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IN THE DISTRICT COURT OF APPEAL

OF FLORIDA

THIRD DISTRICT

JANUARY TERM A.D., 2004

JOHN W. SULLIVAN, D.C., and FLORIDA CHIROPRACTIC PHYSICIANS' ASSOCIATION, INC.,	**	
Appellants,	**	CASE NO. 3D03-2932
vs.	**	
DEPARTMENT OF HEALTH, BOARD OF CHIROPRACTIC MEDICINE,	**	LOWER TRIBUNAL NO. DOAH02-4916RX
Appellee.	**	

LPS CLOS

Opinion filed June 16, 2004.

An Appeal from Division of Administrative Hearings, Lawrence P. Stevenson, Administrative Law Judge.

Neil F. Garfield (Plantation), for petitioners.

Donna ~~Burrick~~ Erlich (Tallahassee), for respondent Board of Chiropractic Medicine; Robert P. Daniti (Tallahassee), for respondent Department of Health.

Before SCHWARTZ, C.J., and LEVY, J., and COBB, Warren H., Senior Judge.

COBB, Senior Judge.

The issue posed by this appeal, which we consider de novo, is whether the Florida Legislature, while statutorily authorizing chiropractors in this state to administer vitamins and nutrients to their patients orally, has also authorized them to do so by injection.

The Department of Health, Board of Chiropractic Medicine ("the Board"), is the state agency responsible for the licensure and regulation of chiropractic medicine. John W. Sullivan, D.C., and the Florida Chiropractic Physicians Association, Inc., ("petitioners") filed a "Petition for Declaratory, Injunctive and Supplemental Relief" at the Division of Administrative Hearings. The petition challenged Rule 64B2-17.0025(4), Florida Administrative Code, as an invalid exercise of delegated legislative authority by the Board. Rule 64B2-17.0025(4) provides:

> All chiropractic physicians are explicitly prohibited by Chapter 460.403, Florida Statutes, from prescribing or administering to any person any legend drug. A legend drug is defined as a drug required by federal or state law to be dispensed only by prescription. For the purpose of this rule, any form of injectable substance is beyond the scope of practice for chiropractors.

Petitioners claim that the statutes from which this rule was derived cannot be read to prohibit chiropractors from injecting vitamins and nutrients into patients. Rule 64B2-17.0025(4) was issued in 1990 and was essentially the Board's interpretation of

legislative changes made in 1986. Some thirty years earlier, in 1957, the Florida Legislature amended section 460.11(2) (b) to provide:

> Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical or natural methods, or by the use of physical means, physiotherapy (including light, heat, water or exercise) or by the oral administration of foods and food concentrates, food extracts, and may apply first aid and hygiene, but chiropractic physicians are expressly prohibited from prescribing or administrating to any person any medicine or drug . . . .

(Emphasis added).

In 1979, that section was renumbered section 460.403. In 1986, section 460.403(3) (c) was amended to provide:

> Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical, or natural methods; by the use of physical means or physiotherapy, including light, heat, water, or exercise; by the use of acupuncture; or by the administration of foods, food concentrates, food extracts, and proprietary drugs and may apply first aid and hygiene, but chiropractic physicians are expressly prohibited from prescribing or administering to any person any legend drug . . . .

(Emphasis added).

In a detailed Final Order the Administrative Law Judge ("ALJ") found Rule 64B-17.0025(4) to be a valid exercise of delegated legislative authority by the Board.

The appellate argument of the petitioners is, quite simply, that the Board's 1990 administrative rule reinstating an oral restriction that had been removed by the legislature in 1986

constitutes an invalid exercise of delegated legislative authority. The petitioners contend the ALJ erred by inferring that the legend drug prohibition in section 460.403(3) (c) prohibits injections when the legislature specifically granted the authority to chiropractors to administer "foods, food concentrates and food extracts" (generally referred to in this cause by the parties and the ALJ as vitamins and nutrients).

The response of the Board is that section 460.403 expressly prohibits chiropractic physicians from prescribing or administering to any person any "legend drug," that legend drugs are synonymous with prescription drugs, that both Florida and federal law consider any injected substance (except for insulin) to be a prescription drug, and that the ALJ was correct in upholding the prohibition in Rule 64B2-17.0025(4) against injections.

