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Commonwealth of Kentucky

Supreme Court

No. 2009-SC-00027-BG

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COMMONWEALTH OF KENTUCKY

APPELLANT

Court of Appeals Nos. 2009 CA 00014 and 2009 CA 00050
Circuit Court Nos. 08 CR 00141 and 08 CR 00145
Hon. Gregory A. Lay, Circuit Judge

FRANK D. HAMILTON and
HEATHER COLE

APPELLEES

Brief for Commonwealth

Submitted by:

JACK CONWAY

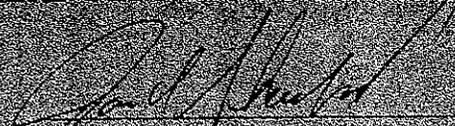
Attorney General of Kentucky

James C. Shackelford

Assistant Attorney General
Office of Criminal Appeals
Office of the Attorney General
1624 Capitol Center Drive
Frankfort, Kentucky 40601
(502) 696-5322

CERTIFICATE OF SERVICE

Certify that the record on appeal has been returned to the Clerk of this Court and that a copy of the Brief for Commonwealth has been served May 19, 2012 as follows: by mailing to the trial judge, Hon. Gregory A. Lay, Judge, P.O. Box 1799, London, KY 40343-1799; by sending electronic mail to Hon. Jackis Steck, Commonwealth Attorney, and by delivery through United States Mail to Hon. D. Randall Jewell, Jewell and Hall Law Offices, PLLC, P.O. Drawer 670, Barbourville, KY 40906.


James C. Shackelford
Assistant Attorney General

INTRODUCTION

The Appellants each conditionally pled guilty to possession of a controlled substance in the second degree but claimed the General Assembly unconstitutionally delegated authority to the Cabinet for Health and Family Services to schedule controlled substances based on federal regulations. The Court of Appeals remanded the case and ordered the Cabinet and the Attorney General be named as parties. This Court accepted discretionary review.

Notation Concerning Citation of Record

The Commonwealth will cite to the transcript of record in Appellant Frank Hamilton's case (Indictment Number 08-CR-141) as "Ham. TR" together with the page number. Citation to the transcript of record in Appellant Heather Cole's case (Indictment Number 08-CR-155) will be in the form "Cole TR" and page number. All relevant portions of the video record are contained in each record on appeal and the Commonwealth will simply cite the video record as "VR" together with the date and time index.

STATEMENT REGARDING ORAL ARGUMENT

The Commonwealth requests the Court grant oral argument as it may be beneficial.

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STATEMENT OF THE CASE

A. Summary

A grand jury charged the Appellees with trafficking in buprenorphine, which is classified as a Schedule III controlled substance by both state and federal regulation. Ham. TR 1-2; Cole TR 1-2. Suboxone is the trade name of a drug which contains buprenorphine (an opiate compound) and naloxone. VR 2/25/2009, 10:03:52. Buprenorphine had been rescheduled from a Schedule V to a Schedule III controlled substance. In a series of motions explained further below, the Appellees repeatedly tried to distinguish between buprenorphine and Suboxone.

Appellees did not challenge the constitutionality of any statute in any pleadings. An evidentiary hearing evolved to one questioning the legislature's delegation of authority to the Cabinet to classify Suboxone as a Schedule III controlled substance. The Appellees also claimed the methodology used by the federal government to schedule Suboxone (actually buprenorphine) was improper.¹

The trial court overruled the motions and the Appellees conditionally

¹ "Notice of Intent to Challenge the Classification of Suboxone as a Schedule III Narcotic" (Ham. TR 40-41, Cole TR 28-29); "Motion to Exclude Scientific Evidence Which Does Not Meet the Daubert Standard And To Exclude Unqualified Opinion Testimonies" (Ham. TR 53-63, Cole TR 36-46) (including attachments). (Ham. TR 53-63, Cole TR 36-46) (including attachments); and "Motion to Dismiss Or In The Alternative To Assign For An Evidentiary Hearing" (Ham. TR 64-66, Cole TR 33-35). *See also* Evidentiary hearing at VR 02/25/2009, 09:19:45 -09:23:25.

pled guilty to trafficking in buprenorphine and given probated sentences. Judgements at Ham. TR 142-145 (App. 1) and Cole TR 98-101 (App. 2); Orders at Ham. TR 111-120 (App. 3); Cole TR 86-90 and Ham. TR 129-133 (App. 4).

The Court of Appeals *sua sponte* ruled the Appellees did not have standing to appeal because they did not join the Cabinet for Health and Family Services as a party and dismissed the appeal. On petition for rehearing, the Court of Appeals repeated that Hamilton and Cole did not have standing but remanded and ordered that both the Cabinet and the Kentucky Attorney General be named as parties. *Hamilton and Cole v. Commonwealth*, slip op., Nos. 2009-CA-00949 and 2009-CA-00950, *as modified on r'hg.*, Mar. 25, 2011 (Ky. App.); App. 5.

