STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DISCOVERY EXPERIMENTAL AND DEVELOPMENT, INC.,	)	
Petitioner,	)	
vs.	)	Case No. 99-0005RX
DEPARTMENT OF HEALTH,	)	
Respondent.	)	
JAMES T. KIMBALL,	)	
Petitioner,	)	
vs.	)	Case No. 99-0006RX
DEPARTMENT OF HEALTH,	)	
Respondent.	)	

FINAL ORDER

These consolidated cases were heard by David M. Maloney, Administrative Law Judge of the Division of Administrative Hearings, on January 26, 1999, in Tallahassee, Florida.

APPEARANCES

For Petitioner Discovery: R. Elliott Dunn, Jr., Attorney
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STATEMENT OF THE ISSUE

Whether Rules 64F-12.006 and 64F-12.019, Florida Administrative Code, in whole or in part, constitute invalid exercises of delegated legislative authority?

PRELIMINARY STATEMENT

On January 5, 1999, Discovery Experimental and Development, Inc., (Discovery) filed with the Division of Administrative Hearings a petition denominated, "Petition for Rule Challenge." The petition requested that three rules of the Department of Health be declared invalid exercises of legislative authority. The rules listed in the petition were Rules 10D-45.0545, 64F-12.006, and 64F-12.019, Florida Administrative Code.

On the same date, January 5, James T. Kimball filed a petition by the same denomination. Just as Discovery's petition, Mr. Kimball's petition requested that several rules of the Department of Health be declared invalid. Unlike the Discovery petition, however, Mr. Kimball's petition did not seek a declaration with regard to Rule 64F-12.006. The petition was limited to Rules 10D-45.0545 and 64F-12.019.

On January 6, 1999, a letter advising that two petitions had been filed was sent by the Division of Administrative Hearings to the Bureau of Administrative Code in the Department of State. On the same date, the Division assigned the two cases (DOAH Case Nos. 99-0005RX and 99-0006RX) to David M. Maloney, Administrative Law Judge.

Orders establishing prehearing procedures and notices of hearing setting separately the final hearings in the two cases were issued January 7, 1999. Following orders to show cause why the cases should not be consolidated, the cases were consolidated without objection. The cases proceeded to hearing on January 26, 1997.

In the interim, the Department filed in each case motions to dismiss. The motions were denied. Together, the parties filed a joint prehearing stipulation four days before final hearing. In the stipulation, the parties "agreed that, since Rule 10D-45.0545 is no longer in effect, the challenges to that rule are moot."[1] Joint Exhibit No. 1.

At final hearing, no witnesses were called. The joint exhibit was offered and admitted into evidence as well as three exhibits of Discovery's, Discovery Exhibits No. 1 - 3, and four of the Department's, Department's Exhibits No. 1 - 4. An exhibit offered by Petitioner Kimball was marked as Kimball Exhibit No. 1. The Department objected to the exhibit's

admission into evidence. Before a ruling was entered on the objection, Mr. Kimball withdrew the offer.

The transcript of the proceeding was filed on January 29, 1999. Petitioners Discovery and Kimball filed their proposed final orders on February 9, 1999; the Department filed its proposed final order on February 10, 1999. All proposed final orders were timely filed.

FINDINGS OF FACT

a. The Challenged Rules

1. Following the parties' stipulation that the challenges by Petitioners to Rule 10D-45.0545 are moot, two rules remain in this proceeding subject to challenge: Rules 64F-12.006 and 64F-12.019, Florida Administrative Code. The parties further stipulated that "[P]etitioners do not contest the rulemaking procedures or requirements, used or followed by the Department in the adoption of the rules which are the subject of these rule challenges." Joint Exhibit No. 1, (c)(5), page 3.

i. Rule 64F-12.006; the Labeling Requirements Rule

2. Formerly numbered Rule 10D-45.39 and later 10D-45.039, Rule 64F-12.006, (the "Labeling Requirements Rule") was amended by a substantial rewording on June 11, 1996. The amendment took effect July 1, 1996 (when it was numbered 10D-45.039). It has not been amended since although it has been renumbered as Rule