The ALJ, following extensive testimony and evidence, and the consideration of legal argument, made detailed findings of fact, inter alia:

> 63. Petitioners challenge the definition of "legend drug" provided in the rule. They must concede that Section 460.403(9) prohibits chiropractic physicians from "prescribing or administering to any person any legend drug," except for certain named items not relevant to this case. However, petitioners contend that the statute does not define "legend drug," and argue that the definition set forth in the rule is in derogation of the statute. This argument is premised on the claim that since 1986, the statute has allowed chiropractic physicians to administer

vitamins and nutrients via injection but that the rule impermissibly prohibits such administration.

64. Through testimony, petitioners attempted to create the impression that the term "legend drug" is something of a mystery, a "slang term" with a murky past and no precise meaning that is here employed by the Board to circumvent the intent of the statute.

65. In response, the Board noted two definitions of the term found in the Florida Statutes. Chapter 465 regulates the practice of pharmacy. Section 465.003(8) provides:

> "Medicinal drugs" or "drugs" means those substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations as hereafter defined.

66. Chapter 499 is the "Florida Drug and Cosmetic Act." Section 499.003 sets forth the definitions of terms employed in the Florida Drug Cosmetic Act, and includes:

> "Legend drug," "prescription drug," or "medicinal drug" means any drug, including but not limited to, finished dosage forms, or active ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003(8), s.499.007(12), or s. 499.0122(1)(b) or (c).

. . .

68. 21 U.S.C. Section 353(b) fully supports the testimony ... as to the FDA's methods of defining items as "drugs," not merely based on their substance, but on their methods of use and/or collateral measures necessary to their use.

. . .

71. The term "legend drug" also appears in the practice act for physicians, which contains the following, in Section 458.331:

> (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
>
> ***
>
> (q) Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.

72. Virtually identical grounds for denial of a license or disciplinary action in relation to "legend drugs" are found in the statutes governing osteopaths, podiatrists, naturopaths, pharmacists, dentists, and veterinarians. See respectively Sections 459.015(1)(t), 461.013(1)(o), 462.14(1)(q), 465.016(1)(i), 466.028(1)(p), and 474.214(1)(ff). None of these disciplinary statutes sets forth a separate definition of the term "legend drug."

73. The fact that Section 460.403(9) lacks a separate definition for the term "legend drug" does not empower the Board to ignore the definitions set forth in other sections of the Florida Statutes. At the time the 1986 legislation was passed, the term "legend drug" was employed in Chapter 465 and in the various professional licensure statutes cited above and was explicitly defined in Chapter 499. The Legislature must be presumed to have been aware of these uses and definitions when it employed the term "legend drug" in Chapter 86-285, Laws of Florida, and to have intended the Board to make reference to them in implementing the legislation.

74. To adopt petitioners' view of the term, the Board would have to ignore the multifarious provisions of the Florida Statutes defining and using the term "legend drug" and further ignore the federal statutes and the authoritative pronouncements of the FDA as to the classification of injectable vitamins and nutrients as legend drugs. The Board's imprimatur would place chiropractic physicians in jeopardy of prosecution for possessing and dispensing prescription drugs without statutory authority to do so.

75. The mere deletion of the word "oral" from the statute in the 1986 legislation cannot be considered in isolation. The same 1986 legislation changed the items that chiropractic physicians were prohibited from prescribing or administering from "any medicine or drug" to "any legend drug." In Chapter 96-296, Section 1, Laws of Florida, the Legislature enacted specific exceptions to the legend drug prohibition, relating to medical oxygen and certain topical anesthetics. The evidence presented at the hearing overwhelmingly demonstrated that injectable vitamins are legend drugs and are not listed in the exceptions to the legend drug prohibition.

76. Section 460.403(9), considered in pari materia with the sections of the Florida Statutes that reference its meaning and the meaning of related items in conjunction with federal law, clearly prohibits chiropractic physicians from administering injectable vitamins and nutrients to their patients. The challenged rule merely makes explicit the prohibition that the statute implicitly states.

We agree with the factual findings and with the legal conclusion of the ALJ that the Board's definition of "legend drug" is a permissible interpretation of the statute. The rule at issue is neither arbitrary nor capricious, and was supported at the administrative hearing by competent, substantial evidence. See De Groot v. Sheffield, 95 So. 2d 912 (Fla. 1957). The petitioners below failed to meet their burden of proof and, as

observed by the ALJ, their remedy lies with the Florida Legislature, which may or may not see fit to expressly expand the scope of practice for chiropractic physicians to include injections.

Affirmed.