The Food and Drug Administration's Discretion to Approve Methods of Detection and to Define the Term "No Residue" Pursuant to the Federal Food, Drug, and Cosmetic Act

The Food and Drug Administration has the discretionary authority under the DES proviso to the Delaney Clause of the Federal Food, Drug, and Cosmetic Act to prohibit the use of an additive in animal feed if the FDA concludes that there is no method that can "reliably measure and confirm" whether the additive contains residues of carcinogenic concern at or above the "no residue" level.

Where the FDA has already approved a method for detecting the presence of residues of carcinogenic concern, the DES proviso does not require the FDA to revise its regulations to adopt the "best available" such method.

The FDA lacks the discretion to determine that an edible tissue contains "no residue" when a method of detection reveals the presence of residues of carcinogenic concern that is below the "no significant risk" level.

October 13, 1995

MEMORANDUM OPINION FOR THE ASSISTANT ADMINISTRATOR AND GENERAL COUNSEL
ENVIRONMENTAL PROTECTION AGENCY
AND THE
GENERAL COUNSEL
DEPARTMENT OF HEALTH AND HUMAN SERVICES

This memorandum responds to the Environmental Protection Agency's ("EPA") and the Food and Drug Administration's ("FDA") request for our opinion regarding the FDA's regulations implementing what is known as the "DES proviso" to the Delaney Clause of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-393 (the "Act").[1] Both agencies have certain responsibilities under the Act, which establishes federal regulatory authority over the safety of food additives, human and animal drugs, certain pesticides, and cosmetics.

I. Background

The Act requires that a food additive (including additives to animal feed) be found to be "safe" before the FDA authorizes its use. The Delaney Clause prohibits such a finding of safety with respect to a substance found to induce cancer in man or animal. The DES proviso carves out an exception to the Delaney Clause, allowing cancer-inducing agents to be added to animal feed if the FDA finds that the additive will not harm the animals, and that no residue of the additive will

[1] Letter for Walter Dellinger, Assistant Attorney General, Office of Legal Counsel, from Jean C. Nelson, General Counsel, Environmental Protection Agency, and Harriet S. Rabb, General Counsel, Department of Health and Human Services (Dec. 8, 1994).

be found in any edible portion of the animal after slaughter or in any food from the animal. The presence of residue is to be determined by "methods of examination prescribed or approved by the Secretary by regulations." *Id.* § 348(c).[2]

The proviso was enacted in 1962 to allow substances such as the animal drug diethylstilbestrol, abbreviated as DES, to be used in appropriate situations. Pub. L. No. 87–781, § 104(f), 76 Stat. 780, 785 (1962). Under the Delaney Clause without the proviso, new applications for the use of drugs like DES, a carcinogen, would ordinarily have been kept from the market. However, because drugs like DES, when used properly, pass quickly out of the treated animal's system, may leave no detectable residue in edible tissue, and do not harm the animal, Congress permitted the use of such substances. *See Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975, 979 (D.C. Cir. 1974).

Over the years since the DES proviso was enacted, the FDA has implemented its terms through a series of regulatory decisions. Its current regulations, which embody the sensitivity of method ("SOM") approach, contain several discrete elements. The central feature of the regulations is the FDA's operational definition of the statutory term "no residue." Under the definition, the FDA determines a level of residue for any given food additive that will be considered to satisfy the "no residue" finding required under the proviso. This "no residue" level is calculated in several steps. *See* 21 C.F.R. § 500.84(c) (1995). First, the FDA determines a maximum level of concentration of any "residue of carcinogenic concern" from the additive in question that poses no significant increase in the risk of cancer to people (the "no significant risk" level). *Id.* § 500.84(c)(1). Next, the FDA evaluates the different foods through which a human might consume some of the additive and estimates the amount of such foods that are consumed in the human diet. Based on these estimates of food intake, the FDA then des-

[2] The Delaney Clause with the DES proviso states:

(1) The Secretary shall —

(A) by order establish a regulation . . . prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used. . . .

. . . . .

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary —

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) of this section) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; . . . .

21 U.S.C. § 348(c). The Delaney Clause with the DES proviso quoted above is similar to the provisions in 21 U.S.C. § 360b(d)(1)(I), which governs the approval of new animal drugs, and 21 U.S.C. § 379e(b)(5)(B), which governs the approval of color additives.

ignates a level of concentration for each edible tissue in which the additive might be found such that the "no significant risk" level for the total diet is not exceeded. *Id.* § 500.84(c)(2). So long as concentrations in an edible tissue are below the maximum level of concentration for that tissue, the FDA considers the edible tissue to contain "no residue." *Id.* [3]

The FDA requires the sponsor of any additive seeking relief under the DES proviso to submit a "regulatory method" of detection that can "reliably measure and confirm" the presence of any residue of carcinogenic concern equal to or above the "no residue" level for that compound. *Id.* §§ 500.86, 500.88. However, the FDA does not necessarily require a sponsor to employ the most sensitive detection method available.

The EPA and the FDA (collectively "the agencies") have posed three separate questions with respect to the FDA's current approach to implementing the DES proviso. The first two raise issues concerning the FDA's discretion to approve a method of detection, the results of which will be accepted by the FDA for purposes of the proviso. The third question concerns the FDA's discretion to define "no residue" as set forth above. Specifically, we address the following questions: (1) whether the FDA has the discretion to refuse to permit the use of an additive in animal feed if it finds that there is no method that can "reliably measure and confirm" the presence of residues of carcinogenic concern at and above the "no residue" level for such residues; (2) whether the FDA must revise its regulations to adopt more sensitive methods when they become available once it has approved a method of detection; and (3) whether the FDA has the discretion to determine that an edible tissue contains "no residue" when a method of detection reveals the presence of residues of carcinogenic concern that is below the "no significant risk" level. We discuss our answers to each of these questions below.

