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I. Introduction

What do a Food and Drug Administration (FDA) guidance document and a Hans Christian Andersen fable have in common? Unfortunately, more than one might hope.

The fable of the emperor's new clothes is iconic for the human tendency towards collective avoidance of speaking truth to power. The fable is also a metaphor for smooth-talking tricksters hoodwinking a government leader.

A recent FDA guidance document indicates one or both of these failings. On March 7, 2016, FDA published a notice in the *Federal Register*, stating that it was revising the agency's guidance on dietary supplement labeling.[1] The reason for the revision, FDA declared, was that the agency was, "made aware that the guidance was inaccurate in one detail."[2] FDA's modification of this detail—the new clothes—permits dietary supplements to be generically labeled. Specifically, FDA states, "the term 'dietary supplement' may be used as the *entire* statement of identity for a dietary supplement".[3]

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1. A Dietary Supplement Labeling Guide: Chapter II. Identity Statement; Guidance for Industry; Availability, 81 Fed. Reg. 11,813, 11,814 (Mar. 7, 2016).

2. *Id.* at 11,814.

3. *Id.* (emphasis added).

Who the smooth-talking weavers were who sold FDA this invisible garment is not transparent. Nonetheless, it is transparent that the FDA's "correction" is in clear error. The original 2005 guidance language was accurate based on the following:

- the plain language of the Food, Drug, and Cosmetic Act;
- the plain language of 21 C.F.R. § 101.3(g); and
- even if one accepts, *arguendo*, that the law is ambiguous, the new interpretation does not comport with numerous rules of statutory interpretation.

Moreover, this change violates the Administrative Procedures Act and the FDA's rules on notice and comment. This change is a disguised rescission of 21 C.F.R. § 101.3(g) without a proper opportunity for the public to be heard under notice and comment rulemaking.

II. Interpretation of the Law on Dietary Supplement Naming

A. The 2005 Guidance Accurately Interpreted the Plain Language of the Statute

The starting point for analysis is the text of the statute.[4] The Federal Food, Drug, and Cosmetic Act states that a dietary supplement is misbranded if: "the label or labeling of the dietary supplement fails to identify the product by using the term 'dietary supplement', which term may be modified with the name of such an ingredient."[5] Thus, the term "dietary supplement" or the modification must be included in the identification of a dietary supplement. This is how dietary supplements are distinguished from conventional foods.

Nothing in the wording indicates that "dietary supplement" is or can be the entire statement of identity for the entire diverse category of dietary supplements. Note the sleight of hand. The requirement to *identify* dietary supplements as dietary supplements disappears. In its place is substituted the creation of

4. *See, e.g.*, Desert Palace, Inc. v. Costa, 539 U.S. 90, 98 (2003) ("Our precedents make clear that the starting point for our analysis is the statutory text.").

5. Federal Food, Drug, and Cosmetic Act 21 U.S.C.A. § 343(s)(2)(B) (2010) [hereinafter FDCA or Act].

a *statement of identity* requirement for dietary supplements. By way of illustration, with a category of conventional food, all cheeses must be identified as cheese, but "cheese" is not the complete statement of identity for all cheeses.

Because the meaning of the language of the statute is unambiguous, further construction of the language is normally neither necessary nor permitted.[6] Any deference to the agency interpretation of the statute is lost when that interpretation is contrary to the plain meaning of the statute or is unreasonable.[7] The plain meaning of the Food, Drug, and Cosmetic Act is that the term "dietary supplement" or a modification must be included within the identification of a dietary supplement, but nothing in the Act's wording indicates that the term may be a complete statement of identity.

