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 IN OPPOSITION TO PLAINTIFFS' MOTION TO STRIKE NON-RECORD MATERIAL

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The Government opposes Plaintiffs' Motion to Strike Non-Record Material, dated April 18, 2012 ("Motion" or "Mot."). Because all of the materials that are the subject of Plaintiffs' Motion are properly before this Court, the Court should deny that Motion, which requests that this Court: (1) "strike" from the record in this case a public statement from the Animal Health Institute (the "2012 AHI Statement"), and (2) "disregard" three documents FDA published on April 11, 2012 (the "April 11 Documents").

I. This Court Should Deny Plaintiffs' Motion to Strike the 2012 AHI Statement

As a preliminary matter, Plaintiffs do not cite any authority in support of the premise of their motion—that a court may strike from the record an exhibit to a declaration submitted in support of a motion for summary judgment. While Rule 12(f) of the Federal Rules of Civil Procedure provides a basis for courts to strike material from a "pleading," a declaration submitted in support of a motion for summary judgment does not constitute such a "pleading." *See, e.g., Rochester-Genesee Reg. Trans. Auth. v. Hynes-Cherin*, 531 F. Supp. 2d 494, 519 n.17 (W.D.N.Y. 2008) (citing cases); *National Union Fire Ins. Co. of Pittsburg, PA v. Hicks, Muse, Tate & Furst, Inc.*, 02 Civ. 1334 (SAS), 2002 WL 1482625, * 6 (S.D.N.Y. Jul. 10, 2002) ("Declarations and affidavits are not pleadings."). In any event, even if Plaintiffs' Motion were properly brought pursuant to Rule 12(f) (it is not), such motions to strike are "disfavored and will be denied unless the allegations have 'no possible relation or logical connection to the subject matter of the controversy and may cause some form of significant prejudice to one or more of the parties to the action.'" *Id.* at 518 (quoting *Bank of Beaver City v. Branham*, No. 3:03-CV-575, 2006 WL 1469300, at *4 (E.D. Tenn. May 24, 2006) (quoting 5C Charles A Wright & Arthur R. Miller, Federal Practice & Procedure § 1382 (3d ed. 2004)). Plaintiffs' Motion has not met that standard.

In any event, the 2012 AHI Statement is properly before this Court regardless of whether it is part of the administrative record underlying the Petition Responses.[1] This Court may properly consider background information about the animal drug industry's current stance towards FDA's plans to regulate the use of antibiotics in food producing animals where that evidence is not part of the formal administrative record. *See Rochester-Genesee*, 531 F. Supp. 2d at 518 (the "district court may go outside the administrative record for the purposes of background information") (collecting cases; internal quotation omitted); *Sadler v. Mineta*, No. 3:05-CV-1189, 2006 WL 2772699, at * 2 n.3 (D. Conn. Sept. 26, 2006) (holding that courts may look to evidence outside the administrative record "as general background information that clarifies the administrative record in assessing Plaintiffs' claim," and noting that "no party has contested" the information contained in the evidence). Even if this Court were to conclude that the AHI's August 2010 comments (more than a year before FDA issued the Petition Responses) reflected some concern with FDA's proposed approach at that time, the Court may properly consider that industry appears now to support FDA's approach and that the *status quo* may have changed.

More fundamental than the significance or admissibility of the AHI statements, however, is the incorrect premise upon which Plaintiffs' Motion is based—*i.e.*, that this court's determination regarding whether to disturb the Petition Responses depends on the strength of FDA's "asserted . . . faith" or "professed confidence" in the voluntary compliance program, Mot. at 2. This flawed reasoning only underscores why FDA's decision not to initiate drug withdrawal proceedings (for now) is committed to its unreviewable discretion. In deciding

[1] Abbreviations in this brief are the same as in the Government's Opening Brief dated March 21, 2012, in support of its cross-motion for summary judgment on the claims contained in Plaintiffs' First Supplemental Complaint (Dkt. No. 64), and Reply Brief in support of that motion (Dkt. No. 77).

whether, when, and how to enforce the law, agencies are called upon to balance "a number of factors which are peculiarly within [their] expertise." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985).[2] Not only are such agency decisions not to enforce "generally unsuitab[le] for judicial review" in the first instance, *id.*, but it would usually be impossible for a court to reliably discern an agency's degree of confidence that its decision was the correct one (assuming the agency could even discern that for itself).

