IN THE DISTRICT COURT OF APPEAL
FIRST DISTRICT, STATE OF FLORIDA

ABBOTT LABORATORIES,

Appellant,

v.

MYLAN PHARMACEUTICALS, INC.,

Appellee.

_____/

NOT FINAL UNTIL TIME EXPIRES TO FILE MOTION FOR REHEARING AND DISPOSITION THEREOF IF FILED.

CASE NO.: 1D08-0602

Opinion filed June 22, 2009.

An appeal from an order of the Division of Administrative Hearings.

Michael J. Glazer and John R. Beranek of Ausley & McMullen, Tallahassee, for Appellant.

William E. Williams and Amy W. Schrader of GrayRobinson, P.A., Tallahassee, for Appellee.

VAN NORTWICK, J.

Abbott Laboratories (Abbott), the manufacturer of a levothyroxine sodium (LS) drug product, Synthroid®, appeals a summary final order of an administrative law judge (ALJ) in a rule challenge proceeding brought by Mylan Pharmaceuticals, Inc. (Mylan), appellee, the manufacturer of a competing generic drug. In the summary final order, the ALJ ruled that Florida Administrative Code Rule 64B16-27.500(6), which

was part of the negative drug formulary (NDF) rule established pursuant to section 465.025(6), Florida Statutes (2007), and which listed LS on the NDF, was invalid on the grounds that it constituted an invalid exercise of legislative delegated authority because it conflicted with the provisions of section 465.0251(1), Florida Statutes (2007). Section 465.0251(1) removes a generic drug from the NDF if the generic drug is "A" rated as therapeutically equivalent to a reference listed drug as referred to in the "Orange Book"[1] published by the United States Federal Drug Administration (FDA). The ALJ's order, in effect, removes LS from the NDF and permits Florida pharmacists to substitute Mylan's generic LS product for a prescription for Synthroid® or any other "A" rated LS drug product, except as provided in section 465.025(2), Florida Statutes (2007). Because the ALJ erred in interpreting section 465.0251(1) to apply to editions of the Orange Book subsequent to the date of the 2001 enactment of the statute, we reverse and remand. Finally, we reject the contention of Mylan that Abbott lacks standing to bring this appeal and that the mootness doctrine should apply to this appeal.

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[1]Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations (2007), commonly known as the "Orange Book," see 21 U.S.C. § 355(j)(7)(A)(i) (2006), identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug and Cosmetic Act. It also includes therapeutic equivalence (TE) evaluations for approved multisource prescription drug products. The Orange Book is updated annually and is supplemented with monthly cumulative updates. It can be found online at FDA, Electronic Orange Book, http://www.fda.gov/cder/ob/ (last visited May 4, 2009) and that version is updated daily.

Regulatory Background

As is undisputed from this record, approval by the FDA is required before a prescription drug product may be marketed, distributed, or sold in the United States. 21 U.S.C. § 355(a) (2006). When a product contains a new active ingredient or otherwise differs significantly from previously approved products, the sponsor must provide the FDA with data demonstrating the product's safety and effectiveness for the intended use. See 21 U.S.C. § 355(b) (2006). When a product is a copy of a previously approved product - - what is commonly called a "generic" version of the original drug - - proof of safety and effectiveness is not required. Instead, the FDA requires a showing that, with regard to certain characteristics, the proposed generic product is essentially the same as the approved product it purports to copy, which is referred to as the "listed drug." See 21 U.S.C. § 355(j) (2006) (because of the language in section 465.0251(1), we will refer to a "reference listed drug"). The FDA's previous finding that the reference listed drug is safe and effective is then imputed to the generic product.

Levothyroxine sodium (LS) is a leading treatment for hypothyroidism, which is the failure of the thyroid gland to produce sufficient thyroid hormone. In 1979, the Florida Legislature directed the Board of Medicine and the Board of Pharmacy to

establish by rule a list of those drugs that "demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medicine." § 465.025(6), Fla. Stat. (1979). The rule establishing the NDF is Florida Administrative Code Rule 64B16-27.500. LS has been listed on the NDF since 1984. The NDF rule, prior to the action taken by the ALJ, provided, in pertinent part, as follows:

> The negative drug formulary is composed of medicinal drugs which have been specifically determined by the Board of Pharmacy and the Board of Medicine to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, could produce adverse clinical effects, or could otherwise pose a threat to the health and safety of patients receiving such prescription medications. . . . The generic name of a drug shall be applicable to and include all brand-name equivalents of such drug for which a prescriber may write a prescription. Substitution by a dispensing pharmacist on a prescription written for any brand name equivalent of a generic named drug product listed on the negative formulary or for a drug within the class of certain dosage forms as listed, is strictly prohibited. In cases where the prescription is written for a drug listed on the negative drug formulary but a brand name equivalent is not specified by the prescriber, the drug dispensed must be one obtained from a manufacturer or distributor holding an approved new drug application or abbreviated new drug application issued by the Food and Drug Administration, United States Department of Health and Welfare permitting that manufacturer or distributor to market those medicinal drugs or when the former is non-applicable, those manufacturers or distributors supplying such medicinal drugs must show compliance with other applicable Federal

Food and Drug Administration marketing requirements. The following are included on the negative drug formulary:

* * *

(6) Levothyroxine Sodium.

