000), because clotting can be “rectified after the fact.” (A:7).

The Fourth District rejected the challenge to rule 11D-8.013 as unnecessary and “over-regulation” (A:8). The Fourth District concluded that “[t]he rules at issue, when combined with basic laboratory practices, are sufficient to protect the safety and interests of the court system and defendants alike.” (A:9). The Fourth District affirmed the ALJ’s determination that the current rules are adequate, but certified two questions of great public importance to this Court (A:10-11).

SUMMARY OF ARGUMENT

Rules 11D-8.012 and 11D-8.013 of the Florida Administrative Code fail to satisfy one of the core policies of the implied consent law—ensuring reliable

scientific testing of blood samples for use in court proceedings. These rules are inadequate in several ways, all of which deprive criminal defendants of due process. The Fourth District erred in affirming the decision of the ALJ denying Goodman's petition to declare these rules invalid and inadequate.

Rule 11D-8.012 contains no standards for needle and tourniquet use during blood collection. Proper blood collection procedures are critical to the accuracy and reliability of blood test results. The ALJ found that improper procedures can lead to irregularities, like clotting, that raise blood alcohol levels. Yet, the ALJ rejected Goodman's rule challenge because these inaccurate results are not inevitable. The ALJ's ruling, which the Fourth District affirmed, violates this Court's decision in *State v. Miles*, 775 So. 2d 950 (Fla. 2000).

The Fourth District erred by finding that homogenization "cures" the problems caused by improper collection procedures. The Fourth District improperly made fact findings regarding homogenization, exceeding its role as an appellate court. And, the facts in the record are insufficient to support the Fourth District's conclusion on homogenization. In all events, if homogenization is a "cure," then it is a critical procedure that must be in the implied consent rules to ensure scientific reliability. It is not contained in those rules, which are, thus,

invalid.

Rule 11D-8.013 is invalid because it fails to require screening blood samples for irregularities, documenting any irregularities, and rejecting samples unfit for testing. And, the FDLE approves standard operating procedures that do not require analysts to perform these procedures. Even though the importance of these procedures was undisputed, the ALJ and the Fourth District ruled they need not be in the rules because they are part of standard laboratory practice. This Court rejected that argument in *Miles*. This Court should quash the decision of the Fourth District.

ARGUMENT

POINT I

THE CURRENT RULES OF THE FLORIDA DEPARTMENT OF LAW ENFORCEMENT (FDLE) ARE INADEQUATE UNDER *STATE v. MILES*, 775 So. 2d 950 (Fla. 2000), BECAUSE THEY FAIL TO SUFFICIENTLY REGULATE PROPER BLOOD DRAW PROCEDURES, AND FAIL TO REQUIRE THE HOMOGENIZATION PROCESS TO “CURE” A CLOTTED BLOOD SAMPLE.

A. Standard of review

This Court reviews the ALJ’s findings of fact to determine whether they are

supported by competent, substantial evidence. *See Dorcely v. State Dep't of Bus. & Prof'l Regulation*, 22 So. 3d 834, 836 (Fla. 4th DCA 2009). The conclusions of law of the ALJ and the Fourth District are reviewed de novo. *Id.*

B. General law on Florida's implied consent statutes and the FDLE rules

1. The core policies of Florida's implied consent laws

Florida's implied consent laws require all persons accepting a driver's license in Florida to consent to a blood or breath alcohol test upon being arrested for driving under the influence. *See* §§ 316.1932, 316.1933, 316.1934, Fla. Stat. (2016); *Robertson v. State*, 604 So. 2d 783, 789 n.4 (Fla. 1992). Two "core policies" of testing underlie Florida's implied consent law: (1) to ensure reliable scientific testing for use in court proceedings by establishing uniform, approved testing procedures; and (2) to protect the health of those being tested. *Robertson*, 604 So. 2d at 789 & n.5 (citing *State v. Bender*, 382 So. 2d 697, 699 (Fla. 1980)); *see also State v. Miles*, 775 So. 2d 950, 953 (Fla. 2000).