Alternatively, even if the Petition Responses were evaluated under an arbitrary and capricious standard, the Petition Responses meet that standard. Govt's Reply Br. at 11-13. The least that can be said is that FDA's choice among competing regulatory strategies qualifies as the type of judgment that a "court is not to substitute . . . for that of the agency." *S.E.C. v. Citigroup Global Markets Inc.*, 673 F.3d 158, 164 (2d Cir. 2012);[3] *see also Bellevue Hosp. Ctr. v. Leavitt*, 443 F.3d 163, 174 (2d Cir. 2006) (a reviewing court has "no license to substitute [its] policy judgment for that of the agency"); *NRDC v. SEC*, 606 F.2d 1031, 1055-56 (D.C. Cir. 1979) ("it is not the judicial province to upset agency structuring of proceedings," because the agency is more "cognizant of the many demands on it, its limited resources, and the most effective structuring and timing of proceedings to resolve these competing demands"). The Petition Responses articulate the reasons for FDA's position that its proposed approach is the best one, *see* Jan. Barcelo Decl. Exs. I & J, and this Court should not disturb that exercise of judgment.

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[2] Such factors include "whether a violation has occurred, [] whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and . . . whether the agency has enough resources to undertake the action at all." *Id.*

[3] *See also* Government's Opening Brief at 24, citing *Vermont Yankee Nuclear Power v. NRDC*, 435 U.S. 519, 543 (1978), and *Mobil Oil Exploration v. United Distrib. Cos.*, 498 U.S. 211, 230 (1991).

Ultimately, if this Court were to find FDA's reasons insufficient or that Petition Responses cannot be sustained unless FDA more convincingly demonstrates its confidence that its preferred approach will be successful, the matter is not resolvable on the AHI statements alone and should be remanded to provide FDA with an opportunity to further explain the bases for its decision. *See Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) (where a court believes it cannot evaluate the agency's action on the basis of the record before it, the "proper course" for the Court, "except in rare circumstances, is to remand to the agency for additional investigation or explanation").

II. The Court Should Not Disregard FDA's New Guidance Documents

Although Plaintiffs' Motion does not request any formal procedural relief with respect to the April 11 Documents, the Court should reject Plaintiffs' request that the Court "disregard" those documents. Mot. at 3. The Government properly provided these documents to the Court to ensure that the Court is aware of the ways in which the regulatory approach that FDA described in the Petition Responses has crystallized. Third Barcelo Decl. Exs. A, B & C; 77 Fed. Reg. 22247 (Apr. 13, 2012); 77 Fed. Reg. 22327 (Apr. 13, 2012); 77 Fed. Reg. 22328 (Apr. 13, 2012). These matters are susceptible of judicial notice, *see infra*, and because Plaintiffs seek to force FDA to abandon its proposed approach to regulating antibiotics in animals, this Court should know what FDA's approach actually is.

Indeed, pursuant to 44 U.S.C. § 1507, "[t]he contents of the Federal Register shall be judicially noticed." *See also Elsroth v. Johnson & Johnson*, 700 F. Supp. 151, 161 (S.D.N.Y. 1988) (permitting judicial notice of preamble to FDA regulation appearing in Federal Register). The Government has properly cited the April 11 Documents to support its legal argument that its decision to abstain from withdrawal proceedings (for now) was within FDA's regulatory

discretion. Govt's Reply Br. at 11-13; *see Military Toxics Project v. E.P.A.* 146 F.3d 948, 954 (D.C. Cir. 1998) (EPA policy document and General Accounting Office reports were "judicially cognizable apart from the record as authorities marshaled in support of a legal argument.").

Ultimately, as with the 2012 AHI Statement, *supra*, were this Court to conclude that it may only consider the April 11 Documents to the extent that they are reflected in the formal administrative record, this matter should be remanded back to FDA so that the new information can be added. *See Fla. Power & Light Co.*, 470 U.S. at 744. But because this Court may consider these new developments now, such remand is unnecessary.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion should be denied.

Dated: New York, New York
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Respectfully submitted,

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