

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY)	MDL NO. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	CIVIL ACTION: 01-CV-12257-PBS
)	Subcategory Docket: 06-CV-11337-PBS
)	
THIS DOCUMENT RELATES TO)	Judge Patti B. Saris
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	
<i>Inc. v. Abbott Laboratories, Inc.,</i>)	Magistrate Judge Marianne B. Bowler
No. 06-CV-11337-PBS)	
)	ORAL ARGUMENT REQUESTED

**ABBOTT LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF ITS
MOTION FOR A FINDING OF SPOILIATION AND FOR SANCTIONS**

Dated: June 4, 2009

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INTRODUCTION

The Department of Justice (“DOJ”) waited twelve years to direct anyone to preserve evidence relevant to this litigation. The record in this case compels a finding that the Government has spoliated, on a massive scale, evidence critical to a fair adjudication of this case. Once Ven-A-Care filed this lawsuit in June 1995, the law imposed a duty to preserve evidence in the possession of the federal and state governments—a duty that DOJ ignored entirely. DOJ kept the lawsuit under seal for more than *eleven years*, conducting one-sided discovery against Abbott, but did nothing to preserve evidence in its own possession or control. Not a single litigation hold order was issued. Not a single agency was told to preserve evidence. Even when manufacturers wrote to DOJ in 2000, specifically reminding it of its obligation to preserve relevant evidence, the DOJ did not lift a pen to stop the destruction of relevant evidence.

Not until January 2007, before the Government’s Rule 30(b)(6) deposition on evidence preservation, did DOJ issue its first litigation hold. But the damage had already been done, as exemplified in a 2006 email from a New York pharmacy official to his colleagues in other states:

Jerry: NY has been involved in AWP litigation issues- (I can’t say how many) through our Attorney General Office. . . . Lesson learned: ***get rid of any papers that are from before state record keeping requirements*** – lawyers want everything available (note: do not get rid of anything once litigation has begun or after lawyers tell you to keep what is available – you could get in a lot of trouble).

(Ex. A) (emphasis added). The DOJ’s belated efforts were too late to mitigate the prejudice to Abbott, and the integrity of these proceedings, of more than a decade of document destruction.

The full measure of the lost evidence will never be known, but through discovery Abbott has been able to identify several specific pieces of evidence that have been destroyed, including:

- Materials related to a 1995 nationwide survey of state Medicaid programs on “the relationship between AWP and pharmacy cost” (*see infra* at 15-16).

- The e-mails and electronic files of 27 of the 28 CMS officials identified by the Government as being primarily responsible for Medicaid and Medicare drug payment issues during the relevant time period, including two former administrators heavily involved in AWP issues (*id.* at 11-13);
- Medicaid claims data and Medicare pricing arrays for most states and Part B carriers necessary to determining causation and damages (*id.* at 14); and
- Work papers from over a dozen relevant studies performed by the Department of Health and Human Services' Office of the Inspector General (*id.* at 17-18).

No truly adequate remedy exists for DOJ's actions. Abbott respectfully moves for the following partial relief: *First*, Abbott requests a finding that the Government failed to take reasonable measures to preserve relevant evidence from the Medicaid and Medicare programs. *Second*, Abbott requests sanctions, including (a) eliminating damages on any claims for which underlying payment data is now unavailable; (b) insisting on state-by-state evidence of fraud and construing evidentiary gaps in Abbott's favor; (c) shifting to the Government the burden of showing that it did not acquiesce in paying providers the spreads it now seeks to recoup from Abbott; (d) monetary sanctions; and (e) additional evidentiary sanctions as appropriate at trial.

FACTUAL BACKGROUND

On June 23, 1995, Ven-A-Care filed its *qui tam* against Abbott and other drug makers. The Abbott pharmaceutical products implicated in the complaint were not typically dispensed by retail pharmacies. Rather, the products were typically sold to hospitals, physicians, and specialty pharmacies, are were usually injected or infused into patients under medical supervision.

Shortly after it filed is complaint, Ven-A-Care met with the DOJ and senior CMS officials to discuss its allegations. (*See* Ex. B.) Ven-A-Care repeated its accusations in several letters to top officials at CMS, OIG, and the DOJ. (*See, e.g.*, Ex. C; Ex. D; Ex. E.) The DOJ began issuing Civil Investigative Demands and subpoenas upon Abbott in February 1996. (Ex. F.) Early in the case, DOJ also discussed Ven-A-Care's claims with relevant state Medicaid

officials, holding “many” meetings and conferences. (Ex. G.) In March 1998, Ven-A-Care and the DOJ discussed their investigation at the annual conference of the National Association of Medicaid Fraud Control Units (“NAMFCU”); nearly every state attended. (*See* Ex. H.)

Soon after this national conference, the DOJ and NAMFCU began working with First Databank to publish alternative, lower AWP for some infusion, injectable, and inhalation drugs, including most of the subject drugs here. (*See* Ex. I.) This “DOJ AWP” project was controversial, as the “spread” on these drugs subsidized considerably higher costs associated with infusion drug therapies.¹ Surprisingly, given Plaintiffs’ allegations in this case, the DOJ AWP had little relative impact on Medicaid or Medicare reimbursement.

The DOJ AWP were rejected by most states. With full knowledge that they were paying healthcare providers far more than their actual acquisition cost for drugs, most states rejected or stopped using DOJ’s lower prices and chose to continue using the compendia AWP as the benchmark for drug payments. (*See, e.g.*, Ex. L (Missouri); Ex. M at 2 (California).) Congress likewise blocked use of the “DOJ AWP” in Medicare, recognizing that slashing the “spread” on drugs without also considering any necessary, off-setting increases in administrative fees paid to providers would cause an upheaval. (*See* Ex. N; Ex. O at 316-17 (CMS Administrator DeParle).)

