

1 \*E-Filed April 4, 2011\*

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9 IN THE UNITED STATES DISTRICT COURT  
10 FOR THE NORTHERN DISTRICT OF CALIFORNIA  
11 OAKLAND DIVISION

12  
13 UNITED STATES

Case No. C 10-2655 DMR

14 Plaintiff,

15 v.

**ORDER GRANTING MOTION FOR  
SUMMARY JUDGMENT**

16 UNDETERMINED QUANTITIES OF 57  
17 ARTICLES OF DRUGS, MORE OR LESS,

18 Defendants.  
19 \_\_\_\_\_/

20 I. INTRODUCTION

21 This suit involves the seizure of fifty-six articles of drugs by Plaintiff United States of  
22 America, which occurred in the process of a civil forfeiture *in rem* action brought under 21 U.S.C. §  
23 334, the seizure provision of the Federal Food, Drug, and Cosmetic Act (“FDCA” or “the Act”).  
24 Plaintiff seeks to have the drugs condemned and destroyed, and has filed a motion for summary  
25 judgment. *See* Docket No. 26. Claimant Dr. James Forsythe opposes the motion for summary  
26 judgment, objecting to the condemnation and destruction of the drugs on the grounds that they are  
27 necessary to a pending civil matter he has in the United States District Court for the District of  
28 Nevada. Both parties consented to the jurisdiction of a magistrate judge under 28 U.S.C. § 636(c),  
and appeared for oral argument on March 31, 2011. After carefully considering the parties’

1 briefings, submissions and oral arguments, the Court grants Plaintiff's motion for summary  
2 judgment and orders that the fifty-six articles of drugs and any vials in which they are contained be  
3 destroyed within 14 days of this Order. The boxes containing any of the fifty-six articles of drugs  
4 are to be preserved and returned to Forsythe, also within 14 days of this Order.

## 5 II. BACKGROUND

6 On June 16, 2010, the United States filed a Complaint for Forfeiture *In Rem* against  
7 undetermined quantities of various articles of drugs in the possession of the United States Food and  
8 Drug Administration's ("FDA") Office of Criminal Investigation ("OCI"). The United States  
9 Marshal seized the drugs pursuant to a warrant on September 2, 2010. Forsythe filed a "Claim  
10 Contesting Forfeiture" on October 7, 2010, however the Court determined that this filing was  
11 improperly noticed as a motion and ordered him to file either an answer or a motion under Rule 12  
12 of the Federal Rules of Civil Procedure within 21 days after filing the Claim.<sup>1</sup> *See* Docket No. 23.  
13 Forsythe then filed his Answer and affirmative defenses on October 29, 2010.

14 The articles of drugs seized by the FDA's OCI comprise the fifty-six drugs listed in the  
15 Complaint. Fifty-two of those drugs are labeled in German or Dutch. *See* Decl. of Michael M.  
16 Levy ("Levy Decl.") ¶ 5. The remaining four are labeled as "Pregnyl," "Suhagra-100," "Marevan"  
17 and "Bio-Tropin," with their labels written at least partially in English. *See* Ex. B to Levy Decl.  
18 OCI came into possession of the drugs following the execution of two search warrants. The first  
19 warrant was executed on February 16, 2005, at the Century Wellness Clinic, Inc. and Forsythe's  
20 residence, both in Reno, Nevada. *See* App. & Aff. for Search Warrant (Feb. 11, 2005) (Ex. A to  
21 Decl. of Michael C. Baxter ("Baxter Decl.")). The second warrant was executed on April 14, 2005  
22 at the Cancer Screening and Treatment Center and the Century Wellness Clinic, Inc., which are in

