

IN THE SUPREME COURT OF FLORIDA

NO. SC11 - _____

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SEP 26 2011

CLERK, SUPREME COURT
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DR. DAVID NICHOLL,
Petitioner,

v.

KENNETH S. TUCKER,
Secretary, Florida
Department of Corrections,
Respondent.

UNKNOWN EXECUTIONER,
Additional Respondent.

UNKNOWN MEDICAL PERSONNEL,
Additional Respondent.

DEATH WARRANT SIGNED
EXECUTION SCHEDULED FOR
SEPTEMBER 28, 2011 AT 4:00 P.M.

EMERGENCY PETITION FOR WRIT OF QUO WARRANTO

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EMERGENCY PETITION FOR WRIT OF QUO WARRANTO

Petitioner seeks a writ of quo warranto prohibiting the Florida Department of Corrections from unlawfully using the controlled substance sodium pentobarbital, manufactured by Lundbeck Inc., to execute criminal defendants. The Controlled Substances Act prohibits the dispensing of pentobarbital except for legitimate medical purposes, and the purpose of execution is not medical. It is incontrovertibly penological.

Petitioner asserts a direct interest in preventing the unlawful use of its products to end human life, rather than the intended uses of preserving and improving human life. However, Petitioner also asserts the interests of the people of the State of Florida, who are “the real party to [an] action” sounding in quo warranto. *State ex rel. Pooser v. Wester*, 170 So. 736, 737 (1936). The people of this State have an interest in preventing a state agency from undermining the rule of law by, paradoxically and unsustainably, violating public policy as well as the law in order, supposedly, to implement the law:

As Justice Brandeis pointed out in *Olmstead v. United States*, 277 U.S. 438, 485, 48 S.Ct. 564, 575, 72 L.Ed. 944 (1928) (Brandeis, J., dissenting):

Decency, security, and liberty alike demand that government officials shall be subjected to the same rules of conduct that are commands to the citizen. In a government of laws, existence of the government will be

imperiled if it fails to observe the law scrupulously. Our government is the potent, the omnipresent teacher. For good or for ill, it teaches the whole people by its example. Crime is contagious. If the government becomes a lawbreaker, it breeds contempt for law; it invites every man to become a law unto himself; it invites anarchy. To declare that in the administration of the criminal law the end justifies the means—to declare that the government may commit crimes in order to secure the conviction of a private criminal—would bring terrible retribution. Against that pernicious doctrine this court should resolutely set its face.

State v. Williams, 623 So. 2d 462, 467 (Fla. 1993). The State of Florida must either operate under the law, or demean its authority in the eyes of Florida's citizens.¹

¹ It is well-known that Florida faces a crisis of rampant unlawful prescription of controlled substances. See, e.g., *Knipp v. State*, Case No. 4D09-2364, 2011 WL 3300186 (Fla. Dist. Ct. App. Aug. 3, 2011) (Warner, J., concurring, recognizing “the increase of ‘pill mills’ in South Florida”). If the State does not conduct itself in accordance with the CSA, it encourages its citizens to do the same.

In his 1881 lecture on the criminal law, Oliver Wendell Holmes, Jr., observed: “The law threatens certain pains if you do certain things, intending thereby to give you a new motive for not doing them. If you persist in doing them, it has to inflict the pains in order that its threats may continue to be believed.”

Apprendi v. New Jersey, 530 U.S. 466, 476 (2000) (citing O. Holmes, *The Common Law* 40 (M. Howe ed. 1963)). If this Court does not take this moment to require state actors to conduct themselves lawfully, it invites the people of Florida to lose faith in the law. The fact that the CSA represents a particularly timely and

Parties

Petitioner is a Consultant Neurologist & Honorary Senior Lecturer at City Hospital, Birmingham, UK. Petitioner has a direct interest in Lundbeck Inc., a global manufacturing company which specializes in the field of neurology and psychiatry. Petitioner uses Lundbeck drugs on a regular basis in his clinical practice and strongly objects to the use of medical drugs intended to improve the health of patients in executions. Petitioner has a financial as well as an ethical interest in the company as the organizer of biennial neurology courses at City Hospital which are sponsored by Lundbeck Inc..²

Petitioner has been directly involved in the movement to prevent the misuse of pentobarbital in executions. Petitioner led a campaign backed by a committee of over 100 neurologists from all over the world against the use of Lundbeck drugs in executions. Petitioner engaged with leading medical journal, *The Lancet*, exposing the misuse of the drug and calling for distribution changes to be put in place.³ Following the distribution changes, Petitioner has been called upon by *The Lancet* and other leading periodicals to comment on the situation. Petitioner has engaged

critical regulatory regime in the State of Florida makes its undermining all the more destructive to the rule of law in Florida.

