STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

JOHN W. SULLIVAN, D.C., and FLORIDA CHIROPRACTIC PHYSICIANS' ASSOCIATION, INC.,	)	
Petitioners,	)	
vs.	)	Case No. 02-4916RX
DEPARTMENT OF HEALTH, BOARD OF CHIROPRACTIC MEDICINE,	)	
Respondent.	)	

FINAL ORDER

Pursuant to notice, Lawrence P. Stevenson, Administrative Law Judge, Division of Administrative Hearings, conducted a formal hearing in the above-styled case on June 3 through 5, 2003, in Tallahassee, Florida.

APPEARANCES

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For Respondent: Donna Erlich, Esquire
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STATEMENT OF THE ISSUE

Whether Rule 64B2-17.0025(4), Florida Administrative Code, constitutes an invalid exercise of delegated legislative authority.

PRELIMINARY STATEMENT

On December 30, 2002, Petitioners, John W. Sullivan, D.C., and Florida Chiropractic Physicians' Association, Inc. ("Petitioners"), filed a "Petition for Declaratory, Injunctive and Supplemental Relief" at the Division of Administrative Hearings ("DOAH"). On January 6, 2003, Respondent, Department of Health, Board of Chiropractic Medicine (the "Board"), filed a motion to dismiss on the ground that the petition requested relief that DOAH could not grant. By Order dated January 16, 2003, Judge Stephen F. Dean granted the motion to dismiss but gave Petitioners until January 23, 2003, to amend their petition.

On January 23, 2003, Petitioners filed an Amended Petition for Determination of Invalidity of Rule 64B2-17.0025(4), Florida Administrative Code. After a lengthy discovery process, the matter was set for final hearing on June 3 through 5, 2003. A conflict in Judge Dean's schedule necessitated the reassignment of the case to the undersigned.

At the hearing, Petitioners offered the testimony of John W. Sullivan, D.C.; Roderic A. Lacy, D.C.; Paul J.

Yocom, D.C.; and Frederick D. Yost, D.C. Joseph L. Johnston, D.C., and Drs. Lacy and Sullivan testified as rebuttal witnesses. Pursuant to order, the parties exchanged and submitted their exhibits in binders. Petitioners had two binders of proposed exhibits. From Book One, Petitioners' Exhibits 17 and 30 were admitted into evidence. From Book Two, Petitioners' Exhibits 1, 2, 4, 7, 8, 9, 12, 14, and 21 were admitted into evidence.

Respondent offered the testimony of Paul Lambert, Esquire, general counsel to the Florida Chiropractic Association; William Nevius, D.C.; Ronald J. Hoffman, D.C.; Jerry Hill, a licensed pharmacist and bureau chief of Statewide Pharmaceutical Services for the Department of Health; and the videotaped deposition testimony of William G. Nychis, acting director of the Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Office of Compliance, in the Federal Food and Drug Administration ("FDA"). Respondent's Exhibits 1 through 6, and B, C, D, F, H, J-1, K, L, M, and N were admitted into evidence. Respondent's Exhibit N was the deposition testimony of Everett A. Kelly, a pharmacist and former member of the Florida House of Representatives. Respondent's Exhibit I, a vial of injectable cyanocobalimin (Vitamin B-12) and its packaging, was inadvertently omitted and is hereby deemed admitted.

A four-volume Transcript of the hearing was filed at the Division of Administrative Hearings on June 26, 2003. By stipulation at the hearing, the parties agreed to file their proposed final orders no later than July 25, 2003. Petitioners filed their Proposed Final Order on July 23, 2003. Respondent's Proposed Recommended Order was filed on July 25, 2003. Both parties' proposals have been given careful consideration in the preparation of this Final Order.

Unless otherwise indicated, all statutory references in this Final Order are to the 2003 version of the Florida Statutes and all references to Rules are to the current version of the Florida Administrative Code.

FINDINGS OF FACT

Based on the oral and documentary evidence adduced at the final hearing and the entire record in this proceeding, the following findings of fact are made:

1. The Board is the state agency responsible for the licensure and regulation of chiropractic medicine in the State of Florida. Section 456.013 and Chapter 460.

2. Petitioner, John W. Sullivan, is a licensed Florida chiropractic physician subject to regulation by the Board. Petitioner, the Florida Chiropractic Physicians' Association, Inc., is a Florida corporation organized as a trade association to represent the interests of the Florida-licensed chiropractic

physicians who compose a large portion of its membership. Dr. Sullivan is the president of the Florida Chiropractic Physicians' Association. The Board does not contest the standing of either Petitioner to initiate this proceeding.