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24 <sup>1</sup> The Claim was initially due on September 10, 2010, although Plaintiff agreed to allow Forsythe an  
25 extension until September 17. Forsythe's October 7, 2010 filing, therefore, was three weeks late.  
26 His October 29 Answer and affirmative defense was also late, as was his Opposition to the Motion  
27 for Summary Judgment. The United States did not oppose Forsythe's request for an extension to  
28 file his Opposition, though did ask the Court to strike his Answer as untimely and to enter Default  
Judgment under Rule 55(b)(2). *See* Docket No. 26 at 2; *see also United States v. All Assets Held at  
Bank Julius Baer & Co.*, 664 F. Supp. 2d 97, 101 (D.D.C. 2009) (striking claim in forfeiture action  
where claimant failed to strictly adhere to the procedures prescribed by the Supplemental Rules for  
Admiralty or Maritime Claims). The Court here declines to strike the Claim, but instead rules on  
the merits of the Motion for Summary Judgment.

1 the same building and are both operated by Forsythe. *See* App. & Aff. for Search Warrant (April  
2 14, 2005) (Ex. B. to Baxter Decl.). Forsythe was indicted on September 27, 2006 by the United  
3 States Attorney in the District of Nevada on one count of introduction of an unapproved new drug  
4 into interstate commerce in violation of 21 U.S.C. §§ 331(d) and 335(a), and one count of  
5 unauthorized distribution of human growth hormone. The first count was dismissed by the District  
6 Court on October 30, 2007, and the jury acquitted Forsythe on the second count on November 1,  
7 2007. *See* Compl. ¶ 6; Answer ¶ 6; J. of Acquittal (Nov. 6, 2007) (Ex. 8 to Opp. to Mot. for Summ.  
8 J.).

9 Forsythe filed a civil suit in this judicial district against various federal officials, which was  
10 ultimately dismissed in August 2009. Orders Granting Federal Def's Mot. to Dismiss (Aug. 14,  
11 2009 & Nov. 30, 2009) (Ex. 2 to Mot. for Summ. J.). He then filed a similar lawsuit in the District  
12 of Nevada. *See* Compl. for Damages, *Forsythe v. United States, et. al.*, 3:10-cv-00508 (D. Nev.)  
13 (Ex. 3 of Mot. for Summ. J.).<sup>2</sup> In his Nevada lawsuit, Forsythe alleges a variety of violations  
14 against his constitutional and contractual rights. As pertaining to the current *in rem* action, he  
15 alleges that certain federal agents tampered with the boxes containing some of the fifty-six drugs  
16 listed in the Complaint.

### 17 III. LEGAL STANDARD

18 Summary judgment is proper where the pleadings, discovery and affidavits show that there  
19 is "no genuine issue as to any material fact and that the moving party is entitled to judgment as a

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20 <sup>2</sup> In fact, each claim filed in the Nevada case was previously filed and dismissed in the Northern  
21 District of California. While Forsythe maintains that the Court dismissed these claims simply  
22 because they were premature under the Federal Tort Claims Act and because Nevada was the proper  
23 venue, a close reading of the Court's November 30, 2009 Order reveals that there were alternate  
24 grounds for dismissal. Of the claims that are also alleged in Nevada: his claims of negligence,  
25 negligent entrustment and malicious prosecution were dismissed without prejudice and without  
26 leave to amend for lack of subject matter jurisdiction because they were outside the statute of  
27 limitations; his claims for intentional interference with prospective business relationships and  
28 interference with contractual relationships were dismissed without prejudice and without leave to  
amend for lack of subject matter jurisdiction because the United States has not waived its sovereign  
immunity with regard to such torts; his request for injunctive and declaratory relief was dismissed  
without prejudice and without leave to amend for lack of jurisdiction because a district court may  
not enjoin a federal agency from investigating a possible crime; and his claims alleging violations of  
the First Amendment, of his due process rights and of his civil rights were dismissed without leave  
to amend because they were barred by the applicable two-year statute of limitations. *See* J. of  
Acquittal (Nov. 6, 2007) (Ex. 8 to Opp. to Mot. for Summ. J.); Compl. for Damages, *Forsythe v.*  
*United States, et. al.*, 3:10-cv-00508 (D. Nev.) (Ex. 3 of Mot. for Summ. J.)

