SC16-1752

In the Supreme Court of Florida

JOHN GOODMAN,
Petitioner,

v.

FLORIDA DEPARTMENT OF LAW ENFORCEMENT,
Respondent.

RESPONDENT'S ANSWER BRIEF

ON DISCRETIONARY REVIEW FROM THE
FOURTH DISTRICT COURT OF APPEAL
Case No. 4D14-3263

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INTRODUCTION

Petitioner John Goodman seeks to invalidate two administrative rules promulgated by Respondent, the Florida Department of Law Enforcement, relating to the collection and testing of blood samples for purposes of Florida's Implied Consent Law. His challenge is grounded in the theory that the rules do not adequately address the potential for irregularities in the samples, such as blood clots (stemming from use of smaller-gauge butterfly needles) and hemoconcentration (stemming from improper tourniquet usage).

After considering the evidence and arguments presented, the Administrative Law Judge determined that Goodman had failed to meet his burden of proof and dismissed the challenge. On appeal, the Fourth District explained that Goodman's arguments present "an overbroad solution in search of a problem that does not exist." *Goodman*, 203 So. 3d at 912. As the court below correctly concluded, the Administrative Law Judge's findings are supported by competent and substantial evidence. Accordingly, this Court should approve the Fourth District's decision.

STATEMENT OF THE CASE AND FACTS

Petitioner John Goodman was charged with 1) DUI Manslaughter/Failed to Render Aid and 2) Vehicular Homicide/Failed to Give Information or Render Aid, stemming from a motor vehicle crash in February 2010. R1:10, R2:394.[1] During the criminal proceedings before the Palm Beach County circuit court, Goodman moved to exclude blood alcohol test results that had been obtained under Florida's Implied Consent Law. R1:11, R2:394; *see* §§ 316.1932, 316.1933, & 316.1934, Fla. Stat. (2010). Goodman argued that the administrative rules governing blood draws—promulgated by Respondent, the Florida Department of Law Enforcement—were inadequate. R1:25, R2:394–95. In response, the State moved to invoke the doctrine of primary jurisdiction, arguing that because Goodman's challenge was essentially an attack upon the validity of an administrative rule, the proper venue to resolve the challenge was the Division of Administrative Hearings (DOAH). R1:26.

The circuit court agreed with the State and concluded that the matter "would be better addressed as a petition to DOAH." R1:27. Accordingly, the circuit court

[1] The record on appeal consists of five volumes and will be referred to as R#:*, where # stands for the volume number and * for the page number. Citations to the transcript of the June 10, 2014 hearing before the Division of Administrative Hearings (contained in volumes IV and V of the record on appeal) will appear as Tr. #, where # stands for the page number.

reserved ruling on Goodman's motion to exclude the blood alcohol test results pending the resolution of the rule challenge before DOAH. *Id.*

The Proceedings and Evidence Before DOAH

Before DOAH, Goodman filed a Petition to Determine the Invalidity of an Existing Rule under section 120.56(3), Florida Statutes. His petition challenged two rules promulgated by Respondent, the Florida Department of Law Enforcement: Rule 11D–8.012, addressing "Blood Samples–Labeling and Collection," and Rule 11D–8.013, addressing "Blood Alcohol Permit–Analyst." R1:10. The Petition alleged that the two rules were an invalid exercise of delegated legislative authority under section 120.52(8)(a)–(e), Florida Statutes. R1:23.

Specifically, the Petition alleged that the "nurse who collected Mr. Goodman's blood substituted a 25-gauge 'butterfly' needle . . . for the larger-bore 21-gauge needle supplied in the blood collection kit given to her by a law enforcement officer." R1:11. Nothing in the record confirms that a 25-gauge needle actually was used to collect Goodman's blood.[2] Asserting that "[n]eedle size is fundamentally important to the blood collection process," the petition

[2] During questioning of an analyst at a deposition, Goodman's counsel asked "You don't know what gauge needle is used to draw blood when it comes into your lab, correct? . . . Generally unless like in this particular case the needle gauge was reported, correct?" R1:196. There is nothing in the record showing whether and how the needle gauge was "reported." This statement by counsel does not establish that a 25-gauge needle was, in fact, used.

argued that the Department should have specified in its rules what gauge needle was permissible for use in blood draws performed for the purpose of blood alcohol testing. R1:18, 20. The petition also asserted the rules were invalid because they do "not require standard operating procedures to incorporate a process to identify—and exclude—unreliable blood samples from the testing process." R1:22.

The case proceeded to a hearing before an administrative law judge (ALJ), at which the following evidence was presented:

In Florida, "whole blood" is required for forensic testing. Tr. 103–04, 280; *see* Fla. Admin. Code R. 11D–8.002(14) (2014) (defining "blood" to mean "whole blood"). "Whole blood" is the term for what is removed from a person's vein during the course of a blood draw. Tr. 56. It contains all the component parts of blood—"cellular elements, the white cells, the platelets, the red cells, all the proteins, the clotting factors, all the enzymes, all the electrolytes." *Id.*; *see also id.* at 103, 211, 280.

During the blood collection process, a tourniquet is used to apply pressure to the arm in order to make the veins visible. Tr. 83, 224. A nonalcoholic wipe is used to clean the skin surface where the needle will be inserted. Tr. 107. Testimony indicated that if a tourniquet is left on for too long, then hemoconcentration may occur, which is when the concentration of red blood cells changes at the site of the

tourniquet. Tr. 225, 242. As a result, more plasma may enter the blood sample, thereby increasing the water and alcohol content of the sample. Tr. 143–44.

Needle gauge refers to the size of the needle's diameter—the higher the number, the smaller the diameter. Tr. 215–16. Although there was testimony that 21- and 22-gauge straight needles were the recommended sizes for collecting blood samples, Tr. 214–15, there was also testimony that, in some cases, use of a "butterfly needle" would be warranted—for example, a physiological reason related to the condition or accessibility of a vein, or the incapacitation of the patient. Tr. 214, 220, 318.