II. The FDA's Discretion to Approve Methods of Detection

A. Must the FDA Approve a Method of Detection?

The DES proviso authorizes the use of a cancer-inducing additive in animal feed if the FDA finds "that no residue of the additive will be found (by methods of examination prescribed or approved by the [FDA] by regulations . . .) in any edible portion of such animal." 21 U.S.C. § 348(c)(3)(A)(ii). The agencies have

[3] As explained by the FDA:

> [T]he [SOM] procedures provide for a quantitative estimation of the risk of cancer presented by the residues of a carcinogenic compound proposed for use in food-producing animals. "No residue" remains in food products when conditions of use, including any required preslaughter withdrawal period or milk discard time, ensure that the concentration of the residue of carcinogenic concern in the total diet of people will not exceed the concentration that has been determined to present an insignificant risk.

52 Fed. Reg. 49,572 (1987). Thus, the SOM regulations base a "no residue" finding on a determination that the additive creates "no significant risk."

asked whether the FDA may use a method's inability to detect residues at the FDA's "no significant risk" level (that is, the method's sensitivity) as a basis for not approving that method, where the approval of at least one method is necessary in order for an additive itself to be approved. This phrasing of the issue suggests two questions that can usefully be separated.

The first is whether the proviso contemplates that at least one method of detection be approved by the FDA; in other words, whether the FDA lacks the discretion to decide that at present no satisfactory method exists with respect to a specific additive. If the proviso were read to require the approval of at least one method, notwithstanding its lack of sufficient sensitivity, this would be equivalent to reading the proviso as imposing a nondiscretionary duty on the FDA to approve some method.[4] The proviso contains no language explicitly imposing such a duty on the FDA. Finding one would require inferring it from elsewhere in the statute, either because of express language found elsewhere or because of the structure of the statute as a whole. In fact, however, far from undermining the initial view that the FDA is under no such duty, the rest of the statutory scheme reinforces this conclusion.

The Delaney Clause and its DES proviso are subparts of the comprehensive statutory scheme under which the FDA approves proposed uses of food additives. *See* 21 U.S.C. § 348(c)(3). Under this scheme the FDA may *not* issue a regulation approving the use of any food additive if "a fair evaluation of the data before the [FDA] fails to establish that the proposed use of the food additive . . . will be safe." 21 U.S.C. § 348(c)(3). The statute, in other words, requires that safety is not to be presumed, but rather must rest on an affirmative showing of the predicate facts necessary to support such a conclusion.[5]

Before the sponsor of a cancer-inducing additive is even put to the task of proving safety, however, that additive must satisfy the DES proviso, because if it does not satisfy the proviso, the Delaney Clause will apply to it, and the Delaney Clause imposes a required finding of "not safe" with respect to cancer-inducing additives. As a necessary condition for satisfying the proviso, the FDA has stated that a food additive must not be present in an edible tissue in concentrations above the "no significant risk" level for that tissue. *See* 21 C.F.R. § 500.84. This means

[4] On occasion, the FDA will withdraw its marketing approval of animal drugs, which are also governed by the Delaney Clause and the DES proviso, because, among other reasons, there is no approved method of detection and, hence, no means to demonstrate that the proviso is satisfied. In the sole instance we found of this position being raised in litigation, the court affirmed the FDA's action without reaching the propriety of the FDA's basing its determination on the absence of any approved method of detection. *See Rhone-Poulenc, Inc. v. FDA*, 636 F.2d 750, 752 n.2 (D.C. Cir. 1980).

[5] That the statute generally requires an affirmative showing of safety—the absence of evidence of risk of harm is insufficient to satisfy the statute—is reinforced by placing the burden of proving safety on the sponsor. As one court summarized the matter: "[I]f the substance is deemed a food additive, it is presumed to be unsafe . . . ." *United States v. Two Plastic Drums, More or Less of an Article of Food, Labeled in Part: Viponte Ltd. Black Currant Oil Batch No. BOOSF 039*, 984 F.2d 814, 816 (7th Cir. 1993). "The thrust of the [Food Additives Amendment Act of 1958] was to put upon processors rather than the government the burden of proving that a newly discovered substance added to food is safe if used within specified quantities." *Id.* at 819.

that a finding of "no significant risk" is also a necessary predicate to FDA's potential ultimate conclusion that the additive is "safe."

It would be odd for Congress to have written a statute whose basic requirement is that the predicate facts for a finding of safety must be affirmatively established by the sponsor of any additive, and subsequently to have amended that statute by inserting a new subpart in which the requirement of an affirmative showing was eliminated, without any indication in the text that such a fundamental change was intended. Yet, just such an odd outcome would result here if the FDA were compelled to approve an insufficiently sensitive method. The requirement that safety be proven, not presumed, was at the very heart of the legislative changes codified in the Food Additives Amendment Act of 1958, of which §348(c)(3) is a key provision. *See, e.g., Two Plastic Drums, More or Less*, 984 F.2d at 816–19. However, if the FDA were required to apply the proviso based solely on results from a method inadequate to confirm "no significant risk," the FDA would be in the position of presuming a predicate fact — the absence of significant risk — that it considered necessary to its ultimate safety determination. There is absolutely no evidence in either the statutory text or the legislative history that such a reversal was intended, and by far the more natural reading of the statute is that the same requirement of an affirmative showing applies throughout.

In sum, the DES proviso does not impose an obligation on the FDA to approve at least one method. To the contrary, the FDA has discretion to refuse to permit the use of unsatisfactory detection methods.

The analysis to this point has assumed that it is within the FDA's discretion to use levels of risk as one determinant in implementing the method selection portion of the DES proviso. This issue presents the second question we must explicitly examine: acknowledging that the FDA has discretion to reject a detection method for some reason, is the method's inability to detect no significant risk levels one of the permissible reasons for the exercise of that discretion? This question arises because an agency's exercise of discretion will not be sustained if the agency considers factors that are either impermissible or irrelevant under the statute under which the agency is acting. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider . . . ."); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (The question is "whether the decision was based on a consideration of the relevant factors.").

