UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC.; CENTER FOR SCIENCE IN THE PUBLIC INTEREST; FOOD ANIMAL CONCERNS TRUST; PUBLIC CITIZEN, INC.; and UNION OF CONCERNED SCIENTISTS, INC.,

Plaintiffs,

v.

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 SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services,

Defendants.

11 Civ. 3562 (THK)
ECF Case

MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO FILE A SUPPLEMENTAL COMPLAINT

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The above-captioned defendants (hereafter, the "Government"), by their attorney, Preet Bharara, United States Attorney for the Southern District of New York, respectfully submit this memorandum of law in opposition to Plaintiffs' motion for leave to file a supplemental complaint dated January 6, 2012 ("Plfs' Br.").

PRELIMINARY STATEMENT

This case, involving two narrow claims, is nearly over. Plaintiffs' first claim, that the Government unreasonably delayed in responding to two Citizen Petitions (the "Citizen Petitions Claim"), has been resolved and dismissed as moot. Briefing on the second claim, which pertains to the legal significance of two 34-year-old "notices of opportunity for hearing" (the "1977 NOOHs") for the possible withdrawal of approvals for the "subtherapeutic" uses of penicillins and tetracyclines in animal feed (the "NOOH Claim"), is nearly complete. Within just a few short weeks, this case will be ready for final judgment.

Now, with the end of the case in sight, Plaintiffs are attempting to bootstrap on an entirely new claim, this one based on different facts and law. Plaintiffs' proposed new claim (the "Third Claim") alleges that the responses to the two Citizen Petitions issued by the Food and Drug Administration ("FDA" or "Agency") on November 7, 2011 (the "Petition Responses"), should be remanded to the Agency on the ground that they are "arbitrary and capricious" under section 706(a)(2) of the Administrative Procedure Act ("APA"), 5 U.S.C. § 501 *et seq*. As discussed further below, the proposed Third Claim is very different from the NOOH Claim, and it should be resolved by way of a new complaint.

Plaintiffs' motion should also be denied because the expedited approach that they advance to resolve the Third Claim would prejudice the Government by not providing it with sufficient time to adequately preparing for and defend against the proposed Third Claim. The

schedule that Plaintiffs propose provides little time for defense counsel to, among other things, compile an administrative record in support of the Petition Responses, if one is ultimately required. Just as troubling is Plaintiffs' proposal that the proposed Third Claim be resolved almost instantly through a "supplemental" motion to be filed on February 13, 2012, to which the Government would have only 13 calendar days to respond.

In the alternative, if this Court grants Plaintiffs' motion, it should allow the Government 60 days to respond to the Third Claim. That amount of time matches the period provided to the United States and its agencies to respond to new complaints. *See* Fed. R. Civ. P. 12(a)(2). No less time should be allowed here given that the Third Claim would substantially broaden the scope of this litigation.

BACKGROUND

Plaintiffs filed their complaint on May 25, 2011, which they amended on July 7, 2011. *See* Dkt. Nos. 1 &11. The amended complaint contains two claims pursuant to APA section 706(1), both seeking to "compel agency action unlawfully withheld or unreasonably delayed." First, the NOOH Claim alleges that the Government has unlawfully failed to withdraw approval for "subtherapeutic" uses of penicillin and tetracycline antibiotics based on the 1977 NOOHs. Am. Compl. ¶ 98 (Dkt. No. 11). The parties are almost finished briefing the NOOH Claim, which is scheduled to be completed on February 10, 2012.

Second, the Citizen Petitions Claim alleges that the Government has "delayed unreasonably" in issuing a final response to Citizen Petitions submitted by certain Plaintiffs in 1999 and 2005, which requested that the Agency withdraw approval of subtherapeutic uses of five classes of antibiotics in livestock. Am. Compl. ¶ 101. The Government issued tentative responses to these Citizen Petitions on February 28, 2001 and October 4, 2005, respectively,

which informed the petitioners that the relief requested could not be granted at that time. *See* Exhibits J & L to the Declaration of Jennifer A. Sorenson dated October 5, 2011 (Dkt. No. 33). The Government issued final response to the two Citizen Petitions on November 7, 2011. *See* Exhibits I & J to the Declaration of Amy A. Barcelo dated January 9, 2012 (Dkt. No. 44). Accordingly, the parties stipulated to the dismissal of the Citizen Petitions Claim as moot, and the Court "so-ordered" that dismissal on January 6, 2012. *See* Dkt. No. 37.

On January 6, 2012—two months after the Government issued the Petition Responses—Plaintiffs filed the instant motion for leave to file a supplemental complaint bringing the Third Claim. Unlike the Citizen Petitions Claim, which challenged the Agency's *delay* in responding to the Citizen Petitions under section 706(1) of the APA, the Third Claim alleges that the Citizen Petition Responses themselves were "arbitrary and capricious" under section 706(2)(A) of the APA. In their motion, Plaintiffs also ask the Court to order an expedited briefing schedule to resolve their Third Claim. *See* Plfs' Br. at 5-6.