3. Petitioners have challenged Rule 64B2-17.0025(4) as an invalid exercise of delegated legislative authority. The challenged rule provides:

> 64B2-17.0025. Standard of Practice for Phlebotomy, Physiotherapy, and the Administration of Items for Which a Prescription is not Required; Prohibition of Prescribing or Administering Legend Drugs.
>
> (1) Any chiropractic physician who in his practice uses physiotherapy, phlebotomizes, or administers items for which a prescription is not required must have acquired the competence to perform said service, procedure, or treatment through appropriate education and/or training. Any chiropractic physician who provides any treatment or service for which he or she has not been specifically educated or trained shall be deemed to be performing professional responsibilities which the licensee knows or has reason to know he or she is not competent to perform, and shall be subject to discipline pursuant to Section 460.413(1)(t), Florida Statutes.
>
> (2) For the purpose of Chapter 460.403(8)(c),[1] Florida Statutes, "items for which a prescription is not required" include "proprietary drugs" such as patent or over-the-counter drugs in their unbroken, original package and which is not misbranded under the provisions of Chapter 499.001-499.081, Florida Statutes.

(3) For the purpose of Chapter 460.403(8)(c), Florida Statutes, and this rule "administration" is defined as the administration of one dose of any proprietary drug, and the recommendation and direction of dosage levels for the patient's needs. Administration shall not include dispensing of repackaged proprietary drugs.

(4) 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.

(5) Notwithstanding the prohibition against prescribing and administering legend drugs under Section 460.403 or 499.0122, Florida Statutes, chiropractic physicians may order, store, and administer, for emergency purposes only at the chiropractic physician's office or place of business, prescription medical oxygen and may also order, store, and administer the following topical anesthetics in aerosol form:

(a) Any solution consisting of 25 percent ethyl chloride and 75 percent dichlorodifluoromethane.

(b) Any solution consisting of 15 percent dichlorodifluoromethane and 85 percent trichloromonofluoromethane.

However, this rule does not authorize a chiropractic physician to prescribe medical oxygen as defined in chapter 499.

Specific Authority 460.405 FS. Law Implemented 460.403(8)(c), (f), 460.413(1)(t), FS. History--New 10-17-90,

Formerly 21D-17.0025, 61F2-17.0025, 59N-17.0025, Amended 2-16-98. (Emphasis added)

4. Section 460.405 cited as the specific authority for the challenged rules, provides:

> The Board of Chiropractic Medicine has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it.

5. Section 460.403(9), paragraphs (c) and (f) of which are cited as a law implemented by the challenged rule, provides:

> (c)1. 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 items for which a prescription is not required and may apply first aid and hygiene, but chiropractic physicians are expressly prohibited from prescribing or administering to any person any legend drug except as authorized under subparagraph 2., from performing any surgery except as stated herein, or from practicing obstetrics.
>
> 2. Notwithstanding the prohibition against prescribing and administering legend drugs under subparagraph 1., or s. 499.0122, pursuant to board rule chiropractic physicians may order, store, and administer, for emergency purposes only at the chiropractic physician's office or place of business, prescription medical oxygen and may also order, store, and administer the following topical anesthetics in aerosol form:

a. Any solution consisting of 25 percent ethylchloride and 75 percent dichlorodifluoromethane.

b. Any solution consisting of 15 percent dichlorodifluoromethane and 85 percent trichloromonofluoromethane.

However, this paragraph does not authorize a chiropractic physician to prescribe medical oxygen as defined in chapter 499.

* * *

(f) Any chiropractic physician who has complied with the provisions of this chapter is authorized to analyze and diagnose abnormal bodily functions and to adjust the physical representative of the primary cause of disease as is herein defined and provided. As an incident to the care of the sick, chiropractic physicians may advise and instruct patients in all matters pertaining to hygiene and sanitary measures as taught and approved by recognized chiropractic schools and colleges. A chiropractic physician may not use acupuncture until certified by the board. Certification shall be granted to chiropractic physicians who have satisfactorily completed the required coursework in acupuncture and after successful passage of an appropriate examination as administered by the department. The required coursework shall have been provided by a college or university which is recognized by an accrediting agency approved by the United States Department of Education.[2] (Emphasis added)

6. Section 460.413(1)(t), cited as a law implemented by the challenged rule, provides:

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

* * *

> (t) Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities which the licensee knows or has reason to know that she or he is not competent to perform.

7. At issue in this case is whether the relevant Florida Statutes authorize chiropractic physicians to administer foods, food supplements and nutrients to patients by way of injection. If the statutes do authorize chiropractic physicians to administer these substances via injection, then the express prohibition on the administration of "any form of injectable substance" by chiropractic physicians contained in Rule 64B2-17.0025(4) is without legislative authorization.

8. In 1923, the Florida Legislature established the "Florida State Board of Chiropractic Examiners" to oversee the licensing and discipline of chiropractic physicians. The scope of chiropractic practice was set forth as follows, in relevant part:

> Any Chiropractor who has complied with the provisions of this Act may adjust by hand the articulations of the spinal column, <u>but shall not prescribe or administer to any person any medicine now or hereafter included in materia medica</u>. . . .

