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Dirty Dancing: The FDA Stumbles on the Chevron Two-Step

Gary Lawson

DIRTY DANCING—THE FDA STUMBLES WITH THE *CHEVRON* TWO-STEP: A RESPONSE TO PROFESSOR NOAH

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Professor Lars Noah deserves much credit for exposing some of the myriad ways in which the Food and Drug Administration (FDA) has consistently sought to expand its authority through questionable, and perhaps in some cases abusive, legal practices.[1] As Professor Noah observes, there are signs that the federal courts' century-long honeymoon with the FDA may be ending[2]—and perhaps the FDA never deserved the solicitude that it has traditionally received from both the judiciary and Congress.[3] If Professor Noah can hasten the onset of a more realistic legal and public attitude toward the FDA, he will have performed a great service.

The purpose of this Response is to highlight two gaps in Professor Noah's commendable survey of questionable FDA practices, one of which invites a sequel to Professor Noah's article, and the other I hope to fill here. First, Professor Noah's article does not provide the comparative context necessary to evaluate the FDA's behavior in the broader regulatory order. If the FDA's dismal record of compliance with legal norms is actually *better* than the even more dismal records of other agencies, then perhaps the FDA is, as Churchill might have said, the worst federal agency except all the others. A critique of the FDA would be more effective if the FDA were compared to other federal agencies. Second, although Professor Noah does not address it in his survey,[4] the FDA appears to lead other federal agencies in misusing the *Chevron* doctrine.[5] The *Chevron* doctrine instructs reviewing courts

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1 Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901 (2008).

2 *See, e.g., id.* at 922–23.

3 *See id.* at 902.

4 Professor Noah has briefly noted this issue in previous writing. *See* Lars Noah, *Divining Regulatory Intent: The Place for a "Legislative History" of Agency Rules*, 51 HASTINGS L.J. 255, 305–06 n.193 (2000).

5 The *Chevron* doctrine draws its name from the Supreme Court's decision in *Chevron U.S.A., Inc. v. Natural Resource Defense Council, Inc.*, 467 U.S. 837 (1984). However, the *Chevron* doctrine has very little to do with the *Chevron* decision itself, which certainly was not written in order to effectuate major legal changes. *See* GARY LAWSON, FEDERAL ADMINISTRATIVE LAW 442–43 (4th ed. 2007); John H. Reese, *Bursting the* Chevron *Bubble: Clarifying the*

to defer to reasonable agency interpretations of ambiguous provisions in statutes that the agency administers.[6] It pertains solely to judicial review of agency legal determinations; it is *not* a tool of interpretation to be employed by agencies in reaching their initial decisions. However, in recent years the FDA has frequently and flagrantly misused *Chevron* by invoking it as a primary interpretive tool in its statements of basis and purpose for rulemaking.[7] This error should be added to Professor Noah's bill of particulars, and courts, administrative lawyers, and agency counsel should vigilantly guard against this abuse by the FDA and other government agencies.

I

Professor Noah canvasses a wide array of tactics that the FDA uses to expand its authority, including attempts to evade procedural requirements, primarily through the substitution of guidance manuals for rules that would require notice-and-comment procedures for valid promulgation;[8] threats to use its formal and informal powers, including punishing recalcitrant objects of regulation through adverse publicity or targeted enforcement, to achieve regulatory objectives and obtain remedies that exceed the agency's statutory authority;[9] expansive interpretations of the agency's statutory authority;[10] as well as a startling disregard by the FDA for First Amendment constraints.[11]

Everything that Professor Noah says of the FDA rings true, and it is more than enough to establish his basic point—that the FDA does not deserve to be placed on a pedestal or to be viewed as somehow above criticism.[12] But similar things could likely be said about any other federal regulatory agency of comparable size and significance.

Scope of Judicial Review in Troubled Times, 73 FORDHAM L. REV. 1103, 1137 (2004). But because there is no other generally recognizable name for the doctrine of judicial deference to agency interpretations of statutes, I continue to follow convention and refer to it as the *Chevron* doctrine.