B. The 2005 Guidance Accurately Interpreted the Plain Language of the Regulation

The plain language in FDA regulation 21 C.F.R. § 101.3(g) is clear that the term "dietary supplement" or a modification must be included in the identity of a dietary supplement. Also clear from the regulation is that the term "dietary supplement," is not a complete statement of identity. The FDA rule, 21 C.F.R. § 101.3(g), reads:

> (g) Dietary supplements shall be identified by the term "dietary supplement" *as a part of* the statement of identity, except that the word "dietary" may be deleted and replaced by the name of the dietary ingredients in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins).[8]

The language of the regulation plainly contradicts the FDA's "correction" in the March 7, 2016, *Federal Register*. The "dietary supplement" *is a part of* the statement of identity and therefore cannot be the entire statement of identity. Even the

6. *See, id.*; Connecticut Nat. Bank v. Germain, 503 U. S. 249, 253-254 (1992) ("When the words of the statute are unambiguous, the 'judicial inquiry is complete.'" (quoting Rubin v. United States, 449 U. S. 424, 430 (1981)).

7. *See* Sullivan v. Everhart, 494 U.S. 83, 88-89 (1990) (citing Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842–43 (1984)).

8. 21 C.F.R. § 101.3(g) (emphasis added).

most tortuous reading of the regulation cannot support the FDA's erroneous "correction."

C. Even if One Accepts, *Arguendo,* That the Phrase is Ambiguous, the New Interpretation Does not Comport With the Rules of Statutory Interpretation

1. Interpret the Language Within the Context of the Provision

Any exercise of statutory construction must be made within the context of the whole statute.[9] Statutory interpretation is a "holistic endeavor".[10]

The context for the provision in question in the Federal Food, Drug, and Cosmetic Act (FDCA) § 403(s), states that a dietary supplement is misbranded if:

> (1) it is a dietary supplement; and
>
> (2)(A) the label or labeling of the supplement fails to list—
>
> (i) the name of each ingredient of the supplement that is described in section 321(ff) of this title; and
>
> (ii)(I) the quantity of each such ingredient; or (II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;
>
> (B) the label or labeling of the dietary supplement fails to identify the product by using the term "dietary supplement", which term may be modified with the name of such an ingredient.[11]

This part of the FDCA describes certain details that must be included on a dietary supplement label or the product will be misbranded. These details are not the beginning and end of the labeling requirements for dietary supplements; there are many other labeling requirements elsewhere in the FDCA that apply to

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9. *See* John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank, 510 U.S. 86, 94-95 (1993); *see also* Massachusetts v. Morash, 490 U.S. 107, 115 (1989) ("'[I]n expounding a statute, we [are] not . . . guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.'").

10. *See* Smith v. United States, 508 U.S. 223, 233(1993) (quoting United Sav. Assn. v. Timbers of Inwood Forest Assocs., Ltd., 484 U.S. 365, 371 (1988).

11. 21 U.S.C.A § 343(s) (2010).

dietary supplements.[12] Clearly, this unique dietary supplement requirement is intended to be read in conjunction with other general labeling requirements in the Food, Drug, and Cosmetic Act. Specifically, the above provision relates to some unique aspects of the dietary supplement label that distinguish it from conventional foods.

Nothing in the context concerns overall naming of dietary supplements. Nowhere does the language even use the term "statement of identity." Within this context, there is no ambiguity in the language in the Act. The plain language indicates terms that, if absent from the label, will result in a misbranded product. Nothing more.

2. If Need be, Interpret the Language Within the Overarching Purpose of the Act

The 1938 Food, Drug, and Cosmetic Act's primary purpose is to protect consumer's health, as well as their pocketbooks. The latter purpose included a provision requiring that food "bear its common or usual name," which was added in 1938 in large part so that consumers could make value comparisons in the marketplace. Allowing a generic statement of identity for all countless, varied dietary supplements is contrary to the purpose of the Act.[13] Clearly, Congress never intended § 403(s)(2)(B) to limit the FDA's ability to require truthful, informative labeling of the statement of identity of dietary supplements. Statutes, when ambiguous, should be interpreted so as best to carry out their statutory purpose.[14]

3. Reconcile With Other Provisions of the Act to Produce a Harmonious Whole

Any interpretation must be read in the context of the entire statute so as to produce a harmonious whole.[15] Section 403(i)(1)

12. *See, e.g.*, 21 U.S.C.A. § 343-2(a); 21 U.S.C.A. § 342(g); 21 U.S.C.A. § 379aa-1(b).

