

**UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

CARETOLIVE,)	
a not-for-profit corp.,)	
)	Civil No. 2:08-CV-00005
Plaintiff,)	
)	JUDGE FROST
v.)	
)	MAGISTRATE JUDGE KING
U.S. FOOD and DRUG)	
ADMINISTRATION,)	
)	
Defendant.)	

**DEFENDANT UNITED STATES FOOD AND DRUG ADMINISTRATION’S REPLY
TO PLAINTIFF’S OPPOSITION TO MOTION TO STAY PROCEEDINGS**

INTRODUCTION

On February 18, 2008, the United States Food and Drug Administration (“FDA” or “the Agency”), Department of Health and Human Services, filed a Motion to Stay Proceedings (“Motion to Stay”) (Doc. No. 10) pursuant to 5 U.S.C. § 552(a)(6)(C). On March 11, 2008, Plaintiff Care to Live (“Plaintiff”) filed its Memorandum in Opposition to the Motion to Stay. (Doc. No. 18).

While Plaintiff’s Opposition is replete with speculation and innuendo, FDA has presented uncontroverted facts demonstrating that a stay of proceedings is warranted under the Freedom of Information Act (“FOIA”). Plaintiff’s unsupported assertions cannot overcome them.

ARGUMENT

In support of its motion for a stay of proceedings to permit it to respond fully to Plaintiff's FOIA request, FDA has shown (1) exceptional circumstances (see Open America v. Watergate Special Prosecution Force, 547 F.2d 605 (D.C. Cir. 1976)); (2) reasonable progress in reducing any backlog of requests accumulated due to a predictable agency workload (see Leadership Conference on Civil Rights v. Gonzales, 404 F. Supp. 2d 246, 259 (D.D.C. 2005)); and (3) good faith and due diligence in complying with FOIA requests in as short a time as practicable (see Center for Biological Diversity v. Gutierrez, 451 F. Supp. 2d 57, 70 (D.D.C. 2006)). See Motion to Stay at pp. 9–20. Plaintiff attempts to counter these showings with three, interrelated arguments: (1) FDA simply refuses, in bad faith, to respond to its FOIA request (Opposition at pp. 5, 9); (2) its FOIA request is “very simple” and could be answered immediately (Opposition at p. 4); and (3) Plaintiff's need is urgent. (Id. at p. 14). In addition, Plaintiff makes an improper demand for discovery that should be denied. (Id. at p. 6). Plaintiff's arguments fail to respond either to the law or the facts of this case.

I. Plaintiff Fails to Overcome the Presumption of Governmental Good Faith

Bad faith is the cornerstone of Plaintiff's various allegations, both in this action and in its prior lawsuit. Currently, Plaintiff baldly asserts that, *inter alia*: (1) FDA possesses and is purposely withholding responsive, damning documents (Opposition at p. 2); (2) Plaintiff's requested documents have likely been identified, discussed “and even reviewed by general counsel and/or by top officials at FDA” but are simply being withheld (Opposition at pp. 5, 9); (3) FDA is attempting “to avoid having to outright lie to this Court” (Opposition at p. 9); and (4) FDA “merely seeks to avoid or delay further scrutiny by the public and Congress.” (Opposition

at p. 11). Plaintiff also supplies an irrelevant, ten- page document, identified as “Appendix A” to its Opposition and entitled “The Science,” which contains no references to primary scientific sources, is unsigned, and is unsworn. If Plaintiff’s Opposition is remarkable for anything—other than its virulence—it is for its absence of factual support for any of the assertions made.

