Supreme Court of Florida

No. SC16-1752

JOHN GOODMAN,
Petitioner,

vs.

FLORIDA DEPARTMENT OF LAW ENFORCEMENT,
Respondent.

[February 1, 2018]

PER CURIAM.

This case is before the Court to review the decision of the Fourth District Court of Appeal in Goodman v. Florida Department of Law Enforcement, 203 So. 3d 909 (Fla. 4th DCA 2016). In its decision, the district court ruled upon the following questions, which the court certified to be of great public importance on rehearing:

> (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. We have jurisdiction. See art. V, § 3(b)(4), Fla. Const. For the following reasons, we answer both certified questions in the negative.

FACTUAL AND PROCEDURAL BACKGROUND

In February 2010, Petitioner, John Goodman, was involved in a car accident, which resulted in a death. Afterward, a nurse at Wellington Regional Hospital drew Goodman's blood for blood alcohol testing pursuant to Florida's implied consent law. Goodman was ultimately convicted of, and sentenced for, DUI manslaughter/failure to render aid and vehicular homicide/failure to give information or render aid.[1]

At trial, Goodman moved to exclude the blood alcohol test results based, in part, on the blood collection method utilized. Goodman asserted that the nurse who collected his blood substituted a 25-gauge butterfly needle for the 21-gauge needle in the blood collection kit supplied by law enforcement. Essentially, this challenge was directed to the sufficiency of Florida Administrative Code Rule

1. His criminal appeal proceeded separately. Recently, the Fourth District affirmed Goodman's DUI manslaughter conviction, but vacated his vehicular homicide conviction on double jeopardy grounds. Goodman v. State (Goodman II), 229 So. 3d 366 (Fla. 4th DCA 2017).

11D-8.012.[2] Thus, the trial court deferred ruling on the motion pending resolution of the challenge at the Division of Administrative Hearings (DOAH).

In his DOAH petition, Goodman challenged the validity of an existing Rule under section 120.56(3), Florida Statutes (2009). Specifically, he disputed whether the Florida Department of Law Enforcement (FDLE) had the authority to promulgate Rules related to blood collection, along with the sufficiency of Rules 11D-8.012 and 11D-8.013 to produce scientifically reliable results.[3] The petition alleged that these deficiencies amounted to an invalid exercise of delegated legislative authority under various provisions of section 120.52(8), Florida Statutes (2009).

Blood Collection Equipment at Issue

There are two relevant types of needles in this case: straight and butterfly needles. Upon insertion, a straight needle evacuates blood directly into a collection tube; whereas, a butterfly needle has plastic tubing which connects the needle to the collection tube. Both needles are connected to vacuum collection tubes. Although Rule 11D-8.012(2) requires collection tubes to contain an

2. Hereinafter, any reference to a "Rule" will be to those in chapter 11D-8 of the Florida Administrative Code, unless otherwise specified.

3. In this Court, Goodman abandoned his challenge of FDLE's authority to promulgate blood collection Rules. Therefore, it will not be addressed here.

anticoagulant, there is no separate anticoagulant in the butterfly needle tubing itself. Anticoagulant that is in the collection tube prevents clotting, but it will not dissolve any already formed clots. Without anticoagulant, blood can begin to clot within seconds after collection, depending on the patient.

Generally, law enforcement blood collection kits contain 21-gauge straight needles. However, butterfly needles may be used for blood collection on certain individuals with damaged veins or to allow movement without displacing the needle and damaging the vein. Dr. Bruce Goldberger, an FDLE expert and the Director of Toxicology at the University of Florida College of Medicine, noted that he has seen butterfly needles substituted for the original needles in law enforcement kits on occasion when his laboratory conducted blood alcohol testing.

Needle gauge refers to the size of the internal diameter of the needle, and it is an important aspect of blood collection. The gauge and actual size of the needle have an inverse relationship; thus, a higher gauge number translates to a smaller diameter. According to Goodman's blood collection expert, George Souza, the standard needles recommended for blood collection are 21- and 22-gauge straight needles. Experts from both sides disputed the suitability of collecting blood with a 25-gauge butterfly needle when the sample will be tested for alcohol. For Goodman, Souza testified that use of a 25-gauge butterfly needle for blood collection is below the standard of care. Conversely, for FDLE, Dr. Goldberger

testified that he considered samples collected with 25-gauge butterfly needles as valid for blood alcohol testing under the testing method used in Florida, which is detailed below.

Both the Rules and relevant statutes are silent as to the appropriate needle type or gauge. Instead, the Legislature restricted medical decisions regarding blood collection to health professionals by statute:

> 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 its alcoholic content . . . .

§ 316.1932(1)(f)2.a., Fla. Stat. (2009).