As an initial matter, a method's ability to detect the "no significant risk" level seems to be a permissible reason for exercising discretion under a statute that requires an affirmative showing of safety, because a finding that an additive does not pose a significant risk is directly relevant to a determination of safety. *See, e.g., Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 642 (1980) (" '[S]afe' is not the equivalent of 'risk free.'. . . [A] workplace can

hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm.''). As plausible as this conclusion appears, two court of appeals decisions interpreting the Delaney Clause may cast doubt on it and cause us to consider a possible counter argument. *See Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), *cert. denied*, 507 U.S. 950 (1993); *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988). Both *Public Citizen* and *Les* hold that the fact that an additive produces extremely low levels of risk (de minimis levels) does not provide the FDA or the EPA with a basis for refusing to ban a cancer-inducing additive under the Delaney Clause. The courts reach this result by concluding that Congress precluded taking risk levels into account in reaching that decision under the Delaney Clause. *Les*, 968 F.2d at 989 (''Thus, the legislative history supports the conclusion that Congress intended to ban all carcinogenic food additives, regardless of amount or significance of risk, as the only safe alternative.''); *accord Public Citizen*, 831 F.2d at 1122.

In *Public Citizen*, the court did not conclude that the FDA completely lacked discretion in implementing the Delaney Clause. Specifically, it confirmed that the FDA did indeed have discretion to determine whether a color additive was cancer-inducing in the first place. 831 F.2d at 1112. The government sought to use the existence of this discretion to support its argument that the FDA had discretion to approve carcinogens that posed merely a de minimis risk by claiming that the FDA's decision could be justified as an exercise of the FDA's admitted discretion to make that prior determination. The court rejected that argument, concluding that there was nothing in the record that could support the exercise of such discretion in this instance, where studies done under accepted agency protocols had produced results that the agency had routinely found supported a finding of carcinogenicity. *Id.* at 1122. In particular, the court held that the FDA could not use the fact that risk was de minimis as the basis for a finding that the substance does not induce cancer.

> Congress did not intend the FDA to be able to take a finding that a substance causes only trivial risk in humans and work back from that to a finding that the substance does not ''induce cancer in . . . animals.'' This is simply the basic question—is the operation of the clause automatic once the FDA makes a finding of carcinogenicity in animals?—in a new guise.

Id. at 1121 (alteration in original).

A broad reading of *Public Citizen* might suggest that levels of risk associated with a substance may not inform *any* discretionary judgments made under the Delaney Clause, because Congress did not intend the FDA to be able to take a finding about the relative risk of a substance and ''work back'' from that to answer any question under the Clause where it could admittedly exercise discre-

tion. We believe this reasoning is unsound as applied to the FDA's using risk as a factor in selecting detection methods under the DES proviso, on two grounds.

First, both *Public Citizen* and *Les* were concerned with situations in which the agencies sought to *approve* the use of substances by escaping from the categorical ban on the Delaney Clause, even though the necessary conditions for triggering the Clause had been found to be present. Once those conditions have been found, both courts held, the operation of the Clause is automatic. Using a "no significant risk" benchmark as a basis for *rejecting* detection methods does not present such a situation, because the absence of a detection method does not provide an escape hatch to the Clause. Rather, it presents the opposite situation: if the DES proviso does not apply, then the Delaney Clause will. Thus, the FDA is not "working back" from a finding of "no significant risk" to a discretionary judgment that stops the automatic bar of the Delaney Clause from taking effect. Instead, accept the results of a detection method means that the automatic ban of the Delaney Clause will apply. As a consequence, the logic of *Public Citizen's* limitation on the use of risk as a factor upon which to base a discretionary judgment does not apply to this particular situation.

The second reason we believe the no-discretion argument based on *Public Citizen* and *Les* is unsound is more fundamental. The DES proviso and the Delaney Clause are separate provisions, and there is no a priori reason to believe that the limitations on factors permitted to influence the exercise of specific discretionary authority under the Clause should also govern the exercise of discretion under the proviso. In fact, the respective legislative histories of the two provisions exhibit significant differences that tend to reinforce the conclusion that the FDA can take the sensitivity of a method into account in deciding whether to approve that method. [6]

The text of the DES proviso and the structure of the statute support the conclusion that the FDA has discretion to employ a method's sensitivity as a criterion in method selection. The statute supports that view by granting the FDA the discretion to prescribe and approve methods of detection. 21 U.S.C. § 348(c)(3)(A). However, it is completely silent on explicit criteria the FDA may employ in the exercise of this discretion. When Congress has failed to speak directly to the precise question at issue, the implementing agency's interpretation

[6] Before highlighting those differences, we note that our methodology is the same as that used by the court in *Public Citizen*. Like that court, we begin with the statutory text and structure, and then look to the legislative history to see whether it supports or undermines our preliminary conclusion. In *Public Citizen*'s case, the court first concluded that the best reading of the Delaney Clause was that the Clause did not permit a de minimis exception to its otherwise categorical, or automatic, ban on cancer-inducing additives. *Public Citizen*, 831 F.2d at 1113. This result, seemingly so contrary to common sense in the case of trivial risks, might have been resisted by the court were it not for the very strong and consistent legislative history of the Delaney Clause, which supported the view that Congress indeed intended the "zero tolerance" result for carcinogenic compounds that the Clause announces on its face. In discussing the color additives version of the Delaney Clause, Judge Williams concluded that "[t]he House committee gave considerable attention to the degree of discretion permitted under the provision. The discussion points powerfully against any *de minimis* exception, and is not contradicted either by consideration on the House floor or by a post-enactment colloquy in the Senate." *Id.; accord Les*, 968 F.2d at 989. "[T]his is perhaps as strong as [legislative history] is likely to get." *Public Citizen*, 831 F.2d at 1117.

will be sustained as long as it is reasonable. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842–44 (1984). We believe that the use of significant risk levels as a criterion for exercising that discretion is reasonable in light of the statute's basic requirement of an affirmative showing of "safety." *See* discussion *supra* pp. 250–51. Accordingly, the FDA's use of levels of risk as a screening criteria for method approval should be sustained as a "reasonable interpretation" of the statute.

