UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

(ECF)

NATURAL RESOURCES DEFENSE COUNCIL, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, FOOD ANIMAL CONCERNS TRUST, PUBLIC CITIZEN, INC., and UNION OF CONCERNED SCIENTISTS, INC.,	11 Civ. 3562 (JCF)
Plaintiffs,	MEMORANDUM AND ORDER
- against -	
UNITED STATES FOOD AND DRUG ADMINISTRATION, MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration, CENTER FOR VETERINARY MEDICINE, BERNADETTE DUNHAM, in her official capacity as Director, Center for Veterinary Medicine, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and KATHLEEN SIBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services,	
Defendants.	

JAMES C. FRANCIS IV
UNITED STATES MAGISTRATE JUDGE

Plaintiffs Natural Resources Defense Council, Inc. ("NRDC"), Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, and Union of Concerned Scientists brought this action against the various government defendants seeking to compel the United States Food and Drug Administration (the "FDA") to initiate proceedings to withdraw its approval of the use of certain antibiotics in livestock for non-therapeutic purposes.[1]

[1] For convenience, I will refer to the plaintiffs collectively as "NRDC" and the defendants collectively as the Government, unless

(Memorandum Opinion and Order dated March 22, 2012, at 2 ("March 22 Order")). The parties consented to the jurisdiction of a magistrate judge, and on March 22, 2012, the Honorable Theodore H. Katz, U.S.M.J., granted the plaintiffs' motion for summary judgment and denied the defendants' motion for summary judgment on the plaintiffs' first claim for relief, which charged the defendants with violating the Administrative Procedure Act (the "APA"), 5 U.S.C. § 706(2), and the Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 360b(e), for failing to implement such proceedings. (March 22 Order at 1, 54). On June 1, 2012, Judge Katz issued an opinion granting the plaintiffs' motion for summary judgment and denying the defendants' motion for summary judgment on the plaintiffs' third claim for relief, which alleged that the FDA violated the same two statutes when it denied two citizen petitions[2] "request[ing] that the FDA begin withdrawal proceedings for all non-therapeutic uses of medically-important antibiotics in food-producing animals." (Memorandum Opinion and Order dated June 1, 2012 ("June 1 Order"), at 2, 9).

The March 22 Order requested additional briefing on the issue of a schedule under which the FDA must act. (March 22 Order at 55 n.19). In the midst of that briefing, the Government appealed the March 22 Order (Notice of Appeal dated May 21, 2012) and filed a

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otherwise necessary for clarity.

[2] FDA regulations authorize the agency to consider petitions submitted by members of the public (including organizations) "request[ing] the Commissioner [of the FDA] to take or refrain from taking" administrative action. 21 C.F.R. § 10.30.

motion requesting that this Court stay the March 22 Order pending resolution of the appeal or, in the alternative, impose an interim stay pending disposition of the Government's not-yet-filed stay application in the United States Court of Appeals for the Second Circuit (Memorandum of Law in Support of the Government's Motion for a Stay Pending Appeal ("Gov't Stay Memo.") at 1). The plaintiffs, for their part, filed a motion to strike documents that the Government submitted in connection with its motion for summary judgment on the third claim for relief. (Plaintiffs' Motion to Strike Non-Record Material ("Motion to Strike")).

Upon Judge Katz' retirement, this case was reassigned to me. Before me now, then, are the parties' briefs regarding timing, the Government's motion for a stay, and the plaintiffs' motion to strike, and I held oral argument on these issues on July 18, 2012. For the reasons that follow, the plaintiffs' motion to strike is granted in part; the Government's proposed schedule for compliance with the March 22 Order is adopted; and the Government's motion for a stay is denied.

Background

The facts of the case are set out in the March 22 and June 1 Orders, with which I assume familiarity. Nevertheless, some background will be helpful in understanding the following discussion.

In the 1950s, the FDA approved the use of antibiotics "to stimulate growth and promote feed efficiency in food-producing animals" and issued permissions (by approving new animal drug

applications or abbreviated new animal drug applications) for penicillin and tetracyclines to be used for such purposes. (March 22 Order at 4-6). By the mid-1970s, however, the FDA, concerned with the public health risk to humans and animals of antibiotic resistance caused by such uses, issued a regulation "providing that the agency would propose to withdraw approval of all [non-therapeutic] uses of antibiotics in animal feed unless drug sponsors and other interested parties" presented data resolving the agency's concerns. (March 22 Order at 6-8). Thereafter, the FDA's Bureau of Veterinary Medicine (the "BVM") (which has since been renamed the Center for Veterinary Medicine (the "CVM")), along with a subcommittee of the FDA's National Advisory Food and Drug Committee (the "NAFDC") reviewed the data submitted. (March 22 Order at 8-9 & n.5). In 1977, the NAFDC adopted the report and recommendations of its subcommittee, which advised the FDA to "withdraw approval for the [non-therapeutic] uses of penicillin" and "discontinue the[] use [of tetracyclines] for growth promotion and/or feed efficiency in all animal species for which effective substitutes are available." (March 22 Order at 9-10 (internal quotation marks omitted)).

Later in 1977, after review of the NAFDC recommendations, the Director of the BVM issued notices of an opportunity for hearing ("NOOHs") on proposals to withdraw approval of all non-therapeutic uses of penicillin in animal feed and most non-therapeutic uses of tetracyclines in animal feed. (March 22 Order at 10). The FDA issued the NOOHs pursuant to a subsection of the provision of the

FDCA governing "New Animal Drugs":

> The Secretary [of the Department of Health and Human Services] 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 not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved . . . .

21 U.S.C. 360b(e)(1)(B). In response, "approximately twenty drug firms, agricultural organizations, and individuals requested hearings," at which, pursuant to the statutory and regulatory scheme, they would have the burden of proving that the relevant uses of the drugs were safe. (March 22 Order at 12).

The Commissioner of the FDA granted the hearing requests, but no hearings were ever scheduled. (March 22 Order at 12-13). Instead, the FDA continued to research the risks connected with the non-therapeutic uses of antibiotics in the feed of food-producing animals, contracting with various agencies to study the problem. (March 22 Order at 13-15). Three reports released in the 1980s -- by the National Academy of Sciences, the Seattle-King County Department of Public Health, and the Institute of Medicine -- were unable to conclude that the non-therapeutic use of antibiotics in animal feed was safe, instead finding support for the FDA's concerns. (March 22 Order at 14-15).