Potential Issues Affecting Reliability of Blood Alcohol Testing

Blood naturally clots through the coagulation of components in the blood. As a result, clotting changes the composition of a blood sample, and it can artificially increase the alcohol content in the sample. Alcohol is also water-soluble; as clots form into solids, the alcohol follows the remaining liquid and elevates the alcohol concentration in the testable, liquid portion of the sample. However, whether clotting affects the test result depends on the degree of clotting. For instance, a serum sample (fully clotted) could produce a result that is approximately a sixteen percent higher alcohol reading than unclotted whole blood. Whereas, microclots—clots that are nearly invisible to the naked eye—might have

absolutely no effect on the test result. According to testimony, if a microclot is large enough to prevent pipetting the sample, then it could impact the accuracy and reliability of the test result.[4]

Testimony indicated that improper blood collection practices, such as using the wrong needle or improperly applying a tourniquet, can increase the chance of a sample having clotting or hemoconcentration. According to Souza, it would be "very unlikely" for either clotting or hemoconcentration to occur in blood collected with a 21-gauge straight needle and the proper tourniquet. Although butterfly needles increase the time between removal of blood and mixture with the anticoagulant compared with straight needles, Dr. Goldberger testified that such time frame difference was "[n]othing significant." Moreover, evidence showed that despite the presence of anticoagulant, clots can still form within the collection tube if the collector fails to properly invert the tube or the blood is improperly collected.

Every blood analyst in this record testified that if a sample had an issue with clotting it would be noted on the laboratory file. Goodman submitted an expert witness on blood alcohol analysis who was a former manager of FDLE's Alcohol Testing Program (the Program). That witness testified that, while at FDLE, she

4. Pipetting is the process of a blood analyst drawing a subsample from the collection tube to transfer it into a testing vial.

would not make any notation of clotting on the toxicology report; rather, she would make a note on the laboratory file, which was also available to defendants through a public records request. Toxicology reports are sent to law enforcement after testing, while laboratory files stay with the analysts and are not automatically sent to defendants. Further, Goodman's expert and Dr. Xiaoquin Shan, a Palm Beach County Sheriff's Office (PBSO) blood analyst, both confirmed that analysts can calculate the correct corresponding whole blood alcohol content even if there are clotted samples.

Neither party presented comprehensive data concerning the extent of any perceived testing reliability issues across the State. Goodman's expert had conducted thousands of blood alcohol analyses during her three and a half years performing blood alcohol analysis at FDLE and only encountered a "bad sample" on approximately "10, 15 times maybe." It should be noted that her definition of a "bad sample" was far broader than merely clotted samples.

FDLE Rules and Blood Alcohol Testing

The two relevant Rules in this case are Rule 11D-8.012, which governs labeling and collection of blood samples, and Rule 11D-8.013, which governs permitting of blood alcohol analysts.

Rule 11D-8.012 sets forth the necessary procedures prior to a sample arriving at a laboratory for analysis. The Rule states that the skin must be cleansed

with an alcohol-free antiseptic, and the collection tube must contain anticoagulant and preservative. Fla. Admin. Code R. 11D-8.012(1)-(2). Moreover, the collection tube must be inverted following collection, labelled with certain identifying information, and refrigerated at certain stages prior to testing. Id. 11D-8.012(3)-(5).

To be permitted as a blood analyst under Rule 11D-8.013, an applicant must have minimum qualifications and submit for approval a "complete description of proposed analytical procedure(s)," or a standard operating procedure (SOP). Fla. Admin. Code R. 11D-8.013(1)-(2). FDLE subjects these analysts to proficiency testing to ensure that each analyst, using his or her SOP, can accurately determine the alcohol content of five different samples. Id. 11D-8.013(2)(b). Subsequently, analysts must renew their permits through proficiency testing. Id. 11D-8.014.

Rule 11D-8.002(14) requires the blood tested by the Program to be "whole blood." Essentially, whole blood is all of the blood together without any parts removed. The only approved method for blood alcohol testing under the Program is gas chromatography (GC), Fla. Admin. Code R. 11D-8.011, and Florida forensic laboratories universally use headspace GC.

Under headspace GC, a blood analyst "thoroughly mix[es]" a sample before pipetting a few drops for testing. Although mixing the sample prior to pipetting it is "good laboratory practice," the Rules do not explicitly require this action. Still,

FDLE's expert described mixing as "just part of the practice in the laboratory." After this sub-sample is separated into a specialized vial, it is mixed with internal standard. Internal standard is a liquid that dilutes the blood and makes the blood alcohol results quantifiable. While the Rules require the addition of an internal standard, the exact amount is not prescribed. Next, the analyst places the prepared sample into a headspace autosampler, which heats and pressurizes the sample. This causes any alcohol contained in the sample to equilibrate in the headspace above it. That headspace gas is then pushed through a transfer line into the gas chromatograph, where the gas interacts with coated columns to give an alcohol content reading.

Nothing in the Rules specifically requires analysts to screen for irregularities such as clotting. Although the Rules do not require blood analysts to document irregular samples, it is standard laboratory practice to do so. Some laboratories' SOPs require analysts to make that notation; however, the PBSO SOP does not. Regardless, the blood analysts from the PBSO testified that they would make a notation of any clotting to place all parties on notice that the results should be interpreted to take into account an irregularity such as clotting. Additionally, Dustin Yeatman—the PBSO blood analyst who analyzed Goodman's blood—testified that any irregularities are always documented and reported. Also, he stated that Goodman's sample was thoroughly mixed prior to testing.

