December 20, 2001

The Honorable David Cain
Chairman
Senate Committee on Administration
Texas State Senate
P.O. Box 12068
Austin, Texas 78711

Opinion No. JC-0445

Re: Whether the Texas Department of Health has exceeded its authority in adopting a rule requiring certain dietary supplements sold in Texas to bear a label with a United States Food and Drug Administration toll-free telephone number for reporting adverse events (RQ-0414-JC)

Dear Senator Cain:

You ask whether the Texas Department of Health ("TDH") has exceeded its authority in adopting a rule requiring certain dietary supplements sold in Texas to bear a label with a United States Food and Drug Administration ("FDA") toll-free telephone number for reporting adverse events. Specifically, in your letter to this office, you pose the following question:

> Does the Texas Department of Health exceed its statutory and regulatory authority in mandating the use of a federal reporting system, which system was not operationally designed or intended by [the] United States Congress or the Texas Legislature for use by or for state agencies, state purposes or state consumers?[1]

The rule you are concerned about requires the product labels of dietary supplements containing ephedrine to include the toll-free number of the FDA's MedWatch medical product reporting program. *See* 25 TEX. ADMIN. CODE § 229.462(f) (2001). For the reasons explained below, we conclude that the rule does not exceed the agency's statutory authority.

We begin with a brief review of the statutory framework. At the federal level, the safety of food and drugs is regulated by the FDA under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (1994 & Supp. V 1999). Congress has not entirely foreclosed state regulation of food and drug safety: "Regulation of the sale and labelling of food and drugs is a field traditionally occupied jointly by the states and the federal government." *Kellogg Co. v. Mattox*, 763 F. Supp. 1369, 1379

[1]Letter from Honorable David Cain, Chair, Senate Committee on Administration, Texas State Senate, to Honorable John Cornyn, Texas Attorney General (Aug. 14, 2001) (on file with Opinion Committee) [hereinafter Request Letter].

(N.D. Tex. 1991). Within the State of Texas, TDH regulates food and drug safety under the Texas Food, Drug, and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. ch. 431 (Vernon 2001).

The rule at issue governs dietary supplements containing ephedrine, an alkaloid derived from the ephedra plant, also known as ma huang. *See* STEDMAN'S MEDICAL DICTIONARY 581, 1054 (26th ed. 1995) (defining "ephedrine," "ma huang"). Dietary supplements are regulated as food under federal and state law rather than as drugs. Under federal law prior to 1994, in order to make claims regarding a dietary supplement's health benefits, the manufacturer had to obtain pre-market approval from the FDA by showing that the product was safe and effective. *Compare* 21 U.S.C. §§ 321, 343 (1993) (prior to 1994 amendments), *with* 21 U.S.C. §§ 321, 343 (1994 & Supp. V 1999). In 1994, Congress enacted the Dietary Supplement Health and Education Act ("DSHEA"), 103 Pub. L. No. 417, 108 Stat. 4325 (1994) (codified throughout 21 U.S.C.), to increase the public's access to dietary supplements. *See generally* DSHEA, § 2, 21 U.S.C. § 321 note (1994) (Congressional Findings Relating to Pub. L. 103-417). The new law stripped the FDA of its authority to approve most dietary supplements before they are marketed. *See* 21 U.S.C. § 321(g)(1) (1994) (exempting "dietary supplement" from definition of "drug"), (s)(6) (1994) (exempting "dietary supplement" from definition of "food additive"), (ff) (1994 & Supp. V 1999) (defining "dietary supplement"); *id.* §§ 331(u) (1994); 342(f), (g) (1994); 343(r) (1994 & Supp. V 1999) (health claims regarding dietary supplements); 343(s) (1994); 343-2 (1994) (dietary supplement labeling exemptions); 350b (1994) (exception for dietary supplements containing new dietary ingredients). Furthermore, under the new law, once a product is marketed, the FDA has the burden of proving that a dietary supplement is unsafe before it can take action to restrict the product's use or to remove the product from the marketplace, *see* 21 U.S.C. § 342(f) (1994). As the FDA has explained,

> Under DSHEA, a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. This means that dietary supplements do not need approval from FDA before they are marketed. Except in the case of a new dietary ingredient, where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products. . . .
>
> Under DSHEA, once the product is marketed, FDA has the responsibility for showing that a dietary supplement is "unsafe," before it can take action to restrict the product's use or removal from the marketplace.

CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., OVERVIEW OF DIETARY SUPPLEMENTS (2001), *available at* www.cfsan.fda.gov/~dms/ds-oview.html.