In contrast, FDA has provided the detailed declarations of the agency’s senior FOIA officials, Frederick Sadler and Nancy Sager. See Declaration of Frederick J. Sadler, dated February 13, 2008, attached to Motion to Stay as Exhibit A (“Sadler Decl.”); Declaration of Nancy B. Sager, dated February 13, 2008, attached to Motion to Stay as Exhibit B (“Sager Decl.”). Agency affidavits are entitled to a presumption of good faith. Rugiero v. United States Dep’t of Justice, 257 F.3d 534, 544 (6th Cir. 2001). Courts, aware of the difficulty of wading into the internal processes and functions of agencies, recognize that such declarations “provide a critical insight into” the adequacy of an agency’s processes and progress in addressing FOIA requests “and are often determinative.” See, e.g. Elec. Privacy Info. Ctr. v. U.S. Dep’t of Justice, 2005 U.S. Dist LEXIS 18876, at *11 (D.D.C. Aug. 31, 2005); Bower v. FDA, 2004 U.S. Dist. LEXIS 18369, *8 (D. Me. Aug. 30, 2004) (accepting FDA’s showings on number of requests, backlog reduction efforts, and available resources); Appleton v. Food and Drug Admin., 254 F. Supp. 2d 6, 10 (D.D.C. 2003) (plaintiff’s assertions of “cavalier disregard,” simplicity of his request, and failure to communicate, overcome by DFOI and DIDP declarations of good-faith, diligent effort to process under first-in, first-out complex track). FDA’s declarations describe FDA’s FOIA process, the agency’s backlog and backlog-reduction efforts, and FDA’s specific actions to address Plaintiff’s FOIA request, demonstrating that FDA’s CDER component has a backlog of several thousand requests (Sager Decl. ¶ 26); that FDA has reduced its backlog by

approximately 50 percent in less than five years (Id.); and that FDA has responded to Plaintiff with documents (Sadler Decl. ¶ 13; Sadler Decl. Exhibit 3) and phone calls regarding the FOIA request's status. (Sager Decl. ¶ 29).

FDA's declarations also show that CDER is not withholding in bad faith any documents, because CDER has not yet searched for any documents: Plaintiff's FOIA request will not reach the head of CDER's complex track until approximately December 2009. Sager Decl. ¶ 29.

Plaintiff's contrary allegations are unsupported and not credible.¹ FDA respectfully requests that the Court grant its Motion for Stay and extend the agency sufficient time fully to answer Plaintiff's FOIA request according to FDA's two-track, first-in/first-out procedure.

II. Plaintiff Misconstrues the Purpose of an Open America Stay

Plaintiff argues that its request is "not voluminous" and that FDA has failed to provide specific reasons for its partial response. (Opposition at p. 5.) Plaintiff believes that because two FDA components—the Center for Biologics Evaluation and Research ("CBER") and the Office of the Commissioner ("OC")—have responded to its FOIA request, the Center for Drug Evaluation and Research ("CDER") can and should immediately do so. (Id.) That being the case, Plaintiff sees no reason for a stay. (Id.)

Plaintiff's argument misses the mark. Courts grant an Open America stay in recognition of an agency's total administrative burden. The single focus of a court's inquiry is not the number of

¹Plaintiff argues that a CDER representative's statement, that any documents CDER possesses would likely be similar to those furnished by CBER, is logically inconsistent with CDER not having already searched. (Opposition at p. 4). The reason CDER would be in a position to make this statement is apparent from the Sadler Declaration. FDA's electronic tracking system, the Agency Information Management Systems ("AIMS"), stores and tracks all FOIA requests *agency-wide*; also, *both* CBER and CDER were involved in Provenge's review. Sadler Decl. ¶¶ 7, 12, 14.

documents any particular FOIA request is likely to produce but whether, in the context of a backlog of thousands of requests, an agency's (or agency component's) process for handling FOIA requests demonstrates due diligence. The law on this point is clear: a system of handling FOIA requests on a "first-in/first-out" basis is a sufficient showing of due diligence. See e.g., Appleton, 254 F. Supp. 2d at 10 (granting FDA a stay based, in part, upon FDA's "demonstrated good-faith efforts and due diligence in processing plaintiff's request on a first-in, first-out basis"); Edmond v. United States Attorney, 959 F. Supp. 1, 3 (D.D.C. 1997); Jimenez v. FBI, 938 F. Supp. 21, 31 (D.D.C. 1996); see also H.R. Rep. No. 104-795, 1996 U.S.C.C.A.N. at 3466 (stating that processing requests on a first-in, first-out basis, coupled with a multi-track processing system, constitutes due diligence). FDA in general—and CDER in particular—uses first-in, first-out processing (Sager Decl. ¶¶ 8-14) and is, therefore, presumptively "diligent."