Butterfly needles get their name from two "wings" located on the outside of the needle, Tr. 216, and come in different-sized gauges, Tr. 214, 218. Tubing connects the butterfly needle to a round, barrel-shaped holder, into which collection tubes are placed. Tr. 217. Because there is no anticoagulant in the connector tubing, small clots could form in the collection tube. Tr. 172, 236. Additionally, once blood enters the glass collection tube, the anticoagulant in the tube does not always prevent clotting from occurring. Tr. 140–41.

As to testing of the blood samples, gas chromatography is currently the only approved blood alcohol testing method in Florida. Tr. 280; *see* Fla. Admin. Code R. 11D–8.011 (2016) (amended July 29, 2015 to remove the Alcohol Dehydrogenase (Enzymatic) method). The method measures the blood alcohol

concentration based on the gas that results from the heating and pressurizing of the sample. Tr. 127–30, 282–83.

Specifically, a small portion (or aliquot) of the blood sample is taken from the collection tube. Tr. 125. This small portion is then mixed with an "internal standard"—a liquid that dilutes the blood, stabilizes the analysis, and quantifies the blood alcohol results. Tr. 126. The sample is heated and pressurized, resulting in the accumulation of gas in the headspace above the sample. Tr. 127–28. This gas is then pushed through a long, thin, capillary column, where it reacts to the inner coating of the column by separating into its component parts. Tr. 129–31. Those individual components are burned, resulting in the creation of carbon ions which can be counted and used to calculate the concentration of alcohol in the sample. Tr. 131.

The former manager of the Department's Alcohol Testing Program, Laura Barfield, testified that she routinely inspected blood samples before testing, and she regularly noted any clotting or other irregularities in the case file. Tr. 135–38, 154. She also confirmed that inspecting samples for clots or irregularities is a "common step" in the toxicology process that occurs upon opening inventory and evidence. Tr. 154. Small clots, or microclots that were not visible during this initial examination, would be detected while pipetting the sample. Tr. 139, 155.

Over the course of three and a half years of performing blood alcohol analyses, Barfield encountered bad samples approximately ten to fifteen times. Tr. 172. Each time, she documented the bad sample in her laboratory file. Tr. 173. This file would have been available as part of a records request by a criminal defendant. Tr. 177. Barfield also noted that, before initiating testing, it is important to "mix" the sample of blood in the collection tube so that it is representative of the whole blood before a portion is removed for testing. Tr. 125, 134, 164–65.

Similar testimony came from Dr. Bruce Goldberger, the Director of Toxicology at the University of Florida College of Medicine, who explained that he requires his analysts to make a notation in the file if a sample is clotted. Tr. 296. Additionally, he testified microclots "would have no [e]ffect on the blood alcohol test. But if you have clots that affect your ability to pipette the sample, those will affect the accuracy and reliability of the" testing. Tr. 297. However, upon discovering a clot that would affect the test results, Dr. Goldberger's laboratory analysts would note in the toxicology report that the "sample is not suitable for testing." Tr. 297, 351. This requirement is in his laboratory's standard operating procedure manual. Tr. 297–98.

Regarding needle gauge, Dr. Goldberger testified that he would consider a blood sample collected with a 25-gauge needle to be valid for analysis using headspace gas chromatography because it would still be whole blood. Tr. 305, 351.

Dr. Goldberger recalls from past experience having seen samples arrive in a kit containing a butterfly needle that had been substituted for the original needle, but he does not know what gauge those butterfly needles were. Tr. 317–18. Dr. Goldberger testified that in some circumstances, it is necessary to substitute the needle that is included in the blood draw kit: "[T]here's instances where the donor, the patient, for example, is incapacitated to a great degree and you can't use the setup that's included in the box, so you rely on the use of a butterfly or some other device to get the blood." Tr. 318. Dr. Goldberger noted that blood draws are performed by someone who is certified for blood collection, such as a phlebotomist, a paramedic, or a nurse. Tr. 319.

Dr. Goldberger further addressed the impact of blood clots upon testing. Significantly, if a whole blood sample contains a clot, nothing has been added or removed from the sample. Tr. 294. Clots, moreover, can be removed through a homogenization process before testing, Tr. 295, 298. The homogenization process is "very easy," and allows an analyst to obtain an accurate blood alcohol content from a clotted sample. Tr. 298.

Dr. Goldberger also discussed mixing of the sample before testing. Mixing is where the collection tube is placed on a surface that vibrates gently to mix the sample. Tr. 351–52. Mixing is "general laboratory practice, just like how to pipette. It's just part of the practice in the laboratory." Tr. 325. Another term for

mixing is "vortexing." Tr. 351–52 ("Vortexing is a way to mix the sample so it's homogeneous."). In preparing a blood sample for testing, the goal is to have a homogeneous sample—one that is "mixed and equal in all aspects; that is, it's fully mixed and it's the same everywhere you look and everywhere you measure." Tr. 290.

The administrative rules governing blood collection and testing provide a framework for the determination of blood alcohol content; the rules are not meant to be standard operating procedures governing all Florida laboratories. Tr. 279–80. Dr. Goldberger discussed the scope of the rules: "[T]here's more than science in the rules. It specifies procedure, it specifies shipping protocol, it specifies storage. So what's found in the rule is based in science but it's all practical in nature. It also takes under consideration how blood is collected, how blood is shipped, and how blood is tested in the laboratory." Tr. 303–04.