² <http://birminghammodis.com/>

³ [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)60843-X/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60843-X/fulltext)

directly with the company, corresponding regularly with Directors of Lundbeck in the Danish headquarters. Petitioner has worked together with Lundbeck to ensure that further supplies of pentobarbital are not sold to prisons for use in executions. Petitioner has a direct financial, professional and ethical interest in preventing the use of the pentobarbital currently held by the prisons from being used to kill people.

The Respondents, the Florida Department of Corrections (“DOC”), the unknown executioner who actually dispenses the drug and any unknown medical personnel involved in executions, unlawfully use pentobarbital produced by Lundbeck to execute criminal defendants sentenced to death in exercise of powers derived from the State of Florida.

Jurisdiction

This Court has original jurisdiction over this matter pursuant to Article V, § 3(b)(8) of the Constitution of the State of Florida, Florida Rules of Civil Procedure 9.030(a)(3) and 9.100 and common law authorities recognizing a cause of action in quo warranto whereby Petitioner may assert the interests of the public, and its own directly affected interests, to ensure that DOC conducts itself lawfully in executing its powers derived from the State of Florida. *See State ex rel. Pooser v. Wester*, 170 So. 736, 737 (1936).

Cause of Action and Standing

In Florida, the writ of quo warranto is a writ of inquiry, meaning “by what authority,” used as “the means by which an interested party can test whether any individual improperly claims or has usurped some power or right derived from the State of Florida.” Harry Lee Anstead, Gerald Kogan, Thomas D. Hall & Robert Craig Waters, *The Operation and Jurisdiction of the Supreme Court of Florida*, 29 *Nova L. Rev.* 431, 536-43 (2005). While the original statutory writ envisions a challenge to a title to office, quo warranto as a matter of common law has been determined to be “the proper method to test the ‘exercise of some right or privilege, the peculiar powers of which are derived from the State.’” *Martinez v. Martinez*, 545 So. 2d 1338, 1339 (Fla. 1989); *Winter v. Mack*, 194 So. 225, 228 (1940); *compare with Martinez v. Martinez*, 545 So. 2d 1338, 1339 (Fla. 1989) (Governor’s authority to call a special session tested through quo warranto); *State ex rel. Butterworth v. Kenny*, 714 So. 2d 404, 411 (Fla. 1998) (authority of CCRC to represent capital defendants in federal civil rights actions denied by writ of quo warranto) (holding overruled by *Darling v. State*, 45 So. 3d 444, 459 (Fla. 2010)); *Smith v. Brummer*, 426 So. 2d 532 (Fla. 1982) (writ issued as public defender had no authority to file class action on behalf of juveniles in federal court); *Orange County v. City of Orlando*, 327 So. 2d 7 (Fla. 1976) (legality of municipal actions

testable through quo warranto); *Austin v. State ex rel. Christian*, 310 So. 2d 289 (Fla.1975) (authority of state attorney testable through quo warranto).

The Florida Constitution permits writs of quo warranto and mandamus to “state officers and state agencies.” Art. V, § 3(b)(8), Fla. Const.; Fla. R. App. P. 9.030(a)(3); *State ex rel. Butterworth v. Kenny*, 714 So. 2d 404, 406 (Fla. 1998). As DOC is a state agency, it is subject to the writ.

By virtue of Lundbeck’s qualification to do business in the State of Florida, Petitioner asserts his direct interest in a company that is subject to and permitted to invoke this Court’s jurisdiction. *See Batavia, Ltd. v. U. S. By & Through Dept. of Treasury, Internal Revenue Serv.*, 393 So. 2d 1207, 1208 (Fla. Dist. Ct. App. 1980); *Bradbery v. Frank L. Savage, Inc.*, 190 So. 2d 183, 184 (Fla. Dist. Ct. App. 1966); Fla. Stat. § 48.181. While Lundbeck itself is not in a position to bring this litigation, the company has made clear both publicly and directly to the Florida Department of Corrections its opposition to the use of its life-saving drugs in the taking of life by executions.