In June 2010, the FDA released a non-binding Draft Guidance, which reviewed recent studies on the risks of non-therapeutic uses

of antibiotics in animal feed and concluded that the evidence supported the conclusion "that using medically important [antibiotic] drugs for production purposes is not in the interest of protecting and promoting the public health." (March 22 Order at 16-17 (internal quotation marks omitted)). The FDA recommended restricting the use of antibiotics in food-producing animals to uses necessary for ensuring medical health and uses including veterinary oversight or consultation. (March 22 Order at 17).

The plaintiffs filed this action in May 2011 "alleging that the FDA's failure to withdraw approval of the [non-therapeutic] use of penicillin and tetracyclines pursuant to the 1977 NOOHs constituted an agency action unlawfully withheld or unreasonably delayed in violation" of the APA and the FDCA. (March 22 Order at 18). In December 2011, the FDA rescinded the 1977 NOOHs, explaining that it continued to be concerned about antibiotic resistance, but that it was "engaging in other regulatory strategies . . . and that if [it] were to move forward with the NOOHs it would need to update [them] to reflect current data, information, and policies and prioritize any withdrawal proceedings." (March 22 Order at 17 (internal quotation marks omitted)). In February 2012, the plaintiffs filed a supplemental complaint against the defendants contending that the FDA had violated the APA and the FDCA when it denied two citizen petitions submitted by certain plaintiffs and non-parties (one in 1995 by Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, Union of Concerned Scientists, and non-party

Environmental Defense Fund; one in 2005 by Union of Concerned Scientists and non-parties Environmental Defense Fund, American Academy of Pediatrics, and American Public Health Association). (June 1 Order at 2, 9, 14-15).

In the March 22 Order, Judge Katz held, first, that § 360b(e)(1) and its accompanying regulations require the FDA to take a series of "discrete actions" upon a "finding" that a new animal drug has not been shown to be safe, thus bringing this case under the rubric of § 706(1) of the APA, which the Supreme Court has held applies only when "an agency failed to take a discrete action that it is required to take." Norton v. Southern Utah Wilderness Alliance, 542 U.S. 55, 64 (2004); (March 22 Order at 21-26). He then held that the FDCA unambiguously requires the Secretary of Health and Human Services to begin proceedings to withdraw approval of a drug by issuing notice and providing an opportunity for a hearing once "[s]he finds that a new animal drug is not shown to be safe," rejecting the Government's position that the "finding" that triggers mandatory withdrawal proceedings occurs only after the opportunity for a hearing. (March 22 Order at 27-39). As a consequence of the conclusion that the statute's meaning is plain, the opinion unsurprisingly holds that the FDA's contrary interpretation does not deserve deference under Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984), and its progeny. (March 22 Order at 35-39). Moreover, Judge Katz found that (1) the Commissioner of the FDA, who has been delegated with the authority vested in the Secretary under the FDCA,

authorized the Director of the BVM "to make the findings on which such notices of withdrawal are based" (March 22 Order at 41-42); (2) in the 1977 NOOHs, the Director of the BVM made such findings requiring the FDA to proceed with the withdrawal of penicillin and tetracyclines (March 22 Order at 45-46); and (3) these findings were later adopted by Commissioner (March 22 Order at 47-48). The March 22 Order therefore held that the Government violated the APA and the FDCA by failing to begin the withdrawal of approval for non-therapeutic uses of penicillin and tetracyclines in animal feed after it had made the findings resulting in the NOOHs. In addition, Judge Katz held that, because the Government's duty was triggered by the Director's findings, and not by the issuance of the NOOHs, the 2011 rescission of the NOOHs did not moot this claim. (March 22 Order at 48-53).

The June 1 Order rejected the Government's argument that the FDA's denials of the citizen petitions were unreviewable "decisions not to enforce," Heckler v. Chaney, 470 U.S. 821, 827 (1985), and held that the denials were judicially reviewable because they were not "'action[s] committed to agency discretion by law'" pursuant to the APA. (June 1 Order at 25 (quoting 5 U.S.C. § 701(a)(2)). Specifically, Judge Katz found that "[t]he process of withdrawing approval of a new animal drug is more analogous to informal rulemaking than to traditional enforcement actions," and thus was amenable to judicial review under Massachusetts v. EPA, 549 U.S. 497 (2007). (June 1 Order at 31 & n.17). In addition, he found that the guiding statute, the FDCA, "provides sufficient guidelines

for the agency to follow in exercising its enforcement powers to rebut" any presumption of unreviewability. (June 1 Order at 35). Reviewing the denials, the June 1 Order found the FDA's asserted reasons -- that engaging in the formal withdrawal process would be too time-consuming and expensive, and that the phase-out of non-therapeutic uses of medically-important antibiotics would be accomplished through a non-binding voluntary guidance program begun in 2009 -- arbitrary and capricious because they did not follow the clear commands of the FDCA. (June 1 Order at 40-52). The Court therefore held that the denials must be vacated under Section 706(2)(A) of the APA, which authorizes a court to set aside arbitrary and capricious agency action. (June 1 Order at 38-40, 52-53).

Discussion

A. Motion to Strike

The plaintiffs ask that the Court strike a statement issued by the Animal Health Institute ("AHI")[3] expressing general support for the FDA's plans to reduce the non-therapeutic use of medically-important antibiotics in animal feed through a voluntary guidance program because the document is not part of the administrative record that was before the FDA when the challenged decisions were taken.[4] (Motion to Strike at 1-2; AHI Statement on FDA Guidance

[3] AHI is an industry organization representing companies that develop and produce animal drugs. See Animal Health Institute, About AHI, available at http://www.ahi.org/about/ (last visited Aug. 2, 2012).

[4] Although summary judgment has already been granted to the plaintiffs on the claim in connection with which this document was

Documents dated April 11, 2012 ("AHI Statement"), attached as Exh. F to Third Declaration of Amy A. Barcelo dated April 16, 2012 ("3d Barcelo Decl.")).