Patrick Murphy, the FDLE manager of the Program, testified that the Rules are intended to be a minimum framework for blood analysts. FDLE's expert opined that the Rules should be broad enough to allow laboratories to use their own individualized methods if they conform to the framework of the Rules. One reason for that is to ensure that the Rules are not "static" because if science changes, the Rules will lag behind due to the strict statutory procedure for amending or adopting Rules. Although Murphy expected that analysts would document irregularities, he would not reject an SOP for failing to include that requirement because it is not explicitly required by any Rule. Goodman's expert testified that analysts visually inspect the sample for irregularities prior to testing. The expert conceded and agreed that gross examination of a sample is a "common step" when analysts open and inventory the evidence, but the Rules do not specifically require it.

DOAH Final Order

The administrative law judge (ALJ) denied all of Goodman's challenges. The ALJ found that despite Rule 11D-8.012 requiring that collection tubes contain preservative and anticoagulant, blood samples "can, on occasion, include [clotted] blood." Moreover, he found that the type of needle used and a failure to properly mix the blood with anticoagulant in the tube could both cause clotting. Finally, he found that the "evidence fails to establish that the mere presence of [clotting]

inevitably precludes the withdrawal of a subsample that properly reflects the components of the whole blood contained in the collection tube." An additional finding supported that conclusion: "the accuracy of the blood alcohol level reported by the subsample is related to the degree of [clotting] present in the sample." To this end, the ALJ concluded that the "omission from the rule of a requirement related to needle gauge and tourniquet usage is of no material consequence." Further, the ALJ found that the evidence established that "analysts routinely examine and document the condition of samples as a matter of standard laboratory practice." Therefore, the ALJ likewise concluded that the "omission of such a requirement does not provide a basis to invalidate the rule."

Appeal to the Fourth District

Goodman appealed the Final Order to the Fourth District, raising the same challenges. Goodman, 203 So. 3d at 912. The Fourth District affirmed the ALJ's rejection of each challenge. Id. at 915.

As to Goodman's challenge of Rule 11D-8.012, the Fourth District concluded that 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." Id. at 914. The Fourth District noted that "clotting can affect the accuracy of a blood alcohol test." Id. at 913. However, it reasoned that

it is still possible to obtain an accurate blood alcohol content (BAC) reading from a clotted sample through a "homogenization process." Id. at 913. Moreover, the court stated that clotting problems are avoided by the standard practice of blood analysts mixing a sample prior to testing. Id. at 914. Distinguishing Miles, the Fourth District concluded that "clotting is notably different than the flaws caused by the lack of refrigeration in Miles, which could not be rectified after the fact." Goodman, 203 So. 3d at 914.

Pertaining to Goodman's challenge of Rule 11D-8.013, the Fourth District noted testimony that blood analysts routinely document "any irregularities in blood samples," which supported the ALJ's finding that "analysts routinely examine and document the condition of samples as a matter of standard laboratory practice." Id. at 914-15. The court explained 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. The Fourth District concluded that the Rules, in conjunction "with basic laboratory practices, are sufficient to protect the safety and interests of the court system and defendants alike." Id. at 915.

Subsequently, the Fourth District denied Goodman's motion for rehearing, but certified the two questions of great public importance. Id. at 916.

This review follows.

ANALYSIS

Section 120.68(1)(a), Florida Statutes (2009), authorizes judicial review of final administrative orders. "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. Accordingly, this court reviews factual findings on administrative rule challenges for competent, substantial evidence. See § 120.68(7)(b), Fla. Stat.; Dep't of Health v. Bayfront Med. Ctr., Inc., 134 So. 3d 1017, 1018 (Fla. 1st DCA 2012). Whereas, conclusions 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).

When challenging an administrative rule, the "petitioner has a burden of proving by a preponderance of the evidence that the existing rule is an invalid exercise of delegated legislative authority." § 120.56(3)(a), Fla. Stat. (2009). This is because "duly promulgated agency rules" are "presumptively valid until invalidated." See City of Palm Bay v. State Dep't of Transp., 588 So. 2d 624, 628 (Fla. 1st DCA 1991). For these reasons, the "challenging party bears a heavy burden." State Bd. of Optometry v. Fla. Soc'y of Ophthalmology, 538 So. 2d 878, 884 (Fla. 1st DCA 1988).

The Implied Consent Law, Bender,[5] and Miles

To address drunk driving in Florida, the Legislature enacted the implied consent law. See §§ 316.1932, 316.1933, 316.1934, Fla. Stat. (2009). One function of this statutory scheme is to imply the consent for a blood alcohol test of any driver arrested under suspicion of driving under the influence. Id. § 316.1932(1)(a)1.a. If properly administered, the test results give rise to criminal presumptions of impairment. See id. § 316.1934(2)(c) (making a BAC of 0.08 or higher prima facie evidence of impairment). Thus, the tests must be scientifically reliable and accurate. See Bender, 382 So. 2d at 699. However, the presumptions are rebuttable and a defendant may introduce "competent evidence bearing upon the question of whether [they were] under the influence of alcoholic beverages." § 316.1934(2), Fla. Stat.; Bender, 382 So. 2d at 699 ("[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.").