64F-12.006. The part of Rule 64F-12.006, Florida Administrative Code, challenged by Discovery, provides:

> (1) The department hereby adopts and incorporates by reference the labeling requirements for prescription drugs and over-the-counter drugs as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Parts 1-1299.
>
> * * *
>
> Specific Authority 499.05 FS.
> Law Implemented 499.007,499.0122,499.013 FS
> History--New 1-1-77, Amended 12-12-82,
>
> 7-8-84, Formerly 10D-45.39, Amended 11-26-86, 7-1-96, Formerly 10D-45.039.

ii. Rule 64F-12.019; the "Inspection Rule"

3. Formerly numbered Rule 10D-45.545 and later as Rule 10D-45.0545, Rule 64F-12.019, Florida Administrative Code, (the "Inspection Rule") was last amended when still numbered 10D-45.0545. The amendment was by a substantial rewording on June 11, 1996; it became effective twenty days later, July 1, 1996. It has not been amended since, but it has been renumbered with its present number. It provides:

> **Inspections, Investigations, Monitoring.**
> (1) Inspections and investigations are conducted to determine compliance with the provisions of Chapter 499, Chapter 893, F.S., and this rule chapter and may include:
>
> (a) entry at reasonable times or during normal business hours to any property, building, establishment, or vehicle;

(b) inspection of furniture and equipment, finished or unfinished materials, containers, labels, labeling, products, supplies, spaces, records, files, papers, processes, controls, and facilities;

(c) review and copying of all records including receiving documents, shipping documents, purchase orders, purchase requisitions, invoices, paid receipts, contracts, checks, deposits, and credits or debits in any form whatsoever;

(d) surveillance of procedures;

(e) collection of facts and information;

(f) questioning of persons who may have information relating to the inspection or investigation and taking sworn statements from these persons;

(g) sampling of products, materials, documents, literature, labels, or other evidence;

(h) photographing materials, physical plant, articles or products;

(i) observations and identification of:

1. drugs, devices or cosmetics consisting wholly or in part of filthy, putrid or decomposed substances;

2. undesirable conditions or practices bearing on filth, contamination, or decomposition which may result in the drug, device or cosmetic becoming adulterated or misbranded;

3. unsanitary conditions or practices which may render a drug, device or cosmetic injurious to health;

4. faulty manufacturing, processing, packaging, or holding of drugs, devices or cosmetics as related to current good manufacturing practices including inadequate or inaccurate recordkeeping;

5. deviations from recommended processing, storage or temperature requirements;

6. deviations of label and labeling requirements;

7. any other action to determine compliance with Chapters 499 and 893, F.S., and this rule chapter.

(j) taking of evidence; and

(k) removing potentially misbranded or adulterated drugs, devices, or cosmetics from commerce or public access.

(2) Inspections and investigations may be announced or unannounced at the discretion of the department.

(3) The department shall take reasonable steps to assure that a sampled product is not reintroduced into commerce if it is or has become adulterated or misbranded.

Specific Authority 499.05 FS. Law Implemented Ch. 499, Parts I, II, and III FS.
History--New 7-8-84, Formerly 10D-45.545, Amended 11-26-86, 7-1-96, Formerly 10D-45.0545.

b. The Parties

4. Discovery (Petitioner in Case No. 99-0005RX) is a drug manufacturer. Its business establishment is located in Pasco

County at 29949 State Road 54 West, Wesley Chapel, Florida. As a drug manufacturer, Discovery is regulated by Chapter 499, Florida Statutes.

5. James T. Kimball (Petitioner in Case NO. 99-0006RX) is a private citizen of the State of Florida and the President of Discovery. He resides at 6036 Country Club Road, Wesley Chapel, Florida 33544.