The "focal point" of judicial review of agency action is the administrative record upon which the agency made its decision, "not some new record made initially in the reviewing court." Camp v. Pitts, 411 U.S. 138, 142 (1973); IMS, P.C. v. Alvarez, 129 F.3d 618, 623 (D.C. Cir. 1997) ("It is a widely accepted principle of administrative law that the courts base their review of an agency's actions on the materials that were before the agency at the time its decision was made."); New York v. Shalala, No. 93 Civ. 1330, 1996 WL 87240, at *5 (S.D.N.Y. Feb. 29, 1996) ("Shalala") ("Judicial review of agency action is generally limited to review of the full administrative record that was before the agency at the time it rendered its decision."). Thus, it is established that a court may strike documents from the record that were not before the agency at the time of its decision.[5] See, e.g., Environmental

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submitted and it is clear that Judge Katz did not rely on this document in deciding that motion, the dispute is not moot, because its resolution will affect the composition of the record on appeal.

[5] Contrary to the Government's apparent position that Rule 12(f) of the Federal Rules of Civil Procedure grants a court its only power to strike documents from the record and that such documents are limited by the rule to "pleadings" (Memorandum in Opposition to Plaintiffs' Motion to Strike Non-Record Material ("Strike Opp. Memo.") at 1), a court has "'inherent authority to strike any filed paper which it determines to be abusive or otherwise improper under the circumstances.'" In re Bear Stearns Cos., Inc., Securities, Derivative, and ERISA Litigation, 763 F. Supp. 2d 423, 581 (S.D.N.Y. 2011) (quoting Sierra v. United States, No. 97 Civ. 9329, 1998 WL 559715, at *9 (S.D.N.Y. Sept. 10, 1998)); see also, e.g., Jenkins v. City of New York, No. 91 Civ. 3639, 1992 WL 147647, at *3-4 (S.D.N.Y. June 15, 1992) (striking affidavit

Defense Fund, Inc. v. Costle, 657 F.2d 275, 285-86 (D.C. Cir. 1981) (affirming district court's decision to strike affidavits that were not part of administrative record); Shalala, 1996 WL 87240, at *5-7 (striking materials outside administrative record from dispositive motion papers).

The Government contends that the AHI Statement is properly included as "background information about the animal drug industry's current stance toward the FDA's plans to regulate." (Strike Opp. Memo. at 2). Some courts have held that information outside of the administrative record may be reviewed as background to help the court understand the relevant issues. See Rochester-Genesee Regional Transportation Authority v. Hynes-Cherin, 531 F. Supp. 2d 494, 518 (W.D.N.Y. 2008) (collecting cases from the Sixth and Ninth Circuits, the District of the District of Columbia, and the Western District of New York). According to the defendants, the AHI Statement shows that the animal drug industry "appears now to support the FDA's approach."[6] (Strike Opp. Memo. at 2).

However, the Government has not explained how an expression of support from the animal drug industry that post-dates the FDA's

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opposing summary judgment as improper).

[6] This characterization overreaches. The AHI Statement merely expresses "agree[ment]" with the "direction and the collaborative, stakeholder process" as a prelude to a complaint that "there are details that must be addressed to make this approach practical and workable." (AHI Statement at 1). Indeed, as Judge Katz pointed out, the Government provides "no hard evidence that the drug sponsors have agreed or will agree[] to the proposed measures." (June 1 Order at 49-50).

decision on the citizen petitions is relevant -- even as background -- to the question of whether the FDA's denial violated the FDCA or the APA. To be sure, the AHI Statement could be used as evidence that the FDA's voluntary compliance program might succeed (although as noted in the footnote, this is something of a stretch), but the Government has expressly disavowed the notion that the FDA's confidence in the program is relevant to its defenses, stating that the premise that the Court's determination might "depend[] on the strength of the FDA's asserted faith or professed confidence in the voluntary compliance program" is "incorrect." (Strike Opp. Memo. at 2 (internal quotation marks and ellipses omitted)). Indeed, at oral argument, the Government admitted that AHI's public statements "have very little relevance" to the FDA's decisions. (Tr. at 13). Moreover, it is clear that Judge Katz did not find the AHI Statement useful or relevant, as he never alluded to it in the June 1 Order.

Because the AHI Statement was not part of the administrative record before the FDA at the relevant time and it is not "useful" to the Court as background information, the plaintiffs' motion to strike is granted to the extent that it requests that the AHI Statement be stricken from the record.

The plaintiffs also asked the Court to disregard three other documents submitted with the Government's motion papers. (Motion to Strike at 3; FDA Draft Guidance for Industry #209 dated April 13, 2012 ("Draft Guidance #209"), attached as Exh. A to 3d Barcelo Decl.; Draft Text for Proposed Regulation dated April 5, 2012

("Draft Regulation"), attached as Exh. B to 3d Barcelo Decl.; FDA Guidance for Industry #213 dated April 13, 2012 ("Draft Guidance #213"), attached as Exh. C to 3d Barcelo Decl.).[7] NRDC has since conceded that the documents were properly part of the record, and it is, therefore, no longer pressing this claim. (Transcript of Oral Argument dated July 18, 2012 ("Tr.") at 5-6).

B. Schedule for Withdrawal Proceedings

In compliance with the March 22 Order, the parties have submitted briefs on the issue of a schedule for the FDA's withdrawal proceedings. The Government asks that I refrain from imposing any deadlines, stating that "subject to any future direction by the appellate courts, it intends to abide by the orders of the Court." (Brief in Support of the Government's Position on the Issue of Timing ("Gov't Timing Br.") at 1-2). In the alternative, the Government proposes a timeline -- derived from an "analysis to estimate the time and resources that would be required" (1st Flynn Decl., ¶ 6) -- that requires reissuance of the NOOHs within 11 to 17 months, with an additional period of years to complete the withdrawal process, including administrative appeals. (Gov't Timing Br. at 10-11; 1st Flynn Decl., ¶¶ 6, 11-15, 18-21, 23-24). NRDC, in contrast, asserts that a schedule is essential, and that the Government's "protracted" timing estimate should be slashed so that the NOOHs are required to be issued within 125 days of commencement of the process and withdrawal proceedings are

[7] The Third Barcelo Declaration mistakenly states that Draft Guidance #213 is attached as Exhibit B and that the Draft Regulation is attached as Exhibit C. (3d Barcelo Decl., ¶¶ 4-5).

complete in an additional two years. (Plaintiffs' Opposition to the Government's Brief Concerning a Schedule for Compliance with the Court's Order ("Pl. Timing Br.") at 21, 24).