13. S*ee* NEAL FORTIN, FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE 31 (Wiley, 2d ed. 2017).

14. *See* Reves v. Ernst & Young, 494 U.S. 56, 60-61 (1990).

15. *See* United Sav. Assn. v. Timbers of Inwood Forest Assocs., Ltd., 484 U.S. 365, 371 (1988) (favors a meaning that produces a substantive effect compatible with the rest of the law).

of the Act requires that a food label must bear the common or usual name of the food.[16] The generic term, "dietary supplement," is not the common or usual name of all dietary supplements.[17] "Dietary supplement" is the name of the entire regulatory category rather than the common or usual name or any specific food.[18]

4. The Rule of Continuity

Similar to the favoring of harmonious interpretation, the rule of continuity directs us to assume that Congress does not discontinue duties or obligations without some clear statement.[19] Nothing in the statute or the legislative history indicates that Congress intended to repeal the obligation that dietary supplements be labeled under the general requirements for a statement of identity for packaged food (including dietary supplements, which are a subcategory of "food" under the Act). In particular, exemptions from other statutory requirements should be read narrowly.[20]

5. Repeal by Implication Disfavored

To reconcile FDA's current interpretation with other provisions of the Act would require negating the FDCA requirement for a statement of identity for dietary supplements.[21] If Congress had intended such major change in the law, the language of the statute would have indicated it. It is absurd to believe that Congress *sub silentio* suspended section 403(i)(1) of the Food, Drug, and Cosmetic Act from application

16. FDCA 21 U.S.C. § 403(i)(1).

17. Brian Scarbrough, *Dietary Supplements: A Review of United States Regulation with Emphasis on the Dietary Supplement Health and Education Act of 1994 and Subsequent Activity*, DIGITAL ACCESS TO SCHOLARSHIP AT HARV. (Nov. 14, 2017), https://dash.harvard.edu/bitstream/handle/1/8852160/scarbrough.pdf?sequence=1.

18. *Id.*

19. *See* Green v. Bock Laundry Mach. Co., 490 U.S. 504, 521 (1989) ("A party contending that legislative action changed settled law has the burden of showing that the legislature intended such a change."); *see also* Finley v. United States, 490 U.S. 545, 554 (1989) ("Under established canons of statutory construction, 'it will not be inferred that Congress, in revising and consolidating the laws, intended to change their effect unless such intention is clearly expressed.'" (quoting, Anderson v. Pacific Coast S.S. Co., 225 U.S. 187, 199 (1912)).

20. *See, e.g.*, Commissioner v. Clark, 489 U.S. 726, 739 (1989).

21. FDCA § 403(i)(1).

to dietary supplements. As a rule, exemptions or exceptions to the general requirements of an act are not created unless specified by Congress.[22]

6. The "Dog Didn't Bark" Canon

Similar to the rule disfavoring repeal of requirements, without express statutory language is the "dog didn't bark" canon. The presumption is that a prior legal rule should be retained if no one in legislative deliberations discussed any changes in the rule.[23]

7. Avoid Unreasonable Results

Under the FDA revised guidance, statements of identity on dietary supplement labels could be changed as follows:

Current statement of identity	**Permitted statement of identity under FDA's new guidance**
Garlic 1000 mg Supplement	dietary supplement
Fiber Supplement	dietary supplement
Iron Supplement 65 mg	dietary supplement
Multivitamin Supplement	dietary supplement
Ginger root dietary supplement	dietary supplement
D3 1000 IU dietary supplement	dietary supplement
Lutein 20 mg dietary supplement	dietary supplement
Fish Oil 1200 mg dietary supplement	dietary supplement

Statutory language should be construed reasonably. The new FDA interpretation is unreasonable.