The statute's silence on this issue means that the Congress has not spoken in statutory language to this question. That Congress intended to leave this issue to the discretion of the FDA is reinforced by an examination of the pertinent legislative history. The history of the DES proviso displays considerable equivocation on the criteria the FDA should employ in implementing the discretionary portions of the statute. On the one hand, some of the legislative history asserts that the "basic principle" of the Delaney Clause itself — its zero tolerance position with respect to carcinogens — would be unaffected by the passage of the proviso. A principal piece of evidence of this view is a letter from Secretary Ribicoff to the chairman of the House Committee on Interstate and Foreign Commerce in 1962, the year the food additives version of the proviso was enacted.[7] The Secretary's section-by-section analysis of the proviso stated:

> Section 302(a) would correct a needless and unintentional inequity in the application of the food-additive anticancer proviso[8] (sec. 409(c)(3) of the basic act) to additives for animal feed, while preserving in its full vigor the consumer protection now afforded by that provision. The basic principle of the anticancer provision, which would remain unimpaired, is that no tolerance for the addition of carcinogenic chemicals to food shall be granted in any amount . . . .

Letter for Hon. Oren Harris, Chairman, Committee on Interstate and Foreign Commerce, from Abe Ribicoff, Secretary, Department of Health, Education, and Welfare (July 21, 1962), *reprinted in Drug Industry Act of 1962: Hearings on H.R. 11581 Before the House Committee on Interstate and Foreign Commerce*, 87th Cong. 49 (1962), *reprinted in* 21 Leg. Hist. at 227.

[7] The DES proviso was first suggested by the Department of Health, Education and Welfare ("HEW") in 1960. HEW drafted the pertinent provisions of the language that were eventually enacted in 1962, and transmitted its proposal to this same House Committee via another letter from then Secretary Flemming to the chairman, expressing HEW's views on how the proviso would operate. Letter for Hon. Oren Harris, Chairman, Committee on Interstate and Foreign Commerce, from Arthur S. Flemming, Secretary, Department of Health, Education, and Welfare (May 13, 1960) ("Flemming Letter"), *reprinted in* H.R. Rep. No. 86–1761, at 88–89 (1960), *reprinted in* 16 Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments at 757–58 (1979) ("Leg. Hist."). Under these circumstances, the views of the executive branch with respect to language it requested and initially drafted are significant sources of statutory meaning.

[8] Secretary Ribicoff refers to the "Delaney proviso" or the "anticancer proviso" where subsequent usage refers to the "Delaney Clause." Secretary Flemming, Ribicoff's predecessor, employs the same terminology.

On the other hand, the proviso has an operational structure that is undeniably different from that of the Clause, such that it would be impossible for the zero tolerance principle of the Clause to be completely unaffected, and some elements of the legislative history reflect an awareness of that fact. A long-time student and expert on the Act and the Delaney Clause, Professor Richard Merrill, has succinctly stated the difference: "By contrast with the Delaney Clause itself, the DES proviso makes the *detection* of residues in edible animal tissues, rather than the addition of the compound to animals or their feed, the critical inquiry." Richard A. Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 Mich. L. Rev. 171, 233 (1978). In other words, the proviso contemplates that a compound will be approved as long as an approved method detects no residue, even though this does not affirmatively mean that no residue was present at all. In fact, there might be a residue remaining, one at a level of concentration below the sensitivity of the approved method. Consequently, because the operation of the proviso is linked to detection, and because methods of detection are limited in their sensitivity, the inclusion of the proviso could not literally leave the "basic principle" of the Clause unimpaired.

Elements of the legislative history demonstrate an awareness that the operation of the proviso would not guarantee that a zero tolerance policy would be carried out with full vigor. A principal piece of evidence plainly pointing out the inconsistency between the proviso and the Delaney Clause is Representative Leonor Sullivan's floor statement when the proviso was being considered in 1962, shortly before actual passage. Representative Sullivan, who introduced another bill on food and drug safety, H.R. 1235, conveyed her doubts about any weakening of the Delaney Clause whatsoever based on her belief that new testing methods would disclose residues that could not be detected in 1962:

> However, I have strong doubts, I must admit, over the retreat on the Delaney anticancer clause on feed additives, as contained in H.R. 11582, particularly in view of the Government's experience several years ago with hormone-treated chickens. It cost us $10 million to remove from the market the fowl treated with a drug considered safe for the purpose — after it was learned that there were residues of the cancer-inducing substance in the skin of the chickens. Too often for complacency, new testing methods disclose the existence of harmful residues which had not shown up in earlier tests, but by then the damage is done.

Drug Industry Act of 1962: Hearings on H.R. 11581 Before the House Committee on Interstate and Foreign Commerce, 87th Cong. 98 (1962) (Statement of Rep. Sullivan), *reprinted in* 21 Leg. Hist. at 276. In order to forestall such weakening,

Representative Sullivan introduced an amendment to eliminate the DES proviso, so as to protect consumers from undetectable levels of carcinogenic residues. 108 Cong. Rec. 21,077 (1962) (Statement of Rep. Sullivan), *reprinted in* 23 Leg. Hist. at 29. Her amendment was defeated.[9]

Representative Sullivan's statement recounts an actual historical example of subsequent improvements in testing sensitivity that revealed a residue where none had been detected earlier. No member of Congress disputed the factual accuracy of her description of the proviso's operation, although several rose to comment on her statement. *See* 108 Cong. Rec. at 21,079–83, *reprinted in* 23 Leg. Hist. at 31–35. This sequence reveals very clearly the tension between the proviso and the original Delaney Clause: in all likelihood the proviso would permit the presence of physical residues of carcinogenic compounds, because testing methods would not be sensitive enough to detect them, while the Clause advocates a zero tolerance approach to the presence of *any* residue.

Finally, the tension between the idea that the proviso would preserve the "basic principle" of the Clause and the idea that detection methods would most likely become more sensitive over time, so that a failure to detect residue with any given method could not be taken to show the complete absence of the compound, is evident in the major statement of the administration's understanding of the proviso, Secretary Flemming's letter of May 13, 1960, which transmitted the language of the proviso to the House committee considering the Color Additives Amendments.