In 1999, citing concerns regarding "the misuse of certain products containing ephedrine and marketed as stimulants, appetite suppressants, and muscle enhancers,"[2] the Texas Legislature amended the Texas Food, Drug and Cosmetic Act to prohibit the sale of products containing ephedrine to persons 17 years of age or younger. *See* TEX. HEALTH & SAFETY CODE ANN. § 431.022 (Vernon 2001). This statute also requires that products containing ephedrine "must be labeled in accordance with rules adopted by the Texas Department of Health to indicate that sale to persons 17 years of age or younger is prohibited." *Id.* § 431.022(c). In 1999 and 2000, TDH promulgated several rules regulating dietary supplements containing ephedrine. *See* 25 TEX. ADMIN. CODE §§ 229.461, .462, .463, .464 (2001). Section 229.462 of title 25 of the Texas Administrative Code contains various labeling requirements for dietary supplements containing ephedrine, including a warning statement that indicates the sale to persons 17 years of age or younger is prohibited. *See id.* § 229.462(h).

Section 229.462 also contains the labeling requirement at issue in your request in subsection (f):

> After September 1, 2001, the product label must include a toll-free number to permit consumers to report adverse effects. This toll-free number shall be 1-800-332-1088, which is the Food and Drug Administration's MedWatch medical product reporting program.

Id. § 229.462(f). Subsection (f) was adopted in July 2000, but TDH delayed its effective date until September 1, 2001, to give manufacturers time to comply. *See* 25 Tex. Reg. 673 (2000), *adopted* 25 Tex. REG. 6514, 6515 (2000) (codified as an amendment to 25 TEX. ADMIN. CODE § 229.462).

Again, you ask whether TDH has exceeded its authority in adopting this rule. In reviewing the rule, we are guided by the maxim that "[a]n agency can adopt only such rules as are authorized by and consistent with its statutory authority." *R.R. Comm'n v. Arco Oil & Gas Co.*, 876 S.W.2d 473, 481 (Tex. App.–Austin 1994, writ denied). The critical factor in determining whether an administrative agency has exceeded its rule-making authority is whether the rule's provisions are in harmony with the general objectives of the statute involved. *See Edgewood Indep. Sch. Dist. v. Meno*, 917 S.W.2d 717, 750 (Tex. 1995); *R.R. Comm'n v. Lone Star Gas Co.*, 844 S.W.2d 679, 685 (Tex. 1992). An agency rule may not impose additional burdens, conditions, or restrictions in excess of or inconsistent with the relevant statutory provisions. *See R.R. Comm'n*, 876 S.W.2d at 481. Applying this standard, we conclude that the TDH rule does not exceed the agency's statutory authority.

TDH and the Texas Board of Health, its governing body, "are established to better protect and promote the health of the people of this state." TEX. HEALTH & SAFETY CODE ANN. § 11.002 (Vernon 2001). The board "has general supervision and control over all matters relating to the health of the citizens of this state," *id.* § 12.001(a), and is vested with general rule-making authority, *see id.* §

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[2]SENATE COMM. ON HEALTH SERVICES, BILL ANALYSIS, Tex. S.B. 656, 76th Leg., R.S. (1999).

12.001(b)(1) (the board shall "adopt rules . . . for the performance of each duty imposed by law on the board, the department").

The Texas Food, Drug, and Cosmetic Act, chapter 431 of the Health and Safety Code, provides for extensive state regulation of foods and drugs by the Texas Department of Health. Chapter 431 expressly authorizes TDH to enact rules "for the efficient enforcement of this chapter," *id.* § 431.241(a), and provides that a violation of a rule adopted under chapter 431 "is a violation of this chapter," *id.* § 431.046. The chapter expressly references and incorporates certain provisions of the Federal Food, Drug and Cosmetic Act and federal rules adopted under that Act and, in addition, grants TDH the general authority to conform its rules with federal rules and to adopt, reject, or modify others, *see, e.g., id.* §§ 431.241(b), (c), (d), .244, .245.

TDH regulates dietary supplements, such as those containing ephedrine, as food.[3] Provisions of chapter 431 clearly contemplate that TDH may promulgate state food labeling rules under the chapter. For example, section 431.021 expressly prohibits "the distribution in commerce of a consumer commodity, if such commodity is contained in a package, or if *there is affixed to that commodity a label that does not conform* to the provisions of this chapter and *of rules adopted under the authority of this chapter.*" *Id.* § 431.021(d) (emphasis added). The term "consumer commodity" as used in chapter 431 expressly includes foods. *See id.* § 431.002(8) (defining "consumer commodity" to include "any food, drug, device, or cosmetic"). Another provision, section 431.082, provides that food shall be deemed misbranded if "any word, statement, or other *information required by or under the authority of this chapter to appear on the label or labeling* is not prominently placed thereon with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." *Id.* § 431.082(g) (emphasis added).