8. Apply Common Sense

An interpretation of the statute should comport with common sense. FDA's new guidance creates an absurd result.

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22. *See* United States v. Smith, 499 U.S. 160, 166-67 (1991).

23. *See* Chisom v. Roemer, 501 U.S. 380, 396 n.23 (1991) ("Congress' silence in this regard can be likened to the dog that did not bark." *See* A. DOYLE, SILVER BLAZE, in THE COMPLETE SHERLOCK HOLMES 335 (1927)).

9. Review the Legislative History and Contemporaneous Interpretation

The primary goal of judicial interpretation of statutes is to ascertain and give effect to the intent of the legislature. In 1996, the FDA received numerous comments on its proposed new rule 21 C.F.R. § 101.3(g).[24] Nowhere in the legislative history did anyone construe the meaning of section 403(s)(2)(B) of the FDCA as supplying the complete statement of identity. All 1996 discussion revolved around including "dietary supplement" *as part of* the statement of identity. For example, "The agency has carefully reviewed these comments but concludes that the best reading of the act, as well as the agency's longstanding regulations that implement the act, require that the term 'dietary supplement,' or some form of this term, appear as part of the statement of identity."[25]

III. FDA's Violation of the Administrative Procedures Act

A. Failure to Give Notice and Comment

This change violates the Administrative Procedures Act and FDA's rules on notice and comment.

B. Disguised Rescission of a Rule Without Proper Notice and Comment

FDA's change is a disguised rescission of 21 C.F.R. § 101.3(g) without a proper opportunity to be heard under notice and comment rulemaking in violation of the Administrative Procedures Act section 553. The FDA rule 21 C.F.R. § 101.3(g) clearly identifies that the term "dietary supplement" is only a part of the statement of identity for a dietary supplement. The FDA's new guidance statement effectively negates 21 C.F.R. § 101.3(g) without the required rescission or amendment of the rule.

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24. Food Labeling: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation, 62 Fed. Reg. 49,826 (Sept. 23, 1997) (to be codified at 21 C.F.R. pt. 101).

25. *Id.* at 49,827.

In addition, this was a major change that should have had public participation—in accordance with FDA rule 21 C.F.R. § 10.115(g)(2)—before it was instituted. Changing the longstanding meaning of the guidance and effectively negating the plain language of the FDA's rule of 21 C.F.R. § 101.3(g) was a major change that required public participation through notice and comment before it could be effectuated.

The April 2005 FDA guidance for industry, "A Dietary Supplement Labeling Guide," was accurate. Therefore, FDA should immediately reinstate the April 2005 guidance language on this detail. Specifically, in Chapter II, Identity Statement, question 3 asked, "Can the term 'dietary supplement' by itself be considered the statement of identity?" The 2005 response to the question said that it could not. This interpretation is consistent with the plain meaning of section 403(s)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 101.3(g).

IV. Conclusion

To be candid, no one wants to see the emperor naked. It is unseemly, undermines respect, and is, frankly, more than a little disturbing. FDA must remedy this situation immediately. No matter how humiliating it might be for FDA to admit it has no clothes, recognizing the truth beats walking around naked.

The truth of the law regarding the naming of dietary supplements is clear. The FDA's new guidance regarding the statement of identity for dietary supplements leaves the agency naked with not even a fig leaf to cover itself. Moreover, FDA is breaking the law on notice and comment rulemaking.

What is not clear is why FDA made such a blatant and obvious error of law. How much of the metaphor of the emperor's new clothes applies? Is FDA collectively avoiding speaking truth regarding the new guidance? Or did FDA get hoodwinked by a smooth-talking trickster? More troubling than naked leadership on a small matter is what the mistake might reveal about the state of this important federal agency.