B. Procedural History in the Trial Court

Appellees filed a "Notice of Intent to Challenge the Classification of Suboxone as a Schedule III Narcotic" and sent a copy to the Attorney General. Ham. TR 40-41 (App. 6), Cole TR 28-29. The notices incorrectly asserted the indictments "listed the drug was suboxone." It alleged the drug Suboxone had no euphoric effect and challenged the Commonwealth's classification of the drug as a Schedule III controlled substance and referred to KRS 218A.020. The notice did **not** claim that any statute was unconstitutional. *Id.* This pleading was the only pleading sent to the

Attorney General until after the judgements were entered. There is no record that the Cabinet was ever formally notified other than a subpoena being issued to an employee. The Cabinet was not named as a party.

Appellees later filed a "Motion to Exclude Scientific Evidence Which Does Not Meet the Daubert Standard And To Exclude Unqualified Opinion Testimonies". Ham. TR 53-63, Cole TR 36-46) (including attachments). The motion asked the trial court to determine if "the classification of Suboxone as a Schedule III narcotic, as charged in the Commonwealth's indictment and the evidence therefore, meets the standards of *Stringer v. Commonwealth*, 956 S.W.2d 883 (Ky. 1997) and *Daubert v. Merrel Dow Pharmaceuticals, Inc.*, 509 U.S. 579." Ham. TR 53, Cole TR 36.

The motion further noted that the Commonwealth had listed Nancy L. Hibbitts and/or Beverly Wagoner as witnesses and, "The Court should determine whether these people are qualified to testify regarding the procedures to classify a drug as a Schedule III narcotic." Ham. TR 55, Cole TR 38.

Simultaneously, Appellees each filed a "Motion to Dismiss Or In The Alternative To Assign For An Evidentiary Hearing" Ham. TR 64-66, Cole TR 33-35. The motion argued, "Suboxone has not been categorized as a Schedule III narcotic. Therefore, it is not a Class D felony to traffic or to sell Suboxone." Ham. TR 64, Cole TR 33.

The Commonwealth filed a written response to the motions to dismiss

and to exclude scientific evidence. Ham. TR 68-95, Cole TR 48-75. The response noted the defendants had attacked “the classification of Suboxone, or more properly, buprenorphine, as a Schedule III narcotic.” Ham. TR 68, Cole TR 48. The response argued statutory authority of the Cabinet for Health and Family Services to schedule a substance for control if “designated, rescheduled, or deleted as a controlled substance under federal law” and that federal regulations had classified buprenorphine as a Schedule III controlled substance. Ham. TR 70-71, Cole TR 50-51) (citations omitted). The response further argued that if the Appellees’ *Daubert* arguments were based on improper classification of buprenorphine, then they were “in the wrong forum” because the trial court “lacks authority to change a federal regulation” Ham. TR 74, Cole TR 54.

C. The Evidentiary Hearing

The trial court held a combined hearing on the two cases February 25, 2009. The Appellees said the issue was whether Suboxone is a Schedule III drug, that the Cabinet must make findings in scheduling substances, and that simply scheduling based on federal law was an unlawful delegation of the legislature’s authority. VR 02/25/2009, 09:19:45 -09:23:25. Appellees also said they wanted to challenge the methodology of the U.S. Drug Enforcement Agency in scheduling the drug and that Suboxone should be separated from its “base drug” (buprenorphine). *Id.* at 09:09:23:35. Appellees said they had no problems with the KSP lab analysts testifying about the results of their

testing of the substances but simply wanted to preclude them from testifying at trial about the methodology used in scheduling the drug. *Id.* at 10:26:18.

The prosecutor replied he had never intended to use the lab analysts to testify about this methodology. *Id.* at 10:28:45.

The prosecutor noted that subsection three (3) of KRS 218A.020 gave the Cabinet authority to schedule a drug upon scheduling by the federal government and notice. *Id.* at 09:27:50. This is separate authority from that authority given the Cabinet to engage in fact finding before scheduling a drug. *See* KRS 218A.020. The Cabinet had been unable to find any records responsive to Appellees' request for "Any and all records pertaining to the reclassification of the drug Suboxone from a Schedule V to a Schedule III narcotic." Ham. TR 62, Cole TR 45. The prosecutor said he received a similar response to a subpoena *duces tecum* requesting the same information. VR 02/25/2009, 09:27:50.

The prosecutor also pointed out that the indictment charged the Appellees with trafficking in buprenorphine and not Suboxone, that Suboxone was a trade name. *Id.* at 09:38:35.

Appellees said their witness would testify on several matters including his opinion that the DEA did not follow proper methodology in scheduling the drug because it relied upon "obscure European studies." *Id.* at 09:40:12; *see also* letter from Harry B. Plotnick, Ham. TR 56-57 and Cole TR 41-42. The

Commonwealth again asserted this was the wrong forum for challenging the DEA's regulation, but the trial court allowed Mr. Plotnick's to testify since he was present. VR 02/25/2009, 09:41:50; 09:42:30.