6. The Department of Health is the agency of the State of Florida responsible, inter alia, to "administer and enforce [Part I of Chapter 499]," Section 499.004, Florida Statutes, the "Florida Drug and Cosmetic Act." These duties are prescribed for the Department in order "to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs . . ." Id. Pursuant to power conferred on the Department's predecessor, the Department of Health and Rehabilitative Services (power to which the Department succeeded), the challenged rules were adopted originally as part of Rule Chapter 10D-45.

c. Warrantless Searches

7. On May 12, 1993, agents of the Department of Health conducted inspections without warrants at both Discovery's business establishment and the residence of Mr. Kimball.

8. On July 13, 1994, agents of the Department of Health conducted an inspection without a warrant at Discovery's business establishment.

9. A number of items were seized by the agents during the second search of Discovery's business establishment.

d. Filings with the Department of State

10. On June 11, 1996, the Department of Health and Rehabilitative Services filed with the Department of State a document denominated, "CERTIFICATION OF MATERIALS INCORPORATED BY REFERENCE IN RULES FILED WITH THE DEPARTMENT OF STATE." Department Exhibit No. 3. Included within an attachment of "a true and complete copy of materials incorporated by reference into Rule Chapter 10D-45, Florida Administrative Code . . ." id., were "21 U.S.C. ss. 301 et. seq. and federal regulations promulgated thereunder in Title 21 Code of Federal Regulations (CFR) referenced in Rule[] . . . 10D-45.039(1) . . ." Id.

11. The filing was confirmed on January 21, 1999, when the Secretary of State certified "that the Food and Drug and European Union Pharmaceutical Libraries (96-02) compact disc, containing 21 U.S.C. ss. 301 et. seq. and federal regulations promulgated thereunder in Title 21 Code of Federal Regulations, was incorporated by reference in rule Chapter 10D-45, Florida Administrative Code, rules and regulations of the Department of Health and Rehabilitative Services, which was filed on June 11,

1996, as shown by the records of this office." Department Exhibit No. 4.

CONCLUSIONS OF LAW

e. Jurisdiction

12. The Division of Administrative Hearings has jurisdiction over the parties and the subject matter of these consolidated cases (challenges to existing rules). Section 120.56, Florida Statutes.

f. Standing

13. The parties stipulated to the standing of Discovery.

14. As to Mr. Kimball, the Department contends that he has failed to prove standing and therefore, that his petition should be dismissed.

15. Mr. Kimball, in turn, relies on both the inspection of his residence in 1993 and his status as corporate president of Discovery, a drug manufacturer, to support standing.

16. The record is not favored with a copy of the rule (the "prior inspection rule") under which the Department conducted inspections authorized by Chapter 499 at the time of the inspection of Mr. Kimball's residence in 1993. No proof was offered by Mr. Kimball of the nexus between either the prior inspection rule or the existing rule and the inspection of his residence in 1993. The department's inspection more than five years ago of his residence, moreover, when another, however

similar, rule was in existence does not demonstrate that he is affected today, or in the future, by the challenged rule.

17. Furthermore, Mr. Kimball neither alleged nor proved that he is a drug manufacturer or that he comes within the ambit of interests regulated either by the Florida Drug and Cosmetic Act, Part I of Chapter 499, Florida Statutes, or the inspection rule adopted by the Department under the Act.

18. Any reliance on his status as a corporate officer to establish standing is subsumed under the standing of the corporation to seek administrative relief in the form of a declaration of the invalidity of the challenged rules.

19. In short, Mr. Kimball did not provide proof at hearing to establish that he is substantially affected by the rules he challenges. The petition in Case No. 99-0006RX should be dismissed.

h. The Labeling Requirements Rule

20. The issues raised by Discovery with regard to the Labeling Requirements Rule are set out in the Joint Prehearing Stipulation:

> Whether the documents filed with the Department of State, in connection with Rule 64F-12.006, are sufficient to comply with [s.] 120.54(1)(i) and (6)(e), Fla. Stat.

Joint Exhibit No. 1, p. 4.