* * *

Fla. Admin. Code R. 64B16-27.500(6).

"Until the mid-1970s, nearly all states required pharmacists to dispense the exact drug specified by the prescribing physician, even if equivalent generic products were available." Jessie Cheng, An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry, 108 Colum. L. Rev. 1471, 1479 (2008). Currently, with the advent of strict federal drug laws, most states more freely allow substitution in order to contain the high cost of drugs. Id. Thus, in Florida, when a patient receives a prescription for a brand name drug and takes it to a Florida pharmacy, the pharmacist is required by law to substitute a less expensive generic drug unless: (1) the patient requests otherwise; (2) the doctor directs otherwise; or (3) the drug is listed on Florida's NDF. § 465.025(2), Fla. Stat. Because LS was listed on the NDF, prior to the invalidation of rule 64B16-27.500(6), when a doctor prescribed a specific LS drug product, the patient would only receive that product, whether it was a brand name or a generic. § 465.025(6)(b), Fla. Stat. As a result of the order under review, except as

provided in section 465.025(2), Florida pharmacists may substitute Mylan's generic LS product for a prescription for Synthroid® or any of the other brand name or generic LS products.

The ALJ's decision invalidating rule 64B-27.500(6) rests on the interpretation and application of section 465.0251, enacted in 2001, and section 465.025 first enacted in 1979. Section 465.025, Florida Statutes (2007), entitled "Substitution of Drugs" provides, in pertinent part, as follows:

> (1) As used in this section:
>
> (a) "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler, or distributor.
>
> (b) "Generically equivalent drug product" means a drug product with the same active ingredient, finished dosage form, and strength.
>
> (c) "Prescriber" means any practitioner licensed to prescribe medicinal drugs.
>
> (2) A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product that is:
>
> * * *
>
> (b) Listed in the formulary of generic and brand name drug products as provided in subsection (5) for the brand name drug prescribed, unless the prescriber writes the words

"MEDICALLY NECESSARY," in her or his own handwriting, on the face of a written prescription; unless, in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary; or unless, in the case of a prescription that is electronically generated and transmitted, the prescriber makes an overt act when transmitting the prescription to indicate that the brand name drug prescribed is medically necessary. When done in conjunction with the electronic transmission of the prescription, the prescriber's overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.

(3)(a) Any pharmacist who substitutes any drug as provided in subsection (2) shall notify the person presenting the prescription of such substitution, together with the existence and amount of the retail price difference between the brand name drug and the drug substituted for it, and shall inform the person presenting the prescription that such person may refuse the substitution as provided in subsection (2).

* * *

(5) Each community pharmacy shall establish a formulary of generic and brand name drug products which, if selected as the drug product of choice, would not pose a threat to the health and safety of patients receiving prescription medication. In compiling the list of generic and brand name drug products for inclusion in the formulary, the pharmacist shall rely on drug product research, testing, information, and formularies compiled by other pharmacies, by states, by the United States Department of Health, Education, and Welfare, by the United States Department of Health and Human Services, or by any other source which the pharmacist deems reliable. Each community pharmacy shall make such formulary available to the public, the Board

> of Pharmacy, or any physician requesting same. This formulary shall be revised following each addition, deletion, or modification of said formulary.
>
> (6) The Board of Pharmacy and the Board of Medicine shall establish by rule a formulary of generic drug type and brand name drug products which are determined by the boards to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication.
>
> (a) The formulary may be added to or deleted from as the Board of Pharmacy and the Board of Medicine deem appropriate. Any person who requests any inclusion, addition, or deletion of a generic drug type or brand name drug product to the formulary shall have the burden of proof to show cause why such inclusion, addition, or deletion should be made.
>
> (b) Upon adoption of the formulary required by this subsection, and upon each addition, deletion, or modification to the formulary, the Board of Pharmacy shall mail a copy to each manager of the prescription department of each community pharmacy licensed by the state, each nonresident pharmacy registered in the state, and each board regulating practitioners licensed by the laws of the state to prescribe drugs shall incorporate such formulary into its rules. No pharmacist shall substitute a generically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type drug product is included in the said formulary.

Reading section 465.25(6) in its entirety, a party seeking to remove a drug product from the NDF has the burden of proof to show that the removal would not "pose a

threat to the health and safety of patients receiving prescription medication."