> There is, however, one respect in which the anticancer proviso has proved to be needlessly stringent as applied to the use of additives in animal feed. For example, in the case of various animals raised for food production, certain drugs are used in animal feed which will leave no residue in the animal after slaughter or in any food product (such as milk or eggs) obtained from the living animal, and which are therefore perfectly safe for man. If this is demonstrated with respect to any particular additive intended for animal feed, and the additive will not adversely affect the animal itself during its expected or intended life cycle, we can see no reason for not permitting such a use of an additive which could be highly useful and beneficial in the raising of animals for food. . . .
>
> We therefore have included in the enclosed draft bill an amendment to permit use of an additive animal feed under the above-mentioned conditions.
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> It may aid public understanding of the Delaney proviso and allay unnecessary apprehension regarding it, to touch here on the pro-

[9] The amendment failed by voice vote. 108 Cong. Rec. at 21,081, *reprinted in* 23 Leg. Hist. at 33. Her amendment to eliminate the DES proviso permitting carcinogenic color additives in animal feed was also rejected. *Id.* at 21,083, *reprinted in* 23 Leg. Hist. at 35.

viso's operation where its application, under present law and the proposed modification, depends on whether a residue of the chemical additive involved is left in the edible tissue or other food products of an animal. This question may arise in two types of case. In the first, a veterinary drug is directly administered—by injection, implantation, or otherwise—to the animal, instead of being mixed with its feed. In that event, the Delaney proviso can have application only if a residue of the added drug occurs in food products (such as milk or eggs) of the living animal or in some edible portion or product of the animal after slaughter. In the second type of case, the drug is mixed with feed consumed by the animal. In that event, it is necessarily a food additive (since animal feed is food within the meaning of the act), but it will nevertheless be taken out of the Delaney proviso's application by the above-proposed amendment even if it is cancer inciting (at particular feeding levels) in test animals, provided that it satisfies the above-mentioned requirements as to the absence of adverse effect on the animals for which the feed is intended and as to the absence of any residue in the food products or edible portions of the animal.

In both these instances, where the question of the possibility of a residue is crucial, it is desirable that industry laboratory technicians, and enforcement officers have a common understanding with the Food and Drug Administration as to the methods of assay that will be recognized by us, and on which we want to rely, in resolving the question of residue. We have, therefore, in the proposed amendment to the Delaney proviso (and likewise in the proposed modification of the anticancer clause of H.R. 7624) provided that, under the amendment, the assay methods applicable in determining whether there will be a residue shall be those prescribed or approved by us by regulations. This will give reasonable certainty in that regard, although, of course, such regulations may from time to time be changed as new scientific developments demonstrate a need for change. It should be clearly understood that the industry still would have the responsibility of developing adequate analytical methods for detecting residues and furnishing them to the Government with a petition for approval of an additive.

During the hearings on color additives legislation, some witnesses expressed a concern because of their fear that the Department intends to press a never-ending search for more and more delicate methods of analysis, so that it may, without regard to scientific reason, rescind permissions granted earlier for use of various

> additives judged to leave no residues in food. This fear is not justified.
>
> The Department applies sound scientific judgment and the rule of reason in determining the sensitivity and precision required in an analytical procedure used to detect residues of added chemicals—even before an additive is approved. And when it has been determined that a given degree of sensitivity and precision is appropriate, based upon sound scientific facts, it has no intention of requiring change in the analytical procedure until new scientific developments clearly demonstrate the need.

Flemming Letter, *reprinted in* H.R. Rep. No. 86–1761, at 88–89, *reprinted in* 16 Leg. Hist. at 757–58.

Secretary Flemming's letter contains some passages that point in the same direction as the section-by-section analysis of Secretary Ribicoff quoted above, namely toward the idea that the proviso is entirely consistent with the Clause. Its claim, for instance, that the proviso would apply to chemicals that leave "no residue" in edible tissue, might be read to adopt the zero tolerance position of the Clause, as might the claim that the Clause is "needlessly" stringent in case to which the proviso would apply. However, in the last three paragraphs quoted above, the Secretary also acknowledges that the application of the proviso would depend upon sensitivity of the method. The portions responding to concerns expressed in the hearing make this point clear.

The sole basis upon which "a never-ending search for more and more delicate methods of analysis, so that [the FDA] may, without regard to scientific reason, rescind permissions granted earlier for use of various additives judged to leave no residues in food," Flemming Letter, *reprinted in* H.R. Rep. No. 86–1761, at 89, *reprinted in* 16 Leg. Hist. at 758, could be a concern to the industry is if it were possible to grant permissions on the basis of methods not sensitive enough to guarantee literally no residue, such that it was then conceivable that more sensitive methods might later be developed that could detect a residue. That is precisely the scenario painted later on the House floor by Representative Sullivan, in the passage quoted earlier. *See supra* p. 255. As was also the case with respect to Representative Sullivan's concerns, the Secretary's response is not that this scenario is strictly impossible—which it would be if the proviso only operated in situations where literally no residue remained. Instead, he assures the Committee that the FDA will exercise "sound scientific judgment and the rule of reason in determining the sensitivity and precision required in an analytical procedure used to detect residues of added chemicals—even before an additive is approved. And when it has been determined that a given degree of sensitivity and precision is appropriate, based upon sound scientific facts, [the FDA] has no intention of

requiring change in the analytical procedure until new scientific developments clearly demonstrate the need." *Id.*

In sum, by permitting approvals to be based on detection methods that cannot confirm that no additions of the compound to edible tissue will occur, the proviso articulates a different principle from the one animating the Delaney Clause. Significant pieces of legislative history confirm an awareness by Congress that the proviso would operate in a manner significantly different from the Clause, although other pieces of that history suggest the opposite. The amendments offered by Representative Sullivan to prevent the weakening of the Clause seem to have put the choice of continuing a strict zero tolerance approach or not squarely to the Congress, and Congress voted to adopt the proviso in the form proposed by the administration. [10]