1. Authority to Impose a Schedule

Even in the area of administrative law, district courts have "broad equitable powers" to order "any appropriate relief" that is not prohibited by Congress. Cobell v. Norton, 240 F.3d 1081, 1108 (D.C. Cir. 2001). However, a court must be careful not to intrude "into the domain which Congress has set aside exclusively for the administrative agency," Federal Power Commission v. Transcontinental Gas Pipe Line Corp., 423 U.S. 326, 333 (1976) (internal quotation marks omitted), by "control[ling] the operations" of the agency, Sierra Club v. U.S. Army Corps of Engineers, 701 F.2d 1011, 1042 (2d Cir. 1983). For example, in the absence of "extremely compelling circumstances," a court oversteps its bounds if it dictates the procedures an agency must follow in performing its statutory duties, see Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, 435 U.S. 519, 543-45 (1978); or retains jurisdiction to oversee an agency's compliance with the court's orders, see Sierra Club, 701 F.2d at 1042-49 (vacating district court's order appointing special master with "highly intrusive" mandate and requiring agency itself to make required investigations and analyses, among other things); Baystate Medical Center v. Leavitt, 587 F. Supp. 2d 37, 41 (D.D.C. 2008) (refusing to retain jurisdiction to oversee agency's compliance with court order). However, it is clear that if an agency has

unreasonably delayed dispatching its duty, it is permissible for a court to impose a timetable for compliance. See Cobell, 240 F.3d at 1107 (affirming district court's order imposing timetable when agency had unreasonably delayed fulfilling its duty); Public Citizen Health Research Group v. Brock, 823 F.2d 626, 627 (D.C. Cir. 1987) (per curiam) (noting that court ordered agency that had unreasonably delayed rulemaking to complete proceedings within one year); White v. Matthews, 559 F.2d 852, 860 (2d Cir. 1977) (affirming district court order imposing schedule on Social Security Administration because of unreasonable delays in adjudicating claims).

The Government asserts that this is not a situation in which the FDA has unreasonably delayed action. (Gov't Timing Br. at 1; Reply Brief on Support of the Government's Position on Timing ("Gov't Timing Reply") at 6). It is true that NRDC did not argue that the FDA's failure to complete withdrawal proceedings was action "unreasonably delayed" under the APA, but rather that it was "unlawfully withheld." (Memorandum of Law in Support of Plaintiffs' Motion for Summary Judgment at 10-13). In granting NRDC's motion for summary judgment, Judge Katz did not make an explicit finding that the FDA unreasonably delayed action. However, he did mark the agency's "prolonged inaction" and repeatedly referred to its decades-long failure to commence withdrawal proceedings. (March 22 Order at 2-3, 17, 51 n.16). Similarly, in its brief regarding timing, NRDC focuses on the agency's delay. (Pl. Timing Br. at 2, 8, 10-11). The fact that

the March 22 Order lacks a discussion of unreasonable delay does not indicate, as the Government would have it, that it is "[not] present here" as a factual matter. (Gov't Timing Reply at 6). Nor does it mean that I cannot consider the whether the agency has in fact unreasonably delayed institution of withdrawal proceedings in deciding how to exercise the court's "broad equitable powers" to order relief.

To decide whether there has been unreasonable delay meriting the imposition of a schedule or deadline, I am guided by "six principles that have helped courts determine when mandamus is an appropriate remedy for agency delay":

> (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by the delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.[8]

In re Barr Laboratories, Inc., 930 F.2d 72, 74-75 (D.C. Cir. 1991) (internal quotation marks omitted) (citing Telecommunications Research & Action Center v. FCC, 750 F.2d 70, 80 (D.C. Cir. 1984)). "[A] finding that delay is unreasonable does not, alone, justify

[8] At oral argument, the Government requested additional briefing on the unreasonable delay factors, as they were not addressed in the initial round of papers. (Tr. at 62). Further briefing, however, is unnecessary and would only create more delay.

intervention." Barr Laboratories, 930 F.2d at 75 (internal quotation marks omitted). Instead, a court should weigh the effect on the agency of the contemplated order, as well as the effect of the delay on other interests involved.

As the March 22 Order makes clear, the finding that triggered the FDA's duty to commence withdrawal proceedings was memorialized in the 1977 NOOHs. This lawsuit was filed over thirty years later, in 2011. During the intervening decades, the FDA did not perform its statutorily-prescribed duty to initiate, let alone complete, withdrawal proceedings. Although Congress has not provided guidance on the issue, I have no difficulty concluding that thirty-plus years is an unreasonable delay.

The Government complains that imposing a timetable will impermissibly re-order its priorities, citing Barr Laboratories. In that case, a drug manufacturer sought a writ of mandamus compelling the FDA to act on its generic drug applications. Barr Laboratories, 930 F.2d at 73. Although the law required action within 180 days of receipt of the applications, the FDA admitted that action on such applications took significantly longer and estimated that in the future, it could take almost two years. Id. at 74. Nonetheless, the court refused to issue the writ, explaining that "a judicial order putting Barr at the head of the queue simply moves all others back one space and produces no net gain." Id. at 75.

This case is easily distinguishable. In Barr Laboratories, the writ of mandamus would have effectively controlled the agency's

generic drug approval process, benefitting one enterprise at the expense of others, failing to improve the efficiency of the process of approving (or disapproving) generic drugs, and having no effect on human health and welfare. Here, the FDA has utterly failed in its duty to initiate congressionally-mandated withdrawal proceedings. Requiring it to do so promptly is not reordering the FDA's priorities; it is correcting the agency's misprision of its duty. In Barr Laboratories, the court found that the contemplated order would have no effect on human health and welfare. Here, in contrast, compelling the FDA to timely fulfill its obligations will speed adjudication on the issue of whether the non-therapeutic use of certain antibiotics in animal feed threatens human health and, if the sponsors or other interested parties cannot demonstrate the drugs' safety, accelerate their compulsory withdrawal. See 21 U.S.C. § 360b(e)(1) (mandating withdrawal proceedings when the evidence demonstrates that the "drug is not shown to be safe"); 21 C.F.R. § 514.115(b)(3) (same); Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 56264 (Oct. 21, 1977) (stating that "the tetracycline-containing products have not been shown to be safe for widespread subtherapeutic use"); Penicillin-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 43772 (Aug. 30, 1977) (stating that "the penicillin-containing products have not been shown to be safe for subtherapeutic use").

