IN THE SUPREME COURT OF THE STATE OF WASHINGTON

CERTIFICATION FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION	)	No. 102829-6
IN	)	En Banc
TRACY HALL, individually and on behalf of all others similarly situated,	)	
Plaintiff,	)	Filed: March 20, 2025
v.	)	
WALGREENS BOOTS ALLIANCE, INC.; WALGREEN CO.,	)	
Defendants.	)	

GONZÁLEZ, C.J.—Washington law prohibits businesses from using deceptive acts or practices. RCW 19.86.020. Businesses that use deceptive acts or practices may be liable under Washington's Consumer Protection Act (CPA). RCW 19.86.093. But our CPA does not apply to "actions or transactions permitted by any other regulatory body or officer acting under statutory authority of this state

or the United States." RCW 19.86.170. The parties refer to this as the CPA's "statutory safe harbor" provision.

The plaintiff here contends that a business has deceptively marketed a cough medicine as nondrowsy even though drowsiness is a known side effect of the active ingredient. The federal agency that regulates the medicine has concluded that it may be sold without warning labels alerting the consumer that it causes drowsiness. The agency has not, however, promulgated regulations that specifically permit such medicines to be labeled as nondrowsy.

A federal court has asked us whether, under RCW 19.86.170, labeling such cough medicines as nondrowsy falls within the statutory safe harbor. We conclude it does not.

BACKGROUND

Walgreens Boots Alliance Inc. and its subsidiary Walgreen Co. (Walgreens) sell company-branded over-the-counter cough medicines containing dextromethorphan hydrobromide. At least some of these cough medicines are sold with a prominent "nondrowsy" label on the front of the packaging.

Over-the-counter medicines are subject to regulation by the United States Food and Drug Administration (FDA). *See* 21 U.S.C. ch. 9 (Federal Food, Drug, and Cosmetic Act). The FDA has the authority to specify what over-the-counter drugs qualify as "safe, effective and not misbranded." 21 C.F.R. §§ 330.1, 330.10.

These regulations set out, among other things, the warnings that must accompany each drug. *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013).

The general class of medicines at issue here, antitussives, are regulated in 21 C.F.R. § 341. This regulation requires a drowsiness warning for certain antitussive drugs, but not for the one at issue here. 21 C.F.R. § 341.74(c)(4). The regulation does not say that sellers may put a "nondrowsy" label on these medicines. *Id*. However, the FDA did note in the administrative record "that there might be a secondary pharmacological action of an antitussive, tantamount to a sedative effect, that helps an individual to sleep." Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for OTC Antitussive Drug Products, 48 Fed. Reg. 48,576, 48,589 (Oct. 19, 1983). The FDA concluded, however, that any drowsiness was not sufficient to warrant a drowsiness warning. *Id.*

Tracy Hall bought one of these over-the-counter cough medicines from Walgreens that, she says, made her unexpectedly drowsy. She contends that drowsiness is a known side effect of medicines containing dextromethorphan hydrobromide. She filed a class action lawsuit against Walgreens in federal court, bringing a variety of claims, including claims under Washington's CPA.

Walgreens moved to dismiss, arguing, among other things beyond the scope of the certified question, that Hall's CPA claim failed because labeling the product nondrowsy was within the statutory safe harbor of RCW 19.86.170. The federal court denied the motion and certified this question to us:

> Under the Revised Code of Washington § 19.86.170, is labeling as "non-drowsy" an over-the-counter antitussive containing dextromethorphan hydrobromide an "action[] . . . permitted by . . . [a] regulatory body . . . acting under statutory authority . . . of . . . the United States" such that this labeling decision falls within the statutory safe harbor?

Ord. Certifying Question, *Hall v. Walgreens Boots All., Inc.*, No. 22-cv-00024, at 4 (N.D. Ill. Aug 14, 2023) (alterations in original). We accepted certification.

ANALYSIS

Under our system of separate and distributed powers, federal courts are sometimes in the position of hearing cases that turn on questions of unsettled Washington law. *E.g.*, *United States v. 1,216.83 Acres of Land*, 89 Wn.2d 550, 574 P.2d 375 (1978). Federal courts may ask, and this court may choose to entertain, such questions. RCW 2.60.020; *Convoyant, LLC v. DeepThink, LLC*, 200 Wn.2d 72, 73, 514 P.3d 643 (2022).