In the meantime, the DOJ met with Abbott in October 1999 to discuss Ven-A-Care’s allegations. In March 2000, several manufacturers submitted a white paper to the DOJ that highlighted evidence showing that Medicaid and Medicare were aware of large discounts from AWP, yet made policy decisions to pay providers based on AWP rather than acquisition cost.

The companies argued that the Government could not colorably claim to have been defrauded.

¹ *See, e.g.*, Ex. J (6/22/00 email from Minnesota pharmacy employee: “If the AWP spread disappears, the dispensing fee may have to be increased, especially for many of the 428 drugs currently in question. Many of these drugs require some type of compounding or other preparation.”); Ex. K (6/9/00 email from Virginia pharmacy employee: “Unfortunately the individuals that have decided upon this tact are our own state MFCU and DOJ. As well as some state pharmacy administrators. . . . I plan to follow rule procedures in order to use these prices if appropriate and only after an impact has been assessed.”); *infra* at 13 (Carmody letter & declaration).

(Ex. P.) Significantly, on August 4, 2000, one of the manufacturers' counsel, noting the potential for litigation, asked the DOJ to:

take appropriate and immediate steps to insure that your client agencies (including at a minimum HHS, HCFA, MFCU units, State Medicaid officials, single state payor agencies, and the Department of Veterans' Affairs) maintain all documents that may be relevant to the subject matter of this litigation or reasonably calculated to lead to the discovery of admissible evidence.

(Ex. Q at 2.) DOJ ignored this request and took no steps to preserve evidence.

AWP-related litigation was first openly filed in 2001, although Ven-A-Care's complaint remained sealed. Starting in 2003, CMS received subpoenas in MDL 1456 and the *Lupron* civil cases (MDL 1430). (Ex. R; Ex. S). CMS collected and produced some responsive documents, yet still made no affirmative effort to preserve evidence. In September 2005, CMS changed its email program, but made no effort to retain relevant emails. The result was a massive destruction of potentially relevant emails, even as CMS purported to respond to a subpoena.

On March 17, 2006, the DOJ filed its Complaint against Abbott, finally exposing this case to the light of day. Even after Abbott served initial document requests in 2006, the DOJ still did not implement a document hold, and only did so in January 2007—after Abbott served a 30(b)(6) deposition notice on document preservation. (*See* Ex. T at 77-85.) Even then, the hold applied only to certain agencies within the federal government. (*See id.* at 77, 133, 137-38.)

The DOJ did nothing at all to preserve evidence from the state programs, which account for more than half of the claimed damages at issue here. This failure has had dire consequences, as exemplified by the aforementioned October 18, 2006, email from New York Medicaid official Richard Butt, whose “lesson learned” from prior experience was to “get rid of any [AWP-relevant] papers” before such litigation holds were put into place. (Ex. A.)²

² Incredibly, it appears the DOJ did not even ask state Medicaid agencies or Medicare carriers to preserve claims data and other underlying payment information necessary to prove liability and calculate damages.

ARGUMENT

I. THE FACTUAL RECORD DEVELOPED IN THIS CASE UNDERSCORES WHY THE GOVERNMENT’S SPOILIATION OF EVIDENCE IS PREJUDICIAL TO ABBOTT.

Plaintiffs’ allegations illustrate why the Government’s spoliation of evidence is so prejudicial to Abbott. The allegations of “false claims” and “overpayments” in this case are dependent on certain core propositions, including:

- federal and state officials “believed” AWP’s reported in the compendia reflected or approximated prices in the marketplace (*see* Dkt. No. 3104 at 15);
- Medicare and each of the Medicaid programs intended to pay, or were required to pay, actual acquisition cost for the subject drugs (*id.* at 20);
- any payment above actual acquisition cost (WAC states) or a small percentage margin (0% to 20%) (AWP states and Medicare) on these inexpensive drugs constitutes an “overpayment” and “false claim”;³ and
- in a “but-for” world, Medicare/Medicaid would slash payments to providers for these drugs without increasing dispensing or administrative fees.

The Government has sought to treat these propositions as unassailable facts, and has vigorously attempted to limit any discovery that might challenge them by pigeonholing such evidence into a defense it labels “government knowledge.”

The relevance of documents that were not preserved is established by information Abbott has adduced through its persistent efforts to gain discovery from state and federal governmental officials. This critical evidence supports the following propositions:

- Medicaid and Medicare officials did *not* understand or refer to AWP in the way that the DOJ Complaint or *amicus* filing does (slides 3-4).⁴ Rather, those officials knew that the compendia AWP’s far exceeded acquisition costs and that percentage

³ *See* Dkt. No. 5492 at 1-2 (statement of DOJ that it “added a 25% markup to Abbott’s actual market prices when determining a substitute AWP” and that its “expert calculated an alternative AWP in the Abbott case that was 125% of the market-based transaction price(s) derived from Abbott’s transactional records”). The 25% markup does not result in a 25% payment margin because most state Medicaid programs took at least a 5% discount off of AWP.

⁴ To simplify the Court’s review, a short Powerpoint presentation with a sampling of this evidence accompanies this brief, and will be sent separately to the Court on a CD (along with a courtesy copy of this filing). The disk and embedded deposition video clips will play automatically. Exhibit WWW contains hard copies of the document and deposition transcript excerpts shown in the presentation. The CD also includes, at slides 26-28, a timeline of the aforementioned events relating to the Government’s failure to preserve evidence.

spreads between AWP and actual cost were much higher for generics generally, and for the subject drugs specifically (slides 5-9).

- Traditional Medicare and Medicaid payment mechanisms were not designed with home healthcare in mind; as a result, those programs purposely allowed a margin on drugs (like the Abbot drugs in this case) to compensate for the higher costs associated with home healthcare (slides 10-17).
- The small-dollar “spreads” at issue are not “mega-spreads” (slides 18-20).
- Medicaid and Medicare reimbursement is a highly complex, political issue with rates established based on input from a variety of stakeholders (slides 21-25).

