IN THE SUPREME COURT OF FLORIDA

CASE NO. SC16-1752

JOHN GOODMAN,

Petitioner,

v.

FLORIDA DEPARTMENT OF LAW ENFORCEMENT,

Respondent.
_____/

L.T. CASE NOS.
4D14-3263
Div. Admin. Hearing No. 14-1918RX

PETITIONER'S REPLY BRIEF ON THE MERITS

JANE KREUSLER-WALSH and
STEPHANIE L. SERAFIN
LAW OFFICE OF KREUSLER-WALSH, COMPIANI & VARGAS, P.A.
501 South Flagler Drive, Suite 503
West Palm Beach, FL 33401-5913
(561) 659-5455

BRIAN A. NEWMAN
PENNINGTON, P.A.
215 South Monroe Street, 2nd Floor
P.O. Box 10095
Tallahassee, FL 32302-2095
(850) 222-3533

ELIZABETH L. PARKER
KAPLAN SCONZO & PARKER, P.A.
3399 PGA Blvd., Suite 150
Palm Beach Gardens, FL 33410
(561) 296-7000

Counsel for Petitioner, John Goodman

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POINT I

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

A. Rule 11D-8.012 fails to ensure scientifically reliable test results by failing to regulate needle gauge, tourniquet use and homogenization.

1. Needle gauge and tourniquet use

The ALJ found that using the wrong kind of needle or failing to mix the sample properly can cause clotting, and that clotting can occur even when the blood is collected in a glass tube containing anticoagulant (R:414; A:34).[1] 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" (R:415; A:35). "[T]he accuracy of the blood alcohol level reported by the subsample is related to the degree of coagulation present in the sample" (R:415; A:35). The ALJ concluded that clotting can raise the blood alcohol level in a sample tested using gas chromatography headspace analysis, the only testing method currently used in Florida for FDLE testing (R:419; A:39).

[1] The ALJ failed to address improper use of the tourniquet and hemocentration.

FDLE ignores these findings and glosses over the venipuncture process. Instead, FDLE contends needle size should not be regulated because some individuals might require a specific needle (AB:31-32). But FDLE's own expert, Dr. Goldberger, agreed proper collection techniques are of "paramount importance" to ensure a scientifically reliable result (R:744; *see* R:776-77).

The possibility that some individuals may require a different type of needle in some circumstances does not mean the rule should not address proper needle use. Florida Administrative Code Rule 11D-8.012 can and should be fashioned to regulate needle gauge and tourniquet use because both are critical aspects of blood collection. The rules could permit the blood drawer to use a different needle gauge, if medically necessary.

As one example already part of the Florida Administrative Code, in the context of Drug-Free Workplace Standards, rule 59A-24.005(1), governing collection site and specimen collection procedures, requires that "[t]he laboratory shall provide to the collection site, or collector, specimen collection kits." (AA:3). Other states similarly require use of a DUI kit for collecting blood samples:[2]

[2] These rules, statutes and forms are contained in the Appendix to this reply brief, which is cited using the symbol (AA:[.pdf page]). All emphasis is supplied unless indicated otherwise.

- **Colorado:** "Blood Specimen(s) must be . . . [c]ollected and labeled following the instruction provided in the forensic blood collection kit" (AA:50). 5 Colo. Code Regs. § 1005-2 (2013), Part 6.1.1;

- **Illinois:** "Officers shall use DUI kits provided by the Department, if possible" (AA:74). Ill. Admin. Code tit. 20, § 1286.320(d) (2015);

- **Louisiana:** "Blood drawn for the purposes of determining the alcoholic content therein shall have been taken with the contents of a sealed 'B-D Blood Alcohol Kit' Numbers 4000, 4990 or 4991 . . . or 'NIK Blood Alcohol Kit' Numbers 4000, 4990, 4991 . . . or similar blood collection kits as approved. Such kits will be made available to all law enforcement agencies by the Louisiana State Police" (AA:77). La. Admin. Code tit. 55, § 555(G) (2017). "Each approved kit must be manufactured specifically for blood alcohol determinations in living or post-mortem subjects" (AA:77). La. Admin. Code tit. 55, § 555(G)(1) (2017);

- **Maine:** "**Equipment for taking specimens.** For purposes of this section [Administration of Tests], only collection kits having a stamp of approval affixed by the Department of Health and Human Services may be used to take a sample specimen of blood or urine, except that

a self-contained, breath-alcohol testing apparatus if reasonably available may be used to determine the alcohol level" (AA:78). Me. Rev. Stat. tit. 29-A, § 2524.5 (2016);

- **North Dakota:** Office of Attorney General, Crime Laboratory Division, Submission of Blood Form 104 "contains directions and a checklist to ensure proper collection and submission of blood samples." *Filkowski v. Dir., N.D. Dep't of Transp.*, 862 N.W.2d 785, 791 (N.D. 2015) (internal citation omitted). The checklist on Form 104 includes, "Used an Intact Kit" and "Used Needle, Guide and Tube Provided in Kit" (AA:81).[3]

Requiring use of a DUI kit is an easy fix that is necessary to ensure scientific reliability of blood alcohol test results. Since the authorized blood kit includes the appropriate gauge and type of needle (21-gauge straight needle) (R:537-39, 591-92), using that kit would ensure that the proper needle is used, absent proof that a different size and type of needle was medically necessary.