We are asked, here, to interpret a Washington statute. We review both certified questions and questions about the meaning of statutes de novo. *Parents Involved in Cmty. Schs. v. Seattle Sch. Dist., No. 1*, 149 Wn.2d 660, 670, 72 P.3d 151 (2003); *Dep't of Ecology v. Campbell & Gwinn, LLC*, 146 Wn.2d 1, 9, 43 P.3d

4 (2002). Our fundamental objective when interpreting statutes "is to ascertain and carry out the Legislature's intent, and if the statute's meaning is plain on its face, then th[is] court must give effect to that plain meaning as an expression of legislative intent." *Campbell & Gwinn*, 146 Wn.2d at 9-10. "Plain meaning 'is to be discerned from the ordinary meaning of the language at issue, the context of the statute in which that provision is found, related provisions, and the statutory scheme as a whole.'" *Lake v. Woodcreek Homeowners Ass'n*, 169 Wn.2d 516, 526, 243 P.3d 1283 (2010) (quoting *State v. Engel*, 166 Wn.2d 572, 578, 210 P.3d 1007 (2009)). While we read the statutory language in its full context, we do not add words to the legislation. *Rest. Dev., Inc. v. Cananwill, Inc.*, 150 Wn.2d 674, 682, 80 P.3d 598 (2003).

The legislature has directed us to interpret the CPA liberally to accomplish its beneficial purposes of protecting the consumer. *Vogt v. Seattle-First Nat'l Bank*, 117 Wn.2d 541, 548, 817 P.2d 1364 (1991) (quoting RCW 19.86.920). As part of that liberal construction, we also interpret exceptions narrowly. *Id.* at 552 (citing *Nucleonics All., Loc. Union 1–369 v. Wash. Pub. Power Supply Sys.*, 101 Wn.2d 24, 29, 677 P.2d 108 (1984)).

The statute in question says in full:

> *Nothing in this chapter shall apply to* actions or transactions otherwise permitted, prohibited or regulated under laws administered by the insurance commissioner of this state, the Washington utilities and transportation commission, the federal power commission or *actions or*

> *transactions permitted by any other regulatory body or officer acting under statutory authority of this state or the United States*: PROVIDED, HOWEVER, That actions and transactions prohibited or regulated under the laws administered by the insurance commissioner shall be subject to the provisions of RCW 19.86.020 and all sections of chapter 216, Laws of 1961 and chapter 19.86 RCW which provide for the implementation and enforcement of RCW 19.86.020 except that nothing required or permitted to be done pursuant to Title 48 RCW shall be construed to be a violation of RCW 19.86.020: PROVIDED, FURTHER, That actions or transactions specifically permitted within the statutory authority granted to any regulatory board or commission established within Title 18 RCW shall not be construed to be a violation of chapter 19.86 RCW: PROVIDED, FURTHER, That this chapter shall apply to actions and transactions in connection with the disposition of human remains.
>
> RCW 9A.20.010(2) shall not be applicable to the terms of this chapter and no penalty or remedy shall result from a violation of this chapter except as expressly provided herein.

RCW 19.86.170 (emphasis added).

The legislature clearly intended to exempt "actions . . . *permitted* by any other regulatory body . . . acting under statutory authority of . . . the United States," such as actions permitted by the FDA. Hall argues that this statutory safe harbor applies to activities that have been specifically permitted by a regulatory agency.

"Permitted" is not defined in the CPA. *See* RCW 19.86.010. "Undefined common statutory terms are given their common dictionary meanings unless there is strong evidence the legislature intended something else." *Michaels v. CH2M Hill, Inc.*, 171 Wn.2d 587, 601, 257 P.3d 532 (2011) (citing *City of Spokane ex rel.*

Wastewater Mgmt. Dep't v. Dep't of Revenue, 145 Wn.2d 445, 454, 38 P.3d 1010 (2002)).

A commonly used dictionary defines the transitive verb "permit" as

> 1 : to consent to expressly or formally
> *permit* access to records
> 2 : to give leave : AUTHORIZE
> 3 : to make possible.

MERRIAM-WEBSTER ONLINE DICTIONARY, https://www.merriam-webster.com/dictionary/permitted (last visited Mar. 12, 2025). Hall's interpretation is consistent with the first and second definitions. Walgreens' interpretation is loosely consistent with the third in that the regulation at issue does not prohibit labeling these medicines nondrowsy.