21. The portions of Section 120.54, Florida Statues, the application of which are at issue, state:

> (1) GENERAL PROVISIONS APPLICABLE TO ALL RULES OTHER THAN EMERGENCY RULES.--
>
> * * *
>
> (i) A rule may incorporate material by reference but only as the material exists on the date the rule is adopted. For purposes of the rule, changes in the material are not effective unless the rule is amended to incorporate the changes. No rule may be amended by reference only. Amendments must set out the amended rule in full in the same manner as required by the State Constitution for laws.
>
> * * *
>
> (6) ADOPTION OF FEDERAL STANDARDS.--
>
> * * *
>
> (e) Whenever all or part of any rule proposed for adoption by the agency is substantively identical to a regulation adopted pursuant to federal law, such rule shall be written in a manner so that the rule specifically references the regulation whenever possible.

22. Discovery's argument with regard to application of Section 120.54(1)(i), Florida Statutes, is that the Labeling Requirements Rule does not by its term specify the date the rule was adopted or whether the material incorporated therein by reference existed on the date the rule was adopted. Further, Discovery argues, the rule does not by its terms identify with

specificity the Federal regulations that are intended to be incorporated by reference therein.

23. With regard to the latter argument, the rule quite clearly identifies the material to be incorporated by reference: "the labeling requirements for prescription drugs and over-the-counter drugs as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Part 1-1299." It is true that the rule does not cull out from the portions of the federal act and the code of federal regulations identified the specific parts that relate to labeling requirements. Without doubt, there are provisions of the portions of the federal act and federal regulatory code cited in the rule that do not relate to labeling. But there is no requirement in Section 120.54(6)(e) for the specificity Discovery demands. The statute requires only that the rule be written in a manner so that it "specifically references the [adopted federal] regulation whenever possible." (emphasis supplied) The reference in the rule to "22 U.S.C. ss. 301 et. seq. and in Title 21 Code of Federal Regulations Part 1-1299" is adequate for any reader of the rule in need of finding the labeling requirements in federal regulatory law. These references, moreover, meet the requirement of the statute that the federal regulation be specifically referenced "whenever possible." In short, while the references to federal

regulations in the rule could be more specific, they are specific enough.

24. Subsection (6) of Section 120.54, Florida Statutes, applies only to rules adopted "in pursuance of state implementation, operation, or enforcement of federal programs." Therefore, the Department argues, paragraph (e) of Subsection (6), has no applicability here since, on its face, it implements provisions of state law found in Chapter 499 of the Florida Statutes, not any federal program. Indeed, Discovery did not prove that the rule was adopted "in the pursuance of state implementation, operation, or enforcement of federal programs." As the Department asserts, the rule, on its face, appears to implement provisions of state law, namely, the Florida Drug and Cosmetic Act. In the implementation of that Act, the Department has adopted certain federal standards as the Department's standards. But there has been no showing that the Department is attempting to enforce those standards as part of a federal program.

25. As for the first argument made by Discovery, the history portion of the rule shows that it was amended July 1, 1996. This date is the effective date of the amendments filed on June 11, 1996. On the latter date, the Secretary of State received a certification of materials incorporated by reference in rules filed with the department of state. Among the material

so incorporated were "21 U.S.C. ss. 301 et. seq. and federal regulations promulgated thereunder in Title 21 Code of Federal Regulations (CFR) referenced in Rule[] . . . 10D-45.039(1) and (2) [the predecessor to Rule 64F-12.006]." The materials filed with the Department of State have not been shown by Discovery to be anything other than material as it existed on the date the rule was adopted.

26. There has been no proof offered by Discovery that the rule violates in any way the requirements of Section 120.54(1)(i), Florida Statutes.

27. In sum, the labeling requirements rule has not been shown to violate either paragraphs (1)(i) or (6)(e) of Section 120.54, Florida Statutes.

i. The Inspection Rule

28. Rule 64F-12.019, Florida Administrative Code, provides for inspections and investigations by the department to determine compliance with both Chapter 499, Florida Statutes, (and the rules which implement Chapter 499) and Chapter 893, Florida Statutes, the "Florida Comprehensive Drug Abuse Prevention and Control Act." The rule implements all provisions of Chapter 499, Florida Statutes.