[3] North Dakota Office of Attorney General, Crime Laboratory Division, Submission of Blood Form 104 is available at https://attorneygeneral.nd.gov/alcoholtoxicology-testing/blood-alcoholtoxicology-submission-forms.

The FDLE concedes that rule 11D-8.012 already regulates the beginning of the collection process (the type of anesthetic that must be used before the blood draw, the type of collection tube, and the contents of the collection tube), and the end of the collection process (immediately inverting the tube several times to mix the blood with a preservative and anticoagulant, labeling the collection tube, refrigeration, and mailing or hand-delivery) (AB:25-26). Needle gauge and tourniquet use are just as critical to the collection process as those steps already regulated, yet there are no standards for needle gauge and tourniquet use.

2. The Fourth District and the trial court applied the wrong standard to the rules.

FDLE ignores Goodman's argument that the ALJ applied the wrong standard. The ALJ denied the rule challenge because irregularities in the blood sample will not "**inevitably**" produce an inaccurate result (R:415; A:35). This Court rejected the argument that producing reliable test results most of the time is enough in *State v. Miles*, 775 So. 2d 950, 955 (Fla. 2000). *See State v. Bender*, 382 So. 2d 697, 699 (Fla. 1980). In *Miles*, like here, the State's experts testified there was only a "remote" chance that lack of preservatives would lead to a higher blood alcohol level, and in some instances, could lead to a lower blood alcohol level. *Id.* at 954 n.5. Despite this remote possibility, this Court concluded that rule 11D-8.012 was inadequate because it did not ensure scientifically reliable test results.

Id. at 955.

The importance of proper collection techniques, in addition to proper screening and documenting by the blood analyst, is undisputed. FDLE's expert, Dr. Goldberger, testified that "**if** the gray-stopper tube is used properly **and** the collection technique has been successful, you end up with a whole blood sample that's not clotted in that tube" (R:725-26). It may be difficult to obtain an accurate blood sample result if the sample is clotted (R:740, 766-68). Dr. Goldberger stressed that ensuring a clotted sample is **not** tested goes to the reliability and suitability of the sample for testing (R:768-69). A clotted sample taken for forensic use should be rejected because it could overestimate the blood alcohol content by 15% (R:753-54, 767-68; *see also* R:719-20, 729-30).

Palm Beach Sheriff's Office (PBSO) analyst, Shan, testified that a clot changes the consistency of the makeup of the blood, adding that whether the clotted sample is whole blood depends on the degree of clotting (R:143). Shan would sometimes "remove" the clot, test the rest of the sample, and report it as whole blood (R:143-44, 150-51). But removing a clot removes a portion of the sample so it is no longer representative of the entire sample (R:670-71). PBSO analyst, Yeatman, admitted that his lab sometimes tests clotted blood, which does

not meet the requirement of the rules to test whole blood (R:185-88, 190).

B. The Fourth District spontaneously raised homogenization and used it as a basis to affirm.

FDLE preliminarily contends this Court should limit its review of the issues and decline to address homogenization because the Fourth District did not "pass upon" that issue (AB:20-22). The decision proves otherwise.

The Fourth District accepted the ALJ's finding that a smaller butterfly needle can increase clotting, which can affect the accuracy of a blood sample (A:6). Rather than addressing the ALJ's actual basis for its denial of Goodman's rule challenge (irregularities in a blood sample will not "inevitably" produce an inaccurate result[4]), the Fourth District concocted a new theory (homogenization cures clotting), which it then used to distinguish *Miles* (A:7). Citing to Dr. Goldberger's testimony about homogenizing clotted samples from dead bodies, the Fourth District concluded: "This 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" (A:7) Leaving aside for a moment the multiple flaws in this conclusion, including the fact that the ALJ made no such finding, it

[4] *See* R:415; A:35; *see also* R:419-20; A:39-40.

clearly formed the basis for the Fourth District's affirmance of Goodman's challenge to rules 11D-8.012 and 11D-8.013.