But we have long rejected the argument that the statutory safe harbor at issue here applies to the activities of a regulated industry unless those activities are specifically prohibited. Instead, to fall within the statutory safe harbor, "an agency must take 'overt affirmative actions specifically to permit the actions or transactions engaged in' by the person or entity involved in a Consumer Protection Act complaint." *Vogt*, 117 Wn.2d at 552 (quoting *In re Real Est. Brokerage Antitrust Litig.,* 95 Wn.2d 297, 301, 622 P.2d 1185 (1980)); *see also Panag v. Farmers Ins. Co. of Wash.*, 166 Wn.2d 27, 51 n.10, 204 P.3d 885 (2009).

Our Court of Appeals has also rejected a very similar argument to that made by Walgreens in *Walker v. Wenatchee Valley Truck & Auto Outlet, Inc.*, 155 Wn.

App. 199, 229 P.3d 871 (2010). In *Walker*, an automobile dealer argued that it was not subject to a CPA action for deceptive advertising under the statutory safe harbor because its business activities were regulated by the Department of Licensing. *Id.* at 210. The Court of Appeals concluded that

> [a]n industry practice falls within the regulation exception when the activities in question were "authorized by statute and that acting within this authority the agency took overt affirmative actions specifically to permit the actions or transactions." Stated another way, the activity in question must be expressly permitted instead of merely being not prohibited. No administrative code provision approved or authorized the advertising utilized here. Rather, the ad simply did not run afoul of the code's prohibitions.

Id. at 211 (alterations in original) (quoting *Real Est. Brokerage*, 95 Wn.2d at 301, and citing *Singleton v. Naegeli Reporting Corp.*, 142 Wn. App. 598, 607-08, 175 P.3d 594 (2008)).

In contrast, our legislature has extended the statutory safe harbor to "actions or transactions *otherwise permitted, prohibited or regulated* under laws administered by" three enumerated agencies: "the insurance commissioner of this state, the Washington utilities and transportation commission, the federal power commission." RCW 19.86.170 (emphasis added). The same sentence that applies the statutory safe harbor to actions "permitted, prohibited or regulated" by the three enumerated agencies applies the safe harbor to actions "permitted" by other state or federal regulatory bodies. *Id.* This difference must mean something, and what it naturally means is that the legislature intended the statutory safe harbor for

activities regulated by nonenumerated agencies to be limited to actions or transactions expressly permitted by the agency.

We recognize that in several cases courts have been less than exacting as to whether an action or transaction was "permitted, prohibited, or regulated" by the insurance commissioner, the utilities and transportation commission, or the federal power commission or permitted by some other agency. *See, e.g.*, *Vogt,* 117 Wn.2d at 552 ("The exemption applies only if the particular practice found to be unfair or deceptive is specifically permitted, prohibited or regulated" by federal banking regulators.); *Kaiser v. CSL Plasma Inc.*, 240 F. Supp. 3d 1129, 1140 (W.D. Wash. 2017) ("RCW 19.86.170 '"does not exempt actions or transactions merely because they are regulated generally; the exemption applies only if the particular practice found to be unfair or deceptive is specifically permitted, prohibited, or regulated."'" (quoting *Estes v. Wells Fargo Home Mortg.*, 2015 U.S. Dist. LEXIS 9359, at *11, 2015 WL 362904, at *5 (W.D. Wash. Jan. 27, 2015) (quoting *Miller v. U.S. Bank of Wash., NA*, 72 Wn. App. 416, 420, 865 P.2d 536 (1994)))).

We reject, however, any argument that *Vogt*, *Kaiser*, or *Miller* added words to the statute. Otherwise, we would run afoul of the rule that we will "not add words where the legislature has chosen not to include them." *Rest. Dev.*, 150 Wn.2d at 682. Instead, we attribute that unfortunate word choice to the density of

the statute, its lack of subsections, and the fact the additional words made no difference to the courts' reasoning.

Importantly, both *Vogt* and *Kaiser* rejected the defendants' argument that they fell within the statutory safe harbor, even though both cases drew it larger than the statute required. The fact those two courts drew the boundaries of that safe harbor larger than that required by the statute and still found the defendants were outside of it likely prevented the courts from examining the question more closely. While the *Miller* court did dismiss the plaintiffs' CPA claim, it did so on the grounds of federal preemption, not the contours of statutory safe harbor. 72 Wn. App. at 422. In all of these cases, the additional words were dicta.