Chapter 9330, Section 12, Laws of Florida (1923). (Emphasis added)

9. Section 12 of Chapter 9330, Laws of Florida, was amended in 1941 to provide, in relevant part:

> B. Any chiropractor who has complied with the provisions of this Act may:
>
> * * *
>
> (2) Chiropractors 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 use of foods and food concentrates, food extracts, and may apply first aid and hygiene, but chiropractors are expressly prohibited from prescribing or administering to any person any medicine or drug included in Materia Medica. . . .

Chapter 20871, Section 1, Laws of Florida (1941). (Emphasis added)

10. In 1957, the Florida Legislature amended the statute, then numbered Section 460.11, Florida Statutes, to provide, in relevant part:

> (2) Any chiropractic physician who has complied with the provisions of this chapter may:
>
> * * *
>
> (b) 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

> administering to any person any medicine or drug. . . .

Chapter 57-215, Section 3, Laws of Florida. (Emphasis added).

11. Aside from being renumbered Section 460.03 by Chapter 79-211, Section 1, Laws of Florida, the relevant language of the statute remained essentially unchanged between 1957 and 1986. Chapter 86-285, Section 2, amended Section 460.03(3), to provide:

> (c) Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical, or natural methods or by the use of physical means or physiotherapy, including light, heat, water, or exercise, or 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)

The underscored language indicates two significant changes made by the Legislature in 1986. First, the term "oral administration" was changed simply to "administration," and "proprietary drugs" were added to the list of items that chiropractic physicians were allowed to administer. Second, the items that chiropractic physicians were prohibited from prescribing or administering was changed from "any medicine or drug" to "any legend drug."

12. Chapter 86-285, Section 1, Laws of Florida, also added the following language to Section 460.403(3)(f), Florida Statutes (currently Section 460.403(9)(f)):

> Any chiropractic physician licensed after October 1, 1986, may not phlebotomize or use physiotherapy or acupuncture or administer proprietary drugs until certified by the board to use any of such procedures. Certification shall be granted to chiropractic physicians licensed after October 1, 1986, who have satisfactorily completed the required coursework in the procedure or procedures for which certification is sought, and after successful passage of an appropriate examination as administered by the department. The required coursework shall have been provided by a college or university which is recognized by an accrediting agency approved by the United States Department of Education. Chiropractic physicians licensed after October 1, 1986, seeking certification in one or more of the procedures for which certification is required may elect to take the certification examination at the time of taking the initial licensing examination or at any subsequent examination. Nothing herein shall be construed to require chiropractic physicians who have met all requirements for licensure prior to the effective date of this act to become certified to phlebotomize or use physiotherapy.

13. Dr. Ronald J. Hoffman testified that he was a member of the Board in 1986 and was directed by the Board's chairman to create the syllabus for the certification course in proprietary drugs required by the 1986 amendment to the statute, quoted above. In conjunction with the National College of

Chiropractic, Dr. Hoffman designed a 72-hour certification course, including three to four hours of instruction relating to injectable nutrients.

14. In Chapter 97-247, Section 1, Laws of Florida, the term "proprietary drugs" was deleted from the list of items that chiropractic physicians may administer. In its place was inserted the term "items for which a prescription is not required," which is the current language of Section 460.403(9)(c), set forth in Finding of Fact 5, supra. Chapter 97-247 also deleted the requirement that a chiropractic physician obtain certification to administer proprietary drugs.

15. Petitioners' challenge focuses on the language in Rule 64B2-17.0025(4) stating that "any form of injectable substance is beyond the scope of practice for chiropractors." Petitioners contend that the statutory language permitting chiropractic physicians to "administer" foods, food concentrates, and food extracts (generally, vitamins and nutrients) by its terms allows chiropractic physicians to inject those substances into their patients. Petitioners admit that between 1955 and 1986, the statute limited their practice to the "oral administration" of the listed substances. However, Petitioners also argue that the Legislature's changing the term "oral administration" to "administration" in 1986, evinced a clear intent to allow chiropractic physicians to administer

foods, food concentrates, and food extracts in any manner, including by injection.

16. In his testimony, Dr. John Sullivan went even further, arguing that the term "administer" can only mean "administer by injection." His contention on this point was echoed by Petitioners' witness Dr. Roderic Lacy. Another witness for Petitioners, Dr. Paul Yocom, D.C., testified that "administration" at least implies some action by the physician and that a physician does not typically place a pill in the patient's mouth.

17. Dr. Lacy testified that when the Legislature removed the word "oral" from the statute in 1986, "everybody was under the impression they were going to be able to do injectable nutrition" because the certification course in proprietary drugs included a section on injectable nutrients. Dr. Lacy stated that this impression changed when "practically nobody passed" the certification examination and the issue of injecting vitamins and nutrients "kind of faded away."

18. Petitioners contend that it is nonsensical that the law would permit them to prescribe and administer foods, food concentrates, and food extracts in an oral form, but not to administer the same substances via subcutaneous injection.