This evidence demonstrates that the facts are not at all what Plaintiffs would have the Court believe. For example, the document in slide 15 explains that Missouri did not use the DOJ AWPs because, without a spread, its \$4.09 dispensing fee did not cover the higher costs of dispensing home infusion drugs. This document, and others, illustrate why an alleged “spread” does not alone establish a “false claim,” and why the evidence that the DOJ has fought so hard to cloak through discretionary privileges and claims of “irrelevance”—and that its spoliation has largely destroyed—is so critical.

II. THE GOVERNMENT VIOLATED ITS OBLIGATION TO PRESERVE RELEVANT EVIDENCE.

The duty to preserve evidence “arises when the party has notice that the evidence is relevant to litigation or when a party should have known that the evidence may be relevant to future litigation.” *Zubulake v. UBS Warburg LLC*, 220 F.R.D. 212, 216 (S.D.N.Y. 2003) (quotation marks omitted)). The scope of the duty rests on two related questions: (1) “*when* does the duty to preserve attach,” and (2) “*what* evidence must be preserved.” *Id.*

A. The Government’s Duty to Preserve Evidence Began When Ven-A-Care Filed Its Initial Complaint in June 1995.

A party’s duty to preserve evidence is triggered “not only during litigation,” but also when litigation is “reasonably foreseeable.” *Silvestri v. Gen. Motors Corp.*, 271 F.3d 583, 590-

91 (4th Cir. 2001); *see also* *Blinzler v. Marriott Int'l, Inc.*, 81 F.3d 1148, 1159 (1st Cir. 1996). “The touchstone is ‘reasonable anticipation.’” The Sedona Conference, *The Sedona Conference Commentary on Legal Holds: The Trigger and the Process* 5 (2007). The Government is not exempt from these standards. “It is the duty of the United States, *no less than any other party before this court*, to ensure, through its agents, that documents relevant to a case are preserved.” *United Med. Supply Co. v. United States*, 77 Fed. Cl. 257, 274 (2007) (emphasis added).

The duty to preserve is particularly crucial while a *qui tam* action is under seal. By “providing for sealed complaints, [Congress] did not intend to affect defendants’ rights in any way.” S. REP. NO. 99-345, at 8 (1986). During the seal period, however, defendants lack even the opportunity to answer the complaint, much less conduct discovery. Indeed, lengthy seal periods “may be sufficiently prejudicial to trigger due process concerns,” *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 498 F. Supp. 2d 389, 399 (D. Mass. 2007); *a fortiori*, excessive delay combined with the spoliation of documents and records is particularly egregious and unjust.

Here, the relator’s filing of its June 23, 1995 complaint triggered the Government’s duty to preserve evidence. At that time, the Government had notice of *actual* litigation and, thus, the duty to preserve evidence related to that litigation. *See* Report and Recommendation, *In re Pharm. Indus. Avg. Wholesale Price Litig.*, MDL No. 1456, at 21-22 (D. Mass. Mar. 14, 2007) (“Nevada R&R”); *see also* *Testa v. Wal-Mart Stores, Inc.*, 144 F.3d 173, 177-78 (1st Cir. 1998) (focusing on the “institutional notice” of the party); Sedona Conference, *supra*, at 5 (“[t]he duty . . . is certainly triggered when a complaint is served or a governmental proceeding is initiated”).

This principle holds true when the Government is on notice of a *qui tam* complaint, even before the Government has decided to intervene. The recent decision in *Miller v. Holzmann*, No.

95-01231, 2007 WL 172327 (D.D.C. Jan. 17, 2007), is instructive. In *Miller*, Magistrate Facciola (a member of the Sedona Conference Advisory Board) held that the Government had a duty to preserve documents once the relator filed its underlying complaint in 1995. *See id.* at *3. The magistrate criticized the DOJ for failing in its duty, noting that the “competent and experienced” government attorneys “knew or should have known these documents were relevant to ongoing litigation and that their destruction could prejudice the defendants.” *Id.* at *6.

B. The Government Should Have Preserved Evidence From HHS, CMS, OIG, State Medicaid Agencies, Medicare Contractors, and Medicaid Fiscal Agents.

When litigation is reasonably anticipated, a party “must suspend its routine document retention/destruction policy and put in place a ‘litigation hold’ to ensure the preservation of relevant documents.” *Zubulake*, 220 F.R.D. at 218. A party must preserve all evidence that is “reasonably calculated to lead to discovery of admissible evidence, is reasonably likely to be requested during discovery, and/or is the subject of a pending discovery request.” James S. Gorelick, *et al.*, *Destruction of Evidence* § 3.11, at 93 (1989 & Supp. 2008).

At a minimum, a party’s litigation hold should target evidence that may be produced by “key players” in the case. *Zubulake*, 220 F.R.D. at 218. The “key players” here include not only HHS, CMS, and OIG, but state Medicaid programs as well. The states, after all, controlled the payments made on the allegedly false Medicaid claims at issue.⁵

The Government’s duty to preserve extended not only to documents in its possession, but also documents in its “control.” *In re NTL Sec. Litig.*, 244 F.R.D. 179, 195 (S.D.N.Y. 2007) (party must preserve documents if it has “the right, authority, or practical ability to obtain [them]

⁵ The DOJ has admitted elsewhere that “[s]tates – not the federal government – set the rate at which they pay pharmacies and other health care providers for Medicaid covered products and services.” (Ex. U at 4 (12/6/07).) The DOJ stressed that the federal government “helps states provide covered services to Medicaid-eligible beneficiaries,” “pays *nothing* to pharmacies for the prescription drugs those pharmacies distribute to Medicaid patients, does not dictate the formula states may use to determine the amount they will pay pharmacies, and does not prescribe limits on state payments to pharmacies.” (*Id.* at 13 (emphasis in original).) In sum, for Plaintiffs’ Medicaid claims, evidence from the states is indisputably critical.