We conclude that an action must be specifically and actively permitted by an agency to fall within the relevant statutory safe harbor. As the FDA has not specifically permitted labeling these over-the-counter drugs nondrowsy, that activity falls outside the statutory safe harbor.

Finally, we note that Walgreens spends much of its briefing arguing that any application of Washington's CPA here is preempted by federal law. We pass no judgment on whether Washington law is preempted by federal law under these facts. That is beyond the scope of the certified question.

CONCLUSION

We conclude that the relevant statutory safe harbor applies only to activities or transactions expressly permitted by the FDA. Accordingly, we conclude the activities alleged here do not fall within the statutory safe harbor and answer the certified question no.

González, C.J.

WE CONCUR:

Yu, J.

Montoya-Lewis, J.

Gordon McCloud, J.

Melnick, J.P.T.

No. 102829-6

MADSEN, J. (concurring)—I concur with the majority's holding that the particular act in question here, namely affixing "nondrowsy" labels on over-the-counter antitussives containing dextromethorphan hydrobromide (DXM), does not fall within the Washington Consumer Protection Act's (CPA) "statutory safe harbor" exemption, RCW 19.86.170. However, I write separately because I believe the majority errs in holding that the safe harbor provision applies only to actions or transactions that are *specifically* or *expressly* permitted by the U.S. Food and Drug Administration (FDA).

First, the plain language of the safe harbor provision does not include the words *specifically* or *expressly* in relation to the FDA. Second, whether the safe harbor provision requires specific or express permission matters because the regulatory framework followed by the FDA is not so categorical. Rather, agencies such as the FDA outline which warnings are required, but they do not list of all permissible labels that may help with advertising a product. Whether an action is permitted may be inferred if the resulting FDA monograph can be read to implicitly permit some labels.

In this case, because the FDA monograph that was prepared for the over-the-counter antitussives noted the lack of sufficient data to evaluate claims of DXM being used as sleep aids, it is not reasonable to infer that a "nondrowsy" label is *permitted*. Therefore, I concur that the answer to the certified question is no.

DISCUSSION

History of the Safe Harbor Provision

It is true that the CPA is to be liberally construed to serve its beneficial purposes. *See* RCW 19.86.920. "[T]he purpose of this act is to complement the body of federal law governing restraints of trade, unfair competition and unfair, deceptive, and fraudulent acts or practices in order to protect the public and foster fair and honest competition." *Id*. An overview of the history of the CPA shows that prior to the amendment of the act in 1974, the CPA safe harbor provision exempted only "actions or transactions otherwise *permitted*, *prohibited* or *regulated* under laws administered by the insurance commissioner of this state, the Washington utilities and transportation commission, the federal power commission or any other regulatory body or officer acting under statutory authority of this state or the United States" and "actions and transactions . . . required or permitted to be done pursuant to Title 48 RCW." Former RCW 19.86.170 (1967).

Under former RCW 19.86.170, this court in *Williamson v. Grant County Public Hospital District No*. 1, 65 Wn.2d 245, 251, 396 P.2d 879 (1964), held that the CPA did not apply to Grant County Public Hospital because it was a municipal corporation created by state statute and that "[i]ts powers are vested in its duly elected officials and medical

staff and regulated by statute." Thus, generally regulated industries were protected from the CPA whether or not the act or transaction at issue was regulated.

Then this court decided *Dick v. Attorney General*, 83 Wn.2d 684, 521 P.2d 702 (1974), which dealt with the question of whether a naturopath is exempt from the CPA because the practice of drugless healing is regulated under chapter 18.36 RCW. The *Dick* court clarified that the mere regulation of a business is not sufficient to be exempt from the CPA; rather, we must focus on whether the actions or transactions at issue are covered by those regulations. *Id*. at 688-89.

About four days after *Dick* was decided, the legislature in 1974 amended RCW 19.86.170. It established three exemptions to the CPA. As amended, it now states that nothing in chapter 19.86 RCW shall apply to actions or transactions that are (1) otherwise *permitted, prohibited*, *or regulated* under laws administered by the insurance commissioner[1] of this state, the Washington utilities and transportation commission, the federal power commission, or required or permitted to be done pursuant to Title 48 RCW, (2) *permitted* by any other regulatory body or officer acting under statutory authority of this state or the United States, or (3) *specifically permitted* within the statutory authority granted to any regulatory board or commission established *within Title 18 RCW*.