2. FDLE's rules serve an important function in criminal cases, and their adequacy is critical.

Florida's implied consent statutes delegate to the FDLE the responsibility of formulating rules governing the process by which a person's blood is analyzed to determine alcohol content. *See Miles*, 775 So. 2d at 952 (citing section

316.1933(2)(b), Florida Statutes (1995)). The FDLE formulated the rules in chapter 11D-8—its “Implied Consent Program”—pursuant to this delegation of legislative authority.

If the State can demonstrate substantial compliance with the FDLE’s rules, certain statutory presumptions arise in a criminal case, including the presumption of the integrity of the testing process and the presumption of impairment. *See* § 316.1934(2) & (3); *Miles*, 775 So. 2d at 952. Thus, it is critical that the FDLE’s rules are sufficient to ensure reliable blood samples and accurate results. *See Miles*, 775 So. 2d at 953; *Bender*, 382 So. 2d at 699.

In a criminal trial, to receive the presumptions of impairment and integrity of the testing process, the State need only prove that the test complied with the FDLE rules. *See* § 316.1934(2) & (3); *Miles*, 775 So. 2d at 952. If these rules are inadequate to ensure reliable samples, as the evidence demonstrates here, the presumptions are fundamentally flawed and ultimately could deprive the defendant of the opportunity to confront the blood test evidence offered against him. Criminal defendants lose some aspects of due process through the implied consent law. The FDLE rules are supposed to counterbalance this loss of due process by ensuring that testing performed in compliance with those rules produces reliable

and accurate results. This is a core policy of the implied consent law. *See Miles*, 775 So. 2d at 953; *Bender*, 382 So. 2d at 699.

Two FDLE rules are at issue in this appeal. Rule 11D-8.012 regulates blood collection, while rule 11D-8.013 regulates the methods of blood alcohol testing and the permitting of blood analysts. They are included in the appendix to this brief (A:17-18).

3. Grounds for declaring administrative rules invalid

Section 120.52(8), Florida Statutes (2016), defines an “invalid exercise of delegated legislative authority” as “action that goes beyond the powers, functions, and duties delegated by the Legislature.” Three of the six statutory grounds for declaring a rule invalid are at issue here:

(c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;

(d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;

(e) The rule is arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational.

§ 120.52(8)(c)-(e).

C. Rule 11D-8.012 fails to ensure scientifically reliable test results.

Rule 11D-8.012 is inadequate under section 120.52(8)(c), (d) and (e) because it fails to establish adequate standards to ensure scientifically reliable blood alcohol test results. Specifically, the rule sets no standards for needle gauge and tourniquet use and no requirement to homogenize clotted samples.

This Court addressed the FDLE's responsibility with respect to its implied consent rules in *State v. Miles*, 775 So. 2d 950 (Fla. 2000). This Court made clear that the FDLE rules must **ensure** reliable test results, not just produce reliable results most of the time:

Without provisions for proper maintenance of a blood sample, the integrity of the sample is guaranteed only from the point of testing, regardless of the length of time that passes before the FDLE actually performs the testing. In the instant case, we note the testing did not occur until some fourteen days after the blood draw. Under the evidence presented in the trial court, fourteen days without refrigeration **may well have impacted** the integrity of the blood sample. **Hence, as found by the trial court, the absence of maintenance standards renders rule 11D-8.012(3) inadequate and inconsistent with the purpose of the implied consent law as it relates to ensuring the reliability of test results.** As such, the State is not entitled to the presumptions of impairment associated with the implied consent statutory scheme.

Id. at 955. This Court held that rule 11D-8.012 did not comply with the core policies of the implied consent laws, as stated in *State v. Bender*, 382 So. 2d 697,

699 (Fla. 1980). *Miles*, 775 So. 2d at 952, 953-54. This Court's analysis in *Miles* is controlling here, where the evidence showed that rule 11D-8.012 fails to **ensure** scientifically reliable results.

- 1. Rule 11D-8.012 contains no standards for proper needle gauge and tourniquet use, which are necessary to produce reliable blood samples for testing.**

Rule 11D-8.012 is invalid because it fails to set forth standards for proper needle gauge and tourniquet use. These standards are necessary to **ensure** that a blood sample will produce scientifically reliable blood alcohol test results for use in a future criminal proceeding.