Given TDH's general authority to protect public health and, moreover, that chapter 431 expressly contemplates state food labeling rules, we conclude that the TDH rule requiring dietary supplements containing ephedrine to bear a label with a telephone number for reporting adverse events is authorized by and consistent with TDH's statutory authority. Furthermore, given that chapter 431 contemplates state food labeling rules, the rule cannot be said to impose additional burdens, conditions, or restrictions in excess of or inconsistent with the relevant statutory provisions.

The argument has been made that this particular labeling requirement exceeds TDH's authority because, as your query suggests, it "mandat[es] the use of a federal reporting system," the FDA MedWatch program, which your query asserts "was not operationally designed or intended by [the] United States Congress or the Texas Legislature for use by or for state agencies, state purposes or state consumers." Request Letter, *supra* note 1, at 1. Other comments we have received suggest

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[3]Brief from Susan K. Steeg, General Counsel, Texas Department of Health, to Susan D. Gusky, Chair, Opinion Committee at 4 (Oct. 4, 2001) (on file with Opinion Committee).

that the rule is problematic because it attempts to "commandeer" a federal system of reporting,[4] or "dictate" the operation of the system.[5]

The required label does not mandate use of the federal reporting system but rather requires that the program's toll-free number be provided to consumers on product labels. Consumers have the choice to report a suspected adverse event to the FDA at this number. Although this office does not find facts in the opinion process,[6] information we have received from the FDA indicates that the MedWatch program is intended for use by the general public and the TDH rule is consistent with the goals of the MedWatch program. First, we have received a letter from the FDA indicating that the MedWatch program is intended for both medical professionals and consumers to use to report adverse events. *See* Letter from Bernard A. Schwetz, D.V.M., Ph.D., Acting Principal Deputy Commissioner, United States Food and Drug Administration, to Honorable John Cornyn, Texas Attorney General (Oct. 5, 2001) (on file with Opinion Committee) [hereinafter FDA Letter] ("The FDA MedWatch system is intended to collect information related to adverse events associated with FDA regulated products. While the system was originally designed to accept reports from healthcare professionals, it has since been expanded to accept calls from consumers and other interested parties."). The FDA's website also states that consumers may report adverse events relating to dietary supplements to the FDA by calling the MedWatch number. *See* www.cfsan.fda.gov/dms/ds-rept.html ("Consumers may also report an adverse event or illness they believe to be related to use of a dietary supplement by calling FDA at 1-800-FDA-1088."). Furthermore, the FDA letter indicates that the federal agency welcomes the exposure it would receive as a result of the TDH labeling requirement. *See* FDA Letter, *supra* ("TDH consulted with us on several occasions, during the Rule 229.462 development and subsequent to its adoption, concerning the capabilities of the MedWatch system and our interest in receiving this data. We advised TDH that we encourage the reporting of adverse events by consumers and other interested parties, that the MedWatch System has the capacity to handle these reports, and that Rule 229.462 could assist us in capturing valuable data associated with ephedra alkaloid adverse events.").

Based on the FDA's assertions, we see no basis for concluding that the TDH rule exceeds TDH's authority because the MedWatch number is not intended for consumers. Furthermore, we do not believe that a state rule that provides publicity for a federal program open to the general public with the consent of the federal agency may be fairly characterized as commandeering the program or dictating its operation. Finally, we do not believe that the Texas Legislature must expressly

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[4]Letter from Nancy A. Bukar, Director of State Government Relations, Consumer Healthcare Products Association, to Susan D. Gusky, Chair, Opinion Committee at 4 (Oct. 10, 2001) (on file with Opinion Committee).

[5]Letter Brief from A. Wes Siegner, Jr., Hyman, Phelps & McNamara, P.C., to Susan D. Gusky, Chair, Opinion Committee (Oct. 5, 2001) (submitted on behalf of American Herbal Products Association) (on file with Opinion Committee) [hereinafter AHPA Brief].

[6]*See, e.g.*, Tex. Att'y Gen. Op. Nos. JC-0020 (1999) at 2 (stating that investigation and resolution of fact questions cannot be done in opinion process); M-187 (1968) at 3 ("[T]his office is without authority to make . . . factual determinations."); O-2911 (1940) at 2 ("[T]his . . . presents a fact question which we are unable to answer.").

authorize a state agency to adopt a rule that may increase use of a federal program that is available to the general public; TDH's authority to impose labeling requirements under chapter 431 of the Health and Safety Code is sufficient.