1 matter of law.” FRCP 56(c). Material facts are those which may affect the outcome of the case.  
2 *Anderson v. Liberty Lobby*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A dispute as  
3 to a material fact is genuine if there is sufficient evidence for a reasonable jury to return a verdict for  
4 the nonmoving party. *Id.* “Only disputes over facts that might affect the outcome of the suit under  
5 the governing law will properly preclude the entry of summary judgment.” *Id.*

6 The party moving for summary judgment bears the initial burden of identifying those  
7 portions of the pleadings, discovery and affidavits which demonstrate the absence of a genuine issue  
8 of material fact. *Celotex Corp. v. Carrett*, 477 U.S. 317, 322-23, 106 S.Ct. 2548, 91 L.Ed.2d 265  
9 (1986); *Nissan v. Fire & Marine Insurance Company*, 210 F.3d 1099, 1102 (9th Cir.2000). When  
10 the moving party has met this burden of production, the nonmoving party must go beyond the  
11 pleadings and, by its own affidavits or discovery, set forth specific facts showing that there is a  
12 genuine issue for trial. *Celotex Corp.*, 477 U.S. at 322; *TW Elec. Service, Inc. v. Pacific Elec.*  
13 *Contractors Ass’n*, 809 F.2d 626, 630 (9th Cir.1987). In reviewing a summary judgment motion, the  
14 court must resolve any doubt as to genuine issues of material fact in favor of the nonmoving party.  
15 *Dreiling v. American Online Inc.*, 578 F.3d 995, 1000 (9th Cir.2009). If evidence produced by the  
16 moving party conflicts with evidence produced by the nonmoving party, the court must assume the  
17 truth of the evidence set forth by the nonmoving party with respect to that fact. *Leslie v. Grupo*  
18 *ICA*, 198 F.3d 1152, 1158 (9th Cir.1999).

19 IV. DISCUSSION

20 A. Condemnation Under 21 U.S.C. § 334

21 The United States argues that no material questions of fact exist as to the statutory  
22 requirement to condemn and destroy the fifty-six articles of drugs. Under the FDCA, an article is  
23 liable to seizure, condemnation and forfeiture if, among other reasons, it: (1) is a drug; (2) was  
24 shipped in interstate commerce; and (3) is misbranded and/or unapproved. 21 U.S.C. § 334(a)(1).<sup>3</sup>

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26 <sup>3</sup> The United States, in its motion for summary judgment, requests only that the seized drugs be  
27 destroyed, and in its reply brief represents that it had offered to release the actual boxes to Forsythe.  
28 *See* Mot. for Summ. J. at 19; Reply to Opp’n at 7. Under 21 U.S.C. § 334(d)(1), upon a finding of  
condemnation and forfeiture, any drug must be destroyed or sold as the court directs. Section  
334(d)(2) applies this condemnation requirement to, among other things, containers of any  
counterfeit drug. *See* 21 U.S.C. §§ 334(a)(2)(C) & 334(d)(2). Under the statute, however, a