29. Inspections conducted under the rule may be "announced or unannounced at the discretion of the department." Rule 64F-12.019(2), Florida Administrative Code. Significantly, the rule

does not require a warrant or probable cause that meets Fourth Amendment "probable cause" standards for an inspection to be conducted. In fact, the rule does not contain any language that hints at the implication of Fourth Amendment rights.

30. Discussion of the Fourth Amendment's relationship to administrative rules authorizing warrantless regulatory inspections or searches occurred recently in appellate review of a final order declaring such a rule of the Division of Pari-Mutuel Wagering to be an invalid exercise of delegated legislative authority. In Department of Professional Regulation v. Calder Race Course, Inc., et al., 23 Fla. L. Weekly D1795, 1st DCA, Op. filed July 29, 1998, the First District Court of Appeal observed that the United State Supreme Court,

> has recognized exceptions to the general rule that warrantless inspections are unconstitutional as violative of the Fourth Amendment in cases such as Colonnade Catering Corp. v. United States [citations ommitted] (liquor dealer); United States v. Biswell [citations ommitted] (gun dealer), and Donovan v. Dewey [citations ommitted] (stone quarry). The reason these exceptions have been allowed involves the nature of the business regulated. As the Court pointed out in Marshall v. Barlow's, Inc., [citations ommitted]:
>
> Certain industries have such a history of government oversight that no reasonable expectation of privacy could exist for a proprietor over the stock of such an enterprise. Liquor (Colonnade) and firearms (Biswell) are industries of this type; when an entrepreneur embarks upon such a

> business, he has voluntarily chosen to subject himself to a full arsenal of governmental regulation.
>
> Industries such as these fall within the "certain carefully defined classes of case," referenced in Camara [387 U.S.] at 528, 87 S.Ct. at 1731. The element that distinguishes these enterprises from ordinary business is along tradition of close government supervision, of which any person who chooses to enter such a business must already be aware.

Calder Race Course, above, at D1796. The pharmaceutical industry is such an industry. It has a long history of pervasive supervision and inspection. United States v. Jamieson-McKames Pharmaceuticals, Inc., 651 F. 2d 532, 537-38 (8th Cir. 1981); cert. den., 455 U.S. 1016 (1982).

31. The rule authorizing warrantless inspection in the pari-mutuel industry had withstood a rule challenge prior to the Calder decision because the rule was determined to be reasonably related to its enabling legislation and found to be not arbitrary or capricious. But the rule was declared invalid in the wake of the 1996 amendments to the Administrative Procedure Act because it was not supported by "a specific law to be implemented." Section 120.52(8), Florida Statutes. This is not the ground advanced by Discovery in making its case against the Inspection Rule.

32. Instead, Discovery argues, in essence, that the rule is "vague, fails to establish adequate standards for agency

decisions, or vests unbridled discretion in the agency," one of the definitions for "invalid exercise of delegated legislative authority," found in Section 120.52(8), Florida Statutes.

33. In making its argument, Discovery draws comparison between the language of the current inspection rule and its predecessor Rule 10D-45.0545, Florida Administrative Code. The predecessor rule had been found to place reasonable limits upon the discretion of the Department's inspectors in Arthritis Medical Center v. State of Florida, Department of Health and Rehabilitative Services, an unreported opinion, Case No. 87-6078-CIV (US District Court, So. Dist. Fla., August 22, 1988), rev. den. 473 F.2d 209 (11th Cir. 1989).

34. Discovery points out that the language of 10D-45.0545 in effect at the time of Arthritis Medical Center was definitive so as to give guidance to the meaning of certain terms used in the Rule. By way of example, Discovery points to language in the rule as it existed at the time of the federal district court decision which modifies the word "records" so as to define with precision the records subject to inspection: "'all records and other information required by Chapter 499 and the rules promulgated thereunder available to the inspecting officer." (Emphasis supplied.) Discovery's Proposed Final Order, p. 8.