There was no dispute over the importance of using proper blood collection techniques when drawing a sample for testing under the implied consent laws. The evidence at the final hearing proved that using the correct needle and properly applying the tourniquet are critical to ensuring accurate blood alcohol test results (R:494-95, 645, 677-78). Dr. Goldberger, the FDLE's expert in forensic toxicology, blood alcohol analysis and laboratory practices, agreed that proper collection techniques are necessary to ensure a scientifically reliable blood alcohol analysis, calling it "of paramount importance" (R:744). He agreed that blood being collected for law enforcement use to obtain samples for alcohol testing

should be collected with the kits created for that purposes (R:749).

In *Miles*, this Court recognized that the steps that occur before a blood sample is analyzed are critical to the integrity of the sample and the reliability of the test results. 775 So. 2d at 955. There, this Court addressed the lack of standards for proper maintenance of a blood sample. *Id.* Here, the issue is the lack of proper standards for collection of the blood sample. Like *Miles*, the evidence shows the collection rule is inadequate.

Using the wrong needle, like a 25-gauge butterfly needle, can cause irregularities like clotting in the sample (R:494-95, 513-14, 602, 651, 666-69, 677, 740-41). Clots can form in the tubing apparatus of the butterfly needle and pass to the collection tube (R:602, 666-69, 740). The anticoagulant in the collection tube does not dissolve the clots (R:602, 766). Clots can also clog the pipette, the instrument used to withdraw a sub-sample from the sample for testing (R:569, 728-29). Improper tourniquet use can cause hemoconcentration (R:513-14, 573, 655-56, 777). Yet, rule 11D-8.012 does not set forth any standards for needle size or tourniquet use.

The evidence directly refuted the Fourth District's conclusion that it is

appropriate to test clotted samples. The evidence also refutes the FDLE's position in the Fourth District that clotting only affects the ability to obtain a subsample, not the accuracy and reliability of the test results. All experts agreed that clotting increases blood alcohol levels under the gas chromatography testing method (R:569-70, 573-74, 726, 728, 730, 767-68). According to Dr. Goldberger, a clotted blood sample could overestimate the blood alcohol content by 15% (R:767-68; *see also* R:719-21, 729-30). Dr. Goldberger stated that if a sample is clotted, and it is for forensic use, it should be rejected (R:753-54). Ensuring a clotted sample is not tested goes to the reliability of the sample for testing (R:768-69). The two PBSO Crime Laboratory analysts agreed that clotting increases the blood alcohol content in the sample (R:143-45, 149-50, 186, 190).

The ALJ recognized that improper blood collection can cause clotting. The ALJ found that “[c]oagulation⁹ can occur for a variety of reasons, **including the type of needle used in the collection process** or the failure to mix the sample properly with the anticoagulant contained in the tube” (R:414; A:34). “Coagulation alters the ratio of liquid to solid in the sample and **can increase the concentration of alcohol in the liquid portion of the sample**” (R:415; A:35). The ALJ determined that a blood sample can contain clots, **even when the glass**

⁹ The ALJ used the term “coagulation” to refer to clotting in the final order.

collection tube contains an anticoagulant, as required by rule 11D-8.012 (R:414; A:34). The ALJ also found that “the accuracy of the blood alcohol level reported by the subsample is related to the degree of coagulation present in the sample” (R:415).

The ALJ completely failed to address the impact of hemoconcentration on blood alcohol testing. The evidence showed that hemoconcentration changes the ratio of red blood cells to the watery portion of the blood, increasing the alcohol concentration (R:573-74, 656, 777). Hemoconcentration can result from applying the tourniquet for too long or from using the wrong needle (R:573, 656, 777).

