

OPINION

This case involves a challenge to the validity of a rule promulgated by the Tennessee Board of Medical Examiners. Gate Pharmaceuticals appeals the judgment of the trial court upholding the rule's validity. We affirm.

In March 1990, the Tennessee Board of Medical Examiners (the "Board") enacted Rule 0880-2-.10(2), which regulated amphetamines and amphetamine-like substances. The rule became effective on November 12, 1990. Effective April 12, 1991, the Board repealed the original version of this rule, replacing it with Rule 0880-2-.14(3) (the "Rule"). The Rule provides in part:

It shall be a [*prima facie*]¹ violation of T.C.A. §§ 63-6-214(b)(1) and 63-6-214(b)(12) to prescribe, order, administer, sell or otherwise distribute any amphetamine-like substance listed below, except when the licensee has applied for and received from the Board of Medical Examiners a written approval for the clinical investigation of such drugs under a protocol satisfactory to the Board

(1) The list of amphetamine-like substances governed by the rule are the following controlled substances

(vii) Phentermine; (examples are Ionamin, Fastin, Adipex and others)

Pursuant to Tenn. Code Ann. § 63-6-214(b)(1) and (b)(12), the Board has the authority to deny, suspend, or revoke a medical license for "[u]nprofessional, dishonorable or unethical conduct" or "[d]ispensing, prescribing or otherwise distributing any controlled substance or any other drug not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease." Tenn. Code Ann. § 63-6-214(b)(1), (b)(12) (1990 & Supp. 1996).

Gate Pharmaceuticals ("Gate") is the marketing division of a pharmaceutical company that manufactures Adipex-P, an anorectic drug used as an appetite suppressant in the treatment of obesity. Phentermine is the drug's active ingredient. In October 1993, Gate filed a petition challenging the Rule. The Board held a contested case hearing on May 4, 1994, rejecting Gate's petition. Gate then filed this lawsuit seeking review of the Rule pursuant to Tenn. Code Ann. § 4-5-322.

After a hearing, the trial court issued an order upholding the Rule. The trial court noted that prescribing Adipex-P without approval from the Board is merely a *prima facie*, and not an automatic, violation of the statute and observed that the physician may put on proof to rebut the presumption. Consequently, the trial court reasoned that the Rule does not proscribe Adipex-P, but

¹This Board added this language in its amendment to the original version of the rule.

rather controls its distribution. The trial court held that such restrictions were well within the Board's authority.

Gate now appeals the decision of the trial court upholding the Rule. On appeal, Gate argues that the Board exceeded its statutory authority in enacting the Rule and that the Board's decision to promulgate the Rule was arbitrary and capricious.

Under the Tennessee Administrative Procedures Act, we may reverse the Board's decision only if Gate's rights have been prejudiced because the Board's decision was:

- (1) In violation of constitutional or statutory provisions;
- (2) In excess of the statutory authority of the agency;
- (3) Made upon unlawful procedure;
- (4) Arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion; or
- (5) Unsupported by evidence which is both substantial and material in the light of the entire record.

Tenn. Code Ann. § 4-5-322(h) (1991 & Supp. 1996).

In this appeal, Gate first challenges the Board's authority to promulgate the Rule. An administrative agency's authority must be based on an express grant of statutory authority or must arise by necessary implication therefrom. *Wayne County v. Tennessee Solid Waste Disposal Control Bd.*, 756 S.W.2d 274, 282 (Tenn. App. 1988); *Tennessee Pub. Serv. Comm'n v. Southern Ry.*, 554 S.W.2d 612, 613 (Tenn. 1977). If an agency's actions exceed its statutory authority, this Court may vacate the agency's decision. *Tennessee Cable Television Ass'n v. Tennessee Pub. Serv. Comm'n*, 844 S.W.2d 151, 163 (Tenn. App. 1992). Review of the scope of an agency's authority necessarily involves a question of law and is therefore *de novo*. See *Carvell v. Bottoms*, 900 S.W.2d 23, 26 (Tenn. 1995).