6 For a description of the doctrine, see *Chevron*, 467 U.S. at 842–43. The two-step process results from the Court's (probably unintentional) language in *Chevron*, which framed the inquiry as involving first a determination of ambiguity and second, if the statute is indeed ambiguous, an assessment of the reasonableness of the agency's interpretation. *See id.*; Gary S. Lawson, *Reconceptualizing* Chevron *and Discretion: A Comment on Levin and Rubin*, 72 CHI.-KENT L. REV. 1377, 1379 (1997). This seemingly simple formulation conceals a monstrously complex and still-evolving doctrinal edifice that includes a "step zero" in which courts determine whether particular agency interpretations are entitled to be analyzed under the *Chevron* framework rather than a perhaps less deferential framework that conducts deference inquiries by all-things-considered reasoning. *See* LAWSON, *supra* note 5, at 402–555, 614–28.

7 *See infra* notes 33–47 and accompanying text.

8 Noah, *supra* note 1, at 904–05, 921–22.

9 *Id.* at 906–16.

10 *Id.* at 917–20.

11 *Id.* at 920–24.

12 *See generally id.*

The FDA's failings would be more meaningful if they were placed in comparative perspective; the FDA does not have a monopoly on expansionist techniques.

The FDA is, for instance, hardly alone in seeking to cut procedural corners. As Professor Kristin Hickman has elegantly pointed out, the Internal Revenue Service (IRS) has thoroughly outdone the FDA—and quite possibly everyone else—by flagrantly abusing the Administrative Procedure Act's (APA) exemptions from rulemaking procedures.[13] The IRS frequently maintains that its rules fall within the APA exemption from notice-and-comment rulemaking procedures for "interpretative rules" or "general statements of policy,"[14] even when the rules obviously are legislative.[15] Professor Hickman has calculated that almost *half* of all IRS regulations promulgated within a substantial sample period are vulnerable to serious legal challenge for procedural error.[16] That is a record of procedural perfidy that the FDA can only envy.

Similarly, agency abuse of regulatory authority, through outright or veiled threats of adverse action or bad publicity, has for decades been a major topic of conversation regarding a broad range of agencies. For example, Professor Noah's seminal 1997 study of "administrative 'arm-twisting'"[17] specifically noted the ability of agencies, such as the Consumer Products Safety Commission, to employ threats of bad publicity to cow regulated parties into submission.[18] More than a quarter century ago, Milton and Rose Friedman recorded an account listed in the October 31, 1977 issue of *U.S. News and World Report* which said, "Oil-industry officials claim that they have received this ultimatum from Energy Secretary James Schlesinger: Support the Administration's proposed tax on crude oil—or else face tougher regulation and a possible drive to break up the oil companies."[19] It would

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13 *See generally* Kristin E. Hickman, *Coloring Outside the Lines: Examining Treasury's (Lack of) Compliance with Administrative Procedure Act Rulemaking Requirements*, 82 NOTRE DAME L. REV. 1727 (2007).

14 5 U.S.C. § 553(b)(A) (2000).

15 *See* Hickman, *supra* note 13, at 1795.

16 *See id.* ("[T]he 40.9% of Treasury regulation projects for which Treasury failed to follow the proper notice-and-comment sequence as required by APA section 553 are unlikely to qualify for any of the exceptions from those procedures."). Professor Hickman's conclusion takes full account of the possibility that the relevant regulations might in some cases qualify for the APA's "procedural rule" or "good cause" exemptions. *See id.*; *see also* 5 U.S.C. § 553(b)(A)–(B).

17 Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873, 874. Professor Noah defined "administrative 'arm-twisting'" as "a threat by an agency to impose a sanction or withhold a benefit in hopes of encouraging 'voluntary' compliance with a request that the agency could not impose directly on a regulated entity." *Id.* at 874.

18 *See id.* at 890–91.

19 MILTON & ROSE FRIEDMAN, FREE TO CHOOSE 67 (1980) (quoting U.S. NEWS & WORLD REP., Oct. 31, 1977, at 16).

be surprising if similar stories could not be found in other fields, such as banking.

Furthermore, agency expansionism of the kind Professor Noah describes has been a staple of public choice theory for decades.[20] While there is reason to doubt the universality of such imperialistic agency motives,[21] expansionism is surely one important motivation in the administrative world, and it is unsurprising to see agencies interpreting their organic statutes to their outer limits and beyond.