1 The United States provides an extensive analysis in its motion for summary judgment of each of  
2 these three elements. In short, Plaintiff presents authority that each of the items are drugs within the  
3 meaning of the Act, that they were all manufactured at foreign facilities (and therefore travelled in  
4 interstate commerce) and that they were misbranded and/or unapproved. As to the last element, the  
5 United States points out that fifty-two were not labeled in English, which constitutes misbranding  
6 under 21 U.S.C. § 352(c) and 21 C.F.R. § 201.15(c)(1). The other four drugs (“Pregnyl,” “Suhagra-  
7 100,” “Marevan” and “Bio-Tropin”) are, according to Plaintiff’s analysis, new drugs that lack  
8 approved “new drug applications,” and therefore are unapproved and cannot bear the required  
9 labeling for new drugs. *See* 21 U.S.C. §§ 331(p) & 355; 21 C.F.R. § 201.100(c)(2). This analysis is  
10 moot, however, because Forsythe does not contest that these items should be condemned. While he  
11 does not stipulate to Plaintiff’s position that the articles are drugs, were shipped in interstate  
12 commerce and are misbranded, he offers no legal or factual basis to dispute this analysis and  
13 consents that the items should be destroyed. Instead, he simply requests that they not be condemned  
14 now for the sole reason that they are relevant to his Nevada civil claims. *See* Opp’n. to Mot. for  
15 Summ. J. at 11 (“Opp’n”) (“[T]he Court need not waste its time analyzing those issues [that the  
16 articles are drugs, misbranded, unapproved and transported in interstate commerce] as Dr. Forsythe,  
17 without conceding that the ‘drugs’ are misbranded, not approved, or involved in commerce, has  
18 AGREED that the ‘drugs’ be destroyed. The only issue now is WHEN they should be destroyed.”)  
19 (emphasis in original). Therefore, the Court only addresses the issue of whether the condemnation  
20 of these drugs should be postponed until after the completion of his Nevada action.

21 B. Preservation of Evidence

22 As an initial matter, Forsythe presents no authority for the proposition that, in a civil *in rem*  
23 action, the fact that articles to be condemned are relevant to a separate proceeding should defeat a

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24 counterfeit drug is separate from a misbranded drug. The latter involves the misleading nature of  
25 any labeling or advertising, while the former refers to the unauthorized use of names or identifying  
26 marks of other drug manufactures. *See* 21 U.S.C. §§ 321(g)(2) & 322(n). The Court has found no  
27 case law either permitting or prohibiting it from ordering the preservation of containers of forfeited  
28 drugs while simultaneously ordering the destruction of the drugs themselves under 21 U.S.C. §  
334(d). The United States contends that it has the right to destroy the drugs, vials and boxes, but  
agrees by stipulation that the boxes will be preserved and returned to Claimant. Forsythe agrees to  
the destruction of the drugs and vials. The Court, therefore, need not reach the issue of whether  
Plaintiff has the right under the Act to destroy the boxes and vials as well as the drugs.

1 motion for summary judgment. While Forsythe maintains that there is a genuine issue of fact as to  
2 the relevance of the drugs to his Nevada action, the standard under Rule 56 addresses only “genuine,  
3 *triable* issue[s] of material fact.” *Celotex*, 477 U.S. at 327 (emphasis added). In other words, in a  
4 summary judgment analysis, the Court looks to the substantive legal elements of a claim to identify  
5 which facts are material, and “[o]nly disputes over facts that might affect the outcome of the suit  
6 under the governing law will properly preclude the entry of summary judgment. Factual disputes  
7 that are irrelevant or unnecessary will not be counted.” *Anderson*, 477 U.S. at 248. Simply put,  
8 “the availability of summary judgment turn[s] on whether a proper jury question was presented.”  
9 *Id.* at 249 (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970)).  
10 Here, the Complaint for Forfeiture *In Rem* was brought pursuant to 21 U.S.C. § 334, and the United  
11 States addresses each of the required elements under that statute in its motion for summary  
12 judgment. Nowhere in 21 U.S.C. § 334, or in any other authority presented by Forsythe, is the  
13 requirement of preservation considered an element of the forfeiture analysis.