In support of its argument, Gate cites *Tennessee Public Service Commission v. Southern Railway*, 554 S.W.2d at 612. In that case, the Public Service Commission ordered Southern Railway to restore a burned-out bridge that crossed its tracks. *Id.* at 612-13. The trial court reversed the Commission's order, and the Supreme Court affirmed, observing:

Had the legislature intended to invest the Commission with the authority to insure the safety and convenience of the public in crossing a railroad right-of-way, it would have been a simple matter for it to have done so explicitly [T]o the extent that jurisdiction over rail-highway crossings has been expressly granted to a state agency, it has been given primarily and in the first instance to the State Department of Transportation.

Id. at 613.

Relying on *Tennessee Public Service Commission*, Gate asserts that the legislature intended for the Tennessee Commissioner of Mental Health and Mental Retardation (the “Commissioner”) to determine the availability of drugs because it granted to the Commissioner the authority to place controlled substances on schedules. Gate notes that the Commissioner placed phentermine on Schedule IV, thereby indicating that the drug has a relatively low potential for abuse. Under the statutes, the Commissioner must consider certain factors when classifying controlled substances, such as the substance’s actual or relative potential for abuse. *See* Tenn. Code Ann. § 39-17-403(a) (1991 & Supp. 1996). Gate argues that the Board failed to consider any of these factors when enacting the Rule. Gate maintains that the legislature specifically delegated the primary authority to determine the availability of drugs to the Commissioner and that this demonstrates that the Board lacked the authority to enact the Rule.

In addition, Gate argues that the Rule is a *de facto* prohibition on Adipex-P, despite the Rule’s statement that prescribing the drug except under an approved protocol is a “*prima facie* violation.” Gate maintains that Tenn. Code Ann. § 63-6-214 only empowers the Board to impose discipline on a case-by-case basis and that the Board exceeded its statutory authority by enacting the presumption contained in the Rule. Gate contends that no physician would ever prescribe the drug because of the onerous requirements of the Rule and the danger of being disciplined by the Board. The legislature has on occasion enacted a ban prohibiting the prescription of a scheduled drug. *See, e.g.*, Tenn. Code Ann. § 53-10-109 (1991 & Supp. 1996) (prohibiting the use of Schedule II amphetamines for the assistance of weight gain or loss). Gate notes that the Federal Drug Administration has approved of phentermine as an anorectic and observes that the legislature has never enacted a ban against Schedule IV drugs, such as phentermine, even though such drugs have been on the market since the 1970s.

In response, the Board states that its authority to regulate and to control the prescription of drugs by Tennessee physicians is separate and apart from the Commissioner’s authority over scheduling controlled substances. The Board contends that the Rule is not a ban or a prohibition on

amphetamine-like drugs. Rather, the Rule merely establishes purposes for which those drugs may be dispensed or prescribed by Tennessee physicians.

In support of its authority, the Board relies on Tenn. Code Ann. § 53-11-301, which provides that “the appropriate occupational or professional licensing board governing persons who may legally dispense controlled substances may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this state.” Tenn. Code Ann. § 53-11-301 (1991 & Supp. 1996). “Dispense” is defined as meaning to “deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.” Tenn. Code Ann. § 39-17-402(7) (1991 & Supp. 1996). “Practitioner” is defined to include “[a] physician . . . in the course of professional practice or research in this state.” Tenn. Code Ann. § 39-17-402(22) (1991 & Supp. 1996).

The Board is the appropriate professional licensing board for physicians. Tenn. Code Ann. §§ 63-6-101, 63-6-201 (1990 & Supp. 1996). As such, the Board contends that it has authority to place controls on the purposes for which certain controlled substances are dispensed or prescribed by physicians, as well as the method of prescription. In the case of amphetamine and amphetamine-like drugs, the Board maintains that the standard of professional practice requires that they be prescribed or dispensed by physicians only when the licensee has applied for and received from the Board written approval for a clinical investigation of such drugs under a satisfactory protocol.

As additional support for its authority to promulgate the Rule, the Board notes that it has the authority to “make such rules and regulations as are necessary to carry out and make effective the provisions of this chapter.” Tenn. Code Ann. § 63-6-101(3) (1990 & Supp. 1996). Two such provisions are its power and duty to discipline licensed physicians for “[u]nprofessional, dishonorable or unethical conduct” and for “[d]ispensing, prescribing or otherwise distributing any controlled substance . . . not in the course of professional practice.” Tenn. Code Ann. § 63-6-214(b)(1), (b)(14) (1990 & Supp. 1996). Because the Board may discipline physicians for conduct outside the standards for professional practice, the Board argues that this necessarily implies authority to enact a rule defining conduct that fails to conform to those standards.

