ADMINISTRATIVE LAW — REVIEWABILITY — SECOND CIRCUIT UPHOLDS FDA'S DECISION NOT TO WITHDRAW APPROVAL FROM POTENTIALLY DANGEROUS ANIMAL DRUGS. — *Natural Resources Defense Council, Inc. v. FDA*, 760 F.3d 151 (2d Cir. 2014).

While the Supreme Court has squarely held that the Administrative Procedure Act[1] (APA) "embodies the basic presumption of judicial review" of agency actions,[2] it has not established clear and complete doctrinal guidelines for judicial review of agency inaction.[3] When the Court has addressed judicial review of agency inaction, it has held on the one hand, in *Heckler v. Chaney*,[4] that agency decisions not to institute enforcement actions are presumptively unreviewable,[5] and on the other, in *Massachusetts v. EPA*,[6] that agency decisions not to initiate notice-and-comment rulemaking are reviewable.[7] But agencies perform myriad actions that do not fit neatly within the categories of "enforcement" or "rulemaking,"[8] and the Court has not set forth a coherent framework for evaluating the reviewability of agency decisions not to perform such miscellaneous actions.[9]

Recently, in *Natural Resources Defense Council, Inc. v. FDA*[10] (*NRDC*), the Second Circuit held that (1) the Food and Drug Administration (FDA or the Agency) was not statutorily compelled to initiate a hearing process that may have led to the withdrawal of FDA approval for certain animal drugs[11] and (2) the FDA permissibly denied citizen petitions asking the Agency to withdraw such approval.[12] The

---

[1] Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified as amended in scattered sections of 5 U.S.C.).

[2] Abbott Labs. v. Gardner, 387 U.S. 136, 140 (1967).

[3] *See* Brief for Administrative Law Professors as Amici Curiae in Support of Petitioner at 20–21, Ochoa v. Holder, 131 S. Ct. 3058 (2011) (mem.) (No. 10-920), 2011 WL 663188 ("[T]here is no clear, coherent framework for evaluating claims of unreviewability under Section 701(a)(2) [of the APA, a provision that renders some forms of agency inaction unreviewable]." *Id.* at 21.).

[4] 470 U.S. 821 (1985).

[5] *Id.* at 832.

[6] 549 U.S. 497 (2007).

[7] *Id.* at 527–28.

[8] *See, e.g.*, Ass'n of Irritated Residents v. EPA, 494 F.3d 1027, 1029–34 (D.C. Cir. 2007) (addressing reviewability of the EPA's decision to enter into "consent agreement[s]" with regulated entities under which those entities would "assist in developing an emissions estimating methodology," *id.* at 1029).

[9] *See* Eric Biber, *Two Sides of the Same Coin: Judicial Review of Administrative Agency Action and Inaction*, 26 VA. ENVTL. L.J. 461, 466–67 (2008) (noting that the question of "how broadly . . . the [*Chaney*] presumption of non-reviewability [should] sweep" is a "confused aspect[] to the doctrine of judicial review of agency inaction," *id.* at 466).

[10] 760 F.3d 151 (2d Cir. 2014).

[11] *Id.* at 171–72.

[12] *Id.* at 175.

FDA's refusal to institute withdrawal proceedings is a form of miscellaneous agency inaction, the reviewability of which is uncertain under Supreme Court precedent.[13] At first glance, certain features of the majority opinion suggest that the court extended *Chaney*'s presumption of unreviewability to the FDA's failure to initiate withdrawal proceedings. Upon closer inspection, however, the majority actually reviewed the FDA's decision and thus implicitly rejected *Chaney*'s application. If anything, *NRDC* could therefore support future courts' efforts to cabin *Chaney*'s presumption of unreviewability to the enforcement context.

Under the Federal Food, Drug, and Cosmetic Act[14] (FDCA), the FDA must approve a new animal drug before it goes to market.[15] In the 1950s, upon finding that adding antibiotics to animal feed helps animals grow faster, drug manufacturers sought and obtained FDA approval to sell antibiotics for this use.[16] In 1972, however, an FDA Task Force concluded that adding antibiotics to animal feed poses health risks to humans and suggested withdrawing approval of the drugs.[17] Accordingly, in anticipation of initiating withdrawal proceedings, the FDA issued notices of opportunity for hearing (NOOHs) to all drug manufacturers selling the drugs.[18]