from a non-party; Fed. R. Civ. P. 34(a)(1) (party must preserve evidence within its “control”). The Government, which is authorized to direct states to gather and submit Medicaid-related information upon request, *see* 42 U.S.C. § 1396a(a)(6), (42), (69), could and should have directed the states to preserve evidence relevant to this case. *See, e.g., Rosie D. v. Romney*, 256 F. Supp. 2d 115, 118-19 (D. Mass. 2003) (holding that state Medicaid officials “controlled,” and were required to produce, Medicaid documents held by non-defendant agencies); *RTC v. Deloitte & Touche*, 145 F.R.D. 108, 110 (D. Col. 1992) (holding that RTC “controlled,” documents held by non-party agency where federal statute gave it “ability to obtain [the] documents on demand”).⁶ In contrast to its cavalier attitude on spoliation, the DOJ has, in fact, obtained evidence from the state programs for its own benefit in its investigation and litigation.

Evidence from state and federal agencies is critically relevant to Abbott’s defense. Since 1999, Abbott has advised DOJ in connection with this case that state and federal officials knew of substantial discounts from compendia AWP’s, particularly for generics and infusion drugs,⁷ but nonetheless chose to pay providers a premium for the drugs for a host of reasons. The Government was thus obliged to preserve evidence supporting Abbott’s defense. Obviously, the Government was required to do more than simply conduct discovery favorable to itself while the case was under seal; it was obligated to preserve both sides of the story, including evidence relevant to Abbott’s defenses. It was not entitled to make a “unilateral decision, supplanting that of the court, that the documents requested were not relevant to the case,” and then allow those documents to be destroyed. *Farm. Constr. Servs., Inc. v. Fudge*, 831 F.2d 18, 21 (1st Cir. 1987).

⁶ *See also, e.g., Bryant v. Gardner*, 587 F. Supp. 2d 951, 967-968 (N.D. Ill. 2008) (“A party has a duty to preserve evidence over which it has control and reasonably knows or could foresee would be material to a potential legal action.”) (citing authorities); *Cyntegra, Inc. v. Idexx Labs., Inc.*, No. 06-4170, 2007 WL 5193736, at *5 (C.D. Cal. Sept. 21, 2007) (same); *Calzaturificio v. Fabiano Shoe Co., Inc.*, 201 F.R.D. 33, 38-39 (D. Mass. 2001) (party “controls” evidence it has the “legal right to obtain . . . on demand”).

⁷ (*See, e.g.,* Slides 5-7 (*supra*); *see also* Ex. V at 287, 358-59 (Arkansas); Ex. W at 213-14, 221-22, 593-94 (California); Ex. X at 72-73, 206-08, 212, 224, 340 (Florida); Ex. Y at 182 (Illinois); Ex. Z at 42-48 (Louisiana); Ex. AA at 93, 111 (Michigan).)

III. THE GOVERNMENT’S FAILURE TO PRESERVE EVIDENCE HAS RESULTED IN EXTENSIVE SPOILIATION.

Spoliation is “the destruction or significant alteration of evidence, or the failure to preserve property for another’s use as evidence in pending or reasonably foreseeable litigation.” *West v. Goodyear Tire & Rubber Co.*, 167 F.3d 776, 779 (2d Cir. 1999). As recently stated by one court, “[a]side perhaps from perjury, no act serves to threaten the integrity of the judicial process more than the spoliation of evidence,” as “when critical documents go missing, judges and litigants alike descend into a world of *ad hocery* and half measures—and our civil justice system suffers.” *United Med. Supply*, 77 Fed. Cl. at 258-59.

A. The Government’s Inaction Has Resulted in the Widespread Destruction of Relevant Documents and Emails.

Through extensive discovery efforts, Abbott has been able to unearth information about a host of important evidence that was lost due to the Government’s inaction. The truly insidious aspect of the Government’s spoliation, however, is not what Abbott *knows* has been lost, but rather the fact that Abbott (and this Court) can never know the full extent or importance of what has been destroyed. Such evidence “could have been useless or the classic ‘smoking gun.’ At this point, all we can do is guess and that is no way to resolve a legal or factual issue.” *Miller*, 2007 WL 172327, at *5; *see also Leon v. IDX Sys. Corp.*, 464 F.3d 951, 959 (9th Cir. 2006) (“[B]ecause the relevance of [spoliated] documents cannot be clearly ascertained . . . a party can hardly assert any presumption of irrelevance as to the destroyed documents.”) (quotation marks omitted.) That “smoking guns” may have been lost is “precisely the reason” that information “should have been preserved and produced” in the first place. *Nursing Home Pension Fund v. Oracle Corp.*, 254 F.R.D. 559, 565 (N.D. Cal. 2008).

Although the full scope of the damage is unknowable, the information that Abbott has gathered is more than sufficient to compel a finding of spoliation against the Government. At

the federal level, hundreds of relevant conversations were lost. During the 1990s, the relevant federal agencies frequently discussed AWP-related issues internally, and with Congress, often via e-mail.⁸ The vast majority of the documents produced from the federal Government files, however, are dated after 2001, and most of these are formal communications between federal and state agencies, or else come from the working files of OIG reports.