Through various statutes, the Legislature delegated authority to FDLE for "formulating and approving the process in which a person's blood is analyzed in determining its alcoholic content." Miles, 775 So. 2d at 952; see §§ 316.1932(1)(a)2., (f)1., Fla. Stat.; § 316.1933(2)(b), Fla. Stat. The delegated

5. State v. Bender, 382 So. 2d 697 (Fla. 1980).

authority under the implied consent law to FDLE's predecessor agencies was constitutionally tested in Bender. 382 So. 2d at 698-99. There, we approved the Legislature's delegation of authority for "breath- and blood-testing" as "proper and allowable." Id. at 700. In doing so, the Court stated the underlying purpose of the implied consent law, otherwise known as the "core policies":

> The purpose of those portions of sections 322.261 and 322.262[6] which direct law enforcement to use only approved techniques and methods is to ensure reliable scientific evidence for use in future court proceedings and to protect the health of those persons being tested, who by this statute have given their implied consent to these tests.

Id. at 699 (emphasis added). Although the adequacy of the Rules was not at issue in Bender, the Court concluded that compliance with the Rules is essential for reliable procedures and that "[n]one of the statutory presumptions can apply in the absence of compliance with the administrative rules." See id. at 699-700. Without compliance with the Rules, the presumptions would not apply; but the State could seek to admit the test results by laying the common law three-prong predicate explained in Robertson v. State, 604 So. 2d 783 (Fla. 1992).

Later, in Miles, this Court considered a certified question regarding the State's entitlement to the presumptions—in the absence of compliance with the implied consent law—by laying the admissibility predicate under Robertson.

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6. The statutes were amended and renumbered after Bender.

Miles, 775 So. 2d at 955-57. This Court's discussion of that certified question is not particularly relevant here; however, before reaching that issue, we addressed the adequacy of Rule 11D-8.012 for the first and only time. 775 So. 2d at 953-55. There, this Court affirmed a finding that Rule 11D-8.012 was inadequate for failing to include requirements for a preservative inside collection tubes or refrigeration of samples prior to testing. See 775 So. 2d at 951-53.

Testimony in Miles established that "proper preservation of a blood sample was fundamental to any quality control scheme." Id. at 954. There, FDLE experts testified that requiring a preservative or refrigeration 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. All of the experts in Miles agreed that the absence of a preservative or refrigeration could impact the alcohol content of a blood sample over time. See id. As to the adequacy of Rule 11D-8.012, this Court held that there was "no error in the First District's approval of the trial court's finding." Id. at 955. We explained that lack of maintenance standards in Miles only assured the integrity of blood samples "from the point of testing." Id. Moreover, the blood test at issue took place fourteen days after collection, and the evidence showed that "fourteen days without refrigeration may well have impacted the integrity of the blood sample." Id. Concluding, this Court reiterated its agreement that the absence of those particular maintenance standards rendered

Rule 11D-8.012 inadequate and inconsistent with the purpose of the implied consent law to ensure reliable test results. Id.

The present case is unique "in that the adequacy of the rule itself was challenged . . . as opposed to the noncompliance with a rule." Id. at 954 n.4 (citing Albritton v. State, 561 So. 2d 19 (Fla. 5th DCA 1990); Donaldson v. State, 561 So. 2d 648 (Fla. 4th DCA 1990)). Such circumstances amount to a facial challenge to the sufficiency of two agency rules. See Fairfield Communities v. Fla. Land & Water Adjudicatory Comm'n, 522 So. 2d 1012, 1014 (Fla. 1st DCA 1988); cf. Butler v. State Dep't of Ins., 680 So. 2d 1103 (Fla. 1st DCA 1996) (addressing a facial challenge to the constitutionality of the statutory delegation of authority to an agency); Sw. Fla. Water Mgmt. Dist. v. Save the Manatee Club, Inc., 773 So. 2d 594 (Fla. 1st DCA 2000) (addressing a challenge to an agency's authority to implement or promulgate rules pursuant to the enabling statute).

Sufficiency of Rule 11D-8.012

Goodman argues that Rule 11D-8.012 is inadequate because it fails to prescribe any requirements for needle gauge or tourniquet usage. We disagree.

It is undisputed that Rule 11D-8.012 governs blood labeling and collection and that the Rule does not specify a needle or the tourniquet techniques to be used. In its entirety, Rule 11D-8.012 follows:

11D-8.012 Blood Samples – Labeling and Collection

(1) Before collecting a sample of blood, the skin puncture area must be cleansed with an antiseptic that does not contain alcohol.

(2) Blood samples must be collected in a glass evacuation tube that contains a preservative such as sodium fluoride and an anticoagulant such as potassium oxalate or EDTA (ethylenediaminetetraacetic acid). Compliance with this section can be established by the stopper or label on the collection tube, documentation from the manufacturer or distributor, or other evidence.

(3) Immediately after collection, the tube must be inverted several times to mix the blood with the preservative and anticoagulant.

(4) Blood collection tubes must be labeled with the following information: name of person tested, date and time sample was collected, and initials of the person who collected the sample.

(5) Blood samples need not be refrigerated if submitted for analysis within seven (7) days of collection, or during transportation, examination or analysis. Blood samples must be otherwise refrigerated, except that refrigeration is not required subsequent to the initial analysis.

(6) Blood samples must be hand-delivered or mailed for initial analysis within thirty days of collection, and must be initially analyzed within sixty days of receipt by the facility conducting the analysis. Blood samples which are not hand-delivered must be sent by priority mail, overnight delivery service, or other equivalent delivery service.