[1] RCW 19.86.170 clarifies that "actions and transactions prohibited or regulated under the laws administered by the insurance commissioner shall be subject to the provisions of RCW 19.86.020 and all sections of chapter 216, Laws of 1961 and chapter 19.86 RCW which provide for the implementation and enforcement of RCW 19.86.020."

The 1974 amendment inserted the "actions or transactions *permitted*" language in the second exemption and the "actions or transactions *specifically permitted* within the statutory authority granted to any regulatory board or commission" language in the third exemption into RCW 19.86.170. *See* H.B. 1276, 43d Leg., 3d Ex. Sess. (Wash. 1974). The amendment mainly affected the scope of the exemptions available to other regulatory bodies or officers. As amended, the current exemptions highlight that broader immunity is granted to the more highly regulated industries, such as the federal power commission, and less immunity is granted to regulatory boards or officers established within Title 18 RCW.[2]

The *Specially Permitted* Language Applies Only to Regulatory Boards or Commissions Established *within Title 18 RCW*

Here, the U.S. District Court certified the question of whether labeling over-the-counter antitussives containing DXM was an action *permitted* by a regulatory body so that it falls within the statutory safe harbor.

The majority looks at the plain language of RCW 19.86.170 and the dictionary definition of the word "permit" to determine whether the statutory safe harbor applies only to activities that have been *specifically* permitted by a regulatory agency. *See* majority at 6-7. Applying rules of statutory construction, the majority finds that the

[2] *See* Martha V. Gross, Comment, *The Scope of the Regulated Industries Exemption Under the Washington Consumer Protection Act*, 10 GONZ. L. REV. 415, 423 (1975).

legislature meant to say that the FDA here must have *specifically* or *expressly* permitted the acts or transactions at issue to be exempt from the CPA.[3]

This interpretation is erroneous because it adds language to the statute in contradiction of the well-established rules of statutory interpretation cited by the majority. "'Where statutory language is plain and unambiguous, courts will not construe the statute but will glean the legislative intent from the words of the statute itself.'" *HomeStreet, Inc. v. Dep't of Revenue*, 166 Wn.2d 444, 451-52, 210 P.3d 297 (2009) (quoting *Agrilink Foods, Inc. v. Dep't of Revenue*, 153 Wn.2d 392, 396, 103 P.3d 1226 (2005)). We are to assume that the legislature meant exactly what it said, and "[w]henever possible, statutes are to be construed so 'no clause, sentence or word shall be superfluous, void, or insignificant.'" *Id*. at 452 (internal quotation marks omitted) (quoting *Kasper v. City of Edmonds*, 69 Wn.2d 799, 804, 420 P.2d 346 (1966)); *State ex rel. Schillberg v. Barnett*, 79 Wn.2d 578, 584, 488 P.2d 255 (1971) ("each word of a statute is to be accorded meaning").

As discussed above, when the legislature amended RCW 19.86.170 in 1974, it inserted the language "actions or transactions *permitted*" as applied to regulatory bodies or officers and added the third exemption relating to "actions or transactions *specifically permitted* within the statutory authority granted to any regulatory board or commission

[3] "We conclude that an action must be specifically and actively permitted by an agency to fall within the relevant statutory safe harbor. As the FDA has not specifically permitted labeling these over-the-counter drugs nondrowsy, that activity falls outside the statutory safe harbor." Majority at 10.

established within Title 18 RCW." Thus, it qualified its previous use of the word "permitted" with the term "specifically" only as to entities established under Title 18 RCW.[4] This indicates an intent that businesses and professions regulated by Title 18 RCW agencies be subject to a more exacting standard to fall under the statutory safe harbor. Specific permission requires that an agency take "overt affirmative actions specifically to permit the actions or transactions engaged in." *In re Real Est. Brokerage Antitrust Litig.*, 95 Wn.2d 297, 301, 622 P.2d 1185 (1980). If the legislature so intended, it could have included the word "specifically" when it added the "permitted" language as applied to other regulatory bodies or officers such as the FDA, but it did not.

As the majority notes, we must "not add words where the legislature has chosen not to include them." *Rest. Dev., Inc. v. Cananwill, Inc.*, 150 Wn.2d 674, 682, 80 P.3d 598 (2003); *see* majority at 9. We cannot simply add the word "specifically" here and attribute it to *unfortunate word choice* by the legislature due to the density of the statute and its lack of subsections. *See* majority at 9. The word "permitted" is used four times in the statute, and the legislature added the word "specifically" only as applied to regulatory boards or commissions established *within Title 18 RCW*.