The fact that two of the three FDA components most likely to possess responsive documents have already provided them evidences FDA's diligence and good faith, not the opposite, as Plaintiff would suggest. FOIA specifically provides that "[e]ach agency may promulgate regulations . . . providing for multitrack processing of requests for records based on the amount of work or time (or both) involved in processing requests." 5 U.S.C.

§ 552(a)(6)(D)(i). Plaintiff fails to note that FDA's regulations, at 21 C.F.R. § 20.43, authorize each agency component (e.g., CDER, CBER, etc.) to implement particularized FOIA processing "tracks." This includes the ability to determine both the number of tracks and criteria for assigning requests to tracks. 21 C.F.R. § 20.43(c). Consequently, different agency components may respond to similar requests at different times. Plaintiff's argument to the contrary, if accepted, would create a perverse incentive; agencies fearing claims of "bad faith" due to partial

responses, might rationally withhold production of *any* documents pending collection of *all* documents from each agency component. Fortunately for FOIA requesters, this is not the course that FDA follows. See, e.g. Appleton v. Food and Drug Admin., 254 F. Supp. 2d 6, 10 (D.D.C. 2003) (crediting agency with logging and acknowledging plaintiff's request, then promptly transmitting readily available records).

In CDER's case, FDA uses a two-track system of simple versus complex requests. "Simple" and "complex" are terms of art: a "simple" request does not require CDER's Division of Information Disclosure Policy ("DIDP") personnel to search for or redact documents, generally because DIDP has previously reviewed and redacted the responsive documents; the requested documents are publicly available; or it is clear from the face of the request that CDER has no responsive documents. (Sager Decl. ¶ 9.) DIDP assigned Plaintiff's request to the complex track because it sought documents not readily available and because the request would require DIDP to search for and possibly redact documents. (Id. ¶ 29.)

CDER's multitrack first-in, first-out processing system satisfies the primary purpose of a stay, which is to allow the agency to continue processing its many thousands² of FOIA requests in an equitable manner, without prejudice to requesters waiting in line prior to a particular plaintiff. See, e.g., Schweih v. F.B.I., 933 F.Supp. 719, 723 (N.D. Ill. 1996) (court declined to "vault" plaintiff's request over others in line). As noted by the Open America court, Congress could not have "intended, by fixing a time limitation on agency action and according a right to bring suit . . . to grant an automatic preference by the mere action of filing a case." Open America, 547 F.2d at 614.

²Plaintiff's was the 8,316th FOIA request FDA received in 2007. (Sadler Decl. ¶ 10).

The remaining, relevant inquiries for determining when to grant a stay are (1) whether the request sits in a FOIA queue generated by exceptional circumstances, and (2) whether CDER (i.e., FDA) is working diligently to reduce the number of requests in the queue. FDA's Motion to Stay provides affirmative answers to each of these inquiries. Plaintiff's Opposition fails to respond to those answers.

III. Plaintiff Has Not Demonstrated an Urgent or Compelling Need within the Meaning of FOIA

Plaintiff also argues that the Court deny FDA's request for an Open America stay because of Plaintiff's "need" and the "reason for urgency." In doing so, Plaintiff apparently attempts to make a claim in this Court for "expedited processing" under FOIA. Plaintiff's claim should be rejected for two reasons.

A. Plaintiff Failed to Request Expedited Processing from the FDA

Plaintiff failed to seek expedited processing of its FOIA request from FDA. FOIA directs agencies to promulgate regulations for expedited processing of requests when (1) "the person requesting the records demonstrates a compelling need" and (2) "in other cases determined by the agency." 5 U.S.C. § 552(a)(6)(E)(i). FOIA requires that "demonstration of a compelling need by a person making a request for expedited processing shall be made by a statement certified by such person to be true and correct to the best of such person's knowledge and belief." 5 U.S.C. § 552(a)(6)(E)(vi). Judicial review of an agency's refusal to provide expedited processing, or failure to respond in a timely manner, shall then be "based on the record before the agency at the time of the determination." 5 U.S.C. § 552(a)(6)(E)(iii).