FDLE's further claim of waiver fails. Goodman did not address homogenization at trial or on appeal because FDLE never advanced the argument that it is a "cure" for clotting. FDLE's argument at trial was two-fold: (1) The anticoagulant in the collection tube will eliminate any clotting in the sample; and (2) clotting will not affect the blood alcohol test result under the gas chromatography method (R:380, 382-83, 389, 452). The concept that homogenization is a cure for clotting surfaced for the first time in the Fourth District's decision. Goodman addressed this new issue in his motion for rehearing and certification (AA:131-41). This Court has jurisdiction in this case and should address this argument.

1. The record does not support the Fourth District's conclusion on homogenization.

FDLE's homogenization argument is flawed. FDLE avoids Goodman's argument that the evidence does not support the premise for which the Fourth District used it. As Goodman explained in his Initial Brief at pages 36-37, the only testimony about homogenization came from Dr. Goldberger and was in the context of dead bodies. Blood clots from dead bodies are not whole blood.

Instead of addressing Goodman's argument, FDLE cites testimony about the standard practice to mix the sample in the lab (AB:28). Mixing is not the same as homogenization, a process designed to grind up clots. Mixing is done to make sure the analyst gets a sample representative of whole blood when he samples a portion of it (R:564, 755). If the sample is not mixed, and the serum has separated, that sample would not constitute whole blood and the analyst could get the wrong result (R:755-56). The anticoagulant in the tube will not erase a clot that is already formed, for example in the butterfly needle tubing (R:570-71, 599, 602, 667-68, 740).

2. If homogenization is the cure for clotting, then the rule is inadequate because it does not require homogenization.

If the Fourth District is correct that homogenization cures clots, then rules 11D-8.012 and 11D-8.013 do not contain the cure, rendering them inadequate. Just as refrigeration was a critical step in the blood testing process in *Miles*, homogenization is critical step here, under the Fourth District's reasoning. Like the lack of refrigeration in *Miles*, failure to homogenize "may well . . . impact[ ] the integrity of the blood sample." 775 So. 2d at 955. So too, mixing, a necessary step to avoid irregularities in the sample, is not required by the rule (R:756). In *Miles*, this Court rejected the FDLE's argument that a critical step can be omitted from the rules because it is part of standard laboratory practice. *Id*. at 951, 954-55.

As with needle gauge, the fix is easy—amend the regulation to include homogenization. As one example, the regulations governing blood alcohol analytical methods in Idaho cite to Idaho Administrative Code Rule 11.03.01.013 (2015), which requires blood to be recorded as grams of alcohol per 100 cubic centimeters of **whole blood** (AA:87). Analytical Method 1, Section 4.1.3.1 of the Blood Alcohol and Analytical Methods for the Idaho State Police Forensic Services,[5] provides as follows:

> Although the absolute determination that the sample is whole blood is beyond the scope of this analytical method, when it is the analyst's opinion that the intended blood sample is serum or otherwise questionable, the analyst has the following options.
>
> 4.1.3.1.1 Option One
> The sample is not analyzed. A comment "Specimen unsuitable for analysis" is placed on the analysis report.
>
> 4.1.3.1.2 Option Two
> The sample is analyzed for volatiles, and the report will make no mention of the sample having a biological origin or contain the disclaimer that the "sample(s) appears to be (insert type)".

(AA:105). Analytical Method 1, Section 4.2.3.4, governing sample preparation,

[5] Idaho Administrative Code Rule 11.03.01 and the Blood Alcohol and Analytical Methods manual for the Idaho State Police Forensic Services are contained in the Appendix to this reply brief. The Blood Alcohol and Analytical Methods manual can be found at https://www.isp.idaho.gov/forensics/index.html (follow "Analytical Methods" hyperlink, then follow "Blood Alcohol" hyperlink under "Current Analytical Methods").

provides: "[i]f a blood sample appears to be coagulated, the sample may require **homogenization** in a tissue grinder, or equivalent" (AA:107).

Rule 11D-8.012 contains no standards for needle gauge, tourniquet use, homogenization or mixing. As such, it fails to ensure reliable scientific testing of blood samples for use in court proceedings, rendering it invalid.

POINT II

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

The critical procedures of screening, documenting, and rejecting unfit samples must be in the rules to ensure scientific reliability. The premise of the FDLE and the Fourth District's argument—no rule regulating screening, documenting or rejecting an unfit blood sample is required because analysts routinely examine and document the condition of the samples as a matter of standard laboratory practice—conflicts with *Miles*, 775 So. 2d at 951, 954-55. In *Miles*, the FDLE argued, as it does here, "that it was not necessary to provide guidelines on this issue [refrigeration] because handling procedures were universally known and followed." *Id.* at 951. "[T]he State's experts testified that

the requirement was so fundamental that it did not need to be in a rule because anyone dealing with blood samples would be aware of the need for proper preservation." *Id.* at 954. This Court disagreed and concluded that the "absence of maintenance standards render[ed] rule 11D-8.012(3) inadequate and inconsistent with the purpose of the implied consent law as it relates to ensuring the reliability of test results." *Id.* at 955.