In *Vogt v. Seattle-First National Bank*, the court stated that the exemption in RCW 19.86.170 "applies only if the particular practice found to be unfair or deceptive is *specifically* permitted, prohibited or regulated." 117 Wn.2d 541, 552, 817 P.2d 1364

[4] *See* Craig C. Beles & Daniel Wm. Wyckoff, Comment, *The Washington Consumer Protection Act vs. the Learned Professional*, 10 GONZ. L. REV. 435, 448 (1975).

(1991) (emphasis added). Contrary to what the majority states, *Vogt* did in fact add words to the statute. Majority at 9. The court in *Miller v. U.S. Bank of Wash., NA*, further added to the confusion when it misquoted the exemption in RCW 19.86.170, incorrectly stating that it exempts "actions and transactions which are 'otherwise *permitted, prohibited or regulated* under laws administered by … *any other regulatory body or officer*.'" 72 Wn. App. 416, 420, 865 P.2d 536 (1994) (alteration in original) (emphasis added). *Miller* subsequently quoted *Vogt* for the incorrect standard that the exemption applies only if the particular practice found to be unfair or deceptive is "*specifically* permitted, prohibited, or regulated." *Id*. at 420-21 (emphasis added). The plain language of the statute does not support such an interpretation.

Specific or *Express* Permission Is Inconsistent with the FDA Regulatory Framework

Another concern is the practical effect of interpreting "permitted" to mean specific or express permission requiring an affirmative action by a regulatory body. The FDA regulates the sale of over-the-counter drugs pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301. The FDA promulgates numerous regulations governing labeling and required warnings on drugs. It does so primarily through "monographs," which are detailed regulations that specify the conditions under which a given therapeutic class of over-the-counter drugs may qualify as "safe, effective and not misbranded." 21 C.F.R. §§ 330.1, 330.10. It is "[l]ike a recipe," setting out the "FDA-approved active ingredients for a given therapeutic class of OTC drugs" and setting out the dosage, formulations, and labeling requirements including precise warnings that must

accompany each drug. *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013). Developing a monograph is an extensive process.

Monographs do not provide an exhaustive list of statements that must *not* appear on labels, thus the FDCA has a general prohibition against labeling that is "false or misleading in any particular." 21 U.S.C. § 352(a). The FDA regulations require over-the-counter labels to comply with the applicable monograph and with the FDCA's prohibition on false or misleading labels. *See* 21 C.F.R. §§ 330.1, 341.1(a). The monographs typically provide which applicable warning labels must be placed on certain over-the-counter drugs, but they do not function to provide an exhaustive list of all labels that are *permitted* to be placed on certain drugs.

If the FDA had sufficient data and, after extensive review, had determined that over-the-counter antitussives containing DXM did not cause drowsiness and therefore did not require a "may cause drowsiness" label, then it would be reasonable to find that the FDA implicitly permitted a "nondrowsy" label. This would be in line with how monographs work; they outline which warning labels are required, but they do not function to make a list of all permissible labels that may be permitted. It would be impractical to expect them to do so.

Here, the monograph is silent on the matter of "nondrowsy" labels. *See* 21 C.F.R. § 341.74(c)(4). The FDA noted that "[t]he Panel made no mention of drowsiness in its discussion of dextromethorphan" and that it was "not aware of data demonstrating that the antitussive ingredient[] . . . dextromethorphan could be classified as a Category I

nighttime sleep-aid[] or that [it] require[s] a drowsiness warning." Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for OTC Antitussive Drug Products, 48 Fed. Reg. 48,576, 48,589 (Oct. 19, 1983). Due to the lack of sufficient data to evaluate such claims of DXM being used as sleep aids, the FDA determined that the "sleep-aid claims directly related to the ability of an antitussive ingredient to cause drowsiness . . . will remain in Category III." *Id*. Due to the lack of data on whether or not over-the-counter antitussives containing DXM cause drowsiness, the FDA could not have permitted the "nondrowsy" label; thus, the statutory safe harbor in the CPA does not apply.

With these considerations in mind, I respectfully concur.

Madsen, J.

Stephens, C.J.

Johnson, J.

Whitener, J.