The Government has produced remarkably few contemporaneous, substantive discussions on AWP-related matters, and spoliation is to blame. For example, in response to an Abbott interrogatory, the Government identified 28 CMS employees who were primarily responsible for Medicaid and Medicare drug payment policy during the time period at issue. (Ex. EE at 16-18.) CMS “did not take any steps to preserve” the e-mail and electronic documents of 27 of these witnesses. (Ex. FF at 175-77, 235-36.) CMS’s regular practice is to destroy an employee’s electronic files within 30 days after she leaves CMS (as most of these 28 employees since have),⁹ yet CMS did nothing to suspend that practice or review and preserve relevant documents before the rest were destroyed. The vast majority of the electronic files for these admittedly central policy witnesses are thus gone forever. (*See id.* at 176-77.)¹⁰

The Government’s spoliation of relevant documents implicates the highest levels of CMS. Bruce Vladeck, CMS Administrator between May 1993 and September 1997, was an “extensive e-mailer” who “could very well have” used e-mail to discuss drug reimbursement issues. (Ex. GG at 102, 309-10.) Ven-A-Care’s earliest communications with CMS were sent

⁸ (*See, e.g.*, Ex. BB at 73, 377 (T. Scully: “fixing AWP” was high priority while at CMS); Ex. CC at 59-61, 71 (CMS’s R. Niemann: AWP was a “frequent topic of conversation” with Congress); Ex. DD at 99-100 (CMS’s L. Reed: “There has been a lot of discussion of average wholesale price as reported by the pricing compendia.”).)

⁹ A vast majority of these individuals left CMS after the Government’s duty to preserve evidence arose.

¹⁰ This failure to preserve employee emails was improper. *See, e.g., In re NTL*, 244 F.R.D. at 198, 201 (imposing sanction for failure to preserve key employees’ emails and documents); *In re Napster, Inc. Copyright Litig.*, 462 F. Supp. 2d 1060, 1070 (N.D. Cal. 2006) (“[E]ven if [defendant’s] ‘long standing policies’ included deleting emails, [defendant] was required to cease deleting emails once the duty to preserve attached”); *E*Trade Sec. LLC v. Deutsche Bank AG*, 230 F.R.D. 582, 592-93 (D. Minn. 2005) (imposing sanctions where defendant “had not placed an adequate litigation hold on email boxes”).

directly to Dr. Vladeck (*see, e.g.*, Ex. C; Ex. D; Ex. HH; Ex. II), and several important events occurred during Dr. Vladeck's tenure, including CMS's proposal to remove AWP from Medicare's reimbursement formula, OIG's issuance of numerous AWP reports, and *Barron's* publication of its "Hooked on Drugs" article. These events would have triggered relevant emails and other correspondence, but Dr. Vladeck's files no longer exist. (Ex. FF at 175-77, 235-36.)

The same can be said for CMS Administrator Thomas Scully. Mr. Scully, who cited "fixing AWP" as one of CMS's top priorities during his tenure, used email extensively. (Ex. BB at 79-80, 376-77, 381.) But CMS wiped Mr. Scully's hard drive clean after he left in 2004, thus destroying his emails and files, notwithstanding the fact that CMS had already been served with a subpoena from this Court in MDL 1456.¹¹ (Ex. FF at 100-05; Ex. R.) Given Mr. Scully's focus on AWP and his testimony about how inflated AWP's were used to cross-subsidize providers (*see* Ex. BB at 122, 203, 228-29, 295, 366-67), critical evidence was almost surely destroyed.¹² Many other key CMS and OIG witnesses similarly testified that they were active users of email, but were never told to retain relevant documents and, therefore, did not.¹³

The situation is worse at the state level. Apart from a few very recent litigation holds, the states were not asked to take—and therefore did not take—any efforts to preserve evidence

¹¹ It is well established that a party's failure to "attempt to preserve or place a litigation hold on the computer hard drives used by [key] employees . . . violate[s] [the party's] obligation to preserve evidence." *Cache La Poudre Feeds, LLC v. Land O'Lakes, Inc.*, 244 F.R.D. 614, 629 (D. Colo. 2007); *see also Optowave Co. Ltd. v. Nikitin*, No. 6:05-cv-1083-Orl-22DAB, 2006 WL 3231422, at *11 (M.D. Fla. Nov. 7, 2006) (same).

¹² Mr. Scully served as CMS Administrator when Congress passed the MMA of 2003. Notably, the MMA kept the 95% of AWP methodology for infusion drugs administered through durable medical equipment. Mr. Scully testified this exemption from the new ASP methodology was intended to "freeze" in a level of "cross-subsidy." (*Id.* at 366-67.) Vancomycin was typically administered through durable medical equipment during the relevant period.

¹³ (*See, e.g.*, Ex. CC at 59-65 (CMS's R. Niemann, Medicare Part B pharmacy issues); Ex. JJ at 29-31 (CMS's D. Smith, Medicaid pharmacy issues); Ex. KK at 93-96 (CMS's S. Gaston, Medicaid pharmacy issues); *cf.* Ex. LL at 97-98 (CMS's T. Gustafson, Office of Legislation, not aware of direction to retain documents before 2006); Ex. MM at 99-100 (OIG's R. Vito not aware of direction to retain documents until within a year of his deposition).)

relevant to this case.¹⁴ Numerous witnesses have admitted that relevant documents have been destroyed, explaining the scarcity of contemporaneous documents in many states' productions.

More troubling, the October 18, 2006 email from New York Medicaid employee Richard Butt—sent via Listserv to over 50 Medicaid pharmacy officials across the country¹⁵—suggests an affirmative effort to “get rid of” documents relevant to the defense before the “lawyers tell you to keep what is available.” (Ex. A.) It is impossible to know how many administrators took Mr. Butt’s advice, but it is suggestive that, although representatives from nearly all of the states were copied on this email, only one state (Georgia) produced it in discovery. Moreover, no state has produced any response to Mr. Butt’s email.

A handful of states produced contemporaneous documents that plainly reveal the evidence of which Abbott was deprived. Illinois, for example, produced documents showing that it—like other states—used the drug spread to fund the higher costs associated with providing home healthcare therapies (which use the drugs at issue here). One provider acknowledged this “tacit agreement” when Illinois announced plans to remove the spread by adopting the “DOJ AWP” in 2000—*i.e.*, that Medicaid officials “understood that IV pharmacies were and are able to purchase pharmaceuticals at well below AWP pricing thus partially compensating them for their [dispensing] costs.” (Ex. RR; *see also* Ex. SS, Carmody Decl. ¶¶ 3-6.) These documents are a “smoking gun” on Government policy regarding cross-subsidization in Illinois. There can be little doubt that such evidence has been destroyed in other states and at CMS.