Section 465.0251, Florida Statutes (2007), permits removal from the NDF under specific circumstances and states:

> **465.0251 Generic drugs; removal from formulary under specified circumstances. -**
>
> (1) The Board of Pharmacy and the Board of Medicine shall remove any generic named drug product from the formulary established by s. 465.025(6), if every commercially marketed equivalent of that drug product is "A" rated as therapeutically equivalent to a reference listed drug or is a reference listed drug as referred to in "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) published by the United States Food and Drug Administration.
>
> (2) Nothing in this act shall alter or amend s. 465.025 as to existing law providing for the authority of physicians to prohibit generic drug substitution by writing "medically necessary" on the prescription.

Although subsection (1) of section 465.0251 requires removal of a drug product from the NDF without an express finding that the removal will not pose a threat to the health and safety to patients as required by section 465.025, subsection (2) emphasizes that section 465.0251 does not "alter or amend s. 465.025."

Section 120.56 Proceeding

This proceeding began on August 17, 2007, when Mylan filed a petition seeking to have rule 64B16-27.500(6) declared invalid. The respondents were the Board of

Medicine and Board of Pharmacy since each agency must authorize changes to the rule. Abbott was allowed to intervene. Subsection 120.56(1)(a), Florida Statutes (2007), provides that "[a]ny person substantially affected by a 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." Subsection 120.52(8), Florida Statutes (2007), defines "invalid exercise of delegated legislative authority," in pertinent part, as follows:

> "Invalid exercise of delegated legislative authority" means action 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:
>
> * * *
>
> (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. . . .

Mylan, as the petitioner, had the "burden of proving by a preponderance of the evidence that the existing rule is an invalid exercise of delegated legislative authority as to the objections raised." § 120.56(3)(a), Fla. Stat. (2007).

Mylan contended that the inclusion of LS on the NDF in rule 64B16-27.500(6) contravenes subsection 465.0251(1), which requires that a drug be removed from the NDF "if every commercially marketed equivalent of that drug product is 'A' rated as

therapeutically equivalent to a reference listed drug or is a reference listed drug as referred to in" the Orange Book. In response, Abbott argued that it would be unconstitutional to utilize the Orange Book as it exists in 2007 and that the 2001 Orange Book, in effect when section 465.0251 was enacted, must be used to determine the validity of rule 64B16-27.500(6).

The distinction made by Abbott is significant because the record reflects that the 2001 Orange Book did not include any "A" rated LS products and did not list most of the LS drug products that were being commercially marketed at the time. Only two reference listed LS drugs were included in the 2001 Orange Book, and they were given the therapeutic equivalence code of BX, which communicated the determination of the FDA that the products had not been shown to be therapeutically equivalent to each other. On the other hand, the 2007 Orange Book lists five reference listed LS drug products: Levoxyl®, Levo-T®, Levothroid®, Unithroid®, and Synthroid®. The 2007 Orange Book also lists two generic drugs manufactured by Mylan and Genpharm International, Inc. The 2007 Orange Book also states that all of the listed LS drugs are "A" rated by the FDA, but the FDA has determined that not all of these LS products are therapeutically equivalent to each other.

As previously noted, for a generic product to be approved by the FDA, it must be therapeutically equivalent to a reference listed drug. 21 U.S.C. § 355(j). To be

"therapeutically equivalent," the generic drug must be both pharmaceutically equivalent and bioequivalent. Rebecca S. Yoshitani, J.D., Ellen S. Cooper, J.D., LL.M, Pharmaceutical Reformulation: The Growth of Life Cycle Management, 7 Hous. J. Health L. & Pol'y 379, 384 (2007). Products are pharmaceutically equivalent if they contain the same active ingredient and the same strength, and are in the same dosage form (tablet, capsule, solution, etc.). Id., citing Drugs @ FDA Glossary of Terms, http://www.fda.gov/cder/drugsatfda/glossary.htm. Products are bioequivalent if they release the active ingredient into the bloodstream at essentially the same rate and essentially to the same extent. See 21 U.S.C. § 355(j)(8)(B) (2006).

In addition, section 465.025(5) provides that each community pharmacy must establish "a formulary of generic and brand named drug products, which, if selected as the drug of choice, would not pose a threat to the health and safety of patients. . . ." Although a pharmacist is required to rely on drug product research, testing, information, and formularies by other agencies, including the FDA, under the statute the pharmacist's formulary is not required to be consistent with the Orange Book formulary. Id. Under section 465.025(2), pharmacists are required to substitute a "less expensive, generically equivalent drug product" for a brand name, unless the prescriber expressly indicates the brand named drug is medically necessary or the purchaser requests otherwise. Section 465.025(1)(b) defines "generically equivalent drug

product" as a drug product with the same active ingredient, finished dosage form, and strength. Abbott asserted that, as a result of these statutory provisions, for products not included in the NDF, Florida law would permit substitution of drug products which are pharmaceutically equivalent, but not necessarily bioequivalent. As a result, a substituted generic product could differ materially from the prescribed drug in the manner in which the active ingredient is released into the bloodstream. Of course, drug products listed in the NDF may not be substituted. Fla. Admin. Code R. 64B16-27.500.