14         The extent of Forsythe’s legal argument in support of his opposition is that the United States  
15 has a duty to preserve evidence in its possession that is relevant to his Nevada civil case. In making  
16 his argument, he cites a case in which this Court held that “[a]s soon as a potential claim is  
17 identified, a litigant is under a duty to preserve evidence which it knows or reasonably should know  
18 is relevant to the action.” *In re Napster, Inc. Copyright Litigation*, 462 F.Supp.2d 1060, 1067 (N.D.  
19 Cal. 2006) (J. Patel) (citing *National Ass’n of Radiation Survivors v. Turnage*, 115 F.R.D. 543, 556-  
20 57 (N.D. Cal. 1987) (J. Patel)). He also cites a California state case, as well as a number of out of  
21 district cases, which primarily address what remedies are available when a party wrongfully  
22 destroys evidence. *See Cedars-Sinai Medical Center v. Superior Court*, 18 Cal.4th 1, (1998). Not  
23 only do many of the cases that Forsythe cites lack binding authority, but none of them help answer  
24 the question of whether evidence that is required to be destroyed by statute must be preserved when  
25 it is relevant to a separate proceeding between the same parties. It is beyond cavil that parties have a  
26 duty to preserve evidence that is relevant to an action in which they are named, but the issue in this  
27 case is whether that duty applies here and whether it trumps the FDCA’s requirement that  
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1 misbranded drugs be destroyed. Forsythe does not address this issue in his opposition.<sup>4</sup> Moreover,  
2 while Forsythe spends a great deal of time in his opposition addressing the consequences and  
3 remedies when a party improperly destroys evidence (such as preclusion of the evidence, adverse  
4 inferences or monetary sanctions), none of his analysis explains why an obligation to preserve  
5 evidence should be considered an element of Plaintiff’s claim for purposes under Rule 56. On this  
6 basis alone, Forsythe’s opposition to summary judgment lacks a legal basis. In fact, his filings  
7 appear to be less an opposition to summary judgment than a request to stay destruction of the  
8 evidence.

9 In making his request to preserve the 56 articles of drugs due to their relevance in the  
10 Nevada civil action, Forsythe argues that his civil complaint alleges that the FDA agent  
11 investigating his criminal case tampered with evidence. Specifically, as pertaining to the articles  
12 involved in this action, he maintains that the agent altered the address information on the outside of  
13 certain boxes containing the seized Bio-Tropin in order to give the impression that the boxes  
14 belonged to Forsythe and had been obtained from Forsythe’s office, when in fact they had been  
15 previously labeled with another doctor’s name. Based on these allegations, Forsythe initially  
16 requested that all of the actual physical evidence seized by the United States (including the boxes,  
17 vials and drugs) be preserved for his civil trial. As to the boxes, he argues that a photocopy of the  
18 allegedly tampered Bio-Tropin boxes is insufficient because the redaction of the other doctor’s  
19 name is only visible when the boxes are seen in person. He also insists that a sample of the seized  
20 articles is not enough because a sampling fails to demonstrate the magnitude of items seized and  
21 will not help him determine if other evidence was manipulated. According to Forsythe, the volume  
22 of materials seized during the criminal investigation, including patient records, ledgers and copies of

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23 <sup>4</sup> In response, the United States argues that Forsythe is improperly asking the Court to enjoin the  
24 government from bringing an enforcement action. The United States cites *Ewing v. Mytinger &*  
25 *Casselberry, Inc.*, in which the Supreme Court held that a court may not enjoin the initiation of  
26 seizure actions by the FDA. 339 U.S. 594, 601 (1950) (the FDA’s determination of whether there is  
27 probable cause to seize items pursuant to 21 U.S.C. § 334(a) is not reviewable in an action separate  
28 from a libel suit brought against the items). *Ewing* is distinguishable from this case, however,  
because in *Ewing* the district court had enjoined the FDA from making multiple seizures without a  
hearing. *Id.* at 595. Here, the FDA has already seized the items in question and the libel  
proceedings have been initiated. In other words, *Ewing* does not restrain the Court’s jurisdiction  
here, where the issue is whether the seized items must be destroyed pursuant to 21 U.S.C. § 334(d).





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Pursuant to 21 U.S.C. § 334(e), the United States shall recover from Claimant Forsythe the applicable court costs and fees, as well as the costs of storage, destruction and the monitoring of the destruction of the condemned fifty-six articles of drugs.

IT IS SO ORDERED.

Dated:4/4/11



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DONNA M. RYU  
UNITED STATES MAGISTRATE JUDGE