Lundbeck President, Staffan Schüberg, has twice written to Edwin Buss, former Secretary of the Florida Department of Corrections and twice to Florida Governor, the Honorable Rick Scott, to express his opposition to the use of Nembutal® (pentobarbital sodium injection) in executions. He states, “Lundbeck is adamantly opposed to the use of Nembutal [...] for the purpose of capital

punishment” and urges the DOC “to refrain from using Nembutal in the execution of prisoners in [Florida] because it contradicts everything [Lundbeck] is in business to do – provide therapies that improve people’s lives” (April 21, 2011). In a letter dated June 8th, 2011, Schüberg further warns, “The use of pentobarbital outside of the approved labeling has not been established. As such Lundbeck cannot assure the safety and efficacy profiles in such instances. For this reason, we are concerned about its use in prison executions.”⁴

In addition to meeting jurisdictional requirements, Petitioner has standing to bring the instant action. Quo warranto standing requirements are broad in Florida. In quo warranto actions seeking enforcement of the public’s right to have their representatives and state actors conduct themselves in accordance with the law, “the people are the real party to the action and the person bringing suit ‘need not show that he has any real or personal interest in it.’” *State ex rel. Pooser v. Wester*, 170 So. 736, 737 (1936). Further, when a party has an interest directly affected by the illegal state action, they certainly have standing. *Martinez*, 545 So. 2d at 1339 (Fla. 1989) (“in the instant case, as a member of the legislature being called into special session, Representative Martinez is directly affected by the governor’s action” and “therefore, [] he has standing to challenge the governor’s power to call a special session.”).

⁴ Lundbeck letters, Attachment A

While Petitioner here asserts the shared interests of the citizens of Florida in having state agencies exercise powers derived from the State in accordance with the law, Lundbeck (and derivatively Petitioner) has a direct financial interest in preventing a negative response from international consumers based on aversion to Lundbeck's involvement in the barbaric and reprehensible practice of U.S. executions. That interest is compromised by Florida's use of Lundbeck's product. Lundbeck has publicly assured its consumers that it is doing everything in its power to put an end to DOC's misuse of its product. To fail in that regard, would have negative consequences for the company. Thus, even if Petitioner could not bring the present action in the interest of the people of Florida, those associated with Lundbeck would be obliged to bring the instant action to protect the interests of the Lundbeck stakeholders.

Statement of Facts

Lundbeck has made its opposition to the use of its products in executions clear. The company was "dismayed" to hear of the use of Nembutal in executions and sent letters directly to the DOCs concerned to express its "strong opposition" to the practice. In a letter to Mr. Edwin Buss, former Secretary of the Florida Department of Corrections, the President of Lundbeck Inc, Staffan Schüberg states, "Lundbeck is adamantly opposed to the use of Nembutal to execute prisoners [...]"

The use of Nembutal to execute prisoners contradicts everything [the company] is in business to do – to provide therapies that improve people’s lives” (letter dated April 21, 2011).⁵

The President also wrote to the Governors of all the states concerned urging them to prevent the misuse of their product in executions. In a letter to the Governor of Florida, Schüberg writes, “Given our strong opposition to this misuse of our product, we previously sent a letter to the Florida Department of Corrections urging it to refrain from using Nembutal for the purpose of capital punishment. The Florida Department of Corrections has not responded to our letter and we therefore request that you take immediate action to stop the use of Nembutal as a means to end lives” (May 16, 2011).

Lundbeck’s opposition to the use of the drug for executions is based on medical as well as ethical grounds. Lundbeck is a pioneer in the field of neurological and psychiatric medication and knows how their products ought – and ought not – be used. The use of Nembutal in lethal injections in the USA has never been clinically tested or approved. Accordingly, Lundbeck scientists were concerned that such use of the drug would cause serious undue pain and suffering to the prisoners. Nembutal is not intended to induce surgical anesthesia; should it

⁵ *ibid*

fail to work effectively in the lethal injection procedure, the prisoner risks suffering a torturous death.