As noted, pursuant to section 465.025(6), a person seeking to remove a drug from the NDF has the burden of demonstrating that substitution of the drug would not "pose a threat to the health and safety of patients." The record reflects that previous efforts to remove LS from the NDF utilizing that standard have been unsuccessful. In this proceeding, Mylan has argued that, by operation of law, LS must be removed from the NDF because section 465.0251, Florida Statutes (2007), requires removal as a matter of law. Although Abbott submitted evidence by affidavit in the proceeding below that substituting generic LS drugs could be harmful to patients, that evidence was not considered by the ALJ, because the ALJ determined that section 465.0251(1) required removal as a matter of law.

Below, as here, Abbott argued that the legislature may adopt federal agency

rules and laws that are in existence at the time the legislature enacts the statute incorporating federal law, but that the legislature is precluded from adopting federal agency rules or federal laws that take effect after the enactment of the Florida Statute. See Fla. Indus. Comm'n v. State, 21 So. 2d 599 (Fla. 1945); Freimuth v. State, 272 So. 2d 473 (Fla. 1972).

Abbott also argued that section 465.0251 was ambiguous and should be construed to require that "A" rated reference listed drugs and generic drugs must be therapeutically equivalent to all the other reference listed drugs. The ALJ rejected this interpretation of the statute, reasoning, as follows:

> The plain and obvious meaning of Subsection 465.0251(1), Florida Statutes, is that a generic named drug product is to be removed from the negative drug formulary if the generic equivalent is "A" rated as therapeutically equivalent to a reference listed drug as referred to in the Orange Book. The statute does not state that all generic drug products must be "A" rated as therapeutically equivalent to all the reference listed drugs in the Orange Book listed for a specific generic named drug product. It just requires that every commercially marketed generic drug be "A" rated as therapeutically equivalent to a reference listed drug in the Orange Book. [The underlined "a"] is singular, meaning one.

The parties filed separate motions for summary final order asserting that there were no genuine issues of material fact. See § 120.57(1)(h), Fla. Stat. (2007). Following a hearing on December 11, 2007, the ALJ found that an evidentiary hearing

was not necessary and issued a summary final order on January 28, 2008.

In the summary final order, the ALJ accepted Mylan's argument that the 2007 version of the Orange Book could be used in applying section 465.0251 on the authority of Eastern Air Lines, Inc. v. Department of Revenue, 455 So. 2d 311 (Fla. 1984). In Eastern Air Lines, the court created an exception to the general rule that a statute may only incorporate federal law in effect at the date the incorporation is made. There, the airline sought a declaratory judgment that a fuel tax calculated by reference to the federal Consumer Price Index (CPI) then in effect was unconstitutional. Eastern contended that the use of the varying price component of the CPI issued by the United States Department of Labor in determining the amount of the fuel tax was an improper delegation of legislative authority because the CPI which was being used was not in existence at the time the provisions of chapter 83-3, Laws of Florida, were enacted. Rejecting Eastern's argument, the Florida Supreme Court explained that:

> Here, the legislature is merely setting forth the manner in which the department is to determine the appropriate total motor fuel and special fuel retail price. The department is directed with precision how to make such a determination. We think the language of Welch [279 So. 2d 11 (Fla. 1973)] and Freimuth [272 So. 2d 473 (Fla. 1972)] should be interpreted to apply to statutes which incorporate federal statutes or administrative rules which substantively change the law, and not to a statute which incorporates a federal index to provide aid in making a ministerial determination.

Id. at 316.

The ALJ found the FDA revisions to the Orange Book analogous to the CPI index in Eastern Airlines. In the order under review, the ALJ explained her reasoning:

> In section 465.0251, Florida Statutes, the Legislature has set out specific standards, which when met require the removal of a drug product from the negative drug formulary. It is akin to the use of the CPI in Eastern Air Lines. The standards which the FDA used in 2001 to determine whether a drug product is therapeutically equivalent are essentially the same standards used in 2007. . . . Naturally, as new drugs are sought to be approved, the list of reference listed, "A" rated, and therapeutically equivalent drug products will vary, like the CPI will vary. When drug products meet the criteria listed in section 465.0251, Florida Statutes, the removal becomes a ministerial duty.

As a result, because Mylan had demonstrated that LS under the 2007 Orange Book now meets the criteria of section 465.0251(1), the ALJ ruled that rule 64B16-27.500(6) was invalid and that LS must be removed from the NDF. Abbott sought a stay below, which was denied. Abbott's motion for review in this court was denied.

Standing

As a threshold matter, Mylan argues that Abbott lacks standing to maintain this appeal because it has not demonstrated that it "is adversely affected by final agency action" as required by section 120.68(1) (emphasis added).[2] The test for determining

[2] Mylan admits that standing was not raised as an issue by either party in the proceeding below. Interestingly, as pointed out by Abbott, Mylan did not challenge

whether a party has standing in appellate proceedings, governed by the quoted language in section 120.68(1), is different from the standing test required to participate in an administrative hearing. To have standing to challenge the validity of an administrative rule in a rule challenge proceeding before an ALJ, a person must be "substantially affected." § 120.56(1)(a), Fla. Stat. An intervenor, like Abbott, must similarly be "substantially affected" to participate in the rule challenge proceedings. § 120.56(1)(e), Fla. Stat.