Finally, although agency disregard for constitutional rights, including First Amendment rights, is not unprecedented, I agree with Professor Noah that the FDA's attempts to regulate speech have been truly extraordinary given its limited statutory mandate,[22] and it is good to see the agency reined in by the courts—and by one of its former general counsels.[23]

However, the question remains: is the FDA's record of legal abuse markedly worse than that of other major federal agencies? It would not at all surprise me if the answer turned out to be "yes," but in order to get an answer, someone would have to do a comparative study across a significant range of federal agencies. Professor Noah could not have undertaken such a project in a symposium on food and drug law, nor can it be my project because I do not know how to construct and conduct such empirical studies. Nonetheless, it would be a valuable task. Until then, it is certainly fair to hold the FDA accountable for its miscues as Professor Noah has done here, but his conclusions must be kept in proper perspective. On the other hand, Professor Noah's chief point is that the FDA should not receive special treatment on the ostensible ground that it is above the fray, and he has made that point with vigor.

II

There is at least one respect, in addition to those enumerated by Professor Noah, in which the FDA has taken the lead among federal agencies in legal expansionism: the misuse of the *Chevron* doctrine as a tool of statutory interpretation at the agency level. The FDA is by no means the only agency to misuse the doctrine, but it has developed the tactic to its fullest. The *Chevron* doctrine instructs reviewing courts to defer to reasonable agency interpretations of ambiguous statutes

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20 *See, e.g.*, WILLIAM A. NISKANEN, JR., BUREAUCRACY AND REPRESENTATIVE GOVERNMENT 38–42 (1971); GORDON TULLOCK, ARTHUR SELDON & GORDON L. BRADY, GOVERNMENT FAILURE: A PRIMER IN PUBLIC CHOICE 54–55 (2002).

21 *See* JAMES Q. WILSON, BUREAUCRACY: WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT 180–81 (2000).

22 *See* Noah, *supra* note 1, at 920–22.

23 *See id.* at 922–24.

that the agencies administer.[24] Despite the twists and turns of the *Chevron* doctrine, one fundamental fact about the doctrine is beyond dispute: it is a tool to be used by reviewing courts and not by the agencies. *Chevron* is a theory of judicial review; it is not a theory of statutory interpretation. The point is basic, it is vital, and it is routinely ignored by the FDA.

Standards of judicial review, in administrative law and elsewhere, are often deferential. A reviewing court that employs deference gives weight to the fact that some other entity has considered an issue before it has reached the court.[25] Judicial deference can be justified by considerations of economy (avoiding duplication of efforts), expertise (acknowledging that the previous decision maker was possibly in a better position than the subsequent one to answer the question), and fairness (not making parties repeat arguments to convince multiple decision makers of the same point).[26] But any plausible rationale for deferential review presupposes that the initial decision maker is engaged in a good-faith effort to get the right answer. If the initial decision maker takes the role of a reviewing court and aims only for a position that is *plausible* rather than *correct*, the case for deference on review is a very hard one to make.

To employ an example that I have used in a slightly different context,[27] consider administrative fact-finding. In administrative law, courts almost always defer to an agency's findings of fact and thus affirm the agency's decision unless it is arbitrary or capricious or unsupported by substantial evidence.[28] Courts will therefore affirm many decisions that they believe, on balance, to be incorrect as long as the agency's decision is plausible.

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24 *See* Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843 (1984).

25 *See* LAWSON, *supra* note 5, at 361–64.

26 *See* Anderson v. City of Bessemer City, 470 U.S. 564, 574–75 (1985). As far as courts are concerned, deference to agency decisions is often not based on any of these considerations but instead is a result of legislative commands. *See, e.g.*, 5 U.S.C. § 706(2)(E) (2000) (ordering courts to set aside agency fact findings in on-the-record proceedings if they are unsupported by "substantial evidence"). In those instances, the legislative decision to require deference is presumably based on considerations similar to those that lead courts to adopt deference doctrines on their own.

27 *See* Lawson, *supra* note 6, at 1381–82; Gary Lawson, *Outcome, Procedure and Process: Agency Duties of Explanation for Legal Conclusions*, 48 RUTGERS L. REV. 313, 328 (1996).