Like the lack of refrigeration in *Miles*, the lack of screening and documenting samples cannot be fixed after the analyst has reported the results. And just because analysts routinely do something, does not mean they must. The evidence in this case proves this point.

Dr. Goldberger believes a laboratory's methods for determining whether a blood sample is suitable for testing should be documented in writing (R:753). His laboratory has checks in its standard operating procedures to make sure a clotted sample is not tested (R:785). Contrary to this procedure, the standard operating procedures for the PBSO laboratory do not detail the specific steps to determine whether a sample is suitable for testing, including visual inspection, do not address clotting, and do not require documentation of irregularities (R:181-84, 186-88).

The steps of screening, documenting irregularities, and rejecting unfit samples are not, as FDLE claims, "hypertechnical requirement[s]" that would lock in current methodology and prevent improvement of the system (AB:39). Requiring screening, documenting and rejection of unfit samples does not tell the analyst how to do his or her job. Adding these requirements will not affect the scientific methodology, but they will ensure that a criminal defendant will know when his or her sample is clotted or otherwise irregular.

The rules regulating Drug-Free Workplace Standards in Florida require such documentation. Florida Administrative Code Rule 59A-24.006(4)(b), "Drug Testing Laboratories--Standards in Licensure," requires that "[t]he laboratory shall establish written standards for the rejection or acceptance of specimens" (AA:21). Analytical Method 1, Section 4.4.2.3 of the Blood Alcohol Analytical Methods for the Idaho State Police, governing reporting of test results, provides: "If the sample and/or sample vial clearly does not comply with [Idaho Administrative Code] 11.03.01, an appropriate comment must be noted on the analysis report" (AA:110).[6] FDLE must adopt a similar regulation to ensure scientific reliability in blood alcohol tests.

[6] Idaho Administrative Code Rule 11.03.01.013 requires blood alcohol tests to be conducted using whole blood (AA:87).

Rules 11D-8.012 and 11D-8.013 fail to require a blood analyst to screen blood samples before testing them, document irregularities and exclude compromised samples. As a result, they fail to meet the core policies of the implied consent law because they do not ensure reliable test results. These rules are inadequate and should be declared invalid.

CONCLUSION

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

JANE KREUSLER-WALSH and
STEPHANIE L. SERAFIN of
LAW OFFICE OF KREUSLER-WALSH,
COMPIANI & VARGAS, P.A.
501 South Flagler Drive, Suite 503
West Palm Beach, FL 33401-5913
(561) 659-5455
Primary: janewalsh@kwcvpa.com
sserafin@kwcvpa.com
Secondary: eservice@kwcvpa.com
and
BRIAN A. NEWMAN
PENNINGTON, P.A.
215 South Monroe Street, 2nd Floor
P.O. Box 10095
Tallahassee, FL 32302-2095
(850) 222-3533
brian@penningtonlaw.com
and

ELIZABETH L. PARKER
KAPLAN SCONZO & PARKER, P.A.
3399 PGA Blvd., Suite 150
Palm Beach Gardens, FL 33410
(561) 296-7000
eparker@ksplaw.com
Counsel for Petitioner, John Goodman

By: /s/ *Jane Kreusler-Walsh*
JANE KREUSLER-WALSH
Florida Bar No. 272371

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 18th day of April, 2017, I will electronically file the foregoing with the Clerk of Court using the Florida Courts E-Filing Portal, which will then send a copy of such filing to:

RACHEL E. NORDBY
DEPUTY SOLICITOR GENERAL
OFFICE OF THE ATTORNEY GENERAL
The Capitol, PL-01
Tallahassee, FL 32399-1050
rachel.nordby@myfloridalegal.com
jennifer.bruce@myfloridalegal.com
Counsel for Respondent, FDLE

ANN MARIE JOHNSON
FLORIDA DEPARTMENT OF LAW ENFORCEMENT
2331 Phillips Road
Tallahassee, FL 32308
annmariejohnson@fdle.state.fl.us
Counsel for Respondent, FDLE

By: /s/ *Jane Kreusler-Walsh*
JANE KREUSLER-WALSH
Florida Bar No. 272371

CERTIFICATE OF FONT

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

By: /s/ *Jane Kreusler-Walsh*
JANE KREUSLER-WALSH
Florida Bar No. 272371