B. Many Specific, Identifiable Documents and Data Are Known to Be Lost.

In addition to the lost evidence described above, Abbott has identified particular, relevant information that has been lost due to the Government’s failure to preserve evidence. Given the

¹⁴ Supporting testimony is provided in Appendix A, with supporting deposition excerpts at Ex. NN.

¹⁵ (*E.g.*, Ex. OO at 120-21 (Georgia); Ex. PP at 148-49 (Minnesota); Ex. QQ (showing list serve members.)

breadth of this case, it is impossible to catalogue all that evidence here. Some items, however, merit discussion.

1. State Claims Data. The Government appears not to have asked *any* Medicaid agencies to preserve Medicaid claims data. Such data is critical to adjudicating Plaintiffs’ claims and calculating damages, including the key question of whether claims were reimbursed on the basis of allegedly inflated prices.¹⁶ Having created these gaps in the evidence, Plaintiffs now wish to use a patchwork of claims data from *only ten states* to extrapolate Medicaid damages *nationwide*, leaving Abbott without the full data necessary to mount a defense.

2. State MAC Information. The Government has spoliated material related to whether, when, and how states instituted maximum allowable cost limits (“MACs”) for the subject drugs. This is critical, as the Court has held that if plaintiffs cannot tie the MAC amount to the reported price of defendants’ drug (an analysis Plaintiffs’ expert does not do), Plaintiffs cannot prove their case.¹⁷ Moreover, several state witnesses have testified that their MACs were not based on compendia prices, and were set based on policy decisions—such as promoting generic use or subsidizing low dispensing fees associated with certain drugs.¹⁸ Even where limited claims data exist that might show the existence of a MAC, the data show neither the details of the MAC computation nor the policy determinations that influenced the payment amount.

3. Medicare Pricing Arrays. The DOJ also spoliated Medicare Pricing Arrays. These arrays, created by over 40 Medicare carriers, used National Drug Codes to calculate “median AWP” for the five J-Codes at issue. As each J-Code represented products from numerous

¹⁶ Pleadings in the Dey case discuss in further detail the need for this claims data. (Dkt. No. 144 at 1-3.)

¹⁷ (Dkt. No. 4056 at 31-32 (dismissing claims reimbursed on the basis of a MAC).)

¹⁸ (*See, e.g.*, Ex. TT at 62-63, 107-08, 153-54 (Tennessee); Ex. PP at 65-69, 360 (Minnesota); Ex. X at 230 (Florida); Ex. UU at 160-61 (Ohio); Ex. AA at 144-45 (Michigan); Ex. VV at 203-04 (Maryland).)

manufacturers and various dosage sizes, there was significant variability in what prices were used in the array and the resultant calculations. (*Compare* Ex. WW; Ex. XX; Ex. YY.)

These historical pricing arrays are necessary to determine whether, and to what extent, any published AWP influenced the median AWP payment amount. Because many carriers' arrays are now lost, the jury cannot reliably determine whether Abbott's reported prices had any bearing at all on the Medicare payment amounts for many of the Medicare claims at issue.

4. *Ven-A-Care's "Continuing Education Project."* Correspondence between Ven-A-Care and state Medicaid programs has also been spoliated. In late 1994, Ven-A-Care officer Zachary Bentley sent a letter to each state Medicaid program seeking information related to "state policy and methodology for reimbursement of intravenous solutions and injectable drugs." (*See, e.g.*, Ex. ZZ.) Ven-A-Care had follow-up communications with state officials—including personnel from Medicaid Fraud Control Units—on this subject,¹⁹ but the states' internal discussions of any information provided by Ven-A-Care have nearly all been destroyed.

5. *1995 "Relationship Between AWP and Pharmacy Cost" State Survey.* The states' responses to a 1995 survey regarding "the relationship between AWP and pharmacy cost" have, with one exception, apparently been destroyed. In the days before state pharmacy officials used an e-mail Listserv to communicate, group communication was done by fax. (*See* Ex. UU at 89-90 (Ohio's R. Reid).) In September 1995—after this case had been filed—South Dakota administrator Robert Coolidge faxed the group "requesting information regarding the relationship between AWP and pharmacy cost," specifically, the "formula used for calculation of reimbursement and the relationship of AWP to the actual cost of the product." (Ex. EEE at 3.) To Abbott's knowledge, only Illinois' response has been produced in discovery—and it is

¹⁹ (*See, e.g.*, Ex. AAA (referencing phone numbers of Ohio MCFU employees); Ex. BBB (referencing phone number of Maryland MCFU employee); Ex. CCC (1996 letter from United States DOJ to New Jersey in Ven-A-Care's files); Ex. DDD (notes of 6/26/97 conversation with Colorado Medicaid employee and MCFU employee).)

revealing: “For multiple source drugs I would make extensive use of State Upper Limits as neither the FUL or AWP mean anything for generic drugs.” (*Id.* at 5.)

Other states’ responses would likely confirm that they also clearly understood that AWP’s were not indicative of market prices, particularly for generics. Yet no other state has produced *any* information relating to this survey. DOJ’s failure to instruct the states to retain documents, or to otherwise collect and preserve them itself, undoubtedly spoliated these responses.