FDA's expedited processing regulations establish two main requirements: (1) the request

for expedited processing must be filed in writing; and (2) the requestor must “include information that demonstrates a reasonable basis for concluding that a compelling need exists” and certify “that the information provided . . . is true and correct to the best of the requester’s knowledge and belief.” 21 C.F.R. § 20.44(d). A compelling need exists when the “failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual,” or “[w]ith respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity.” 21 C.F.R. § 20.44(a); 5 U.S.C. § 552(a)(6)(E)(v).

It is well understood that a FOIA requester must exhaust the available administrative remedies under FOIA before it may seek relief in the federal courts. Oglesby v. United States Dep’t of the Army, 920 F.2d 57, 61-62 (D.C. Cir. 1990). Premature filing of a FOIA claim that has not matured because a party failed to exhaust mandatory administrative remedies prior to filing its complaint “is subject to dismissal for lack of subject matter jurisdiction.” Judicial Watch, Inc. v. U.S. Naval Observatory, 160 F. Supp. 2d 111, 112 (D.D.C. 2001). The rationale behind the exhaustion requirement is that it gives the agency “an opportunity to exercise its discretion and expertise on the matter and to make a factual record to support its decision.” Oglesby, 920 F.2d at 61 (citing McKart v. United States, 395 U.S. 185, 194 (1969)). Moreover, it allows agency supervisors an opportunity to correct mistaken denials of meritorious FOIA requests, thereby obviating the need for judicial review by the courts. Id.; see also American Civil Liberties Union v. Department of Justice, 321 F. Supp. 2d 24, 28 (D. D.C. 2004) (noting judicial review of agency decisions concerning expedited processing requests “is appropriate at

either of two moments: when the agency has denied a request for expedited processing, or when the agency has, upon administrative appeal, affirmed the denial of such a request”).

Plaintiff did not request expedited processing of its FOIA request. (See Letter from Bellinger & Donahue, dated August 15, 2007 (“FOIA request”), attached as Exhibit 1 to Sadler Decl.) Neither did Plaintiff offer and certify, as specified both by statute and regulation, information enabling FDA to make a determination of “compelling need.” (Id.) As a result, Plaintiff has failed to exhaust administrative remedies with respect to expedited processing; further, no record exists for the Court to review and, therefore, Plaintiff’s claim is not “ripe.” When ripeness is at issue, Sixth Circuit courts must, among other factors, “determin[e] . . . whether the factual record is sufficiently developed to produce a fair adjudication of the merits of the parties’ respective claims.” Kentucky Press Ass’n v. Kentucky, 454 F.3d 505, 509 (6th Cir. 2006). Because Plaintiff failed to seek expedited processing and created no factual record, there cannot be judicial review “based on the record before the agency at the time of the determination.” 5 U.S.C. § 552(a)(6)(E)(iii). Accordingly, the Court should not consider Plaintiff’s belated claim of urgency, and FDA’s Motion to Stay should be granted.

B. Plaintiff Does Not Demonstrate a Compelling Need

In any event, Plaintiff cannot meet the requirements for expedited processing. To demonstrate “compelling need” sufficient to secure expedited processing, Plaintiff must show that it is “primarily engaged in disseminating information,” “to the general public and not merely to a narrow interest group,” and that “there is a demonstrated urgency to inform the public.”³ 21

³Plaintiff, a business entity, cannot demonstrate an imminent threat to its life or physical safety if FDA fails to provide requested documents on an expedited basis. Neither does it purport to be a family member, medical or health care professional for, or other authorized

C.F.R. § 20.44(a),(c); accord 5 U.S.C. § 552(a)(6)(E)(v).

1. Plaintiff Is not Primarily Engaged in Disseminating Information to the General Public

Plaintiff, in the instant action, characterizes itself simply as “a not for profit corporation and advocacy group.” (Complaint at 1.) It has not alleged facts demonstrating that it is (1) primarily engaged in disseminating information or that (2) it does so for the general public. To the contrary, Plaintiff has more fully presented itself to this tribunal (in CareToLive v. von Eschenbach et al., Case No. 2:07-cv-00729) as a group whose members “seek to advance the right to life of prostate cancer patients, who could have or would have benefitted from Provenge.” Plaintiff’s Amended Complaint, Case No. 2:07-cv-00729 (Doc. No. 22) at ¶ 3. Plaintiff is clearly an advocacy organization—not one primarily engaged in disseminating information—operating on behalf of “a narrow interest group” (i.e., those who believe they could have or would have benefitted from Provenge approval), not the general public. As such, it fails the first prong of the test to secure expedited processing. 21 C.F.R. § 20.44(c).