Notably, Dr. Goldberger did not think every laboratory practice governing blood analysis should be included in the rules: "I can think of several reasons. One is you might put the labs out of business. Number two is the rule is meant to be static, and if the science changes, you can't adapt [the rule] quick enough so that would be a very bad protocol or precedent that you set. . . . [T]hese rules provide framework but they don't tell you specifically how you do it. The 'how you do it' part is done in the laboratory by the scientists that conduct those tests." Tr. 304.

Dr. Goldberger testified that the standard operating procedure manual at his laboratory at the University of Florida is between 750 to 1,000 pages long. Tr. 319. It is very detailed and contains step-by-step descriptions of what procedure to follow, from "sample receipt, to sample discard, and everything in between, as well as all the quality assurance measures that [are] in place." Tr. 319. He also explained further why the rules should not include every practice used by a laboratory: "I don't know how you would define every good scientific practice or get consensus on good scientific practice. The field of forensic science is moving rapidly forward these days. . . . [G]ood scientific practice is constantly evolving. The work in the laboratory is constantly evolving, constantly improving and modifying." Tr. 356–57. Codifying into rule one set practice would impact this evolution, "and it could take years to excise" such a rule. Tr. 357.

Testimony from Dr. Patrick Murphy, the Program Manager of the Department's Alcohol Testing Program, focused on the analyst permitting process. Analysts must meet the requirements set forth in Rule 11D–8.013 and pass a blood testing proficiency test before they receive a permit. Tr. 373–74. The proficiency test involves the submission of five samples for the applicant to accurately assess the blood alcohol content in each of the five samples. Tr. 373–74. In addition, the applicant must submit his or her standard operating procedure for analyzing blood alcohol content. Tr. 374. These are reviewed by the Department's Alcohol Testing

Program. Tr. 374. After an analyst is permitted, the Alcohol Testing Program conducts proficiency testing to ensure the analyst continues to make accurate and reliable measurements. Tr. 375–77. Eleven laboratories in Florida conduct evidentiary blood alcohol testing; around 65 analysts hold permits to conduct the testing. Tr. 377.

In addition to the testimony presented at the hearing, the ALJ admitted the deposition testimony of two blood analysts from the Palm Beach Sherriff's Office Crime Laboratory, the location where Goodman's blood was tested. Tr. 263–64. Dr. Xiaoquin Shan, an analyst, testified that she visually inspects the collection tubes containing the blood samples and if a blood sample is clotted, she will include that detail in the toxicology report. R1:133, 140, 142–44, 151. Further, after inspecting a blood sample, she will mix the sample to obtain a "homogeneous blood specimen" before testing the sample. R1:140–41. Regarding the impact of clotting on the test results, Dr. Shan testified that it depends on how much the blood is clotted: "If the blood is a hundred percent clotted such as serum, then the blood result is elevated between 10 to 15 percent. But if you have 10 mil[iliters of] blood [] in the blood tube and you have one clot which is about 2 microliter[s in] volume, then the effect of clotting on the result is negligible . . . ." R1:145.

Analyst Dustin Tate Yeatman testified that if a blood sample is clotted, "it's always included on the report itself, so it's made available to everyone." R1:170,

173, 185. Yeatman also explained that the presence of clotted blood would be noted in the affidavit that accompanies the report. R1:186. Although the laboratory's standard operating procedure manual does not specifically require documentation of clots, Yeatman noted that it is standard procedure "to inventory and document the evidence. Part of that documentation is any unusual appearance of the sample." R1:173. Further, although the manual does not state any requirement for mixing a sample, Yeatman testified that mixing of the sample before testing is "the standard practice that all of our analysts have been trained to do." R1:174–175, 182. Yeatman confirmed that he mixed the sample of Goodman's blood before testing it. R1:175.

The ALJ Upholds the Challenged Rules

The ALJ issued a final order which denied Goodman's request to invalidate the rules and dismissed the petition. R3:421. The ALJ's order included several findings of fact regarding coagulation (the term the ALJ used to refer to clotting). The ALJ determined that coagulation may occur in the blood collection process, even though the blood collection tubes contain a preservative and anticoagulant. R3:414. However, such coagulation "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." *Id.*

Coagulation "causes some of the blood components to solidify," thereby "alter[ing] the ratio of liquid to solid" in a given sample, but a sample containing a portion of coagulated blood still "contains all of the components that were present in the 'whole blood' of the subject from whom the blood was collected." *Id.* at 414–15. Significantly, the ALJ found "[t]he evidence fails to establish that the mere presence of coagulation inevitably precludes the withdrawal of a subsample that properly reflects the components of the whole blood contained in the collection tube." *Id.* at 415. To that end, the ALJ concluded as a matter of law that the "omission from the rule of a requirement related to needle gauge and tourniquet usage is of no material consequence." *Id.* at 418.

Further, the Rule was not invalid because it did not explicitly require analysts to identify, document, and exclude any "unreliable" blood samples. *Id.* at 419. The evidence presented established that analysts "routinely examine and document the condition of samples as a matter of standard laboratory practice." *Id.* at 419. Although coagulation in a sample of blood

> may result in elevation of the blood alcohol level reported by a subsample, . . . the accuracy of a blood alcohol test report derived from a sample that exhibits coagulation depends on whether the subsample taken from the sample is an appropriate representation of the components of the whole blood contained in the collection tube. The evidence fails to establish that the mere presence of coagulated blood in a sample inherently precludes the withdrawal of an appropriate subsample.

Id. at 419–20.

In light of these findings and conclusions, the ALJ dismissed Goodman's petition. *Id.* at 421.

The Fourth District Affirms the ALJ's Ruling

Goodman appealed the ALJ's final order to the Fourth District Court of Appeal, R3:428,[3] raising three issues: 1) the Department lacked delegated authority to promulgate the rules at issue; 2) Rule 11D–8.012 was an invalid exercise of delegated authority because it failed to establish standards for the method by which blood is collected for testing; and 3) Rule 11D–8.013 was an invalid exercise of delegated authority because it failed to incorporate a process to identify and exclude unreliable blood samples from testing. *Goodman v. Fla. Dep't of Law Enf't*, 203 So. 3d 909, 912 (Fla. 4th DCA 2016).