Mr. Plotnick testified that he was a licensed attorney in Ohio and had a PHD in toxicology. *Id.* at 09:45:40-09:48:00. He was not specifically aware of the methodology needed to reclassify a drug from a Schedule V to a Schedule III drug. *Id.* at 09:49:15. He said Congress had delegated this to the Drug Enforcement Agency and with certain criteria for DEA to use in scheduling drugs. *Id.* He said that in scheduling or rescheduling a substance, the DEA would post notice in the Federal Register and there would be a comment period. There may or may not be a hearing where evidence is taken and the DEA then makes a determination based on their judgment. *Id.* at 09:50:00.

Regarding the re-scheduling of buprenorphine from a Schedule V to a Schedule III, Mr. Plotnick said the DEA included European studies assessing the "high" effect of buprenorphine. *Id.* at 09:50:47. He said he did not think they had looked at the criteria for abuse potential as they should have. He claimed there was no documentation supplied in support of various positions and the DEA's conclusion was based more on a law enforcement perspective than on science. *Id.* at 09:51:20-09:51:54. The final rule included the provision that any new drugs which contained buprenorphine in combination

with something else would be controlled as a Schedule III drug. *Id.* at 09:52:42.

Mr. Plotnick was allowed to testify over the Commonwealth's objection that the DEA had not referred to any abuse studies on Suboxone, separate from studies of buprenorphine. *Id.* at 09:52:03-09:54:30. Mr. Plotnick admitted that even though he had some scientific disagreement with the federal regulation, it appeared to be a validly enacted regulation. *Id.* at 09:55:45; 10:02:15.

Mr. Plotnick went onto testify that there were two "active" ingredients in Suboxone — buprenorphine, an opiate compound,, and naloxone, an opiate antagonist. *Id.* at 10:03:52. Buprenorphine is the primary active ingredient and naloxone "helps inactivate some of the effects of Suboxone." *Id.* at 10:05:02-10:05:14. In short, Suboxone contained buprenorphine which was classified as a Schedule III substance under both the federal and state regulations. *Id.* at 10:05:15-10:05:38.

Appellees then called Chris Johnson to testify. *Id.* at 10:06:25. Mr. Johnson had a B.S. in pharmacy and received a Doctor of Pharmacy from the University of Kentucky in May of 1995. *Id.* at 10:07:17. He was employed by the Cabinet for Health and Family Services, Department of Inspector General, Drug Enforcement Branch. *Id.* at 10:07:30. He testified the active ingredient of Suboxone was buprenorphine and it was a Schedule III drug

under both federal and state law. *Id.* at 10:08:20. Based on his education and the package insert of the drug itself, Dr. Johnson testified that buprenorphine had the potential to create addiction. *Id.* at 10:10:20. He did not know of any specific articles where Suboxone was distinguished from its active ingredient buprenorphine. *Id.* at 10:10:43.

He testified that naloxone was an opiate blocker. *Id.* at 10:11:38. It was designed to prevent getting the opiate effect from an opiate. *Id.* at 10:12:00. He said buprenorphine was one compound and naloxone was a separate compound. *Id.* at 10:12:05. He was not familiar with any studies or findings by the Cabinet distinguishing between Suboxone and buprenorphine. *Id.* at 10:12:50. He was unaware of any findings made by the Cabinet regarding the scheduling of Suboxone or buprenorphine other than to adopt the federal schedule. *Id.* at 10:13:57.

Dr. Johnson explained that when naloxone is used in Suboxone it is inactive unless the Suboxone is misused by crushing a tablet or a user injecting it. Then, it acts to block the opiate effect of the buprenorphine and causes any addicted user to then suffer withdrawal; the naloxone is therefore a deterrent to misuse of Suboxone. *Id.* at 10:16:52. If Suboxone is used as intended the naloxone is inactive and Suboxone can have an euphoric effect. *Id.* at 10:18:10; 10:19:07. Suboxone specifically produces an euphoric effect on one who is not addicted or is "opiate naive". *Id.* at 10:19:45. Dr. Johnson said

the Cabinet's regulation is the document containing the Cabinet's findings.

Id. at 10:21:30.

The trial court overruled the Appellees' motions by determining the legislature had constitutionally delegated its authority to the Cabinet for Health and Family Resources (Cabinet) in scheduling controlled substances and that the Cabinet had lawfully scheduled buprenorphine as a Schedule III controlled substance. It further concluded that it did not have the jurisdiction to rule on the methodology and validity of the regulation by which the federal Drug Enforcement Agency (DEA) had scheduled buprenorphine as a Schedule III controlled substance under federal law. Ham. TR 111-120, App.3.

Appellees then filed motions for reconsideration or clarification and a motion to continue the trial date in order to investigate the possibility of filing an action in federal court on the federal regulation. Ham. TR 123-127; Cole TR 80-84. At a hearing on the motions, the parties submitted the motion for reconsideration or for clarification for decision and passed the motion for a continuance of the trial. VR 04/02/09, 09:54:00; 09:56:58.

The trial court overruled the motion for reconsideration or clarification. Ham. TR 129-133, App. 4; Cole TR 86-90. The Appellees each entered conditional guilty pleas to one count of trafficking in a controlled substance in the second degree (first offense) and were each sentenced to two years probated for three years. Ham. TR 142-145; Cole TR 98-101.