19. Dr. Sullivan testified that vitamins are food, whether taken orally or by injection. The body uses the vitamins in the

same way regardless of the method by which the vitamins enter the body. The same vitamin does not become a "drug" simply because the means of administering it changes. Dr. Sullivan pointed out that some people cannot metabolize certain vitamins orally and must take them by injection.

20. Dr. Lacy testified that an inability to administer vitamins and nutrients by injection restricts a chiropractic physician's ability to treat patients. He noted that the absorption rate when vitamins are taken orally is 10 to 20 percent, whereas the absorption rate for injections is 100 percent. If a patient is deficient in a certain vitamin or nutrient, the number of oral doses the patient would need to address the deficiency could make the patient sick.

21. Dr. Lacy testified that he was unaware of any instance of a serious adverse reaction related to the injection of a vitamin or nutrient. Dr. Lacy noted that "injectable" simply means that the vitamin is in a sterile, water soluble solution, and that the character of the vitamin itself is unchanged. Both Dr. Sullivan and Dr. Lacy testified that because injectable vitamins are water soluble, any excess amounts are eliminated from the body via urination.

22. Petitioners attacked the term "legend drug" as a vague and overbroad term in the Rule. Dr. Lacy testified that "legend" simply means "label," and, therefore, that any drug

with a label on it could be termed a "legend drug." Given the broad meaning of "legend," Dr. Lacy argued that there could be "legend drugs," "legend vitamins," and even "legend foods," though no one questions the right of a chiropractic physician to prescribe foods and vitamins.

23. Dr. Lacy testified that he contacted the Food and Drug Administration to find out its definition of the term "legend drug." He stated that FDA informed him that it was a "slang term" used interchangeably with the term "prescription drug" and without a written definition.

24. Dr. Yocom testified that he spent "many hours" on the internet in search of a definition of the term "legend drug." He could not find that the term "existed per se." He found references to the term "legend drug," but always without definition. Dr. Yocom testified that in his mind, "legend" simply means "a description, a label."

25. Dr. Sullivan testified that "legend" does not mean "prescription only." A "legend" on a label simply tells the user what is in the product and how to use it. Dr. Sullivan testified that such products as aspirin, Tylenol, Benadryl, Excedrin P.M., and even oral vitamins are "legend" products because their labels contain instructions for their use.

26. In addition to their dispute with the Board's use of the terms "administration" and "legend drug," Petitioners, by

their testimony, indicate that they have a different understanding of the term "prescription" than that employed by the Board. Dr. Yocom testified that he "prescribes" hot packs, cold packs, and exercise to his patients. Dr. Sullivan "prescribes" certain diets to his weight loss patients.

27. This testimony disregards the common understanding of the term "prescription," i.e., an order for medication, therapy, or a therapeutic device given by a properly authorized person to a person properly authorized to dispense or perform the order. In the context of drugs, "prescription" carries a connotation that the patient will receive a medication that the patient could not lawfully procure without a physician's order.[3] While it is literally true that a physician may "prescribe" such things as cold packs, exercise, and diets, the patient does not require a physician's prescription to obtain them. Petitioners' testimony on this point cannot be credited.

28. The Board's position is that Rule 64B2-17.0025 was adopted in 1990 precisely because many chiropractors were confused about the effect of the 1986 legislation. Paul Lambert, the general counsel for the Florida Chiropractic Association, testified that, at the time the legislation passed, he believed that chiropractic physicians were authorized to administer injectable vitamins and that he drafted a legal opinion in support of that position in 1989. Testimony at the

hearing established that many chiropractors, including some members of the Board, shared Mr. Lambert's opinion. The Board's position is that the Rule, defining the terms "administration" and "legend drug," was necessary to dispel this misconception.

29. Dr. Hoffman testified that, after he prepared the certification course, he researched the question of whether Vitamin B-12, the most commonly used injectable vitamin, was a legend drug. He concluded that it was. Dr. Hoffman testified that this fact appeared to be common knowledge among pharmacists but that chiropractors seemed unaware of it. He stated that he likely would not have included instruction on injectable vitamins in the certification course had he known injectable vitamins were considered legend drugs.

30. As a result of his research, Dr. Hoffman became a firm proponent of a rule to disallow the use of injectable vitamins by chiropractic physicians. Dr. Hoffman testified that he helped draft the language of the Rule and helped to promulgate it as a member of the Board in 1990.

31. The Rule defines "legend drug" as "a drug required by federal or state law to be dispensed only by prescription." As noted above, Petitioners challenged this definitional conflation of the terms "legend drug" and "prescription drug." The Department responded that every "federal or state law" relevant to the medical professions and to the profession of pharmacy

treats the terms as equivalent and that the Rule simply clarified that the 1986 legislation intended "legend drug" to carry this common meaning.

32. This issue is significant, if not dispositive, of this case, because the Board introduced persuasive evidence that the FDA considers all injectable drugs, including injectable vitamins and nutrients, to be "legend" or "prescription" drugs. William Nychis, acting director of the FDA's Division of New Drugs and Labeling Compliance, testified that insulin is the only item intended for parenteral administration that the FDA does not classify as a drug.