Soon after the FDA issued the NOOHs, Congress urged the Agency to delay the hearing process until scientists conducted more research.[19] But despite additional scientific studies reaffirming the dangers of using antibiotics in animal feed,[20] the FDA never held the proposed hearings and instead issued guidance documents implementing "a voluntary program for gradually reducing the subtherapeutic use of antibiotics in animal feed."[21] In both 1999 and 2005, public interest organizations petitioned the FDA to withdraw its approval of the drugs, but the Agency did not respond to the petitions until 2011, when it finally denied them.[22]

In 2011, a group of advocacy organizations sued the FDA in the U.S. District Court for the Southern District of New York, pleading two claims.[23] First, they argued that 21 U.S.C. § 360b(e)(1) compelled

---

[13] *See id.* at 188 (Katzmann, C.J., dissenting).

[14] 21 U.S.C. §§ 301–399f (2012).

[15] *NRDC*, 760 F.3d at 153.

[16] *Id.*

[17] *Id.* at 154.

[18] *Id.*

[19] *Id.* at 154–55.

[20] *Id.* at 155.

[21] *Id.* at 156; *see id.* at 155–56.

[22] *Id.* at 155–56. The denials explained that the FDA's voluntary compliance strategy would be more efficient and less costly than withdrawal proceedings. *Id.* at 156. The FDA also formally withdrew the NOOHs at that time. *Id.* at 157.

[23] *Id.* at 156.

the Agency to hold the hearings proposed by the NOOHs.[24] Second, they argued that the Agency's denial of the citizen petitions was arbitrary and capricious under the APA.[25] The parties filed cross-motions for summary judgment on both claims,[26] and, in separate decisions, the district court granted both of the plaintiffs' motions.[27] The court held first that § 360b(e)(1) requires the FDA to hold the hearings once it finds that an animal drug is unsafe[28] and second that the FDA's denial of the citizen petitions was arbitrary and capricious.[29]

The Second Circuit reversed both decisions.[30] Writing for the majority, Judge Lynch[31] first addressed the district court's statutory interpretation ruling. As relevant here, § 360b(e)(1) states that "[t]he Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . . with respect to any new animal drug if the Secretary finds . . . that new evidence . . . shows that such drug is not shown to be safe . . . ."[32] The plaintiffs argued that the mandatory "shall" in the statute created agency obligations both to hold a hearing after initially finding a drug unsafe and to withdraw the drug if it were still found to be unsafe following the hearing.[33] Conversely, the FDA argued that the mandatory "shall" referred only to the Agency's obligation to withdraw an unsafe drug after a hearing and did not trigger a duty to hold a hearing in the first place.[34] Judge Lynch found the FDA's interpretation "far more plausible" for two principal reasons.[35] First, he pointed out that the plaintiffs' reading would require two agency findings — a prehearing finding to trigger the hearing and a posthearing finding to trigger withdrawal — even though the statute only referred to one

---

[24] *Id.*

[25] *Id.* at 157; *see also* 5 U.S.C. § 706(2) (2012). The plaintiffs' original second claim — that the FDA had unreasonably delayed responding to the 1999 and 2005 petitions — became moot when the Agency denied the petitions in 2011. *NRDC*, 760 F.3d at 157. In 2012, the plaintiffs accordingly amended their complaint to argue that the denial was arbitrary and capricious. *Id.*

[26] *NRDC*, 760 F.3d at 157.

[27] Natural Res. Def. Council, Inc. v. FDA (*NRDC I*), 884 F. Supp. 2d 127, 151 (S.D.N.Y. 2012); Natural Res. Def. Council, Inc. v. FDA (*NRDC II*), 872 F. Supp. 2d 318, 342 (S.D.N.Y. 2012).

[28] *NRDC I*, 884 F. Supp. 2d at 141–42. The court explained that such an interpretation best cohered with the statute's "text and grammatical structure." *Id.* at 141.

[29] *NRDC II*, 872 F. Supp. 2d at 342. The court reasoned that the Agency had failed to "evaluate the safety risks of the petitioned drugs," *id.*, and instead had considered only the costs of holding withdrawal proceedings, *see id.* at 341.

[30] *NRDC*, 760 F.3d at 176.

[31] Judge Lynch was joined by Judge Forrest, who was sitting by designation from the U.S. District Court for the Southern District of New York.

[32] 21 U.S.C. § 360b(e)(1) (2012).

[33] *NRDC*, 760 F.3d at 159.

[34] *Id.* at 158–59.