The Government repeatedly asserts that a schedule should not Gov't Timing Br. be imposed because the FDA did not believe it had

"a legal duty to proceed with hearings." (Gov't Timing Br. at 1, 5, 8; Gov't Timing Reply at 2; Declaration of William T. Flynn dated May 15, 2012 ("1st Flynn Decl."), ¶ 5). However, as the District of Columbia Circuit makes clear, "the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed." Barr Laboratories, 930 F.2d at 75. The FDA's asserted belief that neither the FDCA nor its regulations required further action once the 1977 NOOHs were issued, then, does not make this delay any less unreasonable. Moreover, the FDA seems to have a pattern of attempting to avoid instituting proceedings to withdraw approval of the non-therapeutic use of antibiotics in animal feed. As detailed in the June 1 Order, in 1999 and 2005 certain plaintiffs (as well as other entities) filed citizen petitions with the FDA seeking such proceedings. (June 1 Order at 9, 14-15). The FDA delayed final action on the petitions for "thirteen and seven years, respectively." (June 1 Order at 45). It was not until November 7, 2011, during the pendency of this litigation, that the agency issued final responses denying the petitions, citing the time and expense of holding withdrawal proceedings. (June 1 Order at 12-13, 19-20, 44). As Judge Katz held, "the fact that withdrawing approval may be costly or time-consuming is not a sufficient justification . . . for the [FDA] to abdicate its duty . . . ."[9]

[9] Judge Katz also noted that there was "some justification" for the plaintiffs' hypothesis that the FDA's "refusal to evaluate the science [included in the citizen petitions] was motivated in part by a desire to avoid the statutory requirement of initiating formal withdrawal proceedings." (June 1 Order at 48).

(June 1 Order at 45). In these circumstances, I find that the FDA's unreasonable delay merits the imposition of a schedule for compliance with the March 22 Order.[10]

2. Schedule for Compliance

The Government has conducted an analysis to determine the likely amount of time it will take to perform each of the tasks required to comply with the March 22 Order and supports the schedule with a declaration from Dr. William T. Flynn, the CVM's Deputy Director for Science Policy. (1st Flynn Decl., ¶¶ 1, 6, 11-15, 18-21, 23-24). NRDC objects to the proposed time estimates as "protracted" (Pl. Timing Br. at 1), "leisurely" (Pl. Timing Br. at 14), "vague" (Pl. Timing Br. at 14, 16), "excessive" (Pl. Timing Br. at 14, 18), and "generous" (Pl. Timing Br. at 15), and suggests a significantly abbreviated schedule (Pl. Timing Br. at 21). While the Government's position draws on its expertise, including experience with prior withdrawal proceedings (Gov't Timing Br. at 13; 1st Flynn Decl., ¶ 23; Declaration of William T. Flynn dated June 1, 2012 ("2d Flynn Decl."), ¶ 4; Tr. at 57), the plaintiffs' arguments are largely speculative.

Look, for example, at the plaintiffs' complaints about the amount of time it will take for the agency to search CVM's files for information relevant to reissuance of the NOOHs. Dr. Flynn estimates it will take "10 to 14 employees . . . approximately 60

[10] Importantly, the imposition of this schedule does not involve the court retaining jurisdiction over the case or requiring periodic reports on compliance from the FDA. Thus, it differs significantly from the court orders at issue in Sierra Club and Vermont Yankee.

days," with each employee devoting "a substantial amount of time" to the project. (1st Flynn Decl., ¶ 11). NRDC argues that, because Dr. Flynn does not specify the amount of time each employee will spend on each task, the "estimate allows for tremendous variation." (Pl. Timing Br. at 14). It then spins out two variations, one of which assumes that the task would take 10 employees 86 work-hours each.[11] (Pl. Timing Br. at 14). NRDC calculates that if each of these employees worked full time on the project, it could be completed in two weeks. (Pl. Timing Br. at 14). It then notes that congressional testimony from agency personnel "suggests that FDA has already devoted significant time and resources to searching its files," and concludes that "it should take the agency no longer than two weeks to search its own files for relevant information." (Pl. Timing Br. at 15 (emphases added)). As the Government points out, this argument is based on the assumption that "the work required is largely complete," and "amount[s] to little more than speculation about the level of preparation that it takes to initiate a complex set of drug withdrawal proceedings." (Gov't Timing Reply at 8). The Government contends that, even if the literature has been reviewed previously for other purposes, that review not only needs to be updated, but also "tailor[ed] . . . to the specific goal of initiating . . . withdrawal proceedings for individual products." (Gov't Timing Reply at 8). If this is not properly accomplished,

[11] The plaintiffs dismiss the other variation (which assumes fourteen employees working on the task full-time for two months) as "not credible." (Pl. Timing Br. at 14).

the revised NOOHs will be open to challenge on the basis of "incompleteness [and a] lack of scientific rigor." (1st Flynn Decl., ¶ 9).

NRDC's support for its abbreviated schedule consists of a declaration by Dr. Lance Price, an associate professor who directs the Center for Microbiomics and Human Health and the Center for Food Microbiology and Environmental Health at the Translational Genomics Research Institute, a nonprofit biomedical research institute. (Declaration of Lance Price, Ph.D. dated May 23, 2012 ("Price Decl."), ¶ 1). Professor Price estimates that it would take one graduate-level research assistant working full-time sixty days to complete the review or two such research assistants thirty days. (Price Decl., ¶ 6). However, these estimates do not appear to take into account the purposes of the review. Moreover, the fact that such a review could be performed by research assistants working full-time on the project in an academic environment says little about the time requirements for civil servants in a federal agency who have other responsibilities. Indeed, NRDC's two-week estimate appears to rely on the unfounded assumption that agency personnel will be able to devote their undivided time and attention to this project.