As previously noted, the Court of Appeals *sua sponte* ruled the

Appellees did not have standing to appeal because they did not join the Cabinet for Health and Family Services as a party and dismissed the appeal. On petition for rehearing, the Court of Appeals repeated that Hamilton and Cole did not have standing but remanded and ordered that both the Cabinet and the Kentucky Attorney General be named as parties. *Hamilton and Cole v. Commonwealth*, slip op., Nos. 2009-CA-00949 and 2009-CA-00950, as modified on r'hg., Mar. 25, 2011 (Ky. App.).

ARGUMENT

The Commonwealth will first discuss the procedural issues concerning notice to the Attorney General and the Court of Appeals' decision to remand to name both the Attorney General and the Cabinet for Health and Family Services as parties. The Commonwealth will then discuss the substantive issues of whether (i) the General Assembly unconstitutionally delegated its authority to the Cabinet for Health and Family Services to reschedule buprenorphine from a Class V to a Class III controlled substance based on the same reclassification under federal law and (ii) whether the state trial court had the authority to declare a federal regulation invalid under federal law.

I.

The Court of Appeals correctly concluded the Appellees had failed to comply with statutory notice requirements but incorrectly remanded the case and incorrectly ordered that the Attorney General be named as a party

Because this issue was raised *sua sponte* in the modified opinion of the Court of Appeals, no further preservation of error is required.

As previously noted, Appellees mailed a copy of their "Notice of Intent to Challenge the Classification of Suboxone as a Schedule III Narcotic" which

referred to KRS 218A.020. Ham. TR 40-41 (App. 6), Cole TR 28-29. The notice did not, however, refer to the constitutionality of any statute. Only at the evidentiary hearing did Appellees say they were challenging the constitutional authority of the General Assembly to delegate to the Cabinet the authority to schedule substances by adopting findings from a federal regulation. VR 02/25/2009, 09:19:45 -09:23:25..

In its modified opinion, the Court of Appeals said the trial court made the constitutionality of KRS 218A.020 an issue by its findings and that the Kentucky Attorney General “has become a party at the appellate level.” *Hamilton and Cole*, slip op. at 8, citing *Owens v. Commonwealth*, 2008 WL 466132, No. 2008-SC-000713-MR (Ky. Feb. 21, 2008); App. 7 hereto. It ordered the case be remanded to the trial court and further ordered, “The Kentucky Attorney General and the Cabinet should be made parties and the court, after arguments, should examine whether the statute is rendered unconstitutional.” *Hamilton and Cole*, slip op. at 8.

KRS 418.075(1) requires the Attorney General “be served with a copy of the petition” in a proceeding involving the validity of a statute or constitutionality of a statute. It provides that the Attorney General “shall be

entitled to be heard” on the matter “before judgment is entered.”²

Here, the Appellees only notified the Attorney General of their intent to challenge the classification of Suboxone as a Schedule III controlled substance and made a simple reference to KRS 218A.020. This did not give fair notice that they would claim the General Assembly unconstitutionally delegated its authority. Indeed, the Appellees employed a circuitous series of motions to obtain an evidentiary hearing where, for the first time, they announced they were going to challenge the constitutionality of the statute. Even if the Appellees’ defense theory evolved during the course of litigation, they could have notified the Attorney General *after* the evidentiary hearing. The statute only required notice and opportunity of the Attorney General to be heard before judgment was entered. KRS 418.075(1).

Thus, the Court of Appeals correctly determined the Appellees did not comply with the notice statute. It erred, however, in remanding the case and

² KRS 418.075 states in part:

(1) In any proceeding which involves the validity of a statute, the Attorney General of the state shall, before judgment is entered, be served with a copy of the petition, and shall be entitled to be heard, and if the ordinance or franchise is alleged to be unconstitutional, the Attorney General of the state shall also be served with a copy of the petition and be entitled to be heard.

(2) In any appeal to the Kentucky Court of Appeals or Supreme Court or the federal appellate courts in any forum which involves the constitutional validity of a statute, the Attorney General shall, before the filing of the appellant's brief, be served with a copy of the pleading, paper, or other documents which initiate the appeal in the appellate forum. This notice shall specify the challenged statute and the nature of the alleged constitutional defect.

erred in ordering the Attorney General be named as a party.

The Court of Appeals relied upon the unpublished *Owens* decision which held that service of a brief was sufficient notice on appeal in a criminal case under KRS 418.075 because the Attorney General already represented the Commonwealth. *Owens* at *2. A later, published opinion from this Court held that filing an appellate brief does not excuse non-compliance with the notice requirement at the trial court level:

Thus, Benet has failed fully and timely to comply with the strict rubric of KRS 418.075, leaving his constitutional challenge *unpreserved* for our review. Because the plain language of KRS 418.075 requires notice be given to the Attorney General prior to the entry of judgment, we reject any contention that merely filing an appellate brief, which necessarily occurs post-judgment, satisfies the clear requirements of KRS 418.075.