ARGUMENT

I. PLAINTIFF'S MOTION FOR LEAVE TO FILE A SUPPLEMENTAL COMPLAINT SHOULD BE DENIED

A. The Court has Discretion to Deny Leave to File a Supplemental Complaint

Pursuant to Rule 15 of the Federal Rules of Civil Procedure (the "Federal Rules"), a court "may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented," and "may order that the opposing party plead to the supplemental pleading within a specified time." Fed. R. Civ. P. 15(d). The "decision whether to grant leave to amend or supplement a pleading is within the sound discretion of the Court." *Ruotolo v. City of New York*, No. 03 Civ. 5045 (SHS) (DF), 2005 WL 1253936, *5 (S.D.N.Y. May 25, 2005) (citing *Quarantino v. Tiffany & Co.*, 71

F.3d 58, 66 (2d Cir. 1995)). A court may properly exercise its discretion by denying leave to supplement where, as here, the claim asserted in the original complaint is now moot and plaintiffs would have the opportunity to "reassert the matters set out in the purported supplemental complaint in an appropriate proceeding." *See, e.g., Cherry v. Morgan*, 267 F.2d 305 (5th Cir. 1959) (affirming district court's denial of motion for leave to file supplemental complaint). A motion to supplement under Rule 15(d) should also be denied where the supplementation is "proposed in bad faith, or would be unduly prejudicial or futile." *Ruotolo*, 2005 WL 1253936, at *5 (S.D.N.Y. May 25, 2005) (citing *Quarantino*, 71 F.3d at 66).

B. The Court Should Deny Plaintiffs' Motion for Leave to File a Supplemental Complaint

Because Plaintiffs' Third Claim is entirely distinct from both the Citizen Petitions Claim (which has been dismissed as moot) and the NOOH Claim, this Court would be acting well within its discretion to deny Plaintiffs' request. *See Cherry*, 267 F.2d 305.

Plaintiffs are wrong to argue that the Third Claim is "strikingly similar" to their NOOH Claim (Plfs' Br. at 4), merely because both claims relate to the Government's regulation of antibiotics in animal feed. Indeed, both the factual and legal bases for the two claims are very different. The NOOH Claim was brought pursuant to APA section 706(1), "can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*." *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (emphasis in original). As the Government argued in its summary judgment brief, the NOOH Claim raises narrow legal issues that are now positioned for prompt resolution. *See* Dkt. No. 41 at 11-19. Simply put, FDA made no "findings" decades ago that could compel a withdrawal of any drug approvals now. *Id.*

Plaintiffs' proposed Third Claim, on the other hand, is brought pursuant to APA section 706(2)(A), and challenges FDA's November 7, 2011 Petition Responses as "arbitrary and capricious." *See* Plaintiff's proposed First Supplemental Complaint for Declaratory and Injunctive Relief (the "Supp. Comp.") ¶ 38 (Dkt. No. 38). The law to be applied to an APA section 706(2)(A) claim is different from the law applicable to the NOOH Claim. Under section 706(2)(A), agency actions are to be upheld so long as they are "rational, based on consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute." *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 42 (1983). The substantive merits review of final agency action under section 706(2) bears little relation to the determination of whether the agency has a duty to act under a section 706(1) analysis.

The factual bases for the proposed Third Claim also have little to do with FDA's proposed administrative proceedings in 1977, which form the basis for Plaintiffs' NOOH Claim. The proposed Third Claim pertains solely to the bases for FDA's denial of the Citizen Petitions two months ago in November 2011. *See* Supp. Compl. ¶¶ 3, 20. Whether these denials were arbitrary and capricious would depend on an analysis of FDA's justification for its recent action, not the proposed bases for issuing the 1977 NOOHs 34 years ago. Indeed, FDA has recently made clear that it considers the 1977 NOOHs to be largely outdated, and that its current actions with regard to the issue of antimicrobial resistance are guided by the scientific knowledge and scientific policy considerations as they exist today. *See* Memorandum of Law in Support of the Government's Motion for Summary Judgment and in Opposition to Plaintiffs' Motion for Summary Judgment at 10-11 (Dkt. No. 41) (discussing the reasons behind the FDA's recent withdrawals of the 1977 NOOHs).

The Third Claim is also much broader than the NOOH Claim, which provides another sound reason why it can properly be brought only through a freestanding complaint. Specifically, penicillin and tetracycline classes of animal drug products are the only drugs classes at issue in the NOOH Claim (*see, e.g.*, Am. Compl. ¶ 96), and FDA believes that this Court's disposition of that claim could implicate more than 73 approved penicillin and tetracycline animal drug products. The Third Claim, however, pertains not only to penicillins and tetracyclines, but also to antimicrobials in the aminoglycoside, streptogramin, macrolide, lincomycin, and sulfonamide classes (*see* Supp. Compl. ¶ 14), which FDA estimates could implicate more than 107 approved animal drug products in *addition* to those products at issue in the 1977 NOOHs.[1] While it is too early to know what effect the broader scope of the Third Claim would have on the conduct of this litigation, it is plain that a substantial expansion of this case now would not aid in the efficient disposition of the claims that are almost fully briefed and ready for final judgment.