6. Medicaid Pharmacy Bulletins. Copies of the important, but now largely non-existent, *Medicaid Pharmacy Bulletin* have been lost. The *Bulletin* was published between 1987 and the mid-1990s “to assist the Medicaid pharmacy community in keeping abreast of the latest program management practices and developments in health care policy that affect Medicaid pharmacy.” (*See* Ex. FFF at 1; Ex. GGG at 185-87.) The *Bulletin* obtained its information from interviews with state Medicaid officials, including a rotating “Advisory Panel.” (Ex. FFF at 2.) State officials found the *Bulletin* to be a valuable source of data.²⁰

The few currently-existing *Bulletins* produced during discovery have contained important information for Abbott’s defense.²¹ Additional *Bulletins* would have likewise been helpful, and would have been available had the Government preserved evidence. For example, Joseph Fine (a former *Bulletin* Advisory Board member) had a whole book of the *Bulletins*, but destroyed them when he left Maryland Medicaid in 2005 to join CMS. (Ex. VV at 83.)

7. Workpapers and Related Material for Important OIG Reports. The Government’s failure to preserve documents has led to the loss of the official work papers for several key OIG reports discussing the impact of AWP on Medicaid and Medicare drug payments. (*See* Ex.

²⁰ (*See, e.g.*, Ex. GGG at 185-86 (Alaska); Ex. HHH at 348-50 (Delaware); Ex. VV at 81-84 (Maryland); Ex. III at 575 (Indiana); Ex. JJJ at 245-46 (Louisiana).)

²¹ For example, the *Bulletins* contain evidence indicating that state Medicaid programs recognized AWP’s for intravenous solutions were not reliable, that home infusion therapy was considerably more complex than ordinary pill prescriptions, and that state Medicaid programs appreciated that the margin made on the drug provided compensation for the extras costs of home infusion therapies. (*See, e.g.*, Ex. FFF at 3.)

KKK.) OIG maintains these work papers for 10 years. (See Ex. LLL at 24.) The work papers that *are* still available contain significant amounts of relevant information, such as minutes of entrance and exit conferences,²² invoices for Abbott drugs, communications with CMS, Congress, the states, and others; and contemporaneous articles on AWP-related issues. And given the topics of the reports with missing work papers,²³ it can reasonably be presumed that similar relevant evidence was lost. For example, Abbott learned of an important 1987 *Lexington Herald* article because it was cited in a 1989 OIG report. That article was likely in the work paper file, along with related evidence that has since been destroyed.

Moreover, even when some of the workpapers still exist, important documents have often been lost. For example, the Government has been unable to locate key documents relating to its two rounds of “AWP audits” during the 1990s, including (1) electronic spreadsheets that compared 1994 invoice prices to average wholesale prices—and displayed the resulting spread—for the drugs involved in this case; and (2) the minutes of the exit conferences with CMS for either round of the AWP audits in 1994 and 1999. (See Ex. MMM at 598-604 (recalling typical spreads of 10-1 for injectibles in a 1994 study); Ex. NNN; Ex. OOO at 182-83, 383.) In this litigation, the Government has alleged that it knew about small variances in AWP, but not about so-called “mega spreads.” These contemporaneous documents might show (indeed, likely show)

²² The importance of these conferences are discussed in Abbott’s Special Master briefing (Dkt. No. 5674.)

²³ The reports at issue are “Changes to the Medicaid Prescription Drug Program Could Save Millions” (06-40216) (1984); HCFA Region IX “EAC Survey Report, Hawaii Medicaid Program, EAC Patrol Initiative” (1986); “Changes to the Maximum Allowable Cost Medicaid Drug Limit Could Save Millions” (CAN 08-60203) (1986); “Use of Average Wholesale Price in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program” (A-06-89-0037) (1989); “Comparison of Reimbursement Prices for Multiple Source Prescription Drugs in the United States and Canada” (OEI-03-91-000470) (1991); “Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Virginia Department of Medical Assistance Services” (1996); “Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products” (A-06-97-00011) (1997); “OIG’s Partnership Plan – Utah Division of Health Care Financing Reports on Medicaid Pharmacy Acquisition Costs of Brand Name and Generic Drugs” (1999); and “Task Force on Prescription Drugs, the Office of the Secretary, U.S. Dept. of Health, Education and Welfare – Final Report.” (1969).

that CMS and the states knew precisely what the spreads were on Abbott's drugs, undercutting the Government's allegations of fraud.

Similarly, no minutes for the entrance and exit conferences have been produced for two key OIG reports involving the Subject Drug Vancomycin in 1992 and 1997.²⁴ Both of these reports described the "spread" for Vancomycin precisely and accurately.

C. The Government's Spoliation Has Contributed Significantly to Faded Memories and a Deficient Factual Record in this Case.

The Government's spoliation of documentary evidence has also exacerbated another problem in this case: The inability of key state and federal witnesses to recall significant events—itsself a consequence of the Government's gross delay in unsealing this case. Memories naturally fade over time, making it more likely that a witness will "need[] to refresh his or her recollection to prepare for testimony." *Nutramax Labs., Inc. v. Twin Labs., Inc.*, 183 F.R.D. 458, 469 (D. Md. 1998). Numerous witnesses have testified regarding their faded memory of clearly relevant, but long-ago events.²⁵ In one typical response, CMS official Larry Reed agreed that it was "fair to say that you can't tell me one way or the other whether you knew in 1993 that state Medicaid programs were using excess payments of ingredient costs to subsidize insufficient dispensing fees," given that the events occurred 15 years prior to the deposition and his memory had faded. (Ex. DD at 691-92.) But as CMS witness Dr. Vladeck noted, the ability to review contemporaneous documents like emails would have been "a very useful spur to the memory." (Ex. GG at 310-11.) Most of these documents, however, now appear to have been lost.

This problem has affected state witnesses as well. Many state witnesses were wholly unable to provide testimony on issues the Court has acknowledged are critical. (*See* Nov. 13,

²⁴ Cost of Dialysis-Related Drugs" (A-01-91-00526) (Oct. 1992); "Excessive Medicare Payments for Prescription Drugs" (OEI-03-97-00290) (Dec. 1997).