In this case under review, Abbott has alleged that it is adversely affected because the final order will directly lead to significant market share losses. Mylan contends,

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Abbott's standing below, because Mylan's standing to initiate this rule challenge proceeding was also based on its financial interests. Nevertheless, Mylan asks this court to deny Abbott standing to bring this appeal on the ground that Abbott's only interest in the proceeding is financial and to overlook that both parties based their standing below on their financial interests at stake in the implementation of the generic substitution law. As recognized by this court in Grand Dunes Ltd. v. Walton County, 714 So. 2d 473, 475 (Fla. 1st DCA 1998), standing in the administrative context is a matter of subject matter jurisdiction and cannot be conferred by consent of the parties. Thus, if indeed economic interest was not sufficient to grant these parties the necessary standing to participate in the rule challenge proceeding below, the ALJ would have lacked jurisdiction to rule on the merits of the rule challenge and her order would have been a nullity. Examining the case law, we are satisfied that the act of removing LS from the NDF, which has the effect of allowing pharmacists to freely substitute generic drugs for Abbott's brand name drug Synthroid®, is a direct injury in fact "of sufficient immediacy and reality" to grant Abbott (and Mylan) standing in the rule challenge proceeding. Fla. Bd. of Med. v. Fla. Acad. of Cosmetic Surgery, Inc., 808 So. 2d 243, 250 (Fla. 1st DCA 2002). See also Florida Dep't of Offender Rehabilitation v. Jerry, 353 So. 2d 1230, 1236 (Fla. 1st DCA 1978). It cannot be disputed that both parties' interests are within the zone of interest regulated by §§ 465.025 and 465.0251 and rule

however, that economic injury suffered by Abbott is insufficient to establish standing on appeal under Florida Society of Ophthalmology v. State Board of Optometry, 532 So. 2d 1279, 1284 (Fla. 1st DCA 1988). Abbott responds that Mylan is confusing and intermingling the different tests for standing that exist at the trial and appellate levels of the administrative process. More importantly, Abbott argues that this is a rule challenge proceeding and economic injury may be a basis for establishing standing in such a proceeding. See Peace River/Manasota Reg'l Water Supply Auth. v. IMC Phosphates Co., 34 Fla. L. Weekly D348, D349 (Fla. 2d DCA February 10, 2009) ("standing depends on the nature of the injury asserted and the purpose and scope of the administrative proceeding").

Florida Society of Ophthalmology v. State Board of Optometry provides that "party status will be accorded only to those persons who will suffer an injury to their substantial interests in a manner sought to be prevented by the statutory scheme," 532 So. 2d at 1284, for purposes of a section 120.57(1) hearing. That case does not involve a rule challenge, however. As this court explained in Department of Professional Regulation, Board of Dentistry v. Florida Dental Hygienist Association, Inc., 612 So. 2d 646, 651 (Fla. 1st DCA 1993):

> Moreover, it should be noted that unlike Florida Society of Ophthalmology v. State Board of Optometry, 532 So. 2d

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64B16-27.500.

> 1279, 1284 (Fla. 1st DCA 1988), the present case is a rule challenge proceeding, not an attempt to gain access to a 120.57(1) licensing proceeding. This distinction is significant. Prior decisions in licensing or permitting cases have made it clear that a claim of standing by third parties based solely upon economic interests is not sufficient unless the permitting or licensing statute itself contemplates consideration of such interests, or unless standing is conferred by a rule, statute, or based on constitutional grounds. Florida Medical Association, 426 So. 2d at 1117-118; Florida Society of Ophthalmology, 532 So. 2d at 1287. Further, as we reiterated in State Board of Optometry, standing in a licensing proceeding may well have to be predicated on a somewhat different basis than standing in a rule challenge proceeding, because there can be a difference between the concept of "substantially affected" under section 120.56(1) and "substantial interest" under section 120.57(1). 538 So. 2d at 880.

(Emphasis added); see also Fla. Med. Assn, Inc. v. Dep't of Prof'l Regulation, 426 So. 2d 1112, 1115 (Fla. 1st DCA 1983) (recognizing that an interest economic in nature can furnish the basis for standing to challenge a proposed or adopted agency rule).