The ALJ denied Goodman’s rule challenge because irregularities in the blood sample will not “inevitably” produce inaccurate results (R:415; A:35; *see also* R:419-20; A:39-40). The ALJ applied the wrong standard. It is not enough that a test can produce reliable results most of the time. *See Miles*, 775 So. 2d at 953-54 & n.5; *Bender*, 382 So. 2d at 699. A blood test that produces accurate results **most of the time** is insufficient. *See Miles*, 775 So. 2d at 955. The Supreme Court made this point in *Miles*, where the state’s experts testified that there was only a “remote” chance that lack of preservatives would lead to a higher blood alcohol level, and in some circumstances, it could lead to a lower blood

alcohol level. *Id.* at 954 & n.5. This remote possibility was enough for this Court to conclude that rule 11D-8.012 was inadequate. *Miles*, 775 So. 2d at 955.

The purpose of the implied consent rules “is to **ensure** reliable scientific evidence for use in future court proceedings.” *Bender*, 382 So. 2d at 699; *see also Miles*, 775 So. 2d at 953-55. To “ensure” means to make certain. *See* www.merriam-webster.com/dictionary/ensure (last visited Dec. 1, 2016). Rules promulgated under the implied consent laws must ensure scientifically reliable test results because compliance with those rules leads to presumptions in criminal trials. *See Miles*, 775 So. 2d at 953, 955; *Bender*, 382 So. 2d at 699. Rule 11D-8.012 does not satisfy the core policies of the implied consent laws because it fails to ensure reliable test results. It is, therefore, invalid. *See* § 120.52(8)(c), (d) & (e), Fla. Stat. (2016).

The Fourth District relied on *State v. Friedrich*, 681 So. 2d 1157 (Fla. 5th DCA 1996), to support the following statement:

[t]he take away point is that ‘a sample collected using a 25-gauge [is] valid for blood alcohol determination using head space chromatography’ so long as proper procedures are followed, and that Rule 8.012 is not invalid for failure to specify the required needle size for drawing blood.

(A:7). But the facts in *Friedrich* are different, as was the issue. *Friedrich* was not

a rule challenge. The defendants there had moved to exclude evidence of breath test results in DUI cases because of potential problems with the composition of the stock solution used to test the accuracy of intoxilyzer machines. 681 So. 2d at 1160. Expert testimony showed no witness had had a problem with the shelf life of the solution because it was quickly used up in the field and the consistency of the machine's results confirmed using different bottles of solution posed no problem with shelf life. *Id.* at 1161-62. Further, the undisputed evidence showed the stock solution was prepared in a way that was sufficiently accurate for scientific purposes, and the FDLE kept detailed, publically available information about each batch of stock solution. *Id.* at 1162-63. Observing that “[i]nsubstantial differences” for approved techniques and actual testing in any given case do not render the tests or results invalid, the court deemed the defendants’ attack on admissibility “speculative and theoretical.” *Id.* at 1163.

Conversely, there is nothing “speculative” or “theoretical” about the problems caused by improper collection techniques. And the problems caused by using a 25-gauge butterfly needle or misapplying the tourniquet are not “insubstantial differences.” The ALJ found that drawing blood with a 25-gauge butterfly needle can cause clotting (R:414). Clotting alters the ratio of liquid to solid in the blood sample, which can increase the concentration of alcohol in the

liquid portion of the sample (R:415, 419). Unlike *Friedrich*, the absence of collection standards on needle size and type and tourniquet use renders the rules insufficient to “ensur[e] the reliability of test results.” *Miles*, 775 So. 2d at 955.

Rule 11D-8.012 already regulates certain aspects of the blood collection process. It regulates the type of antiseptic that must be used before the blood draw (non-alcoholic), the type of collection tube (glass evacuation), and the contents of the collection tube (anticoagulant and preservative) (A:17). *See Fla. Admin. Code R. 11D-8.012*. Thus, the beginning and end of the collection process are already regulated, only the middle—needle and tourniquet use—is left without any standards. As a result, blood could be drawn with any instrument or object (e.g., a piece of glass) and the tourniquet used in any way, and there would be no violation of rule 11D-8.012. The lack of any standards governing critical aspects of blood collection renders rule 11D-8.012 inadequate.