The court in *Public Citizen* based its conclusion that risk could not enter into the FDA's determination of whether a compound "induces cancer" on its concern that to do so would permit the consideration of a factor that the Delaney Clause prohibits the FDA from taking into account in the ultimate decision whether to ban the substance. For the most part, it based its conclusion that risk could not be taken into account in that ultimate decision on a consistent and strong legislative history rejecting the use of risk as a factor. The court's concern that risk might work its way back into the agency's judgment so as to undermine Congress's prohibition does not apply here, because rejecting methods on the basis of risk does not have that effect. *See* discussion *supra* p. 253. Even if this decision did have that effect, the legislative history of the proviso fails to support the conclusion that Congress meant the same zero tolerance policy of the Clause to be fully applicable in implementing the proviso. As a whole, the legislative history amply confirms what the statute suggests on its face: Congress has not clearly spoken to the question whether the FDA could take risk into account in selecting methods of detection, thus permitting the FDA to adopt a reasonable interpretation of the relevant criteria. [11]

In retrospect, it is not possible to conclude with confidence why Congress failed to specify the precise criteria that the FDA ought to employ in selecting detection methods. *Chevron* identifies a number of possible reasons that an agency may be given discretion to interpret a statute:

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[10] *See supra* note 9.

[11] To the extent the legislative history speaks at all to what might cabin the exercise of discretion in selecting methods of testing, it is only suggestive. Secretary Flemming's letter speaks of using "sound scientific judgment and the rule of reason in determining the sensitivity and precision required." H.R. Rep. No. 86–1761, at 89, *reprinted in* 16 Leg. Hist. at 758. These concepts are nowhere further defined in the subsequent discussions of the proviso, which are not numerous in a legislative history dominated by more contentious issues. If anything, they suggest that levels of risk might well be a consideration in the decision to require more sensitive methods, because the need for greater sensitivity, which might be indicated by the significance of the risks involved, would seem to be one of the most obvious factors triggering a "rule of reason" decision to seek more sensitive methods, if not the most obvious factor.

> Congress [may have] intended to accommodate [competing] interests, but did not do so itself on the level of specificity [necessary to resolve the precise question being litigated]. Perhaps that body consciously desired the Administrator to strike the balance at this level, thinking that those with great expertise and charged with responsibility for administering the provision would be in a better position to do so; perhaps it simply did not consider the question at this level; and perhaps Congress was unable to forge a coalition on either side of the question, and those on each side decided to take their chances with the scheme devised by the agency.

Chevron, 467 U.S. at 865. In light of the language of the statute, the structure of the statute, and the legislative history of the proviso, we conclude that one of these three conditions obtained here — probably the first or the second, although "for judicial purposes, it matters not which of these occurred." *Id.* Whatever the reason may have been, the result is that the FDA's "reasonable interpretation" of its authority — that method sensitivity down to the level of significant risk can be used as a criterion in method selection — is within its discretion to adopt.

B. Must the FDA Adopt the Most Sensitive Method of Detection?

The agencies' second question is whether the FDA must revise its regulations to adopt more sensitive methods when they become available once it has adopted a method that detects the residue. Essentially, this question asks whether the proviso requires the FDA to revise its regulations to adopt the "best available" detection methods for a compound, or whether it has discretion to continue to accept results from less sensitive methods. At one time in the FDA's implementation of the proviso, the agency did take the position that it generally should adopt the best available detection methods.[12] While that interpretation may be one permissible interpretation of the proviso, the narrow question we must resolve is whether the statute compels that course of action. We conclude the answer to this question is also no.

The proviso itself is completely silent with respect to what criteria the FDA must employ in deciding whether to approve a method of detection. It is also completely silent as to any affirmative obligation on the FDA to revisit or revise approved methods. Any case in favor of a "best available" obligation, therefore, must rely heavily on the zero tolerance principle for carcinogens under the Delaney Clause itself, coupled with those portions of the legislative history of the proviso that assert that the proviso maintains this "basic principle" of the

[12] For a history of the FDA's approach to implementing the proviso up to that time, *see* Chemical Compounds in Food-Producing Animals, Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals, 42 Fed. Reg. 10,412 (1977).

Clause. Under this theory, if the method of detection approved by the FDA could not detect residues at levels achievable by the best available methods, and such levels were in fact detected by a more sensitive method, then failing to adopt the best available method as the required method under the proviso seems tantamount to approving a tolerance for the compound. [13] Flemming Letter, *reprinted in* H.R. Rep. No. 86–1761, at 89, *reprinted in* 16 Leg. Hist. at 758.

As we have already discussed, however, the proviso itself does not contain any language from which an affirmative obligation to use best available methods could be derived. The plain language of the proviso stands in tension with the basic principle of the Clause, and the legislative history of the proviso in several places reflects an awareness that the proviso depends upon detection in its operation. In fact, some of the legislative history suggests the FDA intended from the beginning *not* to adopt best available methods, at least under some circumstances, and that Congress acquiesced in that understanding. First, the history acknowledges that an approach depending on detection will most likely result in approved uses of compounds where in fact residues are present in food. *See, e.g.*, Representative Sullivan's statement, *supra* p. 255. Second, Secretary Flemming's influential May 13, 1960 letter seeks explicitly to quell industry concerns that the FDA will engage in a "never-ending search" for more sensitive methods, without regard to scientific reason. The Secretary's rejoinder that HEW will not engage in such a search plainly argues against a requirement to always adopt best available detection methods. To repeat, Secretary Flemming wrote:

> The Department applies sound scientific judgment and the rule of reason in determining the sensitivity and precision required in an analytical procedure used to detect residues of added chemicals—even before an additive is approved. And when it has been determined that a given degree of sensitivity and precision is appropriate, based upon sound scientific facts, it has no intention of requiring

[13] The House Committee that first received Secretary Flemming's request for enacting the DES proviso reported the Secretary's views on whether the Delaney Clause itself permitted the FDA to establish tolerances for carcinogens. The committee report quotes him as stating:

> Whenever a sound scientific basis is developed for the establishment of tolerances for carcinogens, we will request the Congress to give us that authority. We believe, however, that the issue is so important that the elected representatives of the people should have the opportunity of examining the evidence and determining whether or not the authority should be granted.
>
> . . . .
>
> This, I believe, is as far as our discretion should go in the light of present scientific knowledge. We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance.