35. The precision with which the term "records" was described in the former rule underscores, for Discovery, the

vagueness of a number of terms used in the current Inspection Rule. These terms are "records," "property," "building," "space" and "document."

36. As Discovery points out, none of the terms used in the Inspection Rule and listed in paragraph 35, above, are defined in the Inspection Rule, itself, in provisions of Chapter 499, Florida Statutes, or in any of the rules promulgated for the purpose of implementing Chapter 499.

37. Discovery offered into evidence definitions of these same trms from Webster's New World Dictionary, Third College Edition. Among the definitions for the noun, "record," are the following:

> 2/a) anything that is written down and preserved as evidence; account of events; b) anything that serves as evidence of an event, etc.; c) an official written report of public proceedings, as in a legislature or court of law, preserved for future reference; 3/ anything that written evidence is put on or in, as a register or monument; 4/a) the known or recorded facts about anyone or anything, as about one's career;

Discovery Exhibit No. 2., p. 1122. As Discovery points out, this definition, "anything that is written down and preserved as evidence; account of events; . . . anything that serves as evidence of an event, etc." (emphasis supplied) is sweepingly broad. Commonly understood definitions of the other terms of

which Discovery complains are likewise vast in scope and indiscriminately broad:

> **building** . . . *n.* **1.** anything that is built with walls and a roof, as in a house, factory, etc.; structure.

id., at 183 (emphasis supplied);

> **space . . .** *n. . . .* **2** *a)* the distance, expanse, or area between, over, within, etc. things *b)* area or room sufficient for or allotted to something *[a parking space] . . .*

id., at 1284.

38. The Department counters Discovery's argument of vagueness and overbreadth with the assertion that in the argument, "the challenged terms are taken completely out of context." Department's Proposed Final Order, p. 11.

39. The Department points to the language of section (1) of the Inspection Rule which declares the subject of what follows to concern inspections and investigations which the Department conducts for ". . . determining compliance with Chapter 499 and 893, Florida Statutes." Since those statutes relate only to the regulation of drug, devices, cosmetics, ether and controlled substances, the Department concludes, "it is patently absurd to argue that the challenged terms exceed what these statutes require to document compliance." Id.

40. As the Department argues, the terms "records" and "documents" necessarily, of course, include:

> that which is required under good manufacturing practice regulations. Section 499.013, F.S. requires such compliance, and Rule 64F-12.001(2)(r), F.A.C. defines "State Current Good Manufacturing Practises" to incorporate federal regulations on this subject. The records required of a prescription drug wholesale distributor are set forth in section 499.0121(6), F.S., and Rule 64F-12.012, F.A.C., as to sales by the manufacturer of its prescription drugs.

Id.

41. The terms "buildings" and "property" and "spaces" used in the rule do not exceed delegated legislative authority, the Department's argument goes, because Section 499.003, Florida Statutes, and Section 499.051, Florida Statutes, only reference the inspection of an "establishment," so that these terms as used in the rule are limited by the statute to buildings and property that constitute an establishment and spaces within an establishment.

42. Indeed, Section 499.003(12) defines "establishment," as "a place of business at one general physical location." Section 499.005 declares among those acts it is unlawful to perform:

> The refusal:
>
> (a) To allow the department to enter or inspect an establishment in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, or held;

> (b) To allow inspection of any record of that establishment;

Section 499.005(6), Florida Statutes (emphasis supplied) And Section 499.051, Florida Statues, containing the provisions which authorize warrantless inspections within the drug manufacturing industry provides, in pertinent part:

> (1) The agents of the Department of Health . . . and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to [Chapter 499] during business hours for the purpose of enforcing . . . chapter [499], 465, 501 and 893, and the rules of the department that protect public health, safety and welfare.
>
> (2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with the [law].