We have also been urged to conclude that the labeling requirement exceeds TDH's statutory authority because it is not "reasonably necessary," in a brief relying on *Texas Department of Human Services v. Christian Care Centers*, 826 S.W.2d 715 (Tex. App.–Austin 1992, writ denied). *See* AHPA Brief, *supra* note 5, at 40. The court in that case observed that

> [l]ack of express authority for a particular act of an agency does not mean the agency has no authority for that act. An agency may have implied authority to take an action or promulgate a rule even though such authority might not be expressly enumerated in its enabling statute. Indeed, under a general grant of authority, an agency has all the implied authority *reasonably necessary* to accomplish a delegated purpose.

Christian Care Ctrs., 826 S.W.2d at 719 (emphasis added). Although Texas courts in some cases have required a state agency rule that is not expressly authorized by the legislature to be "reasonably necessary" to achieve an expressly delegated purpose, courts are also loath to substitute their judgment for the judgment of the agency. As the Texas Supreme Court has stated, courts must uphold administrative rules if they are reasonable: "The rules need not be, in the court's opinion, wise, desirable, or even necessary. Such rules need only be based on some legitimate position by the administrative agency involved." *Bullock v. Hewlett-Packard Co.*, 628 S.W.2d 754, 756 (Tex. 1982) (citations omitted); *see also Graves v. Morales*, 923 S.W.2d 754, 757 (Tex. App.–Austin 1996, writ denied) (citing *Bullock v. Hewlett-Packard Co.*, 628 S.W.2d at 756; *Chrysler Motors Corp. v. Tex. Motor Vehicle Comm'n*, 846 S.W.2d 139, 142 (Tex. App.–Austin 1993, no writ)); *McCarty v. Tex. Parks & Wildlife Dep't*, 919 S.W.2d 853, 854 (Tex. App.–Austin 1996, no writ). The court in *Christian Care Centers* invalidated the rule at issue in that case because it determined not only that the rule was "not reasonable in light of the circumstances present" but also that the rule was inconsistent with the overall purpose of the governing statutes. *See Christian Care Centers*, 826 S.W.2d at 721.

The record suggests that TDH had a legitimate basis for determining that the labeling requirement at issue was reasonably necessary to further the agency's express duty under chapter 431 of the Health and Safety Code to protect public health. In adopting the labeling requirement, TDH stated:

> The purpose of this section is to allow consumers to report adverse events associated with the use of ephedrine-containing dietary supplements. Adverse events monitoring systems, such as the FDA MedWatch program, are designed to identify unanticipated or unintended safety problems with use of marketed products. Patterns

> of adverse events help the FDA identify the need for further investigation to determine whether public health actions are needed. The information will be collected by the FDA and will be available for review to all interested parties.

25 Tex. Reg. 6514 (2000). In response to the comments that it could not justify singling out dietary supplements products containing ephedrine for special treatment, TDH explained that

> [s]ince there are no established and recognized requirements relative to safe dosing intake or ingredient level, there is a strong likelihood of a lack of any uniformity among different products. Products suspected of causing adverse events can be more expeditiously identified if the consumer has access to a single point for reporting adverse events associated with product consumption.

Id. at 6514. TDH also observed that

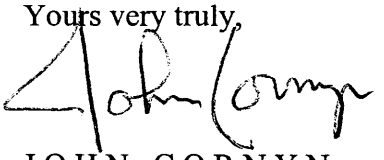
> [a]mple justification has been provided to the department for the need for a toll free number for consumers to report adverse events. Neither the department, nor any other agency, currently has access to all complaints reported concerning dietary supplements. Collection of this information by an agency subject to freedom of information review will allow all interested parties to review the data. Since 1995, over 700 adverse events associated with the consumption of ephedrine have been reported to the department since the passage of the Dietary Supplement Health and Education Act.

Id. at 6515. We conclude that TDH has advanced a legitimate basis for adopting the rule; we believe a court would reach the same conclusion. Moreover, in contrast to the rule at issue in *Christian Care Centers*, the TDH labeling rule is consistent with the purposes of chapter 431 of the Health and Safety Code.

SUMMARY

The Texas Department of Health did not exceed its statutory authority in promulgating a rule requiring dietary supplements containing ephedrine to bear a label with the United States Food and Drug Administration MedWatch program's toll-free telephone number for reporting adverse events.

Yours very truly,



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