33. Mr. Nychis began his analysis by referencing the definition of "drug" found in Section 201(g) of the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. Section 321(g)(1):

> The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or

> sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

34. Mr. Nychis testified that "legend drug" and "prescription drug" are considered synonymous terms by the FDA. He stated that a legend drug is one for which adequate directions for use by the lay person cannot be written, and which therefore must carry the "Rx" or “prescription only” legend. In contrast, a "proprietary" or over-the-counter drug is one that can bear adequate directions for use by the lay person. The classification of drugs is performed on a case-by-case basis.

35. Prescription drugs are articles that because of their toxicity or other potential for adverse effect, or because of their method of use, or because of the collateral measures necessary for their use, are not safe for use except under the supervision of a practitioner authorized by state law to administer such a drug. Prescription drugs are not available to the consumer except through an authorized practitioner.

36. Mr. Nychis testified that any item, except insulin, administered by injection is classified by the FDA as a

prescription drug. Products that are intended to be injected, because of the collateral measure necessary for their use, are not considered safe except under the supervision of a practitioner authorized by law to administer and prescribe such drugs. Mr. Nychis emphasized that it is up to the states to determine who is a practitioner authorized by law to prescribe and administer prescription drugs and that the FDA takes no position as to the propriety of allowing chiropractic physicians to prescribe or administer injectable vitamins.

37. Mr. Nychis testified that as early as 1945, the FDA, in what is called trade correspondence, first began to classify injectable vitamins and nutrients as prescription drugs. In 1951, the definition was clearly set forth in Section 503(b)(1) of the Food, Drug and Cosmetic Act, codified at 21 U.S.C. Section 353(b)(1) and set out in full in the Conclusions of Law below. For at least 50 years, the FDA has not classified an injectable vitamin or nutrient as anything other than a prescription or legend drug. Mr. Nychis testified that even injectable water is classified as a drug.

38. Legend drugs or prescription drugs are identified as "Rx" in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as "The Orange Book." Large numbers of injectable vitamins and nutrients are listed as "Rx" in the Orange Book. Some fat-soluble vitamin

tablets and injections are also listed as "Rx" or prescription. Even "soy bean oil" (vitamin E) can be found listed in the Orange Book as a prescription drug in its injectable form.

39. Appendix C to the Orange Book lists 43 "routes of administration" for drug products, demonstrating that "injection" is not necessarily an equivalent term to "administration," as contended by Dr. Sullivan. In any event, the use of the term "administration" of food products in Section 460.403(9)(c) must be read in conjunction with the statute's prohibition on "administering" legend drugs. Once it is established that injectable vitamins are legend drugs, then it follows that "administration" of food products, whatever it might include, cannot include the method of injection.

40. Jerry Hill has been a pharmacist for more than 30 years and is the bureau chief of statewide pharmaceutical services for the Florida Department of Health, responsible for the licensure of drug wholesale facilities and manufacturing facilities. Mr. Hill testified that the term "legend drug" has been in use for at least as long as he has been a pharmacist. The "legend" on these products is the notice that federal or state law prohibits dispensing them without a prescription or the "Rx only" notice. Mr. Hill testified that the statutes enforced by his agency treat "legend drug," "prescription drug,"

and "medicinal drug" as interchangeable terms. He cited, as an example Section 499.003(25), which provides:

> "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).

41. As did Mr. Nychis, Mr. Hill testified that drugs are classified not merely by their substance, but by their intended use and method of administration as well. Thus, he contradicted the Petitioners' testimony that a vitamin is considered "food" regardless of its method of administration. Mr. Hill noted that in its oral dosage form, Vitamin B-12 may be classified as a dietary supplement. If the label indicates some use to treat a medical condition, Vitamin B-12 may be classified as an over-the-counter medication. In its injectable form, Vitamin B-12 is a legend drug, available only by prescription.

42. Mr. Hill also agreed with Mr. Nychis that, except for insulin, all dosage forms in which the route of administration is injectable are classified as prescription drugs. Mr. Hill stated that no injectable products may be purchased from a Florida pharmacy without a prescription. He testified that it would be his duty to seize any injectable Vitamin B-12 that he found in the possession of a chiropractic physician and to

prosecute the chiropractic physician for unlawful possession of a prescription drug.

43. Everett A. Kelly has been a licensed pharmacist in Florida since 1961 and served in the Florida House of Representatives for 22 years. Mr. Kelly confirmed Mr. Hill's testimony that the term "legend drug" is synonymous with the term "prescription drug." The referenced "legend" is the identification that the item is "Rx only" or may be dispensed only by prescription. Mr. Kelly testified that Florida defers to the FDA's classifications of substances as "drugs." On this point, both Mr. Hill and Mr. Kelly noted that federal law allows the states to make their drug laws more restrictive than the federal laws, but does not allow the states to enact less restrictive laws. Mr. Hill cited the example of ephedrine hydrochloride, which the FDA classifies as an over-the-counter drug, but for which Florida requires a prescription.