[35] *Id.* at 160.

finding.[36] Second, he explained that "the statute does not grammatically link the only 'finding' referred to in the statute to a mandatory *hearing*, but rather to a mandatory *withdrawal* of approval."[37] Accordingly, Judge Lynch held that, under § 360b(e)(1), the scientific findings demonstrating the dangers of using antibiotics in animal feed did not trigger a duty to hold hearings.[38]

Next, Judge Lynch addressed the district court's citizen-petition holding. The plaintiffs claimed that the instant case resembled *Massachusetts*, in which the Supreme Court invalidated the Environmental Protection Agency's (EPA) denial of a citizen petition, which asked the agency to initiate rulemaking under the Clean Air Act[39] (CAA) to regulate greenhouse gases.[40] Judge Lynch, however, rejected the analogy to *Massachusetts*, explaining that the CAA mandates that once the EPA finds that a substance contributes to air pollution, it has to prescribe emissions standards.[41] By contrast, in Judge Lynch's view, the FDCA affords the FDA complete discretion in its decision whether to hold the hearings that would initiate withdrawal proceedings.[42] Judge Lynch therefore found the case more analogous to *New York Public Interest Research Group v. Whitman*,[43] in which the Second Circuit reasoned that a different CAA provision grants the EPA discretion in deciding whether to initiate enforcement actions.[44] Because the FDA's decision was a "discretionary determination left to [its] prudent choice," Judge Lynch deferred to the Agency's preference for a voluntary compliance program instead of a hearing process.[45] Accordingly, Judge Lynch held that "it was neither arbitrary nor capricious for the FDA to deny the [citizen] petitions."[46]

Chief Judge Katzmann dissented. First, he rejected the majority's interpretation of § 360b(e)(1), explaining that under such an interpretation, the FDA would never be "statutorily required to initiate or continue withdrawal proceedings for a drug — no matter how terrifyingly unsafe that drug may be,"[47] which contradicted the FDCA's purpose.[48] Second, Chief Judge Katzmann criticized the majority's "implicit[] accept[ance]" of the FDA's argument that the withdrawal proceedings

---

[36] *Id.*
[37] *Id.* at 161.
[38] *Id.* at 171–72.
[39] 42 U.S.C. §§ 7401–7671q (2012).
[40] *NRDC*, 760 F.3d at 173.
[41] *Id.* at 174.
[42] *Id.* at 174–75.
[43] 321 F.3d 316 (2d Cir. 2003).
[44] *NRDC*, 760 F.3d at 174 (citing *Whitman*, 321 F.3d at 330–31).
[45] *Id.* at 175.
[46] *Id.*
[47] *Id.* at 177 (Katzmann, C.J., dissenting).
[48] *See id.* at 177–81.

were akin to enforcement actions and that its decision not to initiate those proceedings was thus unreviewable under *Chaney*.[49] As evidence of this acceptance, he pointed out that the majority analogized to *Whitman*, a case that relied on *Chaney* and "was limited to the enforcement context."[50] In Chief Judge Katzmann's view, *Whitman* and *Chaney* were inapposite because the withdrawal proceedings resembled rulemaking "at least as much as"[51] enforcement, and, therefore, the FDA's decision not to institute the proceedings should have been presumptively reviewable.[52] Chief Judge Katzmann then reviewed that decision and found it arbitrary and capricious because the FDA failed to address the scientific findings that produced safety concerns about the drugs.[53]

Although the FDA's refusal to commence withdrawal proceedings was a miscellaneous form of agency inaction, the reviewability of which is ambiguous, the majority declined to squarely address the threshold question of reviewability. Nonetheless, certain aspects of the opinion suggest that the majority "implicitly accept[ed]"[54] the FDA's argument that *Chaney*'s presumption of unreviewability applied; thus, the opinion could potentially be construed to endorse the extension of *Chaney*'s presumption beyond the pure enforcement context.[55] The better interpretation, however, is that the majority implicitly rejected the FDA's argument that *Chaney*'s presumption applied when it actually subjected the Agency's decision to APA arbitrary and capricious review. Rather than promoting *Chaney*'s expansion, the decision could therefore support future courts' efforts to confine *Chaney*'s presumption to pure enforcement actions.

In upholding the FDA's rejection of the citizen petitions, the majority declined to address the reviewability question, even though the FDCA withdrawal proceedings could not be seamlessly characterized as either enforcement actions or notice-and-comment rulemaking[56] and the parties had thoroughly briefed the issue.[57] Consequently, the ma-

---

[49] *Id.* at 188.