Standing at the appellate level is governed by section 120.68(1). Under this statute, Abbott has standing if four conditions are satisfied: "(1) the action is final; (2) the agency is subject to the provisions of the [Administrative Procedure] Act; (3) [the person seeking review] was a party to the action which he seeks to appeal; and (4) [the party] was adversely affected by the action." Daniels v. Florida Parole and Probation Comm'n, 401 So. 2d 1351, 1353 (Fla. 1st DCA 1981). The first three requirements are

not at issue in this case and Abbott satisfies the fourth requirement under the case law. See Indian Trail Improvement Dist. v. Dep't of Cmty. Affairs, 946 So. 2d 640, 641 (Fla. 4th DCA 2007) (recognizing that the adverse effect of an agency decision increasing competition in a service area is sufficient to support appellate standing). Abbott's stake in this appeal extends beyond a mere "generalized interest" in the NDF. By removing LS from the NDF, the ALJ's order would require a pharmacist to dispense generic LS products to patients whose physicians have written a prescription for Synthroid®, which Abbott manufactures. Abbott is adversely affected because the final order will directly lead to significant market share losses.

Finally, we reject Mylan's argument that Abbott lacks standing on appeal based upon this court's decision in Florida Chapter of the Sierra Club v. Suwannee American Cement Company, Inc., 802 So. 2d 520, 521 (Fla. 1st DCA 2001). In Suwannee American, the Sierra Club and Save Our Suwannee, Inc. (SOS), two environmental advocacy organizations, possessed standing at the administrative level by virtue of their compliance with section 403.412(5). On appeal, this court held that the Sierra Club and SOS did not possess standing to challenge the administrative order at the appellate level because neither Sierra Club nor SOS had shown that the agency action "created an 'injury in fact' or impending injury to its interest or an adverse effect with respect to any of its individual members." 802 So. 2d at 522 (citations omitted). An

assertion of standing based on a generalized interest in the environment was not sufficient. Id. at 522-23; see also Legal Envtl. Assistance Foundation, Inc. v. Clark, 668 So. 2d 982, 986-87 (Fla. 1996). Unlike the environmental groups in Suwannee American, here Abbott has a very specific interest that is adversely affected by the order under review.

Mootness

While this appeal was pending, Mylan filed a suggestion of mootness arguing that rule 64B16-27.500(6) became void by operation of law under section 120.56(3)(b). That statute provides:

> The administrative law judge may declare all or part of a rule invalid. The rule or part thereof declared invalid shall become void when the time for filing an appeal expires. The agency whose rule has been declared invalid in whole or in part shall give notice of the decision in the Florida Administrative Weekly in the first available issue after the rule has become void.

(Emphasis added). Mylan reasoned that, because neither the Board of Medicine nor the Board of Pharmacy has filed an appeal from the ALJ's determination that rule 64B16-27.500(6) was an invalid exercise of delegated legislative authority, the rule became void. As a result, Mylan points out, the Board of Pharmacy has issued a notification that LS has been deleted from Florida's NDF. Mylan asserts that this court cannot order the Board of Pharmacy to readopt a rule, adoption of which is not

mandated by statute.

Abbott responds that the Board of Pharmacy took no action on rule 64B16-27.500(6), but simply provided notice of the decision by the ALJ. Further, Abbott argues that the plain language of section 120.56(3)(b) states that the rule becomes void if "the time for filing an appeal expires." Thus, if an appeal is filed, "the time for filing an appeal" does not "expire" and the statute does not apply. We agree.

As this court recognized in State Board of Optometry v. Florida Society of Ophthalmology, 538 So. 2d 878, 889 (Fla. 1st DCA 1988):

> The statutory scheme [of section 120.56(3)] is obviously intended to avoid the chaotic uncertainty that would necessarily flow from retroactively invalidating agency action taken in reliance on the presumed validity of its rule prior to a proper rule challenge proceeding holding the rule invalid. Applying the underlying section 120.56(3) to this case, we hold that rule 21Q-10.001, which was held invalid by the hearing officer and our opinion, will become void and ineffective as of the date the decision of this court becomes final.

(Emphasis added). Thus, section 120.56(3) delays the date on which a rule shall become void until after appellate proceedings have ended. To interpret this statute in any other manner would deny a party the right to appellate review of an ALJ order invalidating a rule in the absence of a stay. Such a result is not supported by any authority.

Section 465.0251

We now turn to the merits of the parties' arguments with respect to section 465.0251. We review an ALJ's conclusions of law *de novo*. Steward v. Dep't of Children & Families, 865 So. 2d 528, 530 (Fla. 1st DCA 2003). Further, because the issues we consider here are primarily those of statutory or constitutional interpretation, our standard of review for those issues is also *de novo*. Fla. Hosp. Waterman, Inc. v. Buster, 984 So. 2d 478, 485 (Fla. 2008). Below, the parties agreed that there were no disputed issues of material fact and that the ALJ could resolve the case by summary final order pursuant to section 120.57(1)(h).[3] To the extent that we find that the ALJ's action is based upon a finding of fact, section 120.68(7)(b), Florida Statutes, we may set aside the ALJ's order if it depends upon any finding of fact that is not supported by competent, substantial evidence established in the record of the administrative hearing. Wise v. Dep't of Mgmt. Servs., Div. of Ret., 930 So. 2d 867, 870-71 (Fla. 2d DCA 2006).