28 An agency's organic statute or the Administrative Procedure Act determines the applicable standard of review. *See* 5 U.S.C. § 706(2)(A), (E); *see also* 8 U.S.C. § 1252(b)(4)(B) (2000) (providing, as part of the Immigration and Nationality Act, the standard of judicial review of final removal orders, and stating that "the administrative findings of fact are conclusive unless any reasonable adjudicator would be compelled to conclude to the contrary"); 19 U.S.C. § 1516a(b)(1) (2000) (prescribing, for purposes of the Tariff Act of 1930, either substantial evidence or "arbitrary or capricious" standards of judicial review for various agency actions in countervailing duty and antidumping duty proceedings).

Suppose, hypothetically, that an agency knows that its factual findings will be affirmed on review as long as they are supported by substantial evidence. Imagine that the agency then says, "We believe that the facts as presented to us support, by a preponderance of the evidence, a ruling in favor of A. But there is enough evidence in support of B to allow a ruling in favor of B to survive judicial review under the substantial evidence test. We have policy reasons for wanting B to win the case, so we will rule in favor of B, notwithstanding the weight of the evidence." This would constitute the height of arbitrary or capricious decision making. The agency's job is to make correct findings of fact, not to concoct rulings contrary to the evidence that would survive deferential judicial review. Indeed, if the agency does not make a good-faith effort to get the facts right, there is no justification for giving the agency's views deference on appeal (beyond the fact that the legislature may have commanded such sweeping deference without regard to whether any underlying rationale for deference is satisfied in a particular case). Deferential standards of review do not ask reviewing bodies to reach the right conclusion, but someone should be looking for the right answer somewhere in the chain of decision making. It would be outrageous for an agency to use the substantial evidence standard as a tool for *initial* fact-finding.

The same reasoning holds for questions of law. *Chevron* requires that reviewing courts give deference to an agency's construction of statutes administered by the agency (subject, of course, to the various "step zero" considerations that determine the applicability of *Chevron* under modern law[29]). That means that reviewing courts are not looking to see whether agencies got the *right* answer but only whether they got a *permissible* answer.[30] Could an agency take advantage of this deference and say, "In construing this statute, we are going to pick the interpretation that we like on policy grounds, even though we think that a different interpretation represents the best reading of the statute, because we can get away with it on judicial review"? Such reasoning would be a clear abuse of the deferential standard of review. Deferential review is premised on the initial decision maker's good-faith effort to get the right answer. If the decision maker does not try to get the right answer, there is no justification for judicial deference. It would be just as outrageous for an agency to use *Chevron* deference

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29 *See* Cass R. Sunstein, Chevron *Step Zero*, 92 VA. L. REV. 187, 191 (2006). *Chevron* Step Zero asks whether the doctrine applies at all. *See id.* For a comprehensive survey of the various "step zero" issues surrounding *Chevron*, see Thomas W. Merrill & Kristin E. Hickman, Chevron's *Domain*, 89 GEO. L.J. 833 (2001).

30 Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843 (1984) ("[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.").

as a tool to protect its *initial law findings* as it would be for an agency to use the substantial evidence standard as a tool to protect its *initial fact findings.*

The FDA misuses *Chevron* in precisely this way, and it has apparently inspired other agencies to do the same.[31] This is somewhat ironic because, in the principal cases in which the FDA has misused *Chevron*, it could probably have reached the same outcomes using permissible reasoning. However, the potential for mischief in future cases where the agency misapplies *Chevron* is huge, and the practice should be halted.

The main events in the FDA's "hijacking" of the *Chevron* doctrine were four statements of basis and purpose that it issued in 2003 and 2004, accompanying rules promulgated under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).[32] Each rule had to construe the word "food" as it appeared in various provisions of the statute. In two rules, the FDA gave "food" an ordinary-language meaning that excluded so-called "food contact substances," such as dishes and wrapping materials, that had previously been considered "food" in most regulatory contexts.[33] In two other rules, the FDA gave the term "food" the broader meaning (which includes the "food contact substances" excluded by the alternative definition) that it generally carries in FDA regulations.[34] Without engaging the topic here at any length, the FDA's conclusions are all quite sensible given the specific contexts in which the word "food" appears in the statute.[35] In all likelihood, the FDA correctly interpreted the statute in each instance. The problem is that it is not clear that the FDA was *trying* to interpret the statute correctly when it promulgated these rules.