The Fourth District, in a unanimous decision, affirmed the ALJ's Final Order. Specifically, the Fourth District affirmed as to the first issue without comment, citing this Court's decision in *State v. Bender*, 382 So. 2d 697 (Fla. 1980). As for the other two issues, the court noted that Goodman's argument

[3] In the criminal prosecution against Goodman, the circuit court subsequently denied Goodman's motion to exclude the blood test results. *Goodman v. Fla. Dep't of Law Enf't*, 203 So. 3d 909, 911 (Fla. 4th DCA 2016). Ultimately, Goodman was convicted and sentenced, *id.*, and his appeal from that proceeding is currently pending in the Fourth District Court of Appeal. *See* Docket, *Goodman v. State*, No. 4D14-4479.

presented "an overbroad solution in search of a problem that does not exist." *Goodman*, 203 So. 3d at 912.

With respect to needle gauge, the Fourth District noted that 25-gauge butterfly needles "can be useful for certain patients." *Id.* at 913. As to the potential for clotting, "[a]lthough the testimony presented at the hearing was subject to multiple conclusions on this point, 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." *Id.* at 913. The use of a smaller-gauge needle, therefore, does not inherently render any blood alcohol testing inaccurate; in the event clotting occurred, "there were commonly known and utilized curative procedures." *Id.* at 914. The evidence thus established that the potential for clotting "is notably different than the flaws caused by the lack of refrigeration in [*State v. Miles*, 775 So. 2d 950 (Fla. 2000)], which could not be rectified after the fact." *Goodman*, 203 So. 3d at 914. Accordingly, the Fourth District affirmed the ALJ's decision regarding Rule 11D–8.012.

The Fourth District similarly affirmed the ALJ's decision regarding Rule 11D–8.013. The court explained that expert testimony supported the Department's position that Rule 11D–8.013 "is not meant to be the only source of guidance for analysts, but is instead meant to supplement and reinforce sound scientific principles and laboratory practices." *Id.* at 914–15. The testimony also supported

the conclusion that blood analysts routinely examine and document the condition of blood samples. *Id.* at 915. "The rules at issue, when combined with basic laboratory practices, are sufficient to protect the safety and interests of the court system and defendants alike." *Id.* The absence, therefore, of an explicit requirement in the Rule did not provide a basis for its invalidation. *Id.*

Because Goodman had failed to meet his burden of showing that the rules are invalid, the Fourth District affirmed the final order. *Id.* Subsequently, the Fourth District denied Goodman's motion for rehearing but certified two questions of great public importance to this Court:

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?

Id. at 916. Goodman sought discretionary review in this Court, which accepted jurisdiction. *See* Order Accepting Jurisdiction, No. 16-1752 (Fla. Oct. 14, 2016).

SUMMARY OF THE ARGUMENT

As a threshold matter, the issues properly before this Court are narrower in scope than the issues set forth in Goodman's Initial Brief. In particular, this Court should decline to address Goodman's due process claim as well as his claim the challenged rules are invalid for failing to expressly regulate homogenization of blood samples. Goodman did not raise either issue in the administrative proceedings before DOAH, nor did he seek to raise those issues in his merits briefing to the Fourth District. Instead, Goodman developed those claims for the first time in his motion for rehearing and certification to the Fourth District. Because Goodman did not timely raise those two claims, and the Fourth District did not actually pass upon them, this Court need not and should not address them for the first time at this late stage of the proceeding.

As to the issues that are properly presented in this case, the Court should answer the certified questions in the negative and approve the Fourth District's decision because the challenged rules are valid. The Department's rules sufficiently regulate blood draws and blood alcohol testing in a manner that ensures the reliability and accuracy of blood alcohol test results for purposes of Florida's Implied Consent Law.

Based on all the evidence presented, Goodman's challenge—grounded in alleged problems stemming from blood clots and hemoconcentration—fails. The

Department's rules adequately ensure the reliability and consistency of blood alcohol testing, and the absence of a regulation expressly governing needle gauge, tourniquet usage, or the screening, documentation, and rejection of any unfit blood samples does not render the challenged rules invalid.

As the Fourth District correctly concluded, competent and substantial evidence supports the ALJ's factual finding that the mere presence of a blood clot does not preclude the ability of an analyst to obtain an accurate blood alcohol test result. Further, the record supports the ALJ's finding that analysts routinely examine and document the condition of samples as a matter of standard laboratory practice. Multiple witnesses testified that they routinely inspect blood samples and document any irregularities, such as clots.

This Court should answer the certified questions in the negative and approve the Fourth District's decision.

STANDARD OF REVIEW

Because this case arose as an administrative challenge to rules under section 120.56(3), Florida Statutes, Goodman bore the burden of "proving by a preponderance of the evidence that the existing rule is an invalid exercise of delegated legislative authority as to the objections raised." § 120.56(3), Fla. Stat. (2014). "If an administrative law judge's final order depends on any fact found by the administrative law judge, the court shall not substitute its judgment for that of

the administrative law judge as to the weight of the evidence on any disputed finding of fact." § 120.68(10), Fla. Stat. (2014). Accordingly, the administrative law judge's factual findings must be accepted if they are supported by competent, substantial evidence. *Dep't of Health v. Bayfront Med. Ctr., Inc.*, 134 So. 3d 1017, 1018 (Fla. 1st DCA 2012). Issues of law are reviewed de novo. *Volusia Cty. Sch. Bd. v. Volusia Homes Builders Ass'n, Inc.*, 946 So. 2d 1084, 1089 (Fla. 5th DCA 2006).