44. Mr. Kelly also confirmed the testimony of Mr. Nychis and Mr. Hill that all injectable items, except insulin, are legend drugs. Mr. Kelly explained that insulin is excepted because diabetics must use it daily for their entire lives, and that the diagnosing physician's initial prescription is considered sufficient for the patient to receive insulin in perpetuity. Mr. Kelly stated that, aside from insulin, every

other injectable product, including water for injection, is a legend drug.

45. The testimony of Mr. Hill, Mr. Nychis, and Mr. Kelly as to the meaning of the term "legend drug" is credited insofar as it represents their understanding of the common usage in their respective professions, based upon federal and state statutory definitions. The contrary testimony of Petitioners' witnesses as to the meaning of "legend drug" cannot be credited. These chiropractic physicians were essentially offering a layman's view of the term derived from internet searches, phone calls to unidentified FDA employees, and a self-serving disregard of the fact that "legend drug" is defined in state and federal statutes.

46. In summary, the testimony established that when the 1986 legislation became law, many chiropractors focused on the change of "oral administration" to "administration" and concluded that they were now free to administer injectable vitamins and nutrients to their patients. Even some members of the Board shared this belief, as evidenced by the inclusion of instruction regarding injectable nutrients in the certification course for proprietary drugs. However, closer examination of the issue and consultation with professionals in other health fields led the Board to an understanding that the term "legend drug" includes any injectable substance, even vitamins and

nutrients that may be considered foods or over-the-counter drugs in their oral form. This understanding, and the need to make all chiropractic physicians aware of the true state of the law, led the Board to adopt Rule 64B2-17.0025 in 1990.

47. Petitioners raised several other issues that merit brief discussion. Petitioners attempted to offer evidence of legislative intent regarding the 1986 legislation by way of statements by Dennis Jones, the state representative who sponsored the relevant amendments. The Board attempted to counter this evidence with testimony by Mr. Kelly, who was also in the state House of Representatives in 1986. The undersigned declined to accept any of this testimony, finding that an individual legislator's statements cannot form the basis for a finding of legislative intent. See State v. Patterson, 694 So. 2d 55, 58 n.3 (Fla. 5th DCA 1997), and cases cited therein (testimony of individual legislators as to what they intended to accomplish is of doubtful worth in determining legislative intent and may not even be admissible).

48. Petitioners argued that certain members of the Florida Chiropractic Physicians' Association, having completed the certification course and passed the examination in the late 1980's, continue to hold certification in the administration of proprietary drugs, including injectable vitamins. As noted above, the Legislature in 1997 removed the statutory authority

for the Board to grant certification to chiropractic physicians in proprietary drugs. In fact, the current statutory scheme permits any chiropractic physician to administer "items for which a prescription is not required," rendering the old certification program meaningless. Further, the evidence at the hearing established that the certifications in proprietary drugs could not have certified their holders to administer injectable vitamins, which are legend drugs that no chiropractic physician can be authorized to administer under the relevant statutes.

49. Petitioners offered the 1987, 1989, and 1990 editions of the "Florida Health Care Atlas" as evidence that the 1986 legislation authorized chiropractic physicians to administer injectable vitamins. Each of the cited editions of the Atlas does, in fact, state that "chiropractors may now . . . administer proprietary drugs and injectable vitamins upon certification . . . ." However, the Board pointed out that the Atlas was a publication of the Department of Health and Rehabilitative Services, not the Board of Chiropractic Medicine or its parent agency at the time, the Department of Professional Regulation. The Board disavowed the inaccurate information in the Atlas, which was in any event a reference guide lacking the legal effect of a statute or rule.

50. Finally, Petitioners offered documentation that the Board in 2000 approved a 50-hour continuing education course

that included a three hour section on "injectable nutrients." However, the notice of Board approval included an italicized notice that the three-hour section on injectable nutrients would not be accepted. Subsequently, in January 2001, the Board approved a three-hour course in injectable nutrients for continuing education credit but required the presentation to include a disclaimer that all or portions of the material presented constituted practice outside the scope of the profession.

CONCLUSIONS OF LAW

51. The Division of Administrative Hearings has jurisdiction over the parties and the subject matter of this proceeding according to Section 120.56(1) and (3).

52. Section 120.56, provides in pertinent part:

> 1) GENERAL PROCEDURES FOR CHALLENGING THE VALIDITY OF A RULE OR A PROPOSED RULE.--
>
> (a) Any person substantially affected by a rule or a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority.
>
> (b) The petition seeking an administrative determination must state with particularity the provisions alleged to be invalid with sufficient explanation of the facts or grounds for the alleged invalidity and facts sufficient to show that the person challenging a rule is substantially affected by it, or that the person challenging a

> proposed rule would be substantially affected by it.
>
> * * *
>
> (3) CHALLENGING EXISTING RULES; SPECIAL PROVISIONS.--
>
> (a) A substantially affected person may seek an administrative determination of the invalidity of an existing rule at any time during the existence of the rule.