[50] *Id.*

[51] *Id.* at 190.

[52] *Id.* at 189–90.

[53] *Id.* at 192.

[54] *Id.* at 188.

[55] This comment uses the phrase "pure enforcement" to mean agency actions that punish past violations of the law. *Cf. id.* ("The prototypical enforcement action . . . is an action taken by the agency to punish a past violation of the law . . . .").

[56] *Id.* at 188–89 (explaining that the withdrawal proceedings "envision an adversarial process," like an enforcement action, but also "have only future effect" and "cannot punish any past violation of the law," like rulemaking, *id.* at 189).

[57] *See* Brief for Defendants-Appellants at 38–47, *NRDC*, 760 F.3d 151 (Nos. 12-2106(L), 12-3607(Con)), 2012 WL 4834272 (arguing that *Chaney*'s presumption extended beyond the pure enforcement context and applied in the instant case); Brief of Plaintiffs-Appellees at 45–52, *NRDC*,

jority eschewed taking a clear stance on the scope of *Chaney*'s presumption of unreviewability. Although certain characteristics of the majority opinion could indicate that the court supported extending *Chaney*'s presumption beyond the enforcement context, closer inspection reveals that none of these features indicate that the court favored such an extension.

First, the majority's statutory interpretation analysis relies, in part, on *Chaney* and seems to equate withdrawal proceedings with enforcement actions,[58] thus raising the specter of unreviewability. When addressing whether § 360b(e)(1) compelled the FDA to commence withdrawal proceedings, the majority stated that under *Chaney*, "[i]t is rare that agencies lack discretion to choose their own enforcement priorities" and, because "[p]laintiffs' interpretation of § 360b(e)(1) would deny that discretion to the FDA," it should be rejected.[59] To be sure, this language suggests that the FDCA's withdrawal proceedings qualify as enforcement actions. But however suggestive the majority's statutory interpretation analysis appears, it did not preclude the court from reviewing the agency inaction and thus was not controlling.

Second, the majority explicitly distinguished *Massachusetts*, the case that rejected extending *Chaney*'s presumption to the rulemaking context.[60] The majority argued that unlike the CAA, which requires the EPA to regulate greenhouse gases if it determines that they contribute to air pollution, the FDCA grants the FDA full discretion over whether to hold withdrawal hearings.[61] Yet although *Massachusetts* addressed whether the EPA's inaction was reviewable,[62] the *NRDC* majority only engaged with the merits portion of that decision, which asked whether the EPA's denial of a citizen petition was arbitrary and capricious.[63] The *NRDC* majority contrasted the relative discretion conferred by the FDCA and CAA only to show that the FDA's refusal to hold hearings, unlike the EPA's refusal to initiate rulemakings, could not be arbitrary and capricious — not to show that the FDA's refusal was unreviewable altogether.[64]

Third, the majority analogized to *Whitman*, a case in which the Second Circuit held that the EPA's decision not to issue a notice of deficiency when it found defects in a state permitting program was pre-

760 F.3d 151 (Nos. 12-2106(L), 12-3607(Con)), 2012 WL 5462771 (contending that *Chaney*'s presumption did not apply because it was relegated to agency decisions regarding how "to hold a regulated party accountable for a 'violation' of existing law," *id.* at 47).

58 *NRDC*, 760 F.3d at 170–71.

59 *Id.* at 171.

60 *Id.* at 174.

61 *Id.* at 174–75.

62 Massachusetts v. EPA, 549 U.S. 497, 527–28 (2007).

63 *Id.* at 528–35.

64 *See NRDC*, 760 F.3d at 174–75.

sumptively unreviewable under *Chaney*.[65] Yet, as the majority pointed out in a footnote, it did not cite *Whitman* in order to "equat[e] a withdrawal action to an enforcement action" and thereby contend that *Chaney* controlled.[66] Rather, it cited *Whitman* because the statutory provision at issue there, like the relevant FDCA provision, "le[ft] action dependent upon agency discretion," and, consequently, the case helped the majority "determine whether the FDA abused its discretion."[67] In other words, as with *Massachusetts*, the majority used *Whitman* to help resolve the merits question of whether the FDA's inaction was arbitrary and capricious, not to support a determination that the FDA's inaction was unreviewable.