(7) Notwithstanding any requirements in Chapter 11D-8, F.A.C., any blood analysis results obtained, if proved to be reliable, shall be acceptable as a valid blood alcohol level.

Fla. Admin. Code R. 11D-8.012. Because Rule 11D-8.012 does not specifically address the blood collection standards that are challenged here, this Court must decide if the absence of those standards renders the Rule facially inadequate in light of the core policies of the implied consent law. See Goodman, 203 So. 3d at 916; Miles, 775 So. 2d at 955; Bender, 382 So. 2d at 699-700.

In the Final Order, the ALJ found that blood clotting "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." The ALJ also found that clotting "alters the ratio of liquid to solid in the sample and can increase the concentration of alcohol in the liquid portion of the sample." Both of these findings were supported by competent, substantial evidence from experts on both sides. The ALJ did not specifically make findings as to needle gauge; however, the record demonstrated that clotting may be more likely to occur in blood draws using smaller needles (i.e., 25-gauge needles). Relatedly, butterfly needles increase the time between evacuation of blood from the body and mixture with the anticoagulant in the collection tube. Souza and Dr. Goldberger disputed the relevance of that fact. The ALJ did not make any findings on hemoconcentration. The record contains scant evidence of hemoconcentration except a cursory indication that it can increase the alcohol content of a sample if a tourniquet is applied for too long prior to blood collection.

The ALJ further found that "analysts routinely examine and document the condition of samples as a matter of standard laboratory practice." In fact, checking for blood clots is an incidental requirement of headspace GC testing because analysts must pipette the sample prior to analysis. Competent, substantial evidence supported this finding through every blood analyst's testimony. Importantly, the

ALJ determined that the "evidence fails to establish that the mere presence of [clotting] inevitably precludes the withdrawal of a subsample that properly reflects the components of the whole blood contained in the collection tube." He explained, noting that "the accuracy of the blood alcohol level reported by the subsample is related to the degree of [clotting] present in the sample." As detailed below, these last two findings were supported by competent, substantial evidence and supported the ALJ's final determination.

Goodman argues that the ALJ's finding that clotting does not "inevitably preclude" an accurate result indicates that the ALJ failed to take Miles and the core policies into account; however, Goodman fails to grasp the relationship between the ALJ's two findings on clotting. The ALJ correctly identified that there are various degrees of blood clotting, and the accuracy of a result directly relates to that degree. According to evidence, that spectrum of blood clotting in samples could range anywhere from invisible microclots to fully clotted serum. As FDLE's expert confirmed, microclots that do not affect a blood analyst's ability to pipette a sample have absolutely no effect on a test under headspace GC. Whereas, due to clotting, the alcohol content in a serum sample is artificially elevated compared to its whole blood alcohol content by approximately sixteen percent. As a result, the ALJ correctly found that not all clotted blood samples present reliability issues. This finding was a corollary to the immediately preceding finding: that clotting

does not "inevitably preclude[] the withdrawal of a subsample that properly reflects the components of the whole blood."

Multiple portions of the record shed further light on the ALJ's finding that clotting does not "inevitably preclude" accurate results. First, unlike Miles where an analyst had no way to know that a defect existed or any ability to rectify the defect after the fact, analysts here check for blood clots as a matter of standard laboratory practice prior to testing. Because analysts inspect and pipette samples prior to testing, any clotting irregularities that could impact a result would be evident. Second, Goodman's witness and a PBSO blood analyst both testified that analysts can perform simple calculations to account for clots and determine a sample's alcohol content without the clot. Fully clotted serum samples are not valid for testing under Rule 11D-8.002(14). Regardless, this testimony demonstrates that analysts theoretically work backwards to eliminate any effect of clotting because—as the ALJ found—the degree of clotting has a direct relationship to the accuracy of a test result. This evidence is in stark contrast to Miles, where the potential effects of heat and bacteria were irreversible after the fact and there was no way to account for the impact. See Miles, 775 So. 2d at 954-55, 954 n.5. Finally, defendants are free to challenge the accuracy of their result in any given case. § 316.1934(2), Fla. Stat.; Bender, 382 So. 2d at 699. Indeed, defendants may dispute whether clotting affected their sample or an analyst erred

in preparing the sample. However, Goodman failed to present any such challenge or evidence.

What is more, we must recognize that Miles came to this Court with a different procedural posture. There, as it pertained to the sufficiency of Rule 11D-8.012, this Court affirmed the First District's approval of a trial court finding that Rule 11D-8.012 was inadequate. See Miles, 775 So. 2d at 953-55. Here, the ALJ came to the opposite conclusion. This detail is particularly relevant in light of the statutory limitation on judicial review of final administrative orders:

> [T]he 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. Despite the fact that clotting and hemoconcentration can theoretically increase BAC, the ALJ made factual findings—supported by competent, substantial evidence—to buttress his rejection of Goodman's challenge. The ALJ determined that Goodman failed to satisfy his burden and, based on this record, we cannot disturb that conclusion.

However, whether Rule 11D-8.012 is facially adequate under Miles presents a legal question, which the ALJ did not address and this Court reviews de novo. See Volusia Home Builders, 946 So. 2d at 1089.