As it did below, on appeal Abbott asserts that, because section 465.0251 provides that "if every commercially marketed equivalent of that drug product is 'A' rated as therapeutically equivalent to a reference listed drug . . ." (emphasis applied),

[3]The parties have not raised, and we do not address, whether disputed issues of fact do exist or whether the proceeding was appropriate for resolution by summary final order.

every commercially marketed LS product must be "A" rated to all of the reference listed drugs. If that position had been accepted by the ALJ, the ALJ would have been required to leave LS on the NDF because it is uncontroverted that no generic LS is "A" rated to Levothroid®. We hold that the ALJ correctly interpreted section 465.0251(1) in ruling that the statute is clear and unambiguous and provides that a generic drug product is to be removed from the NDF list if the generic equivalent is "A" rated as therapeutically equivalent to any single reference listed drug in the Orange Book. The use of the indefinite article "a" in the statute requires a reading of "reference listed drug" as a singular noun. See Webster's Third New Int'l Dictionary 1 (1966) ("a" is "used as a function word before most singular nouns other than proper and mass nouns. . . ."). Accordingly, we reject Abbott's contention that a named drug product like LS can be removed from the negative drug formulary only if all generic LS products are "A" rated as to each reference listed drug.

Alternatively, Abbott argues that reversal is nonetheless required because the ALJ unconstitutionally applied section 465.0251. Abbott contends that the legislature could not have intended to incorporate updated editions of the Orange Book to govern section 465.0251 because of the long-established constitutional rule in Florida that the legislature's adoption "in advance [of] any federal act or ruling of any federal administrative body which may be adopted in the future would amount to an unlawful

delegation of legislative authority." State v. Rodriguez, 365 So. 2d 157, 160 (Fla. 1978).

Article II, § 3 of the Florida Constitution provides:

> The powers of the state government shall be divided into legislative, executive and judicial branches. No person belonging to one branch shall exercise any power appertaining to either of the other branches unless expressly provided therein.

This constitutional provision has been construed "to prohibit the legislature, absent constitutional authority to the contrary, from delegating its legislative power to others." Gallagher v. Motors Ins. Corp., 605 So. 2d 62, 71 (Fla. 1992). Under this non-delegation principle, Florida courts have long held that while the legislature may enact laws that adopt provisions of federal statutes or other regulations of a federal administrative body that are in existence and in effect at the time the legislature acts, where the legislature incorporates in a Florida statute a future federal act or ruling of a federal administrative body, such incorporation constitutes unconstitutional delegation of legislative power. See, e.g., Fla. Indus. Comm'n v. State, 21 So. 2d at 603 (holding that chapter 19637, Laws of Florida (1939), which excluded from its application any employer who was "within the operation of Title IX of the Federal Social Security Act, or amendments thereto," must be confined to the federal act as it existed when the exception clause was enacted in 1939); State v. Welch, 279 So. 2d at 13-14 (upholding

the determination of the trial court that section 404.015 stating "the intent of the legislature that all drugs controlled by the drug abuse laws of the United States, now or in the future, shall, in addition to the drugs specified by the laws of Florida, be controlled by the terms of this chapter" was susceptible to a constitutional challenge because it sought "to incorporate by reference future legislative and/or administrative actions of jurisdictions outside of Florida"); State v. Camil, 279 So. 2d 832 (Fla. 1973) (holding that the defendant could not be convicted of possessing PCP, when PCP was not a prohibited drug when section 404.01(3) was enacted in 1967; that statute defined "hallucinogenic drug" as "any other drug to which the drug abuse laws of the United States apply" and PCP was not outlawed by United States law until after 1967); Dep't of Legal Affairs v. Rogers, 329 So. 2d 257, 265 (Fla. 1976) (construing Florida's "little FTC act," which required rules adopted pursuant to the act to be consistent with decisions of the Federal Trade Commission and federal courts interpreting provisions of the Federal Trade Commission Act, to require compliance with the federal trade law standard in effect on or before the effective date of the act); State v. Rodriguez, 365 So. 2d at 160 (construing section 409.325(2)(a) as incorporating federal food stamp law "in effect at the time Section 409.325(2)(a) was enacted"); Hughes v. State, 943 So. 2d 176, 190 (Fla. 3d DCA 2006) (holding that, because section 860.13 governing operation of aircraft while intoxicated was last reenacted without any amendments in

1983, "incorporation of a federal standard that did not come into existence until after 1983 would be unconstitutional"); Brazil v. Div. of Admin., State Dep't of Transp., 347 So. 2d 755, 757-58 (Fla. 1st DCA 1977) (holding that it would be permissible for DOT to remove a sign which violated the spacing requirement which was part of the federal regulations when section 479.02, containing the phrase "subject to current federal regulations," became effective, but it would be unconstitutional to construe the statute as allowing the legislature to adopt, in advance, any federal act or ruling); see generally F. Scott Boyd, Looking Glass Law: Legislation by Reference in the States, 68 La. L. Rev. 1201, 1251-1280 (2008).