ARGUMENT

In challenging Rules 11D–8.012 and 11D–8.013 as invalid exercises of delegated legislative authority under section 120.52(8), Florida Statutes, Goodman had the burden of showing the rules' invalidity by a preponderance of the evidence. He attempted to do so by raising blood clots (stemming from use of smaller-gauge butterfly needles) and hemoconcentration (stemming from improper tourniquet usage) as potential issues affecting the reliability of blood alcohol testing conducted under the Department's rules. As the ALJ determined, however, Goodman failed to meet his burden of proof. Moreover, on appeal, after reviewing the record for competent, substantial evidence and upholding the ALJ's final order, the Fourth District explained that Goodman's arguments present "an overbroad solution in search of a problem that does not exist." *Goodman*, 203 So. 3d at 912.

This Court should answer the certified questions in the negative and approve the Fourth District's decision because the challenged rules are valid. The Department's rules sufficiently regulate blood draws and blood alcohol testing in a manner that ensures the reliability and accuracy of blood alcohol test results for purposes of Florida's Implied Consent Law.

I. THE ISSUES PROPERLY BEFORE THIS COURT ARE NARROWER IN SCOPE THAN THE ISSUES GOODMAN SEEKS TO RAISE IN HIS INITIAL BRIEF.

As a threshold matter, the issues before this Court are narrower than what the Fourth District's certified questions and Goodman's Initial Brief have set forth.

Although the Fourth District noted the record evidence concerning the process of homogenizing blood samples to support the ALJ's finding that "clotting . . . does not inherently render blood alcohol testing inaccurate," *Goodman*, 203 So. 3d at 914, the Fourth District did not actually pass upon the question of whether the rules were invalid for failing to "sufficiently regulate . . . the homogenization process to 'cure' a clotted blood sample." *Id.* at 916 (denying rehearing and certifying questions). Nor could it have passed on that issue, because that specific basis for invalidating the rules was never raised before DOAH. *See* R1:10–27 (Goodman's Petition setting forth the bases for his rule challenge). If the issue had been properly raised before DOAH, then the parties would have been on notice to develop a sufficient factual record to address the issue.

Nor was it raised in Goodman's merits briefing to the Fourth District. As the Fourth District noted, "[o]n appeal, [Goodman] has focused his arguments with respect to Rule 8.012 solely on the increase in clotting caused by a smaller needle and deficient tourniquet usage." *Id.* at 913 n.3.

Indeed, Goodman did not raise homogenization as a basis for invalidating the rules until his motion for rehearing and certification before the Fourth District. *See* Motion for Rehearing and Certification of Questions of Great Public Importance at 5–6, 10, *Goodman v. Fla. Dep't of Law Enf't*, No. 4D14-3263 (June 28, 2016). It is well settled that the rehearing process authorized under Florida's Rules of Appellate Procedure does not allow for the raising of new issues. Fla. R. App. P. 9.330(a) ("A motion for rehearing . . . shall not present issues not previously raised in the proceeding."); *see also Blinn v. Fla. Dep't of Transp.*, 781 So. 2d 1103, 1110 (Fla. 1st DCA 2000) (noting the "the long-established rule that authorities not cited and issues not raised in the briefs or on oral argument cannot be raised for the first time on motion for rehearing"). Accordingly, Goodman waived homogenization as a basis for invalidating the rules by not presenting it before the ALJ.

Because the homogenization issue was not raised in the administrative proceedings, and because the Fourth District did not actually pass on it, this Court should decline to address that particular portion of the first certified question. *See*

S. Baptist Hosp. of Fla., Inc. v. Welker, 908 So. 2d 317, 320 (Fla. 2005) ("In the present case, we decline to answer the certified question because it presupposes the existence of an otherwise viable cause of action . . . .The issue of whether such a cause of action exists was not raised by the parties in the trial court, the First District, or this Court. . . . [W]e conclude that it would be unwise to address that issue as a matter of first impression in this Court. Instead, we conclude that this issue is properly addressed first in the trial court."); *see also Pirelli Armstrong Tire Corp. v. Jensen*, 777 So. 2d 973, 974 (Fla. 2001) ("Because in rendering its decision, the Second District did not pass upon the question certified to this Court, we are without jurisdiction to review this case."); Harry Lee Anstead et. al., *The Operation and Jurisdiction of the Supreme Court of Florida*, 29 Nova L. Rev. 431, 525 (2005) ([T]he Court has firmly established that it will not review a certified question that the district court actually failed to pass upon."). In the event this Court decides to address the merits of this newly raised issue, the Department's arguments are detailed below, *infra* Issue II, at 32–33.

In a similar vein, Goodman's Initial Brief attempts to raise a due process challenge to the rules. Petitioner's Initial Brief at 44–45. But this issue also was not raised until Goodman's motion for rehearing before the Fourth District. *See* Motion for Rehearing and Certification of Questions of Great Public Importance at

6–9.[4] Because this case originated as an administrative rule challenge before DOAH, at a minimum, Goodman should have raised any due process argument in his initial brief to the Fourth District. *Cf. Key Haven Associated Enters., Inc. v. Bd. of Trs. of Internal Imp. Trust Fund*, 427 So. 2d 153, 159 (Fla. 1982) (allowing adjudication of constitutional issues on direct review of an administrative proceeding "if an adequate record is available"). Because the issue was waived, it is not properly before this Court. In the event this Court does decide to address the merits of this newly raised issue, the Department's arguments are detailed below, *infra* Issue III, at 36.