Plaintiffs' attempt to expedite review of this new claim with a substantially expanded factual scope would prejudice the Government because it would not provide the Government with an adequate opportunity to prepare by assessing and integrating new legal and factual claims. Plaintiffs' argument that the Government will not suffer prejudice because no "trial" date has been set for Plaintiffs' NOOH Claims (Plfs' Br. at 5), is inapposite because there is no "trial" in APA cases. In an action under the APA, no trial is necessary because "when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal [and]

[1] These totals include the number of approved applications held by companies for the relevant antimicrobial drugs (including generic versions), for use in animal feed, either alone or in combination with other approved drugs. These totals do not include approvals the use of the relevant antimicrobial drug in water, inclusion of which would likely increase the totals by several dozen.

the 'entire case' on review is a question of law." *American Bioscience, Inc. v. Thompson*, 269 F.3d 1077 (D.C. Cir. 2001); *see also Florida Power & Light Co. v. Lorian*, 470 U.S. 729, 744 ("The factfinding capacity of the district court is thus unnecessary to judicial review of agency decisionmaking").

The Government would likewise suffer substantial prejudice if the Court were to endorse the briefing schedule that Plaintiffs proposed unilaterally. *See* Plfs' Br. at 5-6. The proposed schedule would give the Government less time to respond to Plaintiffs' summary judgment motion than this Court's Local Civil Rules and the Federal Rules provide.[2] Indeed, Plaintiffs do not provide any reason why such a rushed resolution of this new claim is necessary or warranted, particularly in light of the two-month period that Plaintiffs waited after the Government issued the Petition Responses before they filed the instant motion to supplement.

Plaintiffs' proposed briefing schedule is also objectionable because it presumes that the Third Claim must be immediately resolved through cross-motions for summary judgment. However, nothing in Rule 15(d) precludes the Government from filing a motion to dismiss Plaintiffs' Third Claim on any of the grounds enumerated in Rule 12(b). Nor does Plaintiffs'

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[2] Assuming that Plaintiffs would electronically serve the Government with copies of their motion papers, as they have done with the motions they have filed in this action to date, if Plaintiffs were to file their proposed motion on February 13, 2012 as they propose, the rules would provide for Government's opposition to be due on March 1, 2012, not February 27, 2012. *See* Local Civil Rule 6.1(b) (providing 14 days to oppose a motion filed pursuant to Fed. R. Civ. P. 56, and referring to Fed. R. Civ. P. 6 for purposes of "computing period of days"); Fed. R. Civ. P. 6(d) (adding "3 days" to the period of a time granted to a party to take action "within a specified time" where service is made electronically).

Indeed, the original briefing schedule that the parties' negotiated to address the Citizen Petitions Claim and the NOOH Claim granted the Government more than a month to oppose Plaintiffs' motion for summary judgment and cross-move for summary judgment. *See* Dkt. No. 18 (the Court's endorsement of the parties' original briefing schedule for the Citizen Petitions Claim and the NOOH Claim).

proposed schedule provide time for the Government to file an answer to Plaintiffs' new claims or compile the administrative record that may be necessary to resolve this action.[3]

C. In the Alternative, the Government Should be Allowed 60 Days to Respond to the Supplemental Complaint

If the Court were to grant Plaintiffs' request for leave to file the supplemental complaint, Rule 15(d) requires that any such grant be on "just terms." *See* Fed. R. Civ. P. 15(d). Here, the Government should at least be granted 60 days to respond to the supplemental complaint, which is the time that the Government would have to respond to a new complaint under Federal Rule 12(a)(2). This time would allow the Government to better evaluation Plaintiffs' challenges and determine whether it will be necessary to compile and file an administrative record. If the Court allows Plaintiffs to file the supplemental complaint and grants the Government 60 days to respond to the supplemental complaint, and if the Government answers the supplemental complaint rather than file a motion pursuant to Rule 12, the Government proposes that the parties then attempt to reach agreement on a briefing schedule that accommodates the needs of all parties.

[3] In an action brought pursuant to the APA, the court's review of a challenged agency action is generally limited to the administrative record that formed the basis for the agency's decision. *See, e.g.*, *IMS, P.C. v. Alvarz*, 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."); *see also James Madison Ltd. v. Ludwig*, 82 F.3d 1085, 1095 (D.C. Cir. 1996) (same).

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motion for to leave to file a supplemental complaint. If the Court does allow Plaintiffs to file the supplemental complaint, the Court should order the Government to respond to the supplemental complaint within 60 days.

Dated: New York, New York
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Respectfully submitted,

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