Similarly, NRDC's insistence that any hearings can be completed within 21 months of issuance of the revised NOOHs (Pl. Timing Br. at 24) is unsupported and, as the Government points out, completely speculative. (Gov't Timing Reply at 9). For example, it does not appear to take into account the potential number of

requested hearings that the FDA will have to hold.

The agency is in the best position to analyze the issue and propose a realistic schedule that is not based on unsupported assumptions, but rather on its expertise, and it has done so. See International Chemical Workers Union, 958 F.2d 1144, 1150 (D.C. Cir. 1992) (accepting agency's estimate of time needed to complete rulemaking); Brock, 823 F.2d at 629 (adopting agency's proposed timetable even though target date was "disappointing"); cf. Qwest Communications International v. Federal Communications Commission, 398 F.3d 1222, 1239 (10th Cir. 2005) (declining to impose "arbitrary" deadline where agency did not propose schedule for compliance). Therefore, I adopt the Government's proposed schedule, which requires issuance of revised NOOHs for penicillin and tetracyclines in 17 months, and provides an additional 41 months for the hearing process. (1st Flynn Decl., ¶¶ 16, 25).

C. Motion to Stay

The Government has requested a stay of the March 22 Order pending the Second Circuit's decision on its appeal or, in the alternative, a stay pending the Second Circuit's resolution of the Government's planned application for a stay in that court. (Gov't Stay Memo. at 1). "A stay is not a matter of right, even if irreparable injury might otherwise result. It is instead an exercise of judicial discretion, and the propriety of its issue is dependent upon the circumstances of the particular case." Nken v. Holder, 556 U.S. 418, 433 (2009) (internal quotation marks and citations omitted). In deciding whether to issue a stay pending

appeal, a court considers four factors:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Id. at 434 (internal quotation marks omitted). "The first two factors . . . are the most critical," id., and these factors have typically been evaluated on a sliding scale, so that a strong showing that the applicant is likely to succeed excuses a weaker showing of irreparable injury. Nevertheless, the Supreme Court has recently emphasized that the applicant must demonstrate that both factors are satisfied, so that even if a party makes a robust showing that it is likely to succeed on appeal, it still must also show that "irreparable injury is likely." Winter v. Natural Resources Defense Council, 555 U.S. 7, 22 (2008).[12] The party seeking the stay bears a heavy burden to "establish[] a favorable balance of these factors." Barcia v. Sitkin, No. 79 Civ. 5831, 2004 WL 691390, at *1 (S.D.N.Y. March 31, 2004) (citing 11 Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure §

[12] Winter dealt with the showing required for the issuance of a preliminary injunction rather than for a stay pending appeal. However, the test for a stay "is essentially the same" as the test for a preliminary injunction. Citizens for Responsibility and Ethics in Washington v. Office of Administration, 593 F. Supp. 2d 156, 159 n.1 (D.D.C. 2009)(internal quotation marks omitted); see also In re St. Johnsbury Trucking Co., 185 B.R. 687, 688 (S.D.N.Y. 1995) ("The standard for issuance of a stay pending appeal is similar to that governing motions for preliminary injunctions."). Winter's clarification of the standard therefore applies to stay applications. Consequently, cases discussing the factors a court must weigh in deciding a preliminary injunction motion are helpful in analyzing this stay application.

2904); see Shays v. Federal Election Commission, 340 F. Supp. 2d 39, 41 (D.D.C. 2004) (noting that the "standards required to justify the extraordinary remedy of a stay pending appeal" are "stringent").

1. Likelihood of Success on the Merits

Although the oft-repeated standard indicates that an applicant must "ma[ke] a strong showing that he is likely to succeed on the merits," Hilton v. Braunskill, 481 U.S. 770, 776 (1987), if "a serious legal question is involved," a stay may issue when the movant "present[s] a substantial case on the merits . . . and show[s] that the balance of the equities weighs heavily in favor of granting the stay," LaRouche v. Kezer, 20 F.3d 68, 72-73 (2d Cir. 1994); see also Sutherland v. Ernst & Young LLP, __ F. Supp. 2d __, 2012 WL 751970, at *1 (S.D.N.Y. March 6, 2012); cf. Citigroup Global Markets, Inc. v. VCG Special Opportunities Master Fund Limited, 598 F.3d 30, 38 (2d Cir. 2010) (holding, in preliminary injunction context, that Winter does not foreclose a "flexible standard" of "assessing a movant's likelihood of success on the merits").

The Government argues, as it did in its motions for summary judgment, that (1) "the plain meaning of [21 U.S.C. § 360b(e)(1)] provides that the Commissioner's statutory finding comes only after [a] hearing or after a sponsor opts not to request a hearing" (Gov't Stay Memo. at 8); (2) to the extent the statute is ambiguous, the FDA's interpretation that the finding triggering withdrawal proceedings occurs after notice and the opportunity for

a hearing is reasonable and deserves deference (Gov't Stay Memo. at 9-10); (3) the withdrawal of the 1977 NOOHs is entitled to deference as an "archetypal exercise of the [FDA's] expert scientific judgment and regulatory discretion" (Gov't Stay Memo. at 11); (4) the withdrawal mooted this dispute (Gov't Stay Memo. at 14 n.8); and (5) the failure to commence withdrawal proceedings is an unreviewable "'decision[] not to enforce'" under Chaney, 470 U.S. at 828 (Gov't Stay Memo. at 12).

Judge Katz' thorough opinion in this case addressed each of these contentions and rejected them. See Schwartz v. Dolan, 159 F.R.D. 380, 384 (N.D.N.Y. 1995) ("Mere repetition of arguments previously considered and rejected cannot be characterized as a 'strong showing' [of likelihood of success on the merits]."); see also International Equity Investments, Inc. v. Opportunity Equity Partners, Ltd., No. 05 Civ. 2745, 2006 WL 1116437, at *3-4 (S.D.N.Y. April 26, 2006) (holding that applicant had failed to show a likelihood of success on the merits when it presented only arguments that the court had already rejected); Shays, 340 F. Supp. 2d at 45-47 (same).