Benet v. Commonwealth, 253 S.W.3d 528, 532 (Ky. 2008) (emphasis added).

This Court later said, "This Court has made it plain that strict compliance with the notification requirement of KRS 418.075 is required, and failure to give notice leaves the constitutional challenge unpreserved. Unpreserved error can be reviewed only for palpable error" *Jones v. Commonwealth*, 319 S.W.3d 295, 297 (Ky. 2010).

Thus, the Court of Appeals erred in remanding the case for Appellees' failure to comply with KRS 418A.075.. It should have declined to review the matter or, upon request, exercised its discretion in determining whether to

review for palpable error.

In neither *Jones*, *Benet*, or even *Owens* was the Attorney General an actual, named party. Instead the Attorney General represented the Commonwealth. KRS 418.075 allows the Attorney General to be heard but does not direct the Attorney General to appear in circuit court. The statute allows the Attorney General to monitor and report challenges to the Legislative Research Commission (subsection three) and to assist and coordinate with local Commonwealth Attorneys. It does not require the Attorney General be named as a party. The Attorney General's response, except for a reporting requirement to the legislature, is completely discretionary.

There is simply no authority for naming the Attorney General as a party to the litigation and doing so raises sharp separation of powers. The Court should reverse the Court of Appeals and affirm the trial court without reviewing the constitutional issue at all.

II.

If the Cabinet for Health and Family Services is a necessary party to challenge the adoption of the regulation, then the appropriate remedy is to dismiss rather to remand.

The Court of Appeals *sua sponte* remanded the case to the circuit court and ordered the Cabinet for Health and Family Services and the Kentucky

Attorney General be named as parties. *Hamilton and Cole v. Commonwealth*, slip op. at 7-8, Nos. 2009-CA-00949 and 2009-CA-00950, as modified on r'hg., Mar. 25, 20011 (Ky. App.).³ As such, no further preservation was necessary.

The Court of Appeals said Hamilton and Cole “argue that the Cabinet did not act under Chapter 218A because it did not make the specific findings mandated in KRS 218A.020(1) and (2) or KRS 218A.080.” *Id.* at 3. The court then noted that 902 KAR 55:025 § 7 appeared with the Commissioner’s stamp and was entitled to the rebuttable presumption of correctness created by KRS 13A.090. *Hamilton and Cole*, slip op. at 4. The court then looked at KRS 13A.140 which directs that “when an administrative regulation is challenged in the courts it shall be the duty of the promulgating administrative body to show and bear the burden of proof to show” that the regulation is within the body’s authority and that the laws relating to promulgation were followed.⁴

³ The original opinion, written by Judge Combs, determined the Cabinet was a necessary party and ordered the appeal to be dismissed. No mention was made in that opinion about making the Kentucky Attorney General a party. Judge Combs dissented in the modified opinion.

⁴ The Commonwealth notes that the majority opinion missed the primary point raised at the trial court level, whether the General Assembly improperly delegated its authority by allowing the Cabinet to schedule substances based upon federal regulations. There was no evidence the Cabinet ever evaluated the factors set forth in KRS 218A.020(1) or 218A.080. This latter point *may* have become an issue had the Cabinet been named a party and given a chance to defend.

With the exception of the provision on proving proper promulgation of the regulations, all the enumerated duties in KRS 13A.140 relate to the *statutory* authority of the *administrative agency* to adopt the regulation questioned. The issue actually raised and addressed at the trial court level deal with the *constitutional* authority of the *General Assembly* to delegate authority. As such, it is not clear that KRS 13A.140 provides authority for requiring the Cabinet be made a party. Nevertheless, the Cabinet should have been named a party for other reasons.

Here, the Cabinet's presence as a party was necessary because Appellees challenged the Cabinet's scheduling of drugs and other substances. A decision favorable to the Appellees would effectively force the Cabinet to modify its regulations and independently assess the classification of each controlled substance upon which it had classified based on federal regulation without an opportunity to be heard. Simply calling an employee of the Cabinet to testify is insufficient. While the Assistant Commonwealth Attorney did an excellent job at the trial court level, lawyers from the Cabinet potentially have greater expertise in this specific area and better access to helpful records than either the Commonwealth Attorney or the Attorney General.

This Court has referred to the "bedrock principle that a failure to name a necessary party to an appeal is a fatal jurisdictional error" *Courier-Journal, Inc. v. Lawson*, 307 S.W.3d 617, 623 (Ky. 2010). The Court added

that “failure to name an indispensable party is a fatal error requiring dismissal.” *Id.* Thus, the Court of Appeals erred in remanding the case for a “do over.” It should have simply dismissed the appeal.

III.

The General Assembly did not unconstitutionally delegate its authority to classify controlled substances when it directed the Cabinet to choose whether to independently study enumerated factors or to rely upon federal regulations which considered the same enumerated factors.

- A. The Court should simply reverse the Court of Appeals and affirm the convictions without reviewing the constitutional issue.**

The Appellees did not preserve this issue for appellate review because of inadequate notice pursuant to KRS 418.075. *See* Argument I. The Commonwealth Attorney did address this question at the trial court level by written response and at the evidentiary hearing. Ham. TR 68-95, Cole TR 48-75; VR 2/25/2009, 09:27:50.