(emphasis supplied)

43. The Department's argument overlooks that not only does the rule not define the terms Discovery sees as objectionable but it lists some of those terms in a group of terms that includes "establishment" as if "property" and "building" were physical areas that go beyond the term "establishment." Accentuating that point is the rule's use of the term "any" as a modifier:

> (1) Inspections and investigations . . . may include:

> (a) entry at reasonable time or during normal business hours to any property, building, establishment, or vehicle;

Rule 64F-12.019, Florida Administrative Code.

44. Were the Department's argument correct, so long as a rule cited to the statutes it implements (which all rules must do), it would never be invalid on one of the very bases for invalidity found in the definition of "invalid exercise of delegated legislative authority," in Section 120.52(8), Florida Statutes:

> [t]he rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;

Section 120.52(8)(c), Florida Statutes.

45. Comparison of the rule and the statute is decisive. The rule does not circumscribe the terms at all. In contrast, the statute makes clear that inspections are limited to "establishments" as defined in Chapter 499. The rule would allow inspection of homes, that is, the rule authorizes warrantless inspections of places not historically subject to pervasive governmental oversight. In other words, the rule authorizes warrantless searches of places where reasonable expectations of privacy do exist, places guaranteed protection from unreasonable searches by the Fourth Amendment. There is no

reading of Chapter 499, Florida Statutes, by which one could determine that this is what the legislature intended.

46. Discovery's challenge to the Inspection Rule fails in one way. The terms complained of are not vague. Quite to the contrary, Discovery has offered into evidence common dictionary definitions of the terms that are strikingly clear.

47. But Discovery has otherwise soundly based its challenge on one of the bases for determining a rule to be "invalid exercise," paragraph (d) of Section 120.52(8), Florida Statutes. The problem with the terms is that within the rule they are not confined in the way the statute demands. The difficulty with the terms is shown under the example of contrast drawn by Discovery between "records required by Chapter 499 and the rules promulgated thereunder," and simply "records" with no delineation as to what "records" under the current rule are meant. What must be meant, then, under the plain wording of the rule is "all" records, whether they relate to or are required by Chapter 499 and its rules or not. The same is true for the other terms, "any building" and "any property." Thus, in acting under the rule, agents of the Department do not have "adequate standards for agency decisions [that is, the decision of where and what to subject to an unannounced warrantless search]." Under the plain wording of the Inspection Rule, they are free to search any building, any property and all records, no matter

whether or not inside an establishment permitted under Chapter 499 or inside a place of business in one general location as authorized by Section 499.051(2) and as defined in Section 499.003(12), Florida Statutes. At the same time, the breadth to which these terms are plainly used in the rule, in contravention of the statute implemented, and therefore, the rule, itself, "vests unbridled discretion in the agency." Section 120.52(8)(d), Florida Statutes.

48. At bottom, the statute not only circumscribes when such searches may take place but also the "where and of what" the searches may take place pursuant to Chapter 499. The rule by using the undefined and unrestrained terms of "property," "building," "spaces," and "records" does not.

49. The Inspection Rule is an invalid exercise of delegated legislative authority.

ORDER

Based on the foregoing, it is, hereby, ORDERED that:

1. Rule 64F-12.006, Florida Administrative Code, is not determined to be invalid.

2. Rule 64F-12.019, Florida Administrative Code, is determined to be an invalid exercise of legislative authority because it fails to establish adequate standards for decisions with regard to inspections by the Department and vests unbridled discretion in the Department.

3. Jurisdiction is reserved to determine any appropriate award of reasonable costs and attorney's fees pursuant to Section 120.595(3), Florida Statutes.

DONE AND ORDERED this 22nd day of February, 1999, in Tallahassee, Leon County, Florida.

DAVID M. MALONEY
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 22nd day of February, 1999.

ENDNOTE

[1] The challenge is not merely moot. That the rule is no longer in existence deprives the division of jurisdiction under Section 120.56, Florida Statutes:

> 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.

COPIES FURNISHED:

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Tallahassee, Florida 32399-0703

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 one copy of a notice of appeal with the Clerk of the Division of Administrative Hearings and a second 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.