However, neither party denies that this case involves serious legal questions regarding the FDA's responsibilities under the APA, the FDCA, and the pertinent regulations. The issues presented, perhaps most particularly the proper identification of the "finding" that triggers the commencement of withdrawal proceedings under 21 U.S.C. § 360b(e)(1)(B) and the consequences that follow, are difficult. Moreover, the appeal will likely present only

questions of law, which the Second Circuit will review without deference. The Government's arguments, although largely regurgitated from its summary judgment papers, are far from frivolous. Although the Government may not have made a strong showing of likelihood of success on appeal, it has presented a "substantial case on the merits." LaRouche, 20 F.3d at 72. Therefore, the success of its stay application depends on whether it can "show that the balance of the equities weighs heavily in favor of granting the stay." Id. at 72-73.

2. Irreparable Injury

To support a stay pending appeal, the applicant must show "injury that 'is neither remote nor speculative, but actual and imminent and cannot be remedied by an award of monetary damages.'" RxUSA Wholesale, Inc. v. Department of Health and Human Services, 467 F. Supp. 2d 285, 301 (E.D.N.Y. 2006) (quoting Rodriguez v. DeBuono, 175 F.3d 227, 234 (2d Cir. 1999) (per curiam)). The potential for irreparable injury should be evaluated taking into account the possibility that the ruling sought to be stayed is erroneous. See National Immigration Project of the National Lawyers Guild v. U.S. Department of Homeland Security, __ F. Supp. 2d __, 2012 WL 375515, at *11 (S.D.N.Y. Feb. 7, 2012) ("Thus, failure to stay the disclosure required by the Order would cause the Government irreparable injury if the ruling [were] erroneous.").

The Government contends that it will suffer irreparable injury if a stay is not granted because the significant resources the FDA

will be required to expend in order to commence withdrawal proceedings will "compromise FDA's ability to pursue its goals with respect to antimicrobial resistance and animal drug licensing by diverting resources away from those programs." (Gov't Stay Memo. at 15-18). This argument does not demonstrate irreparable harm sufficient for the imposition of a stay.

First, the Government undermines its own argument when it asserts that its proposed schedule (which is the schedule I have adopted) "is intended to appropriately balance resources devoted to Withdrawal Proceedings . . . with resources required for CVM's myriad other responsibilities." (Gov't Timing Reply at 9). Next, as a practical matter, the schedule allows up to 17 months for the initial literature review and an additional period of years for completion of the withdrawal proceedings. These generous time limits further weaken the Government's claims of irreparable harm in light of the fact that the appeal will be fully briefed and ready for argument and decision by the end of this year.[13] The only task on the FDA's schedule during the pendency of the appeal, then, is the beginning of the literature review -- an entirely internal process which, even if "resource-intensive" (Gov't Stay Memo. at 14), is hardly likely to infringe significantly on the FDA's operations. Any putative harm attendant on the finalization of the

[13] The Government's opening brief is due September 4, 2012. (Order, Natural Resources Defense Council v. United States Food & Drug Administration, Case No. 12-2106 (2d Cir. June 19, 2012), ECF No. 25). Pursuant to the Second Circuit's rules, briefing must be complete by December 18, 2012, absent extraordinary circumstances. Local Rules and Internal Operating Procedures of the Court of Appeals for the Second Circuit, Rule 31.2.

revised NOOHs and subsequent events is too speculative to consider, as it is likely that by the time these tasks must be completed, the appeal will have been decided. To the extent that the Government worries that compulsory withdrawal proceedings will inhibit drug sponsors from participating in the voluntary withdrawal program, this concern seems misplaced. As noted, the literature review process is internal to the FDA; it does not compel the drug sponsors to do anything. There is no reason that the FDA's literature review should drive sponsors who were already inclined to participate in the voluntary program to reverse course. It is even possible that more sponsors will participate in order to stave off compelled action.

Moreover, the argument "that potentially wasted and diverted staff resources constitutes irreparable harm" has been held "meritless." Shays, 340 F. Supp. 2d at 48; see also Graphic Communications Union v. Chicago Tribune Co., 779 F.2d 13, 15 (7th Cir. 1985) (holding that costs incurred as consequence of compliance with court order do not show irreparable harm). This is a sensible rule. As NRDC points out, accepting the Government's argument would almost always result in a finding of irreparable harm whenever an agency was required to comply with a court order. (Plaintiffs' Opposition to the Government's Motion for a Stay Pending Appeal ("Pl. Stay Memo.") at 16). As a consequence, stays pending appeal would become routine, conflicting with the rule that such relief should be "extraordinary." Shays, 340 F. Supp. 2d at 41; cf. Graphic Communications, 779 F.2d at 15 (noting that if

costs imposed by compliance with court order constituted irreparable harm, every such order "would be deemed to create irreparable harm, and it would be easy to get such orders stayed").

The Government attempts to distinguish Shays, asserting that in that case, "not only did the [agency] not make any claim that its ability to fulfill its mission would be compromised without a stay, but it did not even claim that any specific programs would be harmed at all. Rather the [agency] made a general (and unsupported) claim of diversion of resources from other agency priorities." (Gov't Stay Reply at 7). The Government cites nothing -- no document or brief -- that supports its position that the agency did not in fact present such allegations or submit such evidence. More importantly, the Shays opinion itself provides no support for the Government's characterization of the evidence there. In any case, the Government's assertions about the opinion, even if supported, do not undermine that court's categorical rejection of the argument that the diversion of agency resources constitutes irreparable harm.

The additional cases the defendants marshal as support fare no better. The Government cites James River Flood Control Association v. Watt, 680 F.2d 543 (8th Cir. 1982) (per curiam), and Arkansas Peace Center v. Arkansas Department of Pollution, 992 F.2d 145 (8th Cir. 1993) to bolster its position that diversion of agency resources is irreparable harm sufficient to merit a stay. In James River, the district court issued a preliminary injunction prohibiting the Department of the Interior from acquiring land on

which it intended to build a pumping station, "pending the outcome of proceedings . . . regarding the inadequacy of the Environmental Impact Statement." 680 F.2d at 544. In Arkansas Peace Center, the district court preliminarily enjoined the defendant agencies from incinerating certain hazardous wastes based on allegations that "the incineration was proceeding in violation of certain federal and state regulations regarding incinerator performance." 992 F.2d at 146. In both cases, the court found that preventing the actions would irreparably harm the agencies. Id. at 147; James River, 680 F.2d at 544. However, in neither case did the Eighth Circuit suggest that the enjoined activities were statutorily mandated, as Judge Katz found here. Nor did the appellate court suggest that redistribution of agency resources motivated staying the preliminary injunctions. These cases are therefore of doubtful relevance.