The basic legal methodology the FDA used to determine the meaning of the word "food" was substantially similar for each of the four rules under discussion,[36] so it will suffice to examine only the

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31 *See infra* notes 54–60 and accompanying text.

32 Pub. L. No. 107-188, 116 Stat. 594 (codified as amended in scattered sections of 42 U.S.C.).

33 *See* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,896 (Oct. 10, 2003); Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974, 58,977 (Oct. 10, 2003).

34 *See* Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 31,660, 31,671 (June 4, 2004); Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,562, 71,584–85 (Dec. 9, 2004).

35 *See infra* notes 47–48 and accompanying text.

36 *See* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,907–09; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Re-

FDA's approach in the first rulemaking of the four, which involved registration of food facilities. The Bioterrorism Act added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) a new section that requires "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States [to] be registered with the Secretary [of Health and Human Services]."[37] The FDA's original proposed rule borrowed the definition of "food" from section 201(f) of the FD&C Act,[38] which has been construed to include as food "substances that migrate into food from food packaging."[39] This broad definition could have extended the registration requirements to entities that manufacture, package, process, or hold dishes, appliances, or wrapping materials that could have contact with food at some point.[40] A number of comments filed in response to the proposed rule objected to the breadth of the definition, and the FDA's final rule took a narrower approach.[41]

The FDA explained its approach to interpreting the term "food":

> The comments on food-contact substances raise the question of what Congress intended "food" to mean in terms of registration of facilities that manufacture, process, pack, or hold "food." In construing the registration provision of the Bioterrorism Act[ ], *FDA is confronted with two questions.* First, has Congress directly spoken to the precise question presented? ("*Chevron* step one"). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue. If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent. If, however, the Bioterrorism Act is silent or ambig-

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sponse Act of 2002, 68 Fed. Reg. at 58,984–86; Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. at 31,669–71; Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. at 71,583–85.

37 21 U.S.C. § 350d(a)(1) (Supp. 2005).

38 Federal Food, Drug and Cosmetic Act § 201(f), 21 U.S.C. § 321(f) (2000) ("The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.").

39 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5378, 5382 (Feb. 3, 2003). For an illustration of the (some would say absurdly) broad scope of the 21 U.S.C. § 321(f) definition of "food," see *United States v. Tuente Livestock*, 888 F. Supp. 1416, 1424 (S.D. Ohio 1995), which concludes that live swine are "food" under 21 U.S.C. § 321(f). The definition of "food additive" under 21 U.S.C. § 321(s) is equally broad. *See* Natick Paperboard Corp. v. Weinberger, 525 F.2d 1103, 1107–08 (1st Cir. 1975) (concluding that food packaging materials containing chemicals that might migrate into food are a "food additive").

40 *See Natick Paperboard Corp.*, 525 F.2d at 1107–08.

41 *See* 21 C.F.R. § 1.227(b)(4)(i) (2007) (defining "food" to have the meaning as in 21 U.S.C. § 321(f) but excluding food contact substances and pesticides).

> uous as to the meaning of "food," FDA may define "food" in a reasonable fashion ("*Chevron* step two").[42]

The FDA explained at great length why it found the statute ambiguous, employing traditional tools of statutory construction such as intratextual analysis and reference to legislative history.[43] In particular, the agency noted that the definition of "food" throughout the FD&C Act was inconsistent; thus, it would not be unprecedented for Congress to depart from the § 201(f) definition of "food" in some sections of the Bioterrorism Act.[44] The agency then continued:

> Having concluded that the meaning of "food" in section 415(a)(1) is ambiguous, FDA has considered how to define the term so as to achieve a "permissible construction" of the registration provision. In conducting this *Chevron* step two analysis, the agency has considered the same information evaluated at step one of the analysis. FDA has determined that it is permissible, for purposes of the registration provision, to exclude food contact materials from the definition of "food."[45]

The other three statements of basis and purpose describe similar two-step *Chevron* analyses and largely borrow the language and reasoning of the above analysis.[46]

The basic problem with the FDA's reasoning is indicated by the italicized phrase in the first paragraph quoted above: the FDA is *not* confronted with the questions posed by the *Chevron* two-step analysis. *Reviewing courts* are confronted with those questions after the FDA, or some other federal agency, has construed a statute that it administers. The FDA must only give the statute the best interpretation possible. Ambiguity in the statute simply does not give the FDA license to pick any interpretation that it believes will survive deferential judicial review. The FDA has an obligation—in hard cases as well as in easy ones—to try its best to arrive at the correct answer.