[4] In his Reply Brief to the Fourth District, Goodman made general reference to due process concerns, *see* Reply Brief, *Goodman v. Fla. Dep't of Law Enf't*, No. 4D14-3263, at 6, 11 (May 26, 2015), but he in no way asserted or developed a due process argument. In any event, an issue may not be raised for the first time in a reply brief. *See Hoskins v. State*, 75 So. 3d 250, 257 (Fla. 2011) ("Contrary to Hoskins' representations, this argument was not raised in the initial brief filed here. Accordingly, the claim is barred.").

II. THE CHALLENGED RULES ARE NOT INVALID FOR FAILING TO EXPRESSLY REGULATE NEEDLE GAUGE, TOURNIQUET USAGE, AND THE HOMOGENIZATION OF BLOOD SAMPLES IN PREPARATION FOR TESTING.

A. Florida's Implied Consent Law and the Challenged Rules.

To address the significant problem of impaired driving, the Legislature enacted Florida's Implied Consent Law,[5] under which anyone who operates a motor vehicle within the State is deemed to have consented to testing of their blood alcohol content. *See* §§ 316.1932, 316.1933, 316.1934, Fla. Stat. (2010); *State v. Miles*, 775 So. 2d 950, 952 (Fla. 2000). One of the long-recognized purposes of the law "is to ensure reliable scientific evidence for use in future court proceedings and to protect the health of those persons being tested." *State v. Bender*, 382 So. 2d 697, 699 (Fla. 1980).

The Legislature delegated to the Department the responsibility of promulgating administrative rules governing the testing of blood alcohol content for purposes of the Implied Consent Law. §§ 316.1932(1)(a)2. & (1)(f)1., Fla. Stat. If such blood alcohol testing is performed "substantially in accordance" with the Department's rules by a permitted analyst, then the test results are considered valid, *id.* § 316.1934(3), and certain presumptions may be invoked in court proceedings, *id.* § 316.1934(2). Specifically, if a defendant's blood alcohol content

[5] The law was first enacted in 1967. *See* Ch. 67-308, Laws of Fla., at 1000 (effective July 1, 1968).

is 0.05 or less, there is a presumption that the individual was not impaired. *Id.* § 316.1934(2)(a). If the test reveals a blood alcohol content of 0.08 or higher, then "that fact is prima facie evidence that the person was under the influence of alcoholic beverages to the extent that his or her normal faculties were impaired." *Id.* § 316.1934(2)(c).

These presumptions are rebuttable and "do not limit the introduction of any other competent evidence bearing upon the question of whether the person was under the influence of alcoholic beverages to the extent that his or her normal faculties were impaired." *Id.* § 316.1934(2); *see Bender*, 382 So. 2d at 699. Accordingly, "a defendant may in any proceeding attack the reliability of the testing procedures, the qualifications of the operator, and the standards establishing the zones of intoxicant levels." *Id.*

At issue in this case are two of the Department's rules promulgated under the Implied Consent Law. Rule 11D–8.012 addresses the labelling, collection,[6] and handling of blood samples for testing. The Rule requires use of a nonalcoholic wipe to cleanse the skin puncture area before a blood draw, requires the use of

[6] By statute, "[o]nly a physician, certified paramedic, registered nurse, licensed practical nurse, other personnel authorized by a hospital to draw blood, or duly licensed clinical laboratory director, supervisor, technologist, or technician, acting at the request of a law enforcement officer, may withdraw blood for the purpose of determining the alcoholic content thereof . . . ." § 316.1933(2)(a), Fla. Stat.

blood collection tubes containing both a preservative and anticoagulant, requires the immediate inversion of the collection tube to mix the blood with the preservative and anticoagulant, imposes labelling requirements, requires refrigeration of samples if they are not submitted for analysis within seven days, and imposes delivery and time requirements for analysis. Fla. Admin. Code R. 11D–8.012 (2014).[7]

Rule 11D–8.013 addresses the permitting of blood alcohol analysts and testing procedures. An application for a permit from the Department to conduct blood alcohol analyses must include, among other things, a "complete description of proposed analytical procedure(s) to be used in determining blood alcohol level." Fla. Admin. Code R. 11D–8.013(1)(e) (2014). The Department must review and approve the proposed procedure. *Id.* 11D–8.013(2)(a). The applicant must also satisfactorily determine the blood alcohol level in five proficiency samples. *Id.* 11D–8.013(2)(b). The Rule authorizes the Department to approve the use of gas chromatographic analytical procedures that meet certain requirements. *Id.* 11D–8.013(3). A permit issued by the Department shall be for "a specific method and

[7] Unless otherwise noted, all citations to Florida's Administrative Code refer to the 2014 version. The Appendix to Petitioner's Initial Brief on the Merits (at A:17-18) contains the text of both rules in effect at the time of Goodman's 2014 DOAH Petition. Rule 11D–8.013 was amended effective July 7, 2015 to remove approval of enzymatic analytical procedures based on alcohol dehydrogenase, which is not the analytical procedure at issue in this case.

procedure;" "[a]ny substantial change to the method, analytical procedure, or laboratory facility must receive prior approval from the Department" before the change may be used in testing blood submitted by an agency. *Id.* 11D–8.013(4).

B. The Record Evidence Supports the ALJ's Rejection of Goodman's Challenge to the Rules.

Based on all the evidence presented, Goodman's challenge—grounded in alleged problems stemming from blood clots and hemoconcentration—fails. The Rules adequately ensure the reliability and consistency of blood alcohol testing, and the absence of a regulation expressly prescribing certain procedures pertaining to needle gauge and tourniquet usage does not render the challenged rules invalid.

As the Fourth District concluded after conducting a thorough review of the record, competent and substantial evidence supports the ALJ's factual finding that "the mere presence" of a blood clot does not prevent an analyst from obtaining a subsample for testing "that properly reflects the components of the whole blood contained in the collection tube." R3:415. Specifically, Dr. Goldberger testified that clots can be removed through a homogenization process before testing. Tr. 295, 298. The process is "very easy" and results in accurate test results. Tr. 298 ("Q: Can you still get an accurate blood alcohol content from a clotted sample that you prep by homogenization? A: Yes.").