2. Plaintiff Does not Demonstrate Urgency to Inform

Plaintiff’s claim for urgency rests almost entirely on conspiracy theories first raised in its related Administrative Procedure Act (“APA”) case, CareToLive v. von Eschenbach et al., Case No. 2:07-cv-00729, which this Court dismissed for lack of jurisdiction and which is now on appeal. Plaintiff claims that the FDA is hiding documents (Opposition at p. 5), that the documents “will help to uncover the improper actions of the FDA” (Id.), and disclosure will force “the FDA or Congress to fix the terrible mistake that has been made, even if the Courts will

representative of any specific individual for whom the failure to obtain the requested records on an expedited basis presents an imminent threat to his or her life or physical safety. See 21 C.F.R. § 20.44(a),(b); 5 U.S.C. § 552(a)(6)(E)(v).

not act on the underlying merits.” (Opposition at p. 14). Plaintiff’s argument requires the Court to attribute the worst of motives to FDA while simultaneously assuming away the scientific and regulatory work that must be done prior to any new drug approval. Extending “compelling need” to cover Plaintiff’s request is unwarranted, particularly in the context of drug approval where Plaintiff merely makes self-serving, unsupported assertions as to future Congressional involvement.⁴

Congress intended that the “categories for compelling need . . . be narrowly applied,” explicitly recognizing that “unduly generous use of the expedited processing procedure would unfairly disadvantage other requestors.” H.R. Rep. No. 104-795, at 26 (1996). Plaintiff argues that earlier release of the requested documents will force Congress to intervene and short-circuit the regulatory-review process for a new drug. This is pure speculation; in fact, Congress has already spoken, as Plaintiff recites on its website as follows:

On February 13, 2007, the House Committee on Energy and Commerce said, ‘no’ to congressional hearings on possible conflicts of interest during the review process of Provenge, an immunotherapy treatment for late stage prostate cancer. In a letter to Congressmen Michaud, Ryan, Van Hollen, and Burton, the committee stated, ‘FDA has not yet made a final decision on this product, and it is the practice of this Committee to allow a regulatory agency such as the FDA to complete its statutorily-mandated processes and render a final decision before initiating formal investigative action.’

See <http://caretolive.com/ways-to-help/> (last visited March 25, 2008).

⁴ See also IEEE Spectrum v. Dep’t of Justice, No. 05-0865, slip op. at 2 (D.D.C. Feb. 16, 2006) (denying expedited processing where plaintiff magazine made only self-serving statements that subject of request was “a currently unfolding story” and “newsworthy”); Elec. Privacy Info. Ctr. v. DOD, 355 F. Supp. 2d 98, 102 (D.D.C. 2004) (denying expedited processing where plaintiff failed to show public interest in particular subject of its request, and instead relied on general public interest in “umbrella” subject); Elec. Privacy Info. Ctr. v. U.S. Dep’t of Justice, No. 03-2078, slip op. at 10 (D.D.C. Dec. 19, 2003) (finding no urgency to inform public that warranted expedited access, because “[t]he appearance of thirty-one newspaper articles does not make a story a matter of ‘current exigency.’”).

Nor does CareToLive have any special rights under FOIA as a party to APA litigation seeking the advance approval of Provenge. See NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 143 n. 10 (1975) (a party's rights under FOIA "are neither increased nor decreased by reason of the fact that it claims an interest in [withheld materials] greater than that shared by the average member of the public. [FOIA] is fundamentally designed to inform the public about agency action and not to benefit private litigants"); see also John Doe Agency v. John Doe Corp., 493 U.S. 146, 153 (1989) ("FOIA was not intended to supplement or displace the rules of discovery") (citing NLRB v. Robbins Tire & Rubber Co., 437 U.S. 214, 236–239, 242 (1978)). Regardless of Plaintiff's related litigation, each FDA component that may have responsive documents must be permitted to process CTL's request in the same manner as it processes all other FOIA requests: in the order that it was received, in accordance with the agency component's first-in, first out processing system. Moreover, this Court dismissed Plaintiff's APA case for lack of ripeness and final agency action, recognizing that "[b]ecause the Provenge [Biologics License Application ("BLA")] administrative process is ongoing, the FDA may ultimately approve the application, which would render Plaintiff's claims moot." CareToLive v. von Eschenbach et al., "Opinion and Order" (Doc. No. 64) at 15. As this Court noted, in the absence of FDA's final action on the Provenge application "the only remedy that this Court could issue is a remand to the FDA to continue its review of Dendreon's BLA." (Id. at 12.) Plaintiff fails to explain how expedited disclosure of documents responsive to its FOIA request would change this result.