Goodman's primary contention is that Miles and the core policies mandate that the Rules ensure scientific reliability. Relatedly, he contends that the ALJ

applied the wrong standard by finding that clotting does not "inevitably preclude" a proper BAC result. The ALJ failed to cite Miles, or any other case for the matter. However, as shown below, the ALJ correctly ruled that the absence of needle gauge and tourniquet standards does not render Rule 11D-8.012 facially inadequate. The limited law related to this question demonstrates that the facial requirements of the Rules need not regulate every conceivable contingency to comply with the core policy to ensure reliable results.

In Bender, after first announcing the core policies, we held that failing to promulgate a Rule that incorporated breathalyzer manufacturers' procedures for operation and maintenance did not violate a defendant's due process rights. 382 So. 2d at 700. The Rules there required the operation and maintenance to be in accordance with the procedures, but the procedures were not specifically enumerated. Id. We reasoned that the failure to provide those procedures was not a constitutional infirmity because there was no showing that the documents were unavailable. Id. Moreover, the defendants there had "the right in their individual proceedings to attack the reliability of the testing procedures or the operator's qualifications." Id. Thus, we already rejected a similar challenge to the absence of an express Rule when the Rule and its incidental procedures, in conjunction, facially ensure reliability and there is no evidence to the contrary. See id.

Similarly, in State v. Friedrich, 681 So. 2d 1157 (Fla. 5th DCA 1996), the Fifth District Court of Appeal reversed six orders granting defendants' motions in limine to exclude evidence of breath alcohol test results. Id. at 1159-60. Although Friedrich did not present a direct Rule challenge, the Fifth District considered whether a variation in the alcohol content of stock solution made breath test results scientifically inaccurate or not in compliance with the Rules. Id. at 1162-64. As in this case, in Friedrich, there were no Rules promulgated that concerned the composition of stock solution, which was prepared by FDLE and used in Florida to calibrate breathalyzers. Id. at 1163. Moreover, evidence demonstrated that there was a theoretical, mathematical possibility that stock solution could fall within FDLE's accepted range of variance while allowing certain breathalyzers to produce artificially higher alcohol content results. Id. at 1163-64. Because the defendants there did not provide any evidence to show that their breath tests met that possibility, the Fifth District rejected their claims as "speculative and theoretical." Id. at 1163. However, the Fifth District clarified that defendants could challenge the validity of breath tests if their results were potentially impacted by that variation. Id. at 1163-64. The court explained that when promulgating Rules, FDLE "must do a competent job, but not a perfect one." Id. at 1164.

Below, the Fourth District distinguished Miles by noting that clotting can be "rectified after the fact," unlike the lack of a preservative or refrigeration in Miles.

Goodman, 203 So. 3d at 914. Although the Fourth District was wrong as to the appropriate method to remedy clotting,[7] the record demonstrates that clotted blood can be identified and remedied to ensure reliable testing—a critical distinction from the defect in Miles. Blood analysts routinely check for blood clots when they prepare samples for testing under headspace GC. Conversely, in Miles, no evidence suggested that there was any way for analysts to know if heat or bacteria affected the sample. See Miles, 775 So. 2d at 951-55. We noted there that, absent maintenance standards, "the integrity of the sample is guaranteed only from the point of testing." Id. at 955. Yet, here, we can be confident in the results because analysts check for irregularities. Further, in Miles, an important consideration for this Court was that the experts were in complete agreement that the lack of a preservative or refrigeration could impact a blood sample. See id. Whereas, here, there was a battle of the experts as to the exact effects of clotting on samples and the proper scope of regulation. FDLE's expert testified to microclots having no effect on a sample under headspace GC and 25-gauge butterfly needles being acceptable for blood draws. Goodman's experts provided a blanket statement that clotted samples are always unreliable and testified that using 25-gauge butterfly needles is below the standard of care for blood draws. For these reasons, Miles is

7. The Fourth District misinterpreted Dr. Goldberger's testimony concerning homogenization.

factually distinguishable from this case. See also Vuong v. Fla. Dep't of Law Enf't, 149 So. 3d 174, 176-77 (Fla. 4th DCA 2014) (distinguishing Miles when there was disputed evidence as to the effect of modifications to breathalyzers and the ALJ found that "the evidence failed to establish the complained-of deficiencies had any impact on the reliability of breath alcohol tests").

Therefore, the core policy of the implied consent law to ensure scientifically reliable test results cannot be interpreted as strictly as Goodman contends. Instead, the core policy places on FDLE the "responsibility of establishing uniform and reliable testing methods in this scientific area." See Bender, 382 So. 2d at 700. Although that responsibility is weighty, it does not oppress FDLE with the impossible task of continuously regulating the potential existence of every theoretical problem that could occur during a blood draw.