This Court should simply reverse the Court of Appeals and affirm the orders of the trial court and the judgments against the Appellees without deciding the constitutional issue. If the Court conducts any review, it should only be for palpable error.

According to its plain language, RCr 10.26 relief is discretionary on the

part of the appellate court: “[A]ppropriate relief *may* be granted upon a determination that manifest injustice has resulted from the error.” For an error to be palpable, it must have been “easily perceptible, plain, obvious and readily noticeable.” *Burns v. Level*, 957 S.W.2d 218, 222 (Ky. 1997). There is nothing obvious or readily noticeable about Appellee’s constitutional argument.

Moreover, this Court has emphasized a reviewing court must “plumb the depths of the proceeding ... to determine whether the defect in the proceeding was shocking or jurisprudentially intolerable.” *Martin v. Commonwealth*, 207 S.W.3d 1, 3 (Ky. 2006). The standard for “manifest injustice” requires a “probability of a different result or error so fundamental as to threaten a defendant’s entitlement to due process of law.” *Id.* at 3. The Appellees cannot make such a showing here. They had a fair opportunity to litigate this matter fully before the trial court.

B. The General Assembly has established a framework for the scheduling of controlled substances which utilizes the same factors as those considered under federal law.

The General Assembly delegated to the Cabinet the task of identifying and scheduling substances for control. The statute delegating that authority states:

- (1) The Cabinet for Health and Family Services shall administer this chapter and may by regulation add substances to or delete or reschedule all substances enumerated in the schedules set

forth in this chapter. In making a determination regarding a substance, the Cabinet for Health and Family Services may consider the following:

- (a) The actual or relative potential for abuse;
- (b) The scientific evidence of its pharmacological effect, if known;
- (c) The state of current scientific knowledge regarding the substance;
- (d) The history and current pattern of abuse;
- (e) The scope, duration, and significance of abuse;
- (f) The risk to the public health;
- (g) The potential of the substance to produce psychic or physiological dependence liability; and
- (h) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

(2) After considering the factors enumerated in subsection (1) the Cabinet for Health and Family Services may adopt a regulation controlling the substance if it finds the substance has a potential for abuse.

(3) If any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the Cabinet for Health and Family Services, the Cabinet for Health and Family Services may similarly control the substance under this chapter by regulation.

(4) The Cabinet for Health and Family Services

shall exclude any nonnarcotic substance from a schedule if the substance may be lawfully sold over the counter without prescription under the provisions of the Federal Food, Drug and Cosmetic Act, or the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, or the Kentucky Revised Statutes (for the purposes of this section the Kentucky Revised Statutes shall not include any regulations issued thereunder).

KRS 218A.020.

Based on the testimony at the evidentiary hearing, the Cabinet did not utilize the independent mechanism of subsections (1) and (2) of the statute in the scheduling of buprenorphine as a Class III controlled substance. Instead, the Cabinet operated under the authority of subsection (3) which specifically provides that the Cabinet "may similarly control the substance" if that substance is designated or rescheduled under federal law. Of course, the evidence might have been different if the Cabinet itself been named a party and given a chance to defend the classification.

The Cabinet has scheduled buprenorphine or any compound or mixture containing it as a Schedule III controlled substance by regulation last amended October 16, 2002, "The Cabinet for Health Services designates as Schedule III controlled substance a material, compound, mixture, or preparation which contains any quantity of buprenorphine, or its salts." 902 KAR 55:025 § 7 (complete regulation in Appendix 8).

In preparation for ratification of the 1971 Convention on Psychotropic

Substances, the United States Congress implemented its treaty obligations in 1978 by giving the U.S. Attorney General authority to classify drugs and other substances. *See Gonzales v. Oregon*, 546 U.S. 243, 266 (2006). Congress directed the Attorney General to consider certain factors when scheduling drugs under the Controlled Substances Act. 21 U.S.C. § 811. Among the factors the U.S. Attorney General is required to consider are those which essentially mirror those in KRS 218A.020(1):

| Federal Law - 21 U.S.C. § 811(c) | State Law - KRS 218A.020(1) |
|---|---|
| <p>[T]he Attorney General shall consider the following factors with respect to each drug ... proposed to be controlled ... :</p> <p>(1) Its actual or relative potential for abuse.</p> <p>(2) Scientific evidence of its pharmacological effect, if known.</p> <p>(3) The state of current scientific knowledge regarding the drug or other substance.</p> <p>(4) Its history and current pattern of abuse.</p> <p>(5) The scope, duration, and significance of abuse.</p> <p>(6) What, if any, risk there is to the public health.</p> <p>(7) Its psychic or physiological dependence liability.</p> <p>(8) Whether the substance is an</p> | <p>(1) [T]he Cabinet for Health and Family Services may consider the following:</p> <p>(a) The actual or relative potential for abuse;</p> <p>(b) The scientific evidence of its pharmacological effect, if known;</p> <p>(c) The state of current scientific knowledge regarding the substance;</p> <p>(d) The history and current pattern of abuse;</p> <p>(e) The scope, duration, and significance of abuse;</p> <p>(f) The risk to the public health;</p> <p>(g) The potential of the substance to produce psychic or physiological dependence liability; and</p> <p>(h) Whether the substance is an</p> |

| | |
|--|---|
| immediate precursor of a substance already controlled under this subchapter. | immediate precursor of a substance already controlled under this chapter. |
|--|---|