As it happens, in all four of the rulemakings at issue here, the FDA did a commendable job of reaching a good answer. It examined the text, structure, history, and purposes of the relevant statutes with

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42 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,908 (Oct. 10, 2003) (emphasis added) (citations omitted).

43 *See id.* at 58,908–09.

44 *Id.* at 58,908.

45 *Id.* at 58,909 (citations omitted).

46 *See* Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974, 58,984–86 (Oct. 10, 2003); Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 31,660, 31,669–71 (June 4, 2004); Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,562, 71,583–85 (Dec. 9, 2004).

admirable care, and it amply justified the different meanings that it gave to the word "food" in different contexts. The agency showed great sensitivity to the different contexts in which the word "food" appeared in the various statutory provisions throughout the FD&C Act.[47] It also articulated good reasons for treating the registration and prior-notice provisions, on the one hand, and the administrative-detention and record-keeping provisions, on the other hand, as paired sets of provisions to be read *in pari materia*, which helps justify the narrower meaning of "food" applied to the registration and prior-notice provisions.[48] The FDA's interpretations were not merely permissible but were quite likely the best interpretations possible under the circumstances. However, the persistence of the FDA's faulty methodology raises concerns about future cases in which the agency's chosen "permissible" interpretation is incorrect. In such cases, the FDA is poised to choose the incorrect interpretation, and that is a serious problem.

Of course, given the demise of the nondelegation doctrine,[49] there will be many statutes for which there is no "correct" interpretation. In the modern world, one can expect conventional tools of statutory interpretation—text, structure, history, purpose, canons, etc.—frequently to fail to yield any results (other than perhaps to exclude certain interpretations). In those circumstances, agencies have no choice but to select an interpretation on policy grounds because statutes reaching that level of vagueness are delegations of policymaking authority.[50] However, such cases do not really involve "interpretation" in any meaningful sense of the term and therefore do not call for application of *Chevron* even on the FDA's premises. When the Federal Communications Commission, for example, grants a license on the ground that it serves the "public convenience, interest, or necessity,"[51] the Commission is in some sense "interpreting" a statute, but the stat-

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47 *See, e.g.*, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,985 (noting that the narrower definition of "food" applied to the Prior Notice of Imported Food regulations was consistent with the use of the term "food" in other registration provisions); Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. at 31,671 (noting that the broader definition of "food" applied to the Administrative Detention of Food regulations was consistent with other detention provisions in the FD&C Act).

48 *See, e.g.*, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. at 58,985 (noting that the registration and prior notice provisions work together as an integrated scheme).

49 For the story of the doctrine's demise and my lament about it, see generally Gary Lawson, *Discretion as Delegation: The "Proper" Understanding of the Nondelegation Doctrine*, 73 GEO. WASH. L. REV. 235 (2005), which describes the constitutional foundation and scope of the nondelegation doctrine, and Gary Lawson, *Delegation and Original Meaning*, 88 VA. L. REV. 327 (2002), which discusses the checkered history of the nondelegation doctrine.

50 *See* Richard J. Pierce, Jr., Chevron *and Its Aftermath: Judicial Review of Agency Interpretations of Statutory Provisions*, 41 VAND. L. REV. 301, 305 (1988).

51 47 U.S.C. § 307(a) (2000).

ute merely empowers the Commission to make a legislative-like decision. Conventional tools of statutory interpretation will not assist in determining whether a particular license grant does or does not come "within the statute."[52] Accordingly, those are precisely the sorts of cases in which a reviewing court would employ so-called "hard look" review instead of *Chevron*.[53] The law has developed standards of review for agency policymaking that are distinct from the standards of review for agency factual and legal determinations precisely because many agency decisions cannot plausibly be characterized as factual or legal.