53. Petitioner John W. Sullivan and those members of the Florida Chiropractic Physicians' Association, who are Florida licensed chiropractic physicians, are affected persons with standing to challenge the validity of Rule 64B2-17.0025(4). See Florida Board of Medicine v. Florida Academy of Cosmetic Surgery, Inc., 808 So. 2d 243, 250-251 (Fla. 1st DCA 2002).

54. As the moving party asserting the affirmative by attacking the validity of an existing agency rule, Petitioners in this case retain the burden of proof throughout the entire proceeding. Espinoza v. Department of Business and Professional Regulation, 739 So. 2d. 1250, 1251 (Fla. 3d DCA 1999); Balino v. Department of Health and Rehabilitative Services, 348 So. 2d 349 (Fla. 1st DCA 1977); Section 120.56(3).

55. The party attacking an existing rule has the burden to prove that the Rule constitutes an invalid exercise of delegated legislative authority. Cortes v. State Board of Regents, 655

So. 2d 132 (Fla. 1st DCA 1995). The standard of proof is a preponderance of the evidence. See Section 120.56(3).

56. An Administrative Law Judge may invalidate an existing Rule only if it is an invalid exercise of delegated legislative authority. See Section 120.56(1)(a) and (3)(a).

57. Section 120.52(8) defines "invalid exercise of delegated legislative authority" to mean:

> [A]ction which goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:
>
> (a) The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in this chapter;
>
> (b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1.;
>
> (c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;
>
> (d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;
>
> (e) The rule is arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational; or ;
>
> (f) The rule imposes regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less

> costly alternatives that substantially accomplish the statutory objectives.
>
> A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the same statute.

58. Petitioners' challenge to Rule 64B2-17.0025(4) is based on paragraphs (b), (c), (d), and (e) of Section 120.52(8).[4] At the hearing, Petitioners abandoned their challenge to the Rule based on paragraph (a) of Section 120.52(8).

59. Petitioners also alleged in the Amended Petition that the Rule violates "the powers set forth in the Florida Constitution delegating legislative powers solely to the Florida Legislature." The alleged constitutional deficiencies are not analyzed in this Final Order because it is well-settled that an Administrative Law Judge cannot declare an existing Rule unconstitutional. See Department of Administration v. Division

of Administrative Hearings, 326 So. 2d 187, 189 (Fla. 1st DCA 1976).

60. Petitioners challenge Rule 64B2-17.0025(4), which 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.

61. The Board's grant of rulemaking authority is found at Section 460.405, which provides:

> The Board of Chiropractic Medicine has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it.

62. The Board is charged with regulating the practice of chiropractic medicine. Section 460.403(9), the statute pursuant to which the Board promulgated Rule 64B2-17.0025(4), consists of the very definition of the practice of chiropractic medicine. The Board clearly possesses the authority to adopt rules implementing the statute defining the practice of chiropractic, provided those rules do not deviate from the statutory definitions.

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 and Cosmetic Act, and includes:

> (25) "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).

67. The first of the laws cited in Section 499.003(25) is Section 503(b) of the Federal Food, Drug, and Cosmetic Act, which is codified at 21 U.S.C. Section 353(b), and provides:

> (b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws
>
> (1) A drug intended for use by man which--
>
> (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
>
> (B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug; shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug

contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only."

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

> (5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in sections 4721, 6001, and 6151 of Title 26, or to marihuana as defined in section 4761 of Title 26.

68. 21 U.S.C. Section 353(b) fully supports the testimony of Mr. Nychis 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.

69. The second law cited in Section 499.003(25), Florida Statutes, is Section 499.007, which provides:

> A drug or device is misbranded:
>
> * * *
>
> (12) If it is a drug intended for use by humans which is a habit-forming drug or which, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs; or which is limited by an effective application under s. 505 of the federal act to use under the professional supervision of a practitioner licensed by law to prescribe such drug, unless it is dispensed only:
>
> (a) Upon the written prescription of a practitioner licensed by law to prescribe such drug;

(b) Upon an oral prescription of such practitioner, which is reduced promptly to writing and filled by the pharmacist; or

(c) By refilling any such written or oral prescription, if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

70. The third law cited in Section 499.003(25) is Section 499.0122(1)(b) and (c), which provides:

(1) As used in this section, the term:

* * *

(b) "Prescription medical oxygen" means oxygen USP that is a compressed medical gas and which can only be sold on the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.

(c) "Veterinary legend drug" means a legend drug intended solely for veterinary use. The label of the drug must bear the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

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.[5] 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.