Further, multiple witnesses testified that it is standard practice to mix the blood sample before testing to ensure that the sample tested is homogeneous. Laura

Barfield explained that, before initiating testing, it is important to "mix" the sample of blood in the collection tube so that it is representative of the whole blood. Tr. 125, 134, 164–65. Dr. Goldberger explained that mixing is "general laboratory practice, just like how to pipette. It's just part of the practice in the laboratory." Tr. 325. Dr. Shan, an analyst from the laboratory where Goodman's blood was tested, similarly testified that after inspecting a blood sample, she will mix the sample to obtain a "homogeneous blood specimen" before testing the sample. R1:140–41. Those standard procedures were followed here. Analyst Yeatman, who tested Goodman's blood, confirmed that he mixed the sample of Goodman's blood before testing it. R1:175.

Goodman takes issue with the Fourth District's citation, made in passing and relegated to a footnote, to a treatise addressing forensic issues in alcohol testing. *See* Initial Br. at 34-35; *Goodman*, 203 So. 3d at 913 n.4. As the Fourth District's opinion makes clear, however, the court below did not base its decision on inadmissible evidence. Rather, the Fourth District carefully reviewed the record and determined 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." *Goodman*, 203 So. 3d at 913 (emphasis added). This evidence consisted of expert testimony confirming that it is still possible to obtain an accurate test result from "a properly prepared sample even after clotting had occurred because the clot does

not add or subtract anything from the blood that would affect the test." *Id.* The complained-of citation, to *additional* supporting evidence, does not and cannot negate the existence of competent and substantial record evidence, nor does it provide any basis for quashing the Fourth District's sound decision.

Goodman also heavily relies on *State v. Miles*, in which this Court approved a lower court finding that an earlier version of Rule 11D–8.012 was inadequate because it did not contain any requirements to ensure proper preservation of a blood sample before testing. 775 So. 2d 950 (Fla. 2000). The Rule at that time contained certain labelling requirements, required use of a nonalcoholic wipe to cleanse the skin, and required samples to be collected in a tube containing an anticoagulant. *Id.* at 954. The Rule did not, however, impose any requirements addressing refrigeration or use of a blood preservative, two factors that were—in addition to use of an anticoagulant—"essential" to preserving the integrity of the blood sample. *Id.*

The record evidence in *Miles* supported the trial court's finding that "the absence of maintenance standards renders [the rule] inadequate and inconsistent with the purpose of the implied consent law as it relates to ensuring the reliability of test results." *Id.* at 955; *see also id.* at 954 n.5 ("The State experts, in their testimony, reiterated the vulnerability of a sample when left unrefrigerated and without preservatives."). Without provisions requiring the proper maintenance of

the blood sample, "the integrity of the sample is guaranteed only from the point of testing." *Id.* at 955. This Court noted that Miles' blood sample was not tested until fourteen days after the blood draw, and in light of the evidence presented, "fourteen days without refrigeration may well have impacted the integrity of the blood sample." *Id.* Because the Rule was inadequate for failing to ensure proper preservation of the sample before testing, the State in that case was not entitled to the presumption of impairment. *Id.*

Goodman's reliance on *Miles* is misplaced, as that case involved the maintenance and preservation of the blood sample before testing. The lack of refrigeration and use of a preservative were directly linked to a potential for degradation of the sample and a resulting impact on the accuracy of the test results. The degradation of the sample was not something that could be corrected or cured once it occurred. Here, record evidence indicates that even if a clot occurs in a sample, it is still possible to obtain an accurate result from testing a properly prepared sample. Larger clots can be homogenized, Tr. 295, 298, and smaller clots have no effect on the test results, Tr. 297, R1:145. Moreover, multiple witnesses testified that if a sample is not suitable for testing due to clotting, then a notation is made in the report or file to document the issue. Tr. 173, 296, R1:133, 142–44, 151, 170, 173, 185. Goodman does not allege that any such notation was made here.

As for the purported problem of hemoconcentration, Goodman had the burden of showing that the challenged rule is invalid, there is scant evidence in the record addressing this issue, and there is no evidence in the record indicating there is an actual problem with how tourniquets are used during blood draws. Notably, the Implied Consent Law specifies that only trained or licensed professionals may conduct the blood draws. § 316.1933(2)(a), Fla. Stat. ("Only a physician, certified paramedic, registered nurse, licensed practical nurse, other personnel authorized by a hospital to draw blood, or duly licensed clinical laboratory director, supervisor, technologist, or technician, acting at the request of a law enforcement officer, may withdraw blood for the purpose of determining the alcoholic content thereof . . . ."). Even if hemoconcentration can occur when a tourniquet is left on for an unduly long time, there is no evidence in the record indicating that the professionals authorized to conduct blood draws are not properly trained in tourniquet usage. Nor does Goodman point to any evidence indicating that the professionals who took his blood lacked adequate training.

Notably, no other state appears to regulate needle gauge or tourniquet usage during blood draws. *See Goodman*, 203 So. 3d at 915 n.6 (surveying other state laws and regulations). And for good reason. As this Court has noted, part of the purpose of the Implied Consent Law is to "protect the health of those persons being tested, who by [the] statute have given their implied consent to these tests."

Bender, 382 So. 2d at 699. Testimony before DOAH indicated that in certain circumstances, physiological reasons, patient comfort, or incapacitation of an individual may require the use of a specific needle. Tr. 214, 220, 318. But that determination should be left to the professional "on the ground" assessing the individual circumstances of each blood draw. *Goodman*, 203 So. 3d at 915 ("[W]e would be loath to require the FDLE to mandate a single, one-size-fit-all needle choice for blood collection, as the unique facts of each case may require a different choice. This determination is best left for the trained professionals on the ground . . . .").