Rather than extend *Chaney*, the majority implicitly rejected any claim that a presumption of unreviewability applied by actually reviewing the FDA's decision under the APA's arbitrary and capricious standard.[68] Specifically, the court noted that "[n]othing in the NOOHs suggests that [antibiotics], when administered to animals, are inherently dangerous to human health" and concluded that "[a]s it was neither arbitrary nor capricious for the FDA to deny the petitions for the reasons it did, the district court's decision to the contrary was error."[69] Although the majority's review was somewhat cursory and did not grapple with the scientific findings that show animal drugs pose human health risks, neither a lengthy review nor a scientific analysis was necessary once the court concluded that the statutory scheme afforded the Agency complete discretion.[70]

Because the majority did not squarely confront the threshold reviewability question, the opinion contains no explicit pronouncement about judicial review of miscellaneous agency inaction and therefore

---

[65] *See id.* (citing N.Y. Pub. Interest Research Grp. v. Whitman, 321 F.3d 316, 330–31 (2d Cir. 2003)).

[66] *NRDC*, 760 F.3d at 175 n.28.

[67] *Id.*

[68] *Cf.* Clemons v. Mississippi, 494 U.S. 738, 747 n.3 (1990) (acknowledging that a court may implicitly reject an argument by refusing to address it).

[69] *NRDC*, 760 F.3d at 175.

[70] Section 706(2) of the APA states that a reviewing court must "set aside agency . . . conclusions found to be . . . arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2) (2012). It follows that the more discretion a statute affords an agency in making a particular decision, the less likely it is the decision will be found arbitrary, capricious, or an abuse of discretion. Here, therefore, once the court found that the statute afforded the FDA *complete* discretion, *see NRDC*, 760 F.3d at 175, further analysis became superfluous. Although the distinction between deeming agency inaction unreviewable and reviewing agency inaction while affording the agency nearly complete discretion may seem inconsequential, it in fact carries precedential importance. If *NRDC* had held the FDA's inaction unreviewable, the case could have been used as ammunition by future courts looking to extend *Chaney*'s presumption. But because it reviewed the inaction when it had a prime opportunity to extend *Chaney*'s presumption, the majority opinion may instead be used by future courts looking to *confine Chaney*'s presumption to the enforcement context.

adds no further certainty to that doctrine. Chief Judge Katzmann's dissent proposes one framework to ameliorate such uncertainty. He would have courts determine the reviewability of miscellaneous agency inaction by discerning whether the requested action more closely resembles the prototypical enforcement action or the prototypical notice-and-comment rulemaking process.[71] Another, simpler possibility might be to explicitly confine *Chaney*'s presumption of unreviewability to agency decisions not to bring pure enforcement actions, thus making all other forms of agency inaction reviewable. That approach respects the Court's key justification for *Chaney*'s presumption — the similarity between an agency's decision not to enforce and a prosecutor's decision not to indict[72] — while also recognizing how *Massachusetts* may have narrowed *Chaney*.[73]

The majority opinion in *NRDC* may in fact lay the groundwork for this latter approach. The court had a prime opportunity to extend *Chaney*'s presumption by applying it to withdrawal proceedings, which, unlike pure enforcement actions, do not seek to punish past violations of the law. The FDA argued for such an extension in its brief. Nevertheless, the court declined to address reviewability and instead proceeded to review the FDA's inaction under the traditional arbitrary and capricious standard. By treating the case as one requiring run-of-the-mill arbitrary and capricious review, the majority implicitly rejected *Chaney*'s application and perhaps thereby provided support for a narrow reading of *Chaney* that restricts its presumption to the pure enforcement context.

---

[71] *NRDC*, 760 F.3d at 188–90 (Katzmann, C.J., dissenting).

[72] Heckler v. Chaney, 470 U.S. 821, 832 (1985).

[73] Besides the analogy to prosecutorial discretion, *Chaney*'s presumption rested on: (1) the fact that an agency's decision not to bring an enforcement action involves complex resource and policy considerations, *id.* at 831–32; and (2) the fact that when an agency declines to bring an enforcement action, it does not exercise its "coercive power" over entities' liberty or property rights, *id.* at 832 (emphasis omitted). Because an agency's decision not to initiate rulemaking also involves complex resource and policy considerations and does not involve an exercise of coercive power, *see* Am. Horse Prot. Ass'n v. Lyng, 812 F.2d 1, 4 (D.C. Cir. 1987), *Massachusetts* may have undermined these two justifications for *Chaney*'s presumption.