Finally, the Government's argument is, at its base, an economic one: that the opportunity cost of compliance with the March 22 Order will irreparably harm the FDA. But the Government has not demonstrated that compliance would seriously threaten its mission or operations. Rather, it asserts that the diversion of resources will "compromise" the FDA's pursuit of goals relating to antimicrobial resistance. (Gov't Stay Memo. at 15; Gov't Stay Reply at 6; 2d Flynn Decl., ¶ 4). As support, it cites concerns such as a "drain [of] resources" from certain other FDA programs (1st Flynn Decl., ¶ 26), the possibility of delay in certain programs (1st Flynn Decl., ¶ 27), and difficulty fully staffing

both the voluntary withdrawal project and the formal withdrawal proceedings at all times (2d Flynn Decl., ¶ 8). This evidence does not show that compliance with the March 22 Order will substantially endanger the CVM's or the FDA's mission to "protect the public health by ensuring that . . . human and veterinary drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B).

In short, the Government has not shown that it will be irreparably harmed if a stay pending appeal is not granted.

3. Injury to the Plaintiffs and the Public Interest

The Government recognizes, and NRDC does not appear to dispute, that the plaintiffs "are in the same position as members of the public." (Gov't Stay Memo. at 19). In this case, then, the last two factors are best discussed together. (Gov't Stay Memo. at 18-20; Pl. Stay Memo. at 20-22).

The Government asserts that the public interest supports a stay because the FDA "has determined that the public health concerns regarding production uses of antibiotics in animal feed would be most quickly addressed by finalizing and implementing" the voluntary program it prefers. (Gov't Stay Memo. at 18-19). Additionally, it asserts that the FDA's "preferred regulatory strategy covers a much broader set of drugs than the contemplated by the March 22 Order." (Gov't Stay Memo. at 19).

The Government fails to take into account the fact that the March 22 Order held that the FDCA requires the FDA to initiate withdrawal proceedings. "When administrative agencies fail to follow statutory procedures, the public suffers." Apotex, Inc. v.

U.S. Food & Drug Administration, 508 F. Supp. 2d 78, 88 (D.D.C. 2007).

In addition, for all its insistence that the voluntary program will succeed, the Government has presented "no hard evidence that the drug sponsors have agreed or will agree[] to the proposed measures." (June 1 Order at 49-50). The single piece of evidence it submitted (which has been struck from the record) expressed tepid support, at best, from the affected community. At oral argument, the Government was not able to articulate any more convincing reason for its confidence. (Tr. at 46-49). As the plaintiffs note, the voluntary program is passive insofar as it requires drug sponsors to approach the FDA if they are interested in taking part in the program. (Pl. Stay Br. at 21; Final Response to Citizen Petition dated Nov. 7, 2011, attached at Exh. A to Declaration of Mitchell S. Bernard dated Feb. 21, 2012, at 4). Although the Government may hold fast to its "hope and belief . . . that everyone will move together at the same time" (Tr. at 20), insufficient buy-in by the drug sponsors will likely result, ultimately, in the same formal withdrawal procedures required under the both the March 22 Order and now this order. (Gov't Stay Brief at 16-17; 2d Flynn Decl., ¶ 5).

On the other hand, engaging in the mandated withdrawal procedures promptly will allow drug sponsors the opportunity to show that the challenged drug uses are safe. If they are shown to be safe, the public interest is likely served by allowing their continued use. If, however, they are not shown to be safe, the FDA

will be required to withdraw approval, thus safeguarding the public's (and the plaintiffs') health and welfare. Moreover, as Judge Katz observed, "nothing prevents the [FDA] from seeking voluntary cooperation from the drug industry[] in tandem" with withdrawal proceedings. (June 1 Order at 49). Even if both projects might not be "adequately staffed at all times" (2d Flynn Decl., ¶ 8), simultaneous engagement will have less deleterious effects during the relatively short pendency of the appeal. Finally, the argument that the voluntary program is a better solution because it addresses drugs in addition to penicillin and tetracyclines is a straw man. As the Government concedes, the FDA is not prohibited in this process from issuing amended NOOHs addressing the extended range of drugs covered by the voluntary program. (Tr. at 31).

It is clear, then, that the plaintiffs are at risk of harm if a stay is imposed and that the public interest favors enforcement of the March 22 Order. Indeed, given the substantial harm that further delay of withdrawal proceedings could visit on the plaintiffs and the public, the balance of the equities would not "weigh heavily in favor" of a stay even if the Government had shown irreparable harm. LaRouche, 20 F.3d at 72-73. The Government's request for a stay pending decision on the appeal of the March 22 Order is therefore denied.

d. Interim Stay

As noted, the defendants ask in the alternative that I grant an interim stay pending resolution of the Government's anticipated

stay application in the Second Circuit. (Gov't Stay Brief at 1, 20). In support of this interim stay, the Government relies on its arguments for the stay pending appeal, which are no more successful here. Indeed, as the defendants do not contend that a different standard applies to the interim stay, the arguments fail for the same reasons. Actually, the arguments are weaker in the context of an interim stay, because, given the time schedule adopted here, it is even less likely that the Government will suffer recognizable harm in the short time between issuance of this order and the Second Circuit's decision on the planned application for a stay. Therefore, the Government's request for an interim stay is denied.

Conclusion

For the foregoing reasons, the plaintiffs' motion to strike (Docket no. 79) is granted in part, and Document no. 78-6 is stricken from the record. The Government's motion for a stay pending appeal, or, in the alternative, for an interim stay pending resolution of the Government's planned application for a stay in the Second Circuit (Docket no. 92), is denied. Furthermore, the Government is ordered to comply with the Court's order of March 22, 2012, according to the schedule included in paragraphs 11 through 25 of the Declaration of William T. Flynn dated May 15, 2012 (Docket no. 86).

SO ORDERED.

James C. Francis IV

JAMES C. FRANCIS IV
UNITED STATES MAGISTRATE JUDGE

Dated: New York, New York
August 8, 2012

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