Where a statute generally incorporates a federal law or regulation, to avoid holding the subject statute unconstitutional, Florida courts interpret the statute as incorporating only the federal law in effect on the date of adoption of the Florida Statute. Rodriguez, 365 So. 2d at 160. As the Florida Supreme Court has explained, "the legislature is presumed to have intended to enact a valid and constitutional law and . . . we will construe a statute, if possible, in such a manner as will be conducive to its constitutionality." Rogers, 329 So. 2d at 265. For example, in Rodriguez, the entire court agreed that section 409.325(2)(a), Florida Statutes, which purported to incorporate into the statute future changes to the federal food stamp laws, provided for an unconstitutional delegation. Four justices concluded that the statute should be

interpreted only to incorporate federal law as it existed when the Florida statute was enacted, and, as a result, held the statute constitutional. 365 So. 2d at 160. As the majority explained:

> Since the Legislature is presumed to have enacted a valid and constitutional law and since statutes are to be construed, when reasonably possible and consistent with protection of constitutional rights, in such a manner so as to avoid conflict with the Constitution, we conclude that the Legislature intended to incorporate federal law and regulations in effect at the time section 409.325(2)(a) was enacted.
>
> The incorporation of only the federal law in effect at the time of the enactment of section 409.325 may appear unworkable because changes in the federal law would not take effect in Florida. The Legislature, however, to avoid this problem, may update Chapter 409 each year, as they update Florida's corporate income tax statute by bringing forward the Internal Revenue Code each year.

Id. (citations and footnote omitted). Three justices dissented and would have held the Florida statute unconstitutional as an unlawful delegation of legislative authority because it incorporated future federal law. Id. at 161-62. Similarly, in Freimuth, the court interpreted section 404.01(3), Florida Statutes (1969), which defined "hallucinogenic drug" by reference to federal law, as not incorporating those drugs listed in federal law adopted after the date of enactment of section 404.01 in 1967. 272 So. 2d at 476.

In Eastern Air Lines, the court explained that this well-established non-delegated principle applies "to statutes which incorporate federal statutes or administrative rules which substantively change the law . . ." 455 So. 2d at 316. The court did not apply this principle in Eastern Air Lines, however, because it found that the statute directing the use of the CPI in calculating a Florida fuel tax "merely set forth the manner in which the department is to determine the appropriate total motor fuel and special full retail price [and] [t]he department is directed with precision how to make such a determination." Id.

We agree with Abbott that the CPI index is similar to a mathematical formula which the state agency could use to arrive at the fuel price. Nothing in this record, however, leads us to the conclusion that the Orange Book and the complex science which the FDA uses to develop the list of generic drugs included in the Orange Book is similar in nature to the CPI at issue in Eastern Air Lines. While the FDA standards require therapeutic equivalence for drug products to be "A" rated in the Orange Book, and these standards did not change from 2001 to 2007, this fact is not determinative. The record here is clear that the scientific methodology applied by the FDA in approving drug products for inclusion in editions of the Orange Book is not static and unchanging. The FDA has revised and will revise its methodology to reflect scientific developments. In short, we conclude that the drug products listed in the Orange Book

are much more like the list of hallucinogenic drugs in Freimuth than the CPI index in Eastern Air Lines. Because the FDA makes substantive changes to the Orange Book, to interpret section 465.0251 as allowing the FDA's Orange Book to determine which drugs should be on the NDF would constitute an unlawful delegation of legislative authority to the FDA. See Freimuth.

Moreover, we are persuaded that, when the legislature enacted section 465.0251, it did not intend the result obtained by the ALJ's order. Subsection (2) of that statute clearly states the legislative intent that the statute was not meant to override section 465.025. "It is axiomatic that statutes must be read with other related statutes and other related portions of the same statute." State v. Negrin, 306 So. 2d 606, 607 (Fla. 1st DCA 1975). "Where possible, courts must give effect to *all* statutory provisions and construe related statutory provisions in harmony with one another." Forsythe v. Longboat Key Beach Erosion Control Dist., 604 So. 2d 452, 455 (Fla. 1992).

With these principles in mind, we read section 465.0251 as only applying the edition of the Orange Book in effect on or before the date on which the statute was enacted. This interpretation leaves in full force and effect the provisions of section 465.025(6), which delegates the authority to establish the NDF to the Board of Pharmacy and the Board of Medicine. Thus, those Boards are left with the authority to determine whether certain drug substitutions would pose a threat to the health and

safety of Florida patients. We cannot accept that in section 465.0251 the legislature intended to delegate to the FDA the legislative authority to determine, on a continuing basis, which drug substitutions would pose a threat to health and safety of Florida patients. If, indeed, the legislature intends the NDF to be governed by the revised versions of the Orange Book, as Mylan asserts, then the legislature can update section 465.0251 each year "by bringing forward [the Orange Book] each year." Rodriguez, 365 So. 2d at 160.

REVERSED.

KAHN AND WEBSTER, JJ., CONCUR.