Both federal and state law consider the same factors when scheduling a substance as a Class III substance.

| Federal Law - 21 U.S.C. § 812(b) | State Law - KRS 218A.080 |
|--|--|
| <p>[T]he findings required for each of the schedules are as follows:</p> <p>(3) Schedule III. —</p> <p>(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.</p> <p>(B) The drug or other substance has a currently accepted medical use in treatment in the United States.</p> <p>(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.</p> | <p>The Cabinet for Health and Family Services shall place a substance in Schedule III if it finds that:</p> <p>(1) The substance has a potential for abuse less than the substances listed in Schedules I and II;</p> <p>(2) The substance has currently accepted medical use in treatment in the United States; and</p> <p>(3) Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.</p> |

Pursuant to this authority, the Attorney General, through the DEA, has included any compounds or mixtures containing buprenorphine in Schedule III:

- (e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule: ...
- (2) Any material, compound, mixture, or preparation containing any of the following narcotic

drugs or their salts, as set forth below:

(i) Buprenorphine ...

12 C.F.R. § 13.08.13 Schedule III (copy in Appendix 9).

The DEA adopted the federal regulation rescheduling buprenorphine from a Schedule V to a Schedule III controlled substance by final rule published October 7, 2002 at 67 Fed.Reg. 194, pp. 62354-62370 (Appendix 10). Publication in the Federal Register constitutes notices as a matter of law. 44 U.S.C. § 1507; *Lyng v. Payne*, 476 U.S. 926, 942-43, 106 S.Ct. 2333, 2343, 90 L.Ed. 921 (1986). Thus, the Cabinet was notified of the federal schedule as required by KRS 218A.020(3) in order to adopt buprenorphine from the federal Schedule III into the state Schedule III.

C. The General Assembly's Delegation of Authority Provided Sufficient Guidelines for the Cabinet in Scheduling buprenorphine as a Schedule III Controlled Substance.

In *Commonwealth v. Hollingsworth*, 685 S.W.2d 546 (Ky. 1984) this Court upheld the classification of controlled substances where the Cabinet exercised its authority under KRS 218A.020(1) and (2) to independently assess the potential of drugs for abuse and to schedule them accordingly. The court noted the legislature had "established adequate standards" for the cabinet to schedule substances under Schedule III. *Id.* at 548.

The court in *Hollingsworth* noted the mandatory duty of the Cabinet under KRS 218A.080 to regulate controlled substances but the discretionary

manner in doing so. The Court noted that KRS 218A.020(1) provides that the Cabinet “*shall* administer this chapter and *may* by regulation add substances to or delete or reschedule all substances enumerated in the schedules set forth in this chapter. ...” *Hollingsworth*, 685 S.W.2d at 546, *quoting* KRS 218A.010(1) (emphasis by court).

Thus, while the Cabinet must administer Chapter 218A, it has discretion to delete or reschedule substances and this discretion does not mean the legislature unlawfully delegated its authority. This constitutional, discretionary authority to delete or reschedule substances implies the Cabinet has the lesser discretionary authority to choose between two sets of legislatively defined criteria to consider. The Cabinet may independently evaluate the various factors or it may rely upon the evaluation of the same factors by the U.S. Attorney General through the Drug Enforcement Administration. The General Assembly has simply recognized the role and expertise of the DEA and allowed the Cabinet to rely on that expertise rather than make a separate and costly independent evaluation.

“[W]hile the General Assembly cannot delegate its power to make law, it can make a law that delegates the power to determine some fact or state of things upon which the law makes its own action depend — so long as the law establishes policies and standards governing the exercise of that delegation.” *Fletcher v. Commonwealth*, 163 S.W.3d 852, 862 -863 (Ky.2005). The General Assembly has not delegated its authority to make law in this instance. It has

simply allowed the Cabinet to make findings that substances meet specific legislative criteria and has allowed the Cabinet to rely upon the expertise of the DEA which must consider the same criteria in scheduling drugs.

This Court has upheld a similar administrative adoption of federal standards in *Moore v. Ward*, 377 S.W.2d 881 (Ky.1964). The Court held that the state legislature had lawfully given the state transportation department the authority to adopt federal standards for highway billboards in exchange for federal funding. The court rejected the contention the state had relinquished its authority to the federal government. *Id.* at 884.

Such references to federal standards is hardly unique to the scheduling of controlled substances; nor is the use of the word “may” in adopting federal standards. Kentucky’s Occupational and Safety Health Act is but one example:

(1) Occupational safety and health standards *may* be adopted, modified, or repealed by the board as it shall deem necessary.