The ALJ’s findings on clotting were sufficient to declare rule 11D-8.012 invalid for failing to set standards for use of the proper needle. *See Miles*, 775 So. 2d at 953-54 (holding that rule 11D-8.012 must **ensure** scientifically reliable analysis). Rule 11D-8.012 does not include adequate regulations of blood collection to ensure that blood samples are a representation of the “whole blood” in

the individual's body. The rule is invalid under section 120.52(c), (d) and (e).

- 2. If, as the Fourth District concluded, homogenization is the “cure” for clotting, then the implied consent rules are inadequate because they do not require homogenization.**

The Fourth District accepted the ALJ's fact finding regarding clotting:

[T]here was sufficient evidence in the record to support the ALJ's finding of fact as to the effect of clotting on the accuracy of blood testing. . . . [T]he testimony was clear that a smaller needle can increase clotting, and that clotting can affect the accuracy of a blood test.

(A:6). Referring to Dr. Goldberger's testimony, however, the Fourth District found that clotting, even when increased by the use of a butterfly needle, does not render blood alcohol testing inaccurate because the sample can be homogenized—a “[v]ery easy” process, “necessary only with larger clots.” (A:6-7). It is apparent from the Fourth District's rationale that it believes homogenization is a critical step in the process, which can cure the problems clots create.

There are two flaws with the Fourth District's conclusion: (1) it engaged in improper fact finding; and (2) it misinterpreted the scant evidence of homogenization in the record. Further, if, as the Fourth District found, homogenization is a critical step to prevent artificially inflated blood alcohol levels, then the implied consent rules are inadequate under *Miles*. The implied

consent rules do not require analysts to homogenize clotted samples before testing.

a. The Fourth District engaged in improper fact finding.

Appellate courts are required to accept the lower court's fact findings and cannot reweigh the facts or engage in original fact finding. *See Marcoux v. Marcoux*, 475 So. 2d 972, 972 (Fla. 4th DCA 1985). The Fourth District violated this settled principle and then used it as the sole basis to affirm the ALJ's conclusion that rule 8.012 is adequate and to distinguish *Miles*.

The ALJ made no finding related to homogenization, and certainly did not find that homogenization could cure the problems clots cause with forensic testing. The Fourth District concocted this theory on its own and used it to distinguish *Miles*, 775 So. 2d at 954-55 (A:7). According to the Fourth District, homogenization could "after the fact" cure the effects of clotting, while the lack of refrigeration in *Miles* was incurable (A:7). As later explained in part I.C.2.c., *Miles* is indistinguishable.

The Fourth District compounded its error by relying on inadmissible hearsay that was outside the record. The Fourth District improperly relied on a treatise on post-mortem forensic alcohol testing to bolster Dr. Goldberger's testimony (A:6,

n.4). A treatise is inadmissible hearsay when used as substantive evidence to bolster testimony. *See* § 90.704, Fla. Stat. (2016); *Linn v. Fossum*, 946 So. 2d 1032, 1036 (Fla. 2006); *Donshik v. Sherman*, 861 So. 2d 53, 56 (Fla. 3d DCA 2003). In fact, the FDLE attempted to admit several treatises at trial, but appellant objected and the ALJ excluded them as hearsay (R:93-96, 440-42). It was improper for the Fourth District to rely on inadmissible hearsay that is outside the record. *See Altchiler v. Dep't of Prof'l Regulation Div. of Professions, Bd. of Dentistry*, 442 So. 2d 349, 350 (Fla. 1st DCA 1983) (“It is fundamental that an appellate court reviews determinations of lower tribunals based on the records established in the lower tribunals.”).

b. The record does not support the Fourth District’s conclusion on homogenization.

The Fourth District acknowledged “the testimony was clear that . . . clotting can affect the accuracy of a blood alcohol test.” (A:6). Yet, it reasoned the testimony was “sufficient for the ALJ to find that clotting, even when increased by the use of a smaller butterfly needle, does not inherently render blood alcohol testing inaccurate, as there were commonly known and utilized curative procedures,”— such as homogenizing the clotted sample, which the Fourth District called a “very easy” process that is “necessary only with larger clots.” (A:6-7).