It may well be that an agency, after careful consideration of the applicable statute, will properly conclude that the statute provides no serious guidance and that the agency is therefore authorized, and obliged, to make a pure policy choice. An agency, however, cannot legitimately reach that conclusion until it has first tried its best to interpret the applicable statute. Furthermore, that process of interpretation must involve a search for the *correct* meaning of the statute rather than merely a meaning that is likely to survive judicial review. There may in fact be no correct meaning, in which case the agency has no choice but to fall back on policy considerations and reviewing courts have no choice but to apply hard-look review to those policy choices. Before reaching that conclusion, however, the agency needs to attempt to find a correct statutory meaning. The FDA does not even appear to be trying to interpret its statutes correctly.

This misuse of *Chevron* did not begin in 2003,[54] but the Bioterrorism Act rulemaking process exposes the practice with uncommon clarity. Nor is the FDA the only agency in modern times to employ *Chevron* as a tool of construction at the agency level. Traces of this "dirty dancing" of the *Chevron* two-step, in which an agency views its mission as finding a "reasonable," rather than correct, interpretation of the governing statute can be found in decisions of the Mine Safety and Health Administration,[55] the International Trade Administra-

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52 *Cf.* FCC v. RCA Commc'ns, Inc., 346 U.S. 86, 90 (1953) ("The statutory standard no doubt leaves wide discretion and calls for imaginative interpretation.").

53 "Hard-look review" is the name conventionally given to review of significant agency policy decisions under § 706(2)(A) of the Administrative Procedure Act. *See* 5 U.S.C. § 706(2)(A) (2000). For an introduction to the theory and mechanics of hard-look review, see generally LAWSON, *supra* note 5, at 555–628.

54 The misuse of *Chevron* as a tool of interpretation at the agency level goes back at least to 1990. *See* Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg. 29,487, 29,491 (July 19, 1990).

55 *See* Section 110(c) of the Federal Mine Safety and Health Act of 1977; Interpretation, 71 Fed. Reg. 38,902, 38,904–05 (July 10, 2006).

tion,[56] the Federal Communications Commission,[57] the Maritime Administration,[58] and the Environmental Protection Agency.[59] It is quite possible that these agencies derived their methodologies independently of the FDA, and thus the FDA is not solely responsible for the widespread character of this practice. However, the FDA has offered the most straightforward articulation and applications of the faulty agency-centered *Chevron* doctrine, and therefore the FDA must bear the lion's share of responsibility for the problem.

As is true of many federal agencies, the FDA operates with a great deal of autonomy from political and legal controls. But as Jerry Mashaw has observed, "The recognition that administration operates autonomously much of the time need not mean—indeed, should not mean—that it has no internal normative direction."[60] In other words, the FDA, and every other federal agency, should not misinterpret statutes simply because it can get away with it. Professor Noah's article is a necessary reminder that the FDA is prone to the same pathologies as other agencies, and the Bioterrorism Act rulemaking process is a necessary reminder that the FDA is eminently capable of coming up with its own pathologies as well.

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56 *See* Notice of Determination Under Section 129 of the Uruguay Round Agreements Act: Antidumping Measures on Certain Softwood Lumber Products from Canada, 70 Fed. Reg. 22,636, 22,644 (May 2, 2005).

57 *See* Carriage of Digital Television Broadcast Signals, 70 Fed. Reg. 14,412, 14,418 (Mar. 22, 2005).

58 *See* Administrative Waivers of the Coastwise Trade Laws for Eligible Vessels, 69 Fed. Reg. 51,769, 51,771 (Aug. 23, 2004).

59 *See* Control of Air Pollution from New Motor Vehicles; Compliance Programs for New Light-Duty Vehicles and Light-Duty Trucks, 64 Fed. Reg. 23,906, 23,912–13 (May 4, 1999).

60 Jerry L. Mashaw, *Norms, Practices, and the Paradox of Deference: A Preliminary Inquiry into Agency Statutory Interpretation*, 57 ADMIN. L. REV. 501, 502 (2005).