To be sure, there is no Rule regulating needle gauge or tourniquet usage; still, Rule 11D-8.012 adequately ensures reliable results. Testimony established that any issues would likely result from poor blood collection practices. The Legislature provided for this concern by mandating that only medical experts such as doctors, nurses, or paramedics can collect blood for the purposes of determining its alcoholic content.[8] § 316.1932(1)(f)2.a., Fla. Stat. Further, any clotting that

8. In fact, regulating needle gauge and type could conflict with the other core policy: protecting the health of those tested. Bender, 382 So. 2d at 699. Smaller needles may be necessary for certain people with severely damaged veins.

could affect a test result would be noticeable when an analyst pipettes the sample because the pipette would be unable to cleanly draw a subsample. All analysts testified that they make a notation of any noticeable clotting on the laboratory file, which defendants can obtain via a public records request. In any situation, a defendant could challenge the accuracy of the test or qualifications of the analyst, which has been the law in Florida for nearly forty years. See Bender, 382 So. 2d at 699. Accordingly, we conclude that Rule 11D-8.012 facially ensures reliable blood test results and any question as to the accuracy of a particular test is best determined on a case-by-case basis. See Vuong, 149 So. 3d 174; Wissel v. State, 691 So. 2d 507, 508 (Fla. 2d DCA 1997) (rejecting an "attack, based on the lack of a rule or regulation to cover every step of the testing" because it was "not only speculative and theoretical, but also hyper-technical"); Friedrich, 681 So. 2d 1157; see also State v. Kleiber, 175 So. 3d 319, 321 (Fla. 5th DCA 2015) ("[M]inor deviations from the rules will not prohibit the test results from being presented, as long as 'there is evidence from which the fact finder can conclude that the [test] itself remained accurate.' " (quoting State v. Donaldson, 579 So. 2d 728, 729 (Fla. 1991))).

Likewise, as a practical matter, butterfly needles may be necessary for involuntary blood draws on drunk drivers to allow movement without rupturing their veins. It follows that both decisions are best made by medical professionals, not lawyers.

Finally, Goodman looks to the implied consent laws from five other states in an unpersuasive attempt to convince this Court that FDLE has an easy fix to mandate the use of commercially available blood draw kits. Although other states' rules are not controlling, it is telling that even some of those states provide latitude for medical experts depending on the circumstances. See Ill. Admin. Code tit. 20, § 1286.320(d) (2015) ("Officers shall use DUI kits provided by the Department, if possible. If kits are not available, officers may submit two standard grey top vacuum tubes."). Moreover, no party or court located any rule that prescribes a needle gauge to use during blood alcohol draws. See Goodman, 203 So. 3d at 915 n.6 (surveying other states).[9] The logic behind Goodman's contention risks locking scientific practices into today's methodology. See 203 So. 3d at 915. For example, testimony established that prior to the DOAH hearing, standard, commercial law enforcement blood collection kits contained 21-gauge straight needles, which Goodman reiterated at oral argument. However, Dr. Goldberger testified that butterfly needles have been used in Florida, at least on some occasions. Moreover, a recent Wisconsin Supreme Court decision suggests that straight needle kits may not be ubiquitous, noting the "blood draw kits . . .

9. It is telling that we found a New Jersey regulation mandating a needle gauge for body piercings, N.J. Admin. Code § 8:27-6.5(e); oddly, there is no corresponding requirement for blood alcohol draw needles.

contain[ed] a 'butterfly needle.' " State v. Kozel, 889 N.W.2d 423, 428 (Wis. 2017). Therefore, Goodman's argument regarding a DUI kit requirement is self-defeating. Because the statutory process for amending or promulgating a Rule is difficult, see § 120.54, Fla. Stat. (2017), the Rules set a due-process floor, while allowing some flexibility for science to advance. See Bender, 382 So. 2d at 700 (requiring constant legislative supervision of the administration of FDLE's scientific methods was "neither practically possible nor required by our constitution"). On this record, we cannot impede that legislatively created scheme of FDLE oversight.

Resultantly, we conclude that Rule 11D-8.012 is not inadequate.

Sufficiency of Rule 11D-8.013

Goodman argues that Rule 11D-8.013 is inadequate because it fails to specify that analysts must screen, document, and reject unfit samples. Again, we disagree.

The ALJ found that blood "analysts routinely examine and document the condition of samples as a matter of standard laboratory practice." Concerning this finding, the record is telling. All the blood analysts testified that they examine and document if a sample is clotted. Goodman's expert agreed and testified that examining the sample is a "common step" when analysts open and inventory the evidence. During this gross examination, analysts invert the collection tube and

they would be able to "feel [large clots] going from one end to another." Moreover, analysts incidentally check for microclots due to the nature of conducting a blood analysis under headspace GC. Analysts "thoroughly mix" each sample before pipetting it for transfer to the testing vials. When the sample is pipetted, "the presence of clots become[s] very evident" to an analyst. Importantly, the laboratory file where all analysts note whether a sample exhibited clotting is available to defendants. Because of this, the ALJ concluded that the "omission of such a requirement [to examine and document the condition of samples] does not provide a basis to invalidate the rule." Clearly, competent, substantial evidence supported that determination.

Notwithstanding the routine practice described above, Dr. Goldberger testified that individual laboratories' SOPs should prescribe a procedure for screening, documenting, and rejecting unfit samples. SOPs must be approved by FDLE under Rule 11D-8.013(2)(a), and FDLE would not reject an SOP solely because it did not include these procedures. Moreover, the PBSO SOP does not provide any specific requirements on the challenged procedures. However, Yeatman, who tested Goodman's blood, stated that the PBSO's practice is that "any time a sample is clotted, it is documented on the analyst's case file and is also reported."