The only testimony at trial about homogenization came from Dr. Goldberger. However, Dr. Goldberger's testimony did not prove homogenization "cures" the problems caused by clots for purposes of forensic testing. Dr. Goldberger testified that his analysts do not test clots because "[y]ou can't pipette or sample a clot easily, not from a living person." (R:729). In his laboratories, analysts test clots taken from people's brains, but Dr. Goldberger stated "that's not really the subject of today." (R:729). Dr. Goldberger testified that an analyst would homogenize the clots when removed from the **brains of dead bodies**. (R:729). When asked if an analyst could get an accurate blood alcohol content from a clotted sample prepped by homogenization, he replied:

A: Yes. And that's why I wanted to make the record clear is that **we do take these clots from people's brains**, and we can accurately determine the content -- alcohol content in these sample. **And we simply just homogenize the sample. Very easy.**

(R:729).

Important distinctions between Dr. Goldberger's testimony about his laboratories and the testing at issue here disprove the Fourth District's conclusion that homogenization is the cure for clotting. Samples tested under the implied consent rules must be whole blood samples, and blood clots from dead bodies are not whole blood. In addition, the purpose of testing blood in Dr. Goldberger's

laboratory at the University of Florida is different than the purpose of testing blood samples for use in a criminal DUI trial. Dr. Goldberger testified he does not follow rules 11D-8.012 and 11D-8.013 when he analyzes a blood sample in his laboratory (R:739). Scientific reliability and accuracy are required for all tests performed under the implied consent rules because of the due process concerns in criminal trials. Dr. Goldberger distinguished between the standards for testing blood in a DUI case (“forensic setting”) versus the post-mortem setting (R:753-54).

It was error for the Fourth District to equate Dr. Goldberger’s homogenization testimony with the kind of testing at issue here. No evidence in the record supports the Fourth District’s conclusion that homogenization on a living person’s blood sample is a “very easy” process that can cure the problems that result from clotting in a way that is sufficient to ensure scientific reliability of test results under the implied consent rules.

c. The rules contain no requirement that clotted samples be homogenized before testing.

The Fourth District identified what it believes is a cure to the problems caused by clotting—homogenization. If this is a cure, then it is critical for all laboratories to perform homogenization on clotted samples. Otherwise, the sample will not be reliable. Since the rules do not require this cure, they are inadequate.

The Fourth District stated that “the testimony established that clotting is notably different than the flaws caused by the lack of refrigeration in *Miles*, which could not be rectified after the fact.” (A:7) (citing *Miles*, 775 So. 2d at 954-55). But the “after the fact” alleged cure for clotting is **not** different, and the lack of refrigeration in *Miles* is indistinguishable. *Miles* held that “the absence of maintenance standards renders rule 11D-8.012(3) inadequate and inconsistent with the purpose of the implied consent law as it relates to ensuring the reliability of test results.” 775 So. 2d at 955. Just as refrigeration was a critical step in the blood testing process in *Miles*, homogenization is a critical step here, under the Fourth District’s reasoning. Like the lack of refrigeration in *Miles*, failure to homogenize “may well . . . impact[] the integrity of the blood sample.” *Id.* The absence of a rule requiring homogenization renders the rules inadequate and deficient, particularly in the absence of any evidence that the laboratories’ standard operating procedures require homogenization.

The Fourth District also observed that, “[r]egardless of the size of the clot, testimony also revealed that standard practice is to ‘mix [] the sample’ prior to testing in order to avoid problems such as those created by clots.” (A:7). Dr. Goldberger testified that mixing is not required by the rules, either:

Q: [T]hat procedure mixing of the sample, is not contained in the FDLE rules, either 11D-8.012 or 8.013, is it?

A: No. It's general laboratory practice, just like how to pipette.

(R:756). If, as the Fourth District concluded, homogenization is similar to mixing, then the absence of mixing from the implied consent rules makes the rules inadequate for the same reasons.

POINT II

RULES 11D-8.012 AND 11D-8.013 ARE INADEQUATE BECAUSE THEY FAIL TO SPECIFICALLY REGULATE THE WORK OF ANALYSTS IN SCREENING BLOOD SAMPLES, DOCUMENTING IRREGULARITIES, AND REJECTING UNFIT SAMPLES.