In early June, 2011, Lundbeck issued a public statement voicing their concerns and warning that “[t]he use of pentobarbital to carry out the death penalty in US prisons falls outside its approved indications” and that consequently “Lundbeck cannot assure the associated safety and efficacy profiles in such instances.” In addition, Lundbeck President, Staffan Schüberg, sent letters to the Governors and Departments of Corrections in every state using Nembutal in lethal injections warning them of the dangers and urging them to desist. No heed was taken, and Lundbeck’s worst fears were confirmed when reports revealed that several of the executions carried out using Nembutal had been “botched” (see, for example, that of Eddie Duval Powell in Alabama on 16th June and of Roy Willard Blankenship in Georgia on 23rd June).

The use of Nembutal in executions is a violation of Lundbeck’s own Code of Ethics as well as its obligations under international norms. According to Lundbeck’s Code of Ethics, the company’s Mission is to make drugs which “improve quality of life”, not end life, and their focus is on “Responsibility” and

“doing the right thing”.⁶ The use of Nembutal to end prisoners’ lives is a violation of the very principles upon which the company is founded.

Lundbeck is a European company and as such, is expected to adhere to the principles and standards of European law. By using Lundbeck drugs to execute prisoners in the USA, the DOCs are rendering Lundbeck complicit in executions, a direct violation of the Right to Life, enshrined in Article 2 of the European Convention on Human Rights. Furthermore, as a member of the UN Global Compact, Lundbeck is committed to corporate social responsibility and the respect of fundamental human rights. Principle 1 and 2 of the Compact state that “Businesses should support and respect the protection of internationally proclaimed human rights” and that “Businesses should make sure that they are not complicit in human rights abuses.” The use of Nembutal in executions puts Lundbeck in further violation of its international obligations under the UN Global Compact.

Lundbeck’s stakeholders expect Lundbeck to meet certain ethical standards and their involvement in the execution drug trade did a great deal of damage to their reputation. Media reports criticizing the company proliferated in Denmark, the US and elsewhere in Europe, leading to consumer boycotts of Lundbeck

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http://www.lundbeck.com/corporate_responsibility/policies/code_of_ethics/default.asp

products and anti-Lundbeck campaigns online. Stock prices fell and in May 2011, Danish Pension Fund, Unipension, publicly divested from the company, citing ethical concerns as their primary motive. Lundbeck's "Credibility Rating" fell by a full 23 points according to the Annual Report of leading Danish business paper, the *Berlingske*,⁷ and in June 2011, the leading medical journal, *The Lancet*, published a petition signed by more than 100 neurologists condemning the inaction of the company.⁸

Since then, the company has taken major steps to end the misuse of their product by US executioners. On July 1st 2011, Lundbeck announced that they had completed an overhaul of the distribution system for Nembutal.

Lundbeck today announced that the company has moved to alter the distribution of its medicine Nembutal® (pentobarbital sodium injection, USP) in order to restrict its application as part of lethal injection in the U.S. Going forward, Nembutal will be supplied exclusively through a specialty pharmacy drop ship program that will deny distribution of the product to prisons in U.S. states currently active in carrying out the death penalty by lethal injection. The company notified its distributors of the plan in late June.

The new distribution program ensures that hospitals and treatment centers will continue to have access to Nembutal for therapeutic purposes. Under the program, Lundbeck will review all Nembutal orders before providing clearance for shipping the product and deny

⁷ <http://www.business.dk/biotek/lundbecks-trovaerdighed-styrtdykker>

⁸ [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)60843-X/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60843-X/fulltext)

orders from prisons located in states currently active in carrying out death penalty sentences.

Prior to receiving Nembutal, the purchaser must sign a form stating that the purchase of Nembutal is for its own use and that it will not redistribute any purchased product without express written authorization from Lundbeck. By signing the form, the purchaser agrees that the product will not be made available for use in capital punishment.⁹

Radical distribution change comes at a cost and Lundbeck has shown itself willing to make a financial as well as an ethical commitment to ending the misuse of Nembutal. Thanks to these efforts, as of 1st July 2011, there is no legitimate means by which State Departments of Corrections may procure Nembutal for the purposes of executions. Nevertheless, certain State DOCs managed to procure limited supplies of the drug prior to the distribution change. Petitioner asserts that use of these drugs is not only contrary to the financial, ethical and public interests of the company, it is also unlawful for the reasons detailed below.