IV. Plaintiff Is Not Entitled to Discovery

As in its related APA case, Plaintiff continues its demands for discovery of FDA

personnel (“[i]f the Court is insistent on staying this matter, then . . . the Court should allow Plaintiff to take the deposition of Richard Pazdur and the CDER FOIA representative,” Opposition at 6). It is well settled that discovery is generally unavailable in FOIA actions. See, e.g. Rugiero v. United States Dep’t of Justice, 257 F.3d 534, 544 (6th Cir. 2001) (noting that district courts typically dispose of FOIA cases before plaintiff can conduct discovery); Wheeler v. C.I.A., 271 F.Supp.2d 132, 139 (D.D.C. 2003) (noting that discovery is generally unavailable in FOIA cases) (citing Judicial Watch, Inc. v. Export-Import Bank, 108 F.Supp.2d 19, 25 (D.D.C. 2000)).

The United States has previously addressed the issue of FOIA discovery in its Motion to Continue. See Defendant United States Food and Drug Administration’s Motion to Continue (Doc. No. 11) at 2. In FOIA cases, courts generally review an agency’s declarations accompanying the motion to stay proceedings, without discovery, to determine whether to grant the stay. See, e.g., Cecola v. F.B.I., 1995 WL 143548, *5 (N.D.Ill. 1995) (“This court’s review of cases under § 552(a)(6)(C) indicates that, as in the case of other issues under FOIA, questions of an agency’s diligence are generally resolved on the basis of affidavits, without the taking of formal discovery.”); Summers v. U.S. Dep’t. of Justice, 925 F.2d 450, 452 (D.C. Cir. 1991) (noting that district court relied on declarations to grant stay of further proceedings, including all discovery, pursuant to 5 U.S.C. § 552(a)(6)(C)); Schrecker v. U.S. Dep’t of Justice, 217 F.Supp.2d 29, 35 (D.D.C. 2002) (stating, in context of plaintiff’s motion for discovery to determine adequacy of search for records, “discovery in FOIA is rare and should be denied where an agency’s declarations are reasonably detailed, submitted in good faith and the court is satisfied that no factual dispute remains.”).

Discovery is particularly inappropriate when, as in this case, no search for documents has yet been conducted. (Sager Decl. ¶ 29.) The Plaintiff's unsupported accusations of bad faith do not support the extremely rare step of ordering discovery in this case. E.g., Carter v. United States Dep't of Commerce, 830 F.2d 388, 392 (D.C. Cir. 1987) (“[T]he mere allegation of bad faith does not undermine the sufficiency of agency submissions. There must be tangible evidence of bad faith; without it the court should not question the veracity of agency submissions.”). Accordingly, Plaintiff's request to depose Dr. Pazdur—or any other FDA personnel—should be denied.

CONCLUSION

Plaintiff's Opposition fails to address the legal standards governing the central issues in the FDA's Motion for Stay: (1) exceptional circumstances, (2) reasonable progress, and (3) good faith and due diligence. Plaintiff instead argues that its request is “very simple” (ignoring the question whether FDA's FOIA request processing system is legally sufficient), demands expedited relief that it never requested from the agency, indulges in unsupported, malice-laced allegations against agency officials and departments, and seeks invasive discovery to which it is not entitled.

Therefore, FDA respectfully requests that this Court grant its Motion to Stay Proceedings.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on March 25, 2008, I electronically filed the foregoing Reply to Plaintiff's Opposition to Motion to Stay Proceedings with the Clerk of the Court using the CM/ECF system, which will send notification to Kerry M. Donahue.

s/John J. Stark
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Assistant United States Attorney