A. The critical procedures of screening, documenting, and rejecting unfit samples must be in the rules to ensure scientific reliability.

Screening blood samples before testing them, documenting irregularities, and rejecting compromised samples are essential steps to ensuring that a blood alcohol test produces accurate results. Both parties' experts testified that blood samples should be screened for irregularities, and that irregular samples should be excluded or at least documented in laboratory results (R:470, 566-68, 753). Yet, rule 11D-8.013, which regulates blood analysts and the methods of blood analysis, does not require analysts to screen blood samples before testing, document any

irregularities, or reject compromised samples (R:768-69, 774). In practice, the evidence shows that the FDLE issues permits to laboratories and analysts whose standard operating procedures do not include these steps (R: 172-73, 179-80, 182-83, 463). These insufficiencies render the rule invalid. *See State v. Miles*, 775 So. 2d 950, 955 (Fla. 2000); § 120.52(8)(d), Fla. Stat. (2016).

Blood samples, even when drawn according to the current (inadequate) standards in rule 11D-8.012, can contain clots and other irregularities that affect blood alcohol test results (R:414-15, 419). The FDLE's expert, Dr. Goldberger, agreed that blood samples can change during and after collection, so good laboratory practices "require examination of biological specimens prior to analysis" (R:778). Dr. Goldberger also agreed that "[v]isual observation should be made and recorded of [blood] specimens" and "color evidence of hemolysis [and] presence of clots" should be noted (R:778). He believed the laboratory's methods for determining whether a blood sample is suitable for testing should be documented in writing (R:753). Murphy admitted that the FDLE rules do not require that testing be performed in accordance with good laboratory practices, besides those practices listed in the FDLE rules (R:471). Also, he admitted that he would not reject an application for a blood alcohol testing permit on the basis that the standard operating procedures do not include documenting irregularities and

rejecting compromised samples (R:463).

The ALJ concluded, and the Fourth District agreed, that the FDLE rules need not require analysts to inspect samples, document irregularities, and reject compromised samples because analysts routinely do those things as a matter of standard laboratory practice (R:419; A:7-9). The Fourth District noted the PBSO crime laboratory analyst (Yeatman) who tested Goodman's blood in this case stated that "any time a sample is clotted, it is documented on the analyst's case file and is also reported . . . [a]s additional remarks under the conclusions." (A:8) (quoting R:173). However, that analyst also testified that the standard operating procedures for his laboratory **do not require** the analyst to visibly inspect the samples or document irregularities (R:172-73, 179-80, 182-83). The PBSO Crime Laboratory's standard operating procedures presumably were approved by the FDLE under rule 11D-8.013, even though they lack these requirements. Neither PBSO crime laboratory analyst could recall ever rejecting a sample because of irregularities within the sample (R:138, 180). Both admitted to testing clotted samples for blood alcohol levels, and both agreed that a clot can raise blood alcohol levels in the sample (R:143-45, 150, 185-86).

In *Miles*, the FDLE made exactly the same argument that the Fourth District

relied on here, “that it was not necessary to provide guidelines on this issue because handling procedures were universally known and followed.” 775 So. 2d at 951. “[T]he State’s experts testified that the requirement was so fundamental that it did not need to be in a rule because anyone dealing with blood samples would be aware of the need for proper preservation.” *Id.* at 954. This Court rejected this argument and found that lack of refrigeration “may well have impacted the integrity of the blood sample” and that the “absence of maintenance standards render[ed] rule 11D-8.012(3) inadequate and inconsistent with the purpose of the implied consent law as it relates to ensuring the reliability of test results.” *Id.* at 955. The same is true here. The Fourth District’s decision is directly at odds with *Miles*, which held critical procedures must be in the rules to ensure scientific reliability.