Argument

The Controlled Substances Act “creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances.” *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). The

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http://www.lundbeck.com/investor/releases/ReleaseDetails/Release_1527337_EN.asp

enforcement provision of the CSA states that “[e]xcept as authorized . . . it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute or dispense . . . a controlled substance.” 21 U.S.C. § 841(a). Thus, “[d]ispensing controlled substances without a valid prescription [] is a federal crime.” *Gonzales*, 546 U.S. at 254 (citing 21 U.S.C. § 841(a)(1); *United States v. Moore*, 423 U.S. 122 (1975)).

A “controlled substance” is “a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter.” 21 U.S.C. § 802(6). Pentobarbital is included in Schedule II. Schedule II substances are “generally available only pursuant to a written, nonrefillable prescription by a physician,” *Gonzales*, 546 U.S. at 250 (citing 21 U.S.C. § 829(a)), because there is a high potential for abuse of pentobarbital by failing to use it for a medical purpose.

While it is generally a crime to dispense pentobarbital, an exemption is made for duly licensed and registered physicians and other entities that may lawfully prescribe controlled substances. 21 U.S.C. § 829. The Attorney General has passed a regulation pursuant to the CSA requiring “that every prescription for a controlled substance ‘be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.’” *Id.* at 250 (citing 21 CFR § 1306.04(a)).

The CSA allows prescription of drugs only if they have a ‘currently accepted medical use,’ 21 U.S.C. § 812(b);

requires a “medical purpose” for dispensing the least controlled substances of those on the schedules, § 829(c); and, in its reporting provision, defines a “valid prescription” as one “issued for a legitimate medical purpose,” § 830(b)(3)(A)(ii). Similarly, physicians are considered to be acting as practitioners under the statute if they dispense controlled substances “in the course of professional practice.” § 802(21).

Id. at 257. DOC’s use of pentobarbital does not meet that exception because terminating life for penological purposes is not medical in nature, and DOC’s lethal execution protocol does not require the involvement of a physician. Thus, there is no valid prescription or valid medical purpose pursuant to which an execution can be carried out.

Further, the use of pentobarbital to carry out the death penalty in U.S. executions falls outside the approved uses of pentobarbital. Lundbeck cannot assure the associated safety and efficacy profiles in such instances. Pentobarbital has not been FDA-approved for the induction of anesthesia, has no relevant clinical history, and has no relevant clinical reference doses by which to determine an appropriate dosage for a clinically adequate depth of anesthesia to avoid the excruciating pain caused by an injection of potassium chloride, which drug is used under DOC’s protocol to terminate the life of condemned criminal defendants. Thus, one of the dangers of unlawful misuse of controlled substances which the CSA seeks to prevent is present in this circumstance.

As a matter of discretionary enforcement, the Food and Drug Administration has declined to enforce regulation of controlled substances against states conducting executions. *See Heckler v. Chaney*, 470 U.S. 821, 823 (1985). However, the CSA remains operative, substantive federal law, and Petitioner, and the people of Florida, have cause and standing to demand that the Florida Department of Corrections exercise powers derived from the State of Florida in accordance with the law. Regardless of the prosecutorial decisions of another jurisdiction, the sovereign State of Florida, pursuant to this Court's interpretation of its powers, "should resolutely set its face" against sacrificing the rule of law in the name of convenient enforcement. *Olmstead*, 277 U.S. at 485.

Conclusion and Prayer for Relief

Wherefore, Petitioner respectfully prays that the Writ *Quo Warranto* should issue and that Respondents should be enjoined from using Lundbeck drugs in any execution in the State of Florida.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true copy of the foregoing has been furnished by electronic mail and United States Mail to Sandra Jaggard, Assistant Attorney General, 444 Brickell Ave., Suite 650 Miami, Florida 33131, Kenneth S. Tucker, Secretary, Florida Department of Corrections, Florida 32399, and Suzanne Keffer, Chief Assistant CCRC-South, Ft. Lauderdale, Florida 33301 this 26th day of September, 2011.



PAOLO G. ANNINO for: J. PEYTON QUARLES
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CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that this petition is typed in Times New Roman 14 point font, in compliance with Fla. R. App. P. 9.210(a)(2).



PAOLO G. ANNINO for: J. PEYTON QUARLES