(2) Established federal standards and national consensus standards *may* be adopted by reference.

KRS 338.061 (emphasis added); *see also Fletcher v. Commonwealth*, 163 S.W.3d 852 (Ky.2005) (noting voluntary nature of state participation in this program).

In *Board of Trustees v. Attorney General*, 132 S.W.3d 770 (Ky. 2004), this Court discussed the nondelegation doctrine. It noted that cases striking

the delegation of authority depended upon statutes which were “without legislative criteria” or which had “no criteria whatever” or which “gave no guidance” to the administrative agency. *Id.* at 782-783. The court also recognized that in some of the cases, there was a confluence of the nondelegation doctrine with that of the “unintelligibility rule” where reasonable persons could not understand a statute’s directives. *Id.* at 783.

Here, the statute is clear and gives sufficient guidance for the Cabinet to promulgate regulations scheduling substances for control. The trial court correctly summarized:

[T]he federal law which gives congressional authority to the DEA to list controlled substances contains exactly identical language setting the standards for listing drugs to the schedules of controlled substances as does KRS 218A.020(1). 21 U.S.C.A. 811©). With the Supreme Court having already declared those same standards constitutional within the Commonwealth, KRS 218A.020(3) merely provides an avenue for avoiding costly and redundant action by the Cabinet where a substance has previously been evaluated using the same standards.

(Order, pp. 5-6 at Ham. TR 104-105).

The General Assembly did not improperly delegate its authority by allowing the Cabinet to schedule or reschedule a substance after the DEA had already done so.

IV.

The state trial court correctly concluded it had no authority to strike down a federal regulation.

The Commonwealth preserved its argument on this issue at several points including at the evidentiary hearing. VR 02/25/2009, 09:41:50; 09:42:30.

Appellants considered asking for a continuance to challenge the DEA's scheduling of buprenorphine but ultimately chose not to do so (VR 04/02/09, 09:54:00; 09:56:58). That would have been the correct method of doing so.

The Controlled Substances Act itself directs that the Attorney General's determinations and findings are "final and conclusive ... except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located ..." with a copy of the petition to be served on the Attorney General. 21 U.S.C. 877. Jurisdiction to challenge a final rule of the Attorney general is vested "exclusively in the federal courts of appeals." *Monson v. Drug Enforcement Admin.*, 589 F.3d 952, 960 (8th Cir. 2009).

The Court in *Monson* distinguished challenges to the promulgation of a rule, such as what the Appellees tried to do, from a challenge that a rule does not specifically apply to a party. In those cases, the U.S. district courts have jurisdiction. *Id.* At least two other statutes require such challenges be made

in federal court. 28 U.S.C. § 1331 provides, in part, “The district courts shall have original jurisdiction in all civil actions arising under the Constitution, laws or treaties of the United States. ...” In 5 U.S.C. § 702, Congress provided for a limited waiver of sovereign immunity where non-monetary relief is sought by one claiming to be wronged by or “adversely affected or aggrieved by agency action” but only if there is “[a]n action in a Court of the United States”

In short, the trial court correctly determined that any claim that the federal regulation is invalid must be brought in federal court. The Appellees affirmatively waived any right to do so when they considered asking for a continuance to file an action in federal court but then decided not to do so.

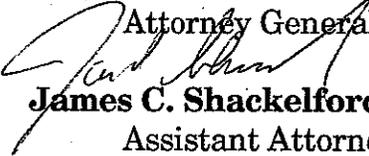
CONCLUSION

For all of the foregoing reasons, this Court should vacate the opinion of the Court of Appeals and affirm the convictions of Appellees.

Respectfully Submitted

JACK CONWAY

Attorney General of Kentucky


James C. Shackelford

Assistant Attorney General

Office of Criminal Appeals

Office of the Attorney General

1024 Capital Center Drive

Frankfort, Kentucky 40061-8204

(502) 696-5342

Counsel for Commonwealth

APPENDIX

| <i>Description</i> | <i>Appendix No.</i> |
|--|---------------------|
| Judgment of Conviction (Ham. TR 142-145) | 1 |
| Judgment of Conviction (Cole, TR 98-101) | 2 |
| Order Overruling Motion to Dismiss Indictment (Ham. TR 112-120) | 3 |
| Order Overruling Motion to Reconsider (Ham. TR 129-133) | 4 |
| <i>Hamilton and Cole v. Commonwealth</i> , slip op., Nos. 2009-CA-00949 and 2009-CA-00950, <i>as modified on r'hg.</i> , Mar. 25, 20011 (Ky. App.) | 5 |
| Notice of Intent to Challenge the Classification of Suboxone as a Schedule III Narcotic (Ham. TR 40-41) | 6 |
| <i>Owens v. Commonwealth</i> , 2008 WL 466132, No. 2008-SC-000713-MR (Ky. Feb. 21, 2008) | 7 |
| 902 KAR 55:025 | 8 |
| 13 C.F.R. 13.08.13 (Schedule III) | 9 |
| 67 Fed.Reg.194, pp. 62354-62370 | 10 |