Screening procedures are not implicit to procedures already set forth in the rules and the laboratories’ standard operating procedures. It is undisputed that the FDLE issues permits to analysts whose standard operating procedures do not include screening (R: 172-74, 179-83, 463, 583, 820-21). If neither the rules nor the FDLE approved standard operating procedures require these procedures, criminal defendants have no guarantee that the blood tested for use in their criminal trial was a reliable sample. *Wissel v. State*, 691 So. 2d 507 (Fla. 2d DCA

1997), which the Fourth District relied on, is not instructive because the procedures there (preparing stock solutions for testing the intoxilizer machine) were implicit and incidental to procedures already in the rules.

Goodman never asked the FDLE to “regulate *every* possible contingency that may arise in the collection or testing process[].” (A:8) (emphasis in opinion). That was an improper “strawman” argument the FDLE raised. *Cf. Consalvo v. State*, 697 So. 2d 805, 814 (Fla. 1996). But the FDLE does have an obligation to promulgate rules that are sufficient to ensure the scientific reliability of the test results. Requiring proper needle and tourniquet use, screening compromised samples before testing, documenting irregularities, and rejecting bad samples are necessary steps that must be included in the rules. The current rules do not guarantee reliability because they lack measures to ensure proper collection (needle and tourniquet use) and also lack measures to ensure that problems caused by bad collection, such as clots, are detected and documented by the analysts.

These steps would not have the drastic effects the Fourth District projected. None would require forensic laboratories to “lock[] in today’s current scientific methodology, preventing the evolution and improvement of the system.” (A:8). Laboratories could implement these steps within their individualized standard

operating procedures. Certainly, requiring analysts to screen samples would not “deprive both the State and criminal defendants of the expertise and discretion of the analysts.” (A:8). No evidence supports the Fourth District’s speculation.

The FDLE has a heavy responsibility with respect to rules governing blood and breath alcohol testing. The FDLE must promulgate rules that ensure scientifically reliable results because compliance with the FDLE’s rules creates presumptions against the defendant in criminal cases. *See* § 316.1934(2) & (3); *Miles*, 775 So. 2d at 952. By failing to require laboratories to inspect, document, and reject compromised samples, the FDLE fails to ensure that these laboratories are producing reliable blood alcohol test results. Rules 11D-8.012 and 11D-8.013 fail to require a permitted blood analyst to screen blood samples before testing them, document irregularities and exclude compromised samples. As a result, these rules fail to meet the core policies of the implied consent law because they do not ensure reliable test results. Rules 11D-8.012 and 11D-8.013 are inadequate and should be declared invalid.

B. The lack of procedures in rules 11D-8.012 and 11D-8.013 deprives defendants of due process.

Dr. Goldberger testified that the FDLE rules have nothing in place to ensure that analysts and laboratories are not testing clotted samples and reporting the

results of those samples (R:768). He also testified that the analyst's ability to identify a clotted sample depends on how well the analyst is trained (R:785-86). Patrick Murphy testified that he would not reject a laboratory's application for a blood alcohol testing permit on the basis that the laboratory's standard operating procedures do not require screening for blood clots or accounting for clots before testing (R:820-21). Without adequate procedures in place to screen and document, there is no way to ensure the reliability of the sample.

Because neither the rules nor the FDLE-approved standard operating procedures require screening and documenting, criminal defendants have no guarantee that the blood samples tested for use in their criminal trials are scientifically reliable. More specifically, a criminal defendant has no guarantee that he or she will know when his or her sample is clotted or irregular because the rules do not require screening or documentation, or rejection of unfit samples. Without adequate procedures in place, there is no way to ensure the scientific reliability of the blood test result. Rules 11D-8.012 and 11D-8.013 are inadequate and inconsistent with this core policy. The Fourth District erred by failing to invalidate rules 11D-8.012 and 11D-8.013.

CONCLUSION

This Court should quash the Fourth District's decision with directions to reverse the final order and remand to enter an order declaring rules 11D-8.012 and 11D-8.013 inadequate and invalid.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 5th day of December, 2016, I will electronically file the foregoing with the Clerk of Court using the Florida Courts E-Filing Portal, which will then send a copy of such filing to:

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CERTIFICATE OF FONT

Petitioner's Initial Brief on the Merits has been typed using the 14-point Times New Roman font.

By: /s/ Jane Kreuzler-Walsh
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