Finally, the rules are not invalid for failing to address the homogenization of blood clots before testing. As detailed above, *supra* Issue I, at 20–22, this Court should decline to address the issue because Goodman did not raise it in the proceedings before DOAH, and the Fourth District did not actually pass upon the issue. However, should this Court decide to address the issue, it should reject Goodman's attempt to invalidate the rules on this basis. As the Fourth District explained, "[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." *Goodman*, 203 So. 3d at 915 (citing *Wissel v. State*, 691 So. 2d 507, 507–08 (Fla. 2d DCA 1997)). There is no evidence that the rules' silence as to the homogenization process for clotted blood samples results in inaccurate or

unreliable test results. What the evidence does reflect is that, if a sample is clotted, then a notation is made to document the issue. Further, if an appropriate subsample cannot be obtained from the collection tube due to clotting, then the sample is deemed "not suitable for testing." And if an analyst uses the homogenization process to break up a large clot, then the blood alcohol test result would still be accurate. Tr. 298 ("Q: Can you still get an accurate blood alcohol content from a clotted sample that you prep by homogenization? A: Yes.").

Goodman's attack upon the rules is theoretical and speculative, and contrary to what the record evidence reflects. *See State v. Friedrich*, 681 So. 2d 1157, 1161 (Fla. 5th DCA 1996) ("Based on this testimony, we conclude that the appellees' attempt to discredit the accuracy of the Intoxilyzer machines, and the breath test results, based on stock solution's lack of shelf-life study and dating, is too theoretical and speculative."). This Court should answer the first certified question in the negative and approve the Fourth District's decision.

III. THE CHALLENGED RULES ARE NOT INVALID FOR FAILING TO EXPRESSLY REGULATE THE SCREENING, DOCUMENTATION, AND REJECTION OF ANY UNFIT BLOOD SAMPLES.

Goodman's challenge to Rule 11D–8.013, which addresses the permitting of blood alcohol analysts and testing procedures, likewise fails. The Rule adequately ensures the reliability and consistency of blood alcohol testing, and the absence of a regulation expressly mandating certain specific procedures pertaining to the screening, documentation, and rejection of any unfit blood samples does not render that provision invalid.

Based on "the evidence presented at the hearing," the ALJ found that "analysts routinely examine and document the condition of samples as a matter of standard laboratory practice." R3:419. Multiple witnesses testified that they routinely inspect blood samples and document any irregularities, such as clots. Specifically, Laura Barfield testified that she routinely inspected samples before testing, and she regularly noted any clotting or other irregularities in the case file. Tr. 137–38, 154. This inspection process is a "common step" in the toxicology process that occurs upon opening inventory and evidence. Tr. 154. Dr. Goldberger similarly testified that he requires his analysts to make a notation in the file if a sample is clotted or not suitable for testing. Tr. 296, 297, 351. Other witnesses, including two analysts from the laboratory where Goodman's blood was tested (one of whom actually tested the sample), confirmed that they routinely inspect

and document in writing any irregularities. R1:133, 142–44, 151, 170, 173, 185. Notably, Goodman does not point to any evidence indicating that there were irregularities in his case.

Witnesses also addressed why the Department's rules should not mandate specific and inflexible procedures governing every step of the testing process. Specifically, Dr. Goldberger explained that including such details in the rule itself would be "bad protocol" because the rules are meant to be static. Tr. 304. "The field of forensic science is moving rapidly forward these days. . . . [G]ood scientific practice is constantly evolving. The work in the laboratory is constantly evolving, constantly improving and modifying." Tr. 356–57. Codifying into rule one set practice would impede this evolution, "and it could take years to excise" such a rule. Tr. 357. As the Fourth

District explained, requiring the Department to regulate to the extent that Goodman urges

> would run the risk of locking in today's current scientific methodology, preventing the evolution and improvement of the system. It would also deprive both the State and criminal defendants of the expertise and discretion of the analysts, as their training and practical experience is necessary to properly address the wide variety of factual scenarios that may arise.

Goodman, 203 So. 3d at 915 (footnote omitted).

This Court should reject Goodman's attempt to impose a hypertechnical requirement on the Department to include step-by-step regulation of what occurs in

a laboratory. *See Wissel*, 691 So. 2d at 508 ("We likewise conclude that appellant's attack, based on the lack of a rule or regulation to cover every step of the testing procedures for breath test instruments, is not only speculative and theoretical, but also hyper-technical."); *Friedrich*, 681 So. 2d at 1162 ("We cannot say FDLE is remiss for not adopting rules or protocols in this regard, based on this record.")

Finally, the Rule is not invalid on due process grounds. As noted above, Goodman's due process argument is not properly before this Court. *See supra* Issue I, at 22–23. It also fails on the merits. In *Bender*, this Court overturned a trial court decision finding a regulation governing breathalyzer tests invalid on due process and equal protection grounds because it failed to incorporate the manufacturers' procedures for maintenance and operation of breathalyzer equipment. 382 So. 2d at 700. Explaining that there had been no showing that the operator manuals were unavailable, this Court found that due process and equal protection were not violated because the defendants each had a right to attack the reliability of the testing procedures or the operator's qualifications in their individual court proceedings. *Id.* Similarly, because the record evidence in this case establishes that blood samples are routinely inspected and any irregularities, such as clotting, are documented, this information would be available to any defendant to use in attacking the reliability of individual blood alcohol test results.

This Court should answer the second certified question in the negative and approve the Fourth District's decision.

CONCLUSION

This Court should answer the certified questions in the negative and approve the Fourth District's decision.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief was prepared in Times New Roman, 14-point font, in compliance with Florida Rule of Appellate Procedure 9.210(a)(2).

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