Goodman argues that despite the established fact that blood analysts routinely perform these procedures, Rule 11D-8.013 does not require them. Therefore, he argues, the Rules cannot ensure reliable results.

In Miles, this Court rejected the argument that blood preservation and maintenance steps were "so fundamental that [they] did not need to be in a rule because anyone dealing with blood samples would be aware of the need for proper preservation." 775 So. 2d at 954. However, Goodman's comparison—between including a preservative inside collection tubes or refrigerating the sample in-transit with requiring a trained scientist to record when the outcome of a test might be inaccurate—is not persuasive. In Miles, the maintenance steps were not incidental to transporting a sample and applied to every person in the chain of custody, including potentially a mailman. See id. at 954-55; Rafferty v. State, 799 So. 2d 243, 247-48 (Fla. 2d DCA 2001). Whereas the challenged procedures here are merely incidental to testing and include elementary steps applying only to blood analysts—whom Rule 11D-8.013(2)(d) requires to be licensed clinical chemists, college-educated in chemistry, or physicians. Further, nothing in Miles suggested that blood samples were being properly preserved prior to the decision. In fact, a case from the Second District Court of Appeal showed that improper preservation and maintenance of blood samples was a problem in Florida prior to Miles, which posed a statewide threat to test reliability. See Rafferty, 799 So. 2d at

247 (calling the case "a textbook example of how not to handle blood"). However, here, the evidence demonstrates that there is no risk to the accuracy of blood tests in the absence of a Rule on screening, documenting, and rejecting unfit samples, because blood analysts are already doing this as a matter of standard laboratory practice.

In Wissel, the Second District considered a Rule challenge for failing to specify FDLE's procedures in preparing stock solution to be used in breathalyzer testing. 691 So. 2d at 507. The Second District held that "procedures that are implicit and incidental to procedures otherwise explicitly provided for in a properly adopted rule or regulation do not require further codification by a further adopted rule or regulation." Id. There, the defendant noted FDLE's failure to promulgate a procedure on how it mixed or produced stock solution, among other claims. Id. at 508. However, the court explained that "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." Id. Below, the Fourth District applied Wissel to this case, noting that 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." Goodman, 203 So. 3d at 915. Similar to Wissel, Goodman's argument fails because blood analysts already screen, document, and reject unfit samples as an implicit and incidental part of headspace GC testing.

And—without more—Goodman's position leaves him tilting at windmills. See Goodman, 203 So. 3d at 912 (calling Goodman's position "an overbroad solution in search of a problem"); Vuong, 149 So. 3d at 176-77 (affirming an ALJ's rejection of a Rule challenge when the impact of a modification was disputed and the evidence failed to establish that the test results were unreliable); Wissel, 691 So. 2d at 508 (repudiating a "speculative and theoretical, but also hyper-technical" rule challenge); Friedrich, 681 So. 2d at 1163 (rejecting "speculative and theoretical" claims).

Relatedly, in Miles, evidence showed that the blood sample was unrefrigerated and without a preservative for fourteen days, which "may well have impacted the integrity of the blood sample." 775 So. 2d at 955. This Court relied on that fact to justify its holding that Rule 11D-8.012 was "inadequate and inconsistent with the purpose of the implied consent law." Id. Whereas, here, there is absolutely no indication that Goodman's sample was clotted or exhibited hemoconcentration. See Wissel, 691 So. 2d at 508 (repudiating a "speculative and theoretical, but also hyper-technical" rule challenge); Friedrich, 681 So. 2d at 1163 (rejecting "speculative and theoretical" attack). In fact, Yeatman, who tested Goodman's blood, testified that he always documents clotting and he thoroughly mixed Goodman's blood, thereby demonstrating that there were no clotting issues in this case and the record provides absolutely no evidence to the contrary.

Taking Goodman's contention to its logical conclusion, Rule 11D-8.013 could be inadequate for an unending litany of reasons. For example, the Rule does not require blood analysts to wear rubber gloves to prevent contamination. Under Goodman's reasoning, even if it is conclusively proven that each and every blood analyst in Florida wears rubber gloves when handling samples, the Rule would be inadequate for failing to require them. Although it may be preferable for FDLE to promulgate a Rule that specifically lays out every minute detail of a test, this Court is not positioned to make that determination. Further, such an exercise "would swiftly devolve into a hopeless endeavor and serve only to expand [FDLE's] regulations to epic lengths." Goodman, 203 So. 3d at 915.

Based on the foregoing, we conclude that Rule 11D-8.013 is not inadequate.

CONCLUSION

Accordingly, we answer both certified questions in the negative and approve the decision of the Fourth District.

It is so ordered.

PARIENTE, LEWIS, QUINCE, CANADY, POLSTON, and LAWSON, JJ., concur.
LABARGA, C.J., recused.

NOT FINAL UNTIL TIME EXPIRES TO FILE REHEARING MOTION AND, IF FILED, DETERMINED.

Application for Review of the Decision of the District Court of Appeal – Certified Great Public Importance

Fourth District - Case No. 4D14-3263

(Palm Beach County)

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