H.R. Rep. No. 86–1761, at 12–13, (quoting Statement by Hon. Arthur S. Flemming, Secretary of HEW, before the House Committee on Interstate and Foreign Commerce, January 26, 1960), *reprinted in* 16 Leg. Hist. at 681–82.

> change in the analytical procedure until new scientific developments clearly demonstrate the need.

Flemming Letter, *reprinted in* H.R. Rep. No. 86–1761, at 89, *reprinted in* 16 Leg. Hist. at 758. In the last sentence of this quotation, the Secretary contemplates a situation in which a more sensitive method is available, but not needed, by acknowledging as possible a situation in which the agency could change to more sensitive methods and yet refrains from doing so. Such a situation is possible only if a superior method were available. This passage, in short, suggests that the FDA must have *some* discretion to decline to adopt the best available method.

Once again, however, the statute itself provides no guidance at all on what factors the FDA may consider in exercising such discretion, and the legislative history provides only suggestive guidance. While "sound scientific judgment and the rule of reason" is not further defined, the level of risk already capable of being detected is certainly one plausible factor that might bear on the FDA's assessment of whether "new scientific developments clearly demonstrate the need." This is because, as just discussed, the Secretary's letter contemplates the case in which a more sensitive method is available, yet determined by the agency not to be needed. Of all the considerations that might support a conclusion that a better test is not "needed," as opposed, say, to being too expensive, or too time-consuming, the consideration that current tests are adequate to detect significant risk is perhaps the most straightforward and appropriate. This interpretation, thus, ties the FDA's discretion in method selection directly to some appraisal of the need to detect low levels of risk, and the significant risk level is certainly a reasonable benchmark for assessing adequacy.

Thus, the Secretary's letter defines two points that are important for our purposes. As the FDA contemplated the operation of the proviso, it would (1) sometimes refrain from requiring the best available detection method; and (2) base its decision on method approval on undefined "sound scientific judgment and the rule of reason," which might well incorporate considerations of the risks associated with the compound. While turning these points into statutory commands probably makes too much of Secretary Flemming's letter, it and the other pieces of legislative history acknowledging that the proviso's operation is linked to detection do refute arguments that such a reading is precluded by the statute. The history is simply too contradictory to support that result.

In this section of our opinion, however, the narrow question under review is whether the statute compels the FDA to push beyond currently approved methods to require more sensitive methods when they become available. As to this question, we are confident the answer is no.

III. Definition of "No Residue"

Under the SOM regulations, the FDA accepts a finding of some residue as satisfying the statutory requirement of "no residue," if the level of residue detected poses no significant risk of increased cancer to people. In other words, it considers the detected presence of small amounts of residue as satisfying the statutory requirement of no residue. The final question the agencies have presented is whether this construction is permissible under the statute. While the first two questions dealt with the FDA's discretion to approve methods of detection, this one deals with the FDA's possible discretion in interpreting the statutory requirement that the FDA find "no residue" by means of whatever methods of detection the FDA has chosen. The question of what action may be taken when the method prescribed or approved by the Secretary by regulations detects a residue demands a different answer.

Once again, we start with the statute. If Congress has "directly spoken to the precise question at issue" in the statute, that instruction must be followed. *Chevron*, 467 U.S. at 842–44; *see also Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 254 (1992) ("When the words of a statute are unambiguous, then, the first canon of construction is also the last: 'judicial inquiry is complete.'") (quoting *Rubin v. United States*, 449 U.S. 424, 430 (1981)). In this instance, Congress has clearly spoken. The DES proviso states that the Delaney Clause will not apply "if the Secretary finds . . . that no residue of the additive will be found (under methods of examination prescribed or approved by the Secretary by regulations)." 21 U.S.C. §348(c)(3)(A). The interpretation of this language seems straightforward and unambiguous. Giving "no residue" its ordinary meaning, the detected presence of any residue by an approved method would be incompatible with a finding of "no residue," and thus would preclude a finding that the proviso applies.

Investigation of the legislative history substantiates this reading of the statute. Previous inquiries into the legislative history of the proviso supported the conclusion that the FDA enjoys considerable discretion to select methods of detection. That conclusion was initially based on a reading of the statute itself, and subsequently reinforced by the findings that Congress's deliberations reflected no single clear view either on precisely how the proviso was consistent with the zero tolerance principle of the Delaney Clause or on the criteria the FDA should use in selecting such methods of detection. As to the question at issue here, the legislative history also reinforces the initial reading of the statute, but this time by revealing a consistent record. There is nothing in that record to suggest that a finding of "no residue" could be based upon the detected presence of residue, however insignificant, and the most pertinent items in the record on this issue in fact support the plain reading of the statute.

Consider first Secretary Flemming's May 13, 1960 letter initially proposing the proviso's language, which states in part:

> There is, however, one respect in which the anticancer proviso has proved to be needlessly stringent as applied to the use of additives in animal feed. For example, in the case of various animals raised for food production, certain drugs are used in animal feed which will leave no residue in the animal after slaughter or in any food product (such as milk or eggs) obtained from the living animal, and which are therefore perfectly safe for man.

Flemming Letter, *reprinted in* H.R. Rep. No. 86–1761, at 88, *reprinted in* 16 Leg. Hist. at 757. It is impossible to read the Secretary's reference to "no residue" as implying that the administration was proposing a statutory revision that would knowingly permit some residue to remain in food products. This is the same letter, after all, that endorses the Delaney Clause's standard of zero tolerance as the only acceptable public health policy with respect to carcinogens. [14] The letter only proposes a proviso that would operate when the Clause was "needlessly stringent"; that is, the proviso will apply in situations where a compound had been added to animal feed — and came within the scope of the food additive statute's Delaney Clause for that reason — but left "no residue" in food to be composed by humans. The operating supposition of the Delaney Clause, endorsed by Secretary Flemming, is that no exposure, no matter how small, to a known carcinogen was then considered "safe." On that supposition, the only residue that could be considered "perfectly safe" for humans, where the Clause's application would be "needlessly stringent," would be zero residue.