There are no Tennessee cases directly on point; consequently, we look to cases in other

jurisdictions. In *Lemmon Co. v. New Jersey State Board of Medical Examiners*, 417 A.2d 568 (N.J. Super. Ct. App. Div. 1980), the court considered the validity of a similar rule enacted by its state board of medical examiners. *Id.* at 570. In *Lemmon*, the rule explicitly prohibited the use of amphetamines or amphetamine-type drugs by physicians for the treatment of exogenous obesity. *Id.* To determine whether the board had authority to enact the rule, the court examined the statutes from which the board derived its authority. *Id.* at 571-73. In that case, the board had the authority to refuse to grant, revoke, or suspend a medical license for dispensing controlled substances not in good faith or without good cause. *Id.* at 572. Because the board could discipline a physician for such conduct even without a rule, the court reasoned that the board must have the power to advise physicians in advance, by rule, of conduct that could subject them to discipline. *Id.*

In addition, *Lemmon* addressed whether the challenged rule contradicted the Food and Drug Administration's approval of the use of amphetamines in weight management programs under certain conditions. *Id.* The court reasoned that federal law merely permitted, rather than mandated, the use of amphetamines in the treatment of obesity. *Id.* Therefore, the court held that the board's rule did not contradict federal law. *Id.*

Finally, the court in *Lemmon* considered whether the board lacked the authority to enact the rule because the legislature had delegated to the Commissioner of Health the responsibility to classify drugs according to schedules. *Id.* The court noted that the board's purpose in enacting the rule was not to classify controlled substances, but rather to announce that it would not consider the prescription of amphetamines for the treatment of obesity to be with good cause. *Id.* at 573. As such, the court held that the Commissioner's authority to classify drugs did not prevent the board from enacting the rule. *Id.* Thus, in a case involving facts and issues similar to those presented in this case, the *Lemmon* opinion supports the trial court's decision.

In *Casey v. State Board of Registration for the Healing Arts*, 830 S.W.2d 478 (Mo. Ct. App. 1992), the court also considered the validity of a rule, enacted by a state licensing board, which regulated the prescription of amphetamines and amphetamine-like controlled substances. *Id.* at 479. The Court examined the board's enabling statute, noting that the board had only the authority to "formulate rules and regulations to govern its actions." *Id.* at 480. The court further noted, however, that the Department of Health possessed the power to "*promulgate rules* and charge reasonable fees *relating to the registration and control of the manufacture, distribution and dispensing of controlled*

substances.” Id. (emphasis supplied by original court). Accordingly, the court reasoned that the board did not have the power to regulate the prescription of drugs because the legislature granted that authority in the first instance to the Department of Health. *Id.*

Thus, as argued by Gate in this case, the court in *Casey* found that the Department of Health, rather than the licensing board for physicians, had been granted the authority to promulgate rules regarding controlled substances. However, the reasoning employed relied primarily on the enabling legislation for each body. In *Casey*, the licensing board, unlike the Board in this case, had only the authority to license and discipline physicians and to “formulate rules and regulations to govern its actions.” In this case, the Board is authorized under Tennessee statutes to license and discipline persons who legally dispense controlled substances and to “promulgate rules . . . relating to the . . . dispensing of controlled substances within this state,” as well as to discipline physicians for “prescribing . . . any controlled substance . . . not in the course of professional practice.” Tenn. Code Ann. §§ 53-11-301 (1991 & Supp. 1996), 63-6-214(b)(1), (b)(14) (1990 & Supp. 1996). This enabling legislation is similar to the enabling legislation for the Department of Health in *Casey*, which gave it authority to “promulgate rules . . . relating to the . . . dispensing of controlled substances within this state.” *Casey*, 830 S.W.2d at 480 (emphasis omitted). Thus, the reasoning in *Casey* supports the decision of the trial court in this case.

The reasoning in these cases is persuasive. As in *Lemmon*, the Board in this case has the authority to discipline physicians for conduct not in the course of professional practice even in the absence of a rule defining nonconforming conduct. It logically follows that the Board has the authority to advise physicians in advance, by rule, of what conduct is subject to discipline. The Commissioner’s authority to classify drugs according to their propensities and to place them on schedules is separate and apart from the Board’s authority to define conduct that is subject to discipline. Furthermore, the FDA’s recognition of the utility of anorectic drugs in the treatment of obesity does not require the Board to permit their use without restriction. Thus, the Rule does not contradict the FDA.