77. This case is clearly analogous to Board of Podiatric Medicine v. Florida Medical Association, 779 So. 2d 658 (Fla. 1st DCA 2001), in which the Board of Podiatric Medicine had proposed a rule defining the terms "human leg" and "surgical treatment," as those terms were used in what is now Section 461.003(5). The cited statute defines the term "practice of podiatric medicine" but does not further define the terms "human leg" and "surgical treatment," although it employs those terms in the definition of the practice. The Administrative Law Judge's Final Order had declared the proposed rule an invalid exercise of delegated legislative authority. In reversing the final order, the court wrote:

> Several experts in various disciplines testified at the rule challenge hearing, and documentary materials were also presented.

> This evidence indicates that references to the human leg may have multiple meanings within the anatomic, medical, and podiatric fields. While a limited meaning is sometimes ascribed to the leg as referring to that portion of the lower limb between the knee and the ankle, a broader meaning is also ascribed whereby the term refers to the entire limb so as to encompass the lower leg below the knee and the upper leg above the knee. The administrative law judge accorded the statutory terminology only the more limited meaning, and reasoned that the challenged rule therefore expanded the scope of podiatric practice which was legislatively established under section 416.003(3). However, this ignores the evidence as to a broader meaning which is consistent with the definition in the proposed rule, and the statute does not suggest that a more limited meaning would pertain. In light of the broad discretion and deference which is accorded an agency in the interpretation of a statute which it administers, Public Employees Relations Commission v. Dade County Police Benevolent Association, 467 So. 2d 987 (Fla. 1985), and because such an interpretation should be upheld when it is within the range of permissible interpretations, Board of Trustees of Internal Improvement Trust Fund v. Levy, 656 So. 2d 1359 (Fla. 1st DCA 1995), the judge should not have rejected the Board's definition of the term "human leg" as used in section 461.003(3), and as provided in rule 64B18-23.001. This definition does not enlarge, modify, or contravene the statute, and is neither arbitrary nor capricious, and is fully supported by competent substantial evidence so as to be a proper exercise of the Board's delegated legislative authority.

Id. at 660.

78. In the instant case, the evidence established that the Board's definition of "legend drug" is well within the range of permissible interpretations; does not enlarge, modify, or contravene the statute; is neither arbitrary nor capricious; and is fully supported by competent substantial evidence so as to be a proper exercise of the Board's delegated legislative authority.

79. Petitioners offered a great deal of testimony, irrelevant to this case, to the effect that it is perfectly safe for chiropractic physicians to administer injectable vitamins and nutrients, that few if any patients have ever had an adverse reaction to a Vitamin B-12 injection. These arguments should be made to the Florida Legislature, which has the authority to amend the statute to expand the scope of practice for chiropractic physicians.

80. Petitioners have not met their burden of proof. They have failed to demonstrate that Rule 64B2-17.0025(4) is an invalid exercise of delegated legislative authority.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is

ORDERED that the Amended Petition is dismissed.

DONE AND ORDERED this 9th day of October, 2003, in Tallahassee, Leon County, Florida.

LAWRENCE P. STEVENSON
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 9th day of October, 2003.

ENDNOTES

1/ Since the text of the Rule was last published in 1998, Section 460.403(8)(c) has been renumbered as Section 460.403(9)(c). See Chapter 99-397, Section 105, Laws of Florida.

2/ The inclusion of paragraph (f) appears to be a holdover from the time when that paragraph included a certification procedure for proprietary drugs, as will be further discussed below.

3/ Section 465.003 sets forth the definitions relevant to the statutes regulating the practice of pharmacy. Subsection (14) provides:

> "Prescription" includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such

> practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term "prescription" also includes a pharmacist's order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

4/ The amended petition also claimed that the Rule was not supported by competent substantial evidence, as required by Section 120.52(8)(f). However, Section 120.52(8)(f) was repealed by Chapter 2003-94, Section 1, Laws of Florida, effective June 4, 2003.

5/ Section 465.003(7), Florida Statutes (1985), provided language identical to that in current Section 465.003(8), i.e.,

> "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.

See also Sections 458.331(1)(q), 459.015(1)(q), 461.013(1)(p), 462.14(1)(q), 465.016(1)(i), and 466.028(1)(q), Florida Statutes (1985), all employing the term "legend drug."

Section 499.003(15), Florida Statutes (1985), provided:

> "Legend drug" means any drug which can be dispensed only by the prescription of a licensed practitioner and which drug on its label must bear either the words:

(a) "Caution: Federal Law Prohibits Dispensing Without Prescription";

(b) "Caution: Florida Law Prohibits Dispensing Without Prescription"; or

(c) "Caution: Federal Law Restricts This Drug to be Dispensed by or on the Order of a Licensed Veterinarian."

Chapter 92-69, Section 3, Laws of Florida, deleted the quoted definition and substituted the definition of "legend drug" found in current Section 499.003(25).

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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing the original Notice of Appeal with the agency clerk of the Division of Administrative Hearings and a copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Appellate District where the party resides. The Notice of Appeal must be filed within 30 days of rendition of the order to be reviewed.