That this was Secretary's Flemming's view, and Congress's understanding of it, is reinforced by the Secretary's earlier statement:

> We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance.

H.R. Rep. No. 86–1761, at 13 (quoting Statement by Hon. Arthur S. Flemming, Secretary of HEW, before the Committee on Interstate and Foreign Commerce, Jan. 26, 1960), *reprinted in* 16 Leg. Hist. at 682. Having proof of the presence of a residue but nonetheless exempting a compound from the Delaney Clause's

[14] *Id.* ("[T]he principle of the [Delaney Clause] reflects, basically, the current state of scientific knowledge, and we would therefore, except [as applied to situations governed by the proposed DES proviso] feel constrained to apply the same principle even in the absence of [the Delaney Clause].").

prohibition, as the SOM's construction of "no residue" does, seems indistinguishable from treating that level of residue as a safe tolerance — precisely the result that Secretary Flemming denies in his statement to the Committee. Likewise, Secretary Ribicoff's assertion that "no tolerance for the addition of carcinogenic chemicals to food shall be granted in any amount," seems to require the conclusion that permitting a detected residue of a carcinogenic chemical to be present in food to be consumed by humans would not be permitted. Letter for Hon. Oren Harris, Chairman, Committee on Interstate and Foreign Commerce, from Abe Ribicoff, Secretary, Department of Health, Education, and Welfare (July 21, 1962), *reprinted in* Drug Industry Act of 1962: Hearings on H.R. 11581 Before the House Committee on Interstate and Foreign Commerce, 87th Cong. 49 (1962), *reprinted in* 21 Leg. Hist. at 227.

There is nothing in the legislative history to suggest that Congress meant to authorize carcinogenic residue to be detected by the FDA and yet to have the proviso operate to exempt that compound from the Delaney Clause's prohibition. We believe that the statutory language of "no residue . . . will be found (under methods of examination prescribed or approved by the Secretary by regulations)," 21 U.S.C. §348(c)(3)(A), means that whatever approved method of detection is used must return a negative finding in order for the proviso to operate. Congress may not have been of one mind in realizing that reliance on detection could well result in actual, but undetected, residues in cancer-inducing additives being approved, but the case of actual, *undetected*, residues is quite distinguishable from the case of actual, *detected* ones. The legislative history consistently supports the conclusion that Congress did not intend for any additive for which a residue was actually detected to have the benefit of the DES proviso. The statute being clear, the FDA has no discretion to deviate from it.

It may be argued that the meaning of "no residue" is not clear, because the clearest literal meaning of "no residue" would preclude the FDA from ever employing the proviso once one acknowledges the considered scientific view that one can never be sure that not even a single molecule of a compound remains in edible tissue. Because it is doubtful that Congress meant "no residue" to be given a meaning that would render the proviso nugatory, the argument would run, what Congress meant by the term is ambiguous, and hence the door is open for the FDA to exercise a reasonable discretion in interpreting it.

As already discussed, we agree that the legislative history displays equivocation on how the proviso was meant to operate, that there are inconsistences in statements concerning its ultimate effect, and that the FDA enjoys some interpretive discretion as a result. In determining the scope of that discretion, however, one must keep in mind the particular discretionary judgment at issue. Here the "precise question at issue" is whether the FDA may treat a detected presence of residue as "no residue" within the meaning of the proviso. As to that precise question, the foregoing argument does not change the analysis. Had Congress insisted

upon an affirmative showing of "no residue," the current scientific understanding would indeed render the proviso a dead letter. That, however, is not the proviso Congress drafted. Instead, the proviso relies upon an affirmative showing that *an approved method of detection* finds "no residue," and that finding can still be made consistent with the belief that a yet more sensitive method might show a physical residue where the approved method does not.

In this regard, our analysis finds the proviso to be structurally similar to the Delaney Clause as interpreted by Judge Williams in *Public Citizen*. Both provisions contain some administrative discretion, but they also both contain some "automatic" elements. To paraphrase Judge Williams, our conclusion is that the proviso requires that if A [an approved method of detection detects the presence of any residue], then B [the proviso is not applicable]. *See Public Citizen*, 831 F.2d at 1112. There is language permitting administrative discretion, but it relates only to the selection of detection methods. [15] Once any residue is detected by an approved method, the compound cannot be listed, because the proviso does not apply, and hence the Delaney Clause itself does.

IV. *Conclusion*

Under the DES proviso, the FDA may choose to disapprove methods of detection because they are not sufficiently sensitive to detect the presence of an additive at the "no significant risk" level. Further, the FDA need not revise its regulatory approval of a method simply because a more sensitive method of detection may be available. However, it is a necessary condition to the application of the DES proviso that an FDA approved method of detection return a finding that no residue has been detected. The FDA may not accept a finding that residue is present, but below the "no significant risk" level, as satisfying the statutory requirement of "no residue."

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[15] Of course, the exercise of the FDA's discretion in selecting a method of detection might result in an approved method failing to detect residues that more sensitive methods could detect. The practical consequences of a finding of no residue by such a less sensitive method might well be indistinguishable from the consequences of following the FDA's current SOM approach, if the less sensitive method were sensitive down to the level of no significant risk, but no further. Indeed, by giving the Secretary discretion in method selection, Congress may well have contemplated that the risk associated with a compound might be a factor in the Secretary's exercise of that discretion. *See* discussion *supra* pp. 261–62. Insofar as the FDA's approach takes no significant risk levels into account, it can be seen as one plausible methodology for accomplishing the purposes of the DES proviso, at least on one possible reading of those purposes.

Nevertheless, the Supreme Court has been quite clear in recent years that where Congress's statutory command is unambiguous as to the precise question at issue, *Chevron*, 467 U.S. at 842, that command must be followed. *E.g., Connecticut Nat'l Bank*, 503 U.S. at 254. The proviso structures the FDA's decision making in a particular way, and the fact that an alternative decision making structure might produce a similar ultimate decision does not justify failing to follow the proviso's instructions.