The reasoning in *Casey* also supports the Board's position. The Board's enabling statute in the present case is nearly identical to the enabling statute of the Department of Health in *Casey*. This statute prompted the *Casey* court to find that the Department of Health in that case was the agency with the authority to enact such a rule. Likewise, the statutes in the present case grant the Board the authority to enact the Rule.

Gate also contends that the Board exceeded its authority by enacting the presumption contained in the Rule because Tenn. Code Ann. § 63-6-214 requires the Board to make case-by-case determinations. In *Miller v. United States*, 294 U.S. 435 (1935), the United States Supreme Court considered the validity of a regulation enacted by the Director of the Veterans' Bureau. In that case, the regulation provided that the loss of one hand and one eye constituted total permanent disability as a matter of law for purposes of war risk insurance. *Id.* at 439-40. By statute, however, the agency was required to make case-by-case factual determinations as to what constituted permanent disabilities. *Id.* at 440. The Court held that when an agency is required to make factual determinations, it cannot enact a rule converting a question of fact, which requires proof, into a conclusive presumption. *Id.*; *see also Swalbach v. State Liquor Authority*, 166 N.E.2d 811 (N.Y. 1960) (holding that an agency may not avoid its duty to adjudicate on a case-by-case basis by adopting a policy that forecloses consideration of the facts the legislature intended to be taken into account).

In this case, the Rule provides that prescribing amphetamine-like substances without prior Board approval is a *prima facie* violation of Tenn. Code Ann. § 63-6-214. As the trial court noted, a physician may put on proof to rebut the presumption raised by the Rule. The Rule does not convert a question of fact into a conclusive presumption of law; consequently, this case is distinguishable from *Miller*. Therefore, the Board acted within its statutory authority in enacting the Rule.

Gate also argues that the Board's decision to promulgate the Rule was arbitrary and capricious. This Court may vacate the decision of an administrative agency when it is "[a]rbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion." Tenn. Code Ann. § 4-5-322(h)(4); *Tennessee Cable*, 844 S.W.2d at 163-64. Courts must "defer to the decisions of administrative agencies when they are acting within their area of specialized knowledge, experience, and expertise." *Wayne County*, 756 S.W.2d at 279 (citations omitted).

As indicated by this narrow scope of review, “courts should be less confident that this judgment is preferable to that of the agency.” *Id.* Consequently, courts should refrain from substituting their judgment for the agency’s regarding the weight of the evidence, even when there is evidence to support a different result. *Id.*; *see also Hughes v. Board of Comm’rs*, 204 Tenn. 298, 305, 319 S.W.2d 481, 484 (1958). In addition, courts should “not inquire into the wisdom of a rule or determine whether a rule embodies good or bad policy.” *Tennessee Cable*, 844 S.W.2d at 168 (citations omitted).

The scope of review in Tennessee under the “arbitrary and capricious” standard is described in *Tennessee Cable*:

Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. (citing *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983)). Therefore, if there is any rational basis for the agency’s conclusions, the agency’s decision should be upheld. *Blue Ridge Transp. Co. v. Pentecost*, 343 S.W.2d 903, 906 (Tenn. 1961); *McCallen v. City of Memphis*, 786 S.W.2d 633, 641 (Tenn. 1990).

Within these narrow confines, we address Gate’s contention that the Board’s decision was arbitrary and capricious. The record in this case indicates that the Board enacted the Rule in response to growing public health, safety, and welfare concerns relating to the abuse of amphetamines, central nervous system stimulants, and amphetamine-like controlled substances. There is no evidence that the Board considered factors not intended by the legislature. The record demonstrates that the Board formulated the Rule based on its review of the medical literature, studies, reports, and the Board’s own knowledge and experience in relevant disciplinary actions. Therefore, the Board’s promulgation of the Rule was not arbitrary or capricious.

The decision of the trial court is affirmed. Costs on appeal are taxed to the Appellant, for which execution may issue if necessary.

HOLLY KIRBY LILLARD, J.

CONCUR:

ALAN E. HIGHERS, J.

DAVID R. FARMER, J.