²⁵ Examples are provided in Appendix B, with supporting deposition excerpts at Ex. PPP.

2008 Status Conference at 10 (“[I]t’s going to be state by state: What did they know, when did they know it, what was the statutory scheme?”).) Many state 30(b)(6) witnesses, in particular, came ready to address only mechanical issues (such as the state’s reimbursement formula) and were often unable to address the more substantive 30(b)(6) topics, such as:

- whether the state set MACs or FULs for the subject drugs, and how those amounts were decided;
- the state’s understanding of spreads for generics generally and the subject drugs in particular, including its review of specified government reports;
- the details of its communications with Ven-A-Care;
- how and why the state developed and maintained its reimbursement formula, including why it did not increase the AWP discount for generics to match survey results from OIG, Myers & Stauffer, and others;
- whether the state believed its dispensing fees were sufficient to cover providers’ cost of dispensing (including extra costs associated with home infusion drugs), provide a profit, and maintain access; and
- whether, and when, the state used the “DOJ AWPs,” and the reasons why it did or did not implement the lower pricing;²⁶

This problem was a direct result of the lack of contemporaneous documents, as the natural turnover in employees at many state Medicaid programs meant that these agencies had no institutional knowledge apart from the few documents that had not been spoliated.

Virginia provides a telling example. From 1989 to 2000, David Shepherd was the Pharmacy Supervisor in Virginia. (*See* Ex. RRR, Shepherd Decl. ¶¶ 1,3.) He served on the CMS-state Pharmacy Technical Advisory Group (“PTAG”), attended scores of meetings with other states, participated in key OIG studies, and communicated with Ven-A-Care about pricing for intravenous and injectable drugs. (*See id.* ¶¶ 8(a)-(b), (d)-(e), (l), 11.) He was also apparently aware that Virginia declined to adopt the “DOJ AWPs” due to concerns over access to home infusion therapies. (*See id.* ¶ 8(f)-(k), Tabs 8-12; Ex. SSS.) In short, without the

²⁶ Supporting testimony is provided in Appendix C, with deposition excerpts at Ex. QQQ.

excessive delays and failure to protect evidence, Mr. Shepherd would likely have been able to explain why Virginia paid premiums on the subject drugs.

Mr. Shepherd's declining health now precludes his testimony, however. (*See* Ex. RRR ¶¶ 4-8, Tab 1.) In his place, Virginia provided two DOJ-prepared 30(b)(6) witnesses who only started in 2003 and 2004, respectively, and who had no contemporaneous involvement in the relevant issues. Because no document hold was implemented and Virginia converted its email system in 2003, extensive documents were destroyed—including all of Mr. Shepherd's files.²⁷ To prepare for their depositions, the 30(b)(6) witnesses met with three former employees (including Mr. Shepherd) for about an hour, but did not discuss the substantive topics in defendants' 30(b)(6) notices (*See* Ex. TTT at 470-75; Ex. UUU at 75-76.) The witnesses were utterly incapable of addressing the issues relevant to the defendants' defenses.²⁸

* * * *

In sum, the Government's failure to preserve evidence has resulted in a massive destruction of relevant state and federal evidence critical to Abbott's defense.

IV. THE COURT SHOULD MAKE A FINDING THAT SPOILIATION AND RESULTING PREJUDICE HAS OCCURRED, AND ISSUE SANCTIONS THAT ARE APPROPRIATE TO THIS STAGE OF THE LITIGATION.

This Court has inherent authority to sanction a party, including the Government, for spoliation. *See Sacramona v. Bridgestone/Firestone, Inc.*, 106 F.3d 444, 446 (1st Cir. 1997); *United Med. Supply Co.*, 77 Fed. Cl. at 264. The range of sanctions available is “within the sound discretion of the court,” *Micron Tech., Inc. v. Rambus, Inc.*, 255 F.R.D. 135, 149 (D. Del. 2009), and a proper sanction should “(1) deter parties from engaging in spoliation; (2) place the risk of an erroneous judgment on the party who wrongfully created the risk; and (3) restore the

²⁷ (*See* Ex. TTT at 541-42 (“And most information in the agency does not go back beyond that [2003], because the system change was so major that it's very difficult to capture information prior to 2003, because it was an entirely different programming”); *id.* at 569 (“we were not able to locate any of [Mr. Shepherd's] files—paper files.”)). Unsurprisingly, the documents cited in Mr. Shepherd's Declaration were not produced.

²⁸ *See* Appendix C (Kevin Hayashi and Bryan Tomlinson).

prejudiced party to the same position he would have been in absent the wrongful destruction of evidence.” *West*, 167 F.3d at 779 (internal quotation marks omitted).

A. The Court Should First Issue a Finding That Spoliation Has Occurred and That Sanctions are Warranted.

The Court should first hold, based on the record before it, that spoliation has occurred and sanctions are warranted as a remedy. This is appropriate even if the Court reserves judgment, until a later date, on the specific nature of those sanctions. *See Miller*, 2007 WL 172327, at *5, *7 (finding spoliation, but holding that “in this complicated case, whether alternatives short of dismissal will suffice can only be determined after the court has heard the trial testimony”); *Phillip M. Adams & Assocs., L.L.C. v. Dell, Inc.*, --- F. Supp. 2d ---, 2009 WL 910801, at *16 (D. Utah Mar. 30, 2009) (same). Such a finding is consistent with this Court’s responsibility for coordinating discovery in this case, and will streamline any further proceedings related to the spoliation issue.

As described below, the current record supports several forms of sanctions. First, it is undisputed that the Government did not issue a document hold or otherwise attempt to appropriately preserve relevant documents to this litigation while the case languished under seal. Second, Abbott has identified a wealth of specific documents, as well as whole document categories, of relevant evidence that were destroyed while the Government failed to adhere to its preservation obligations. (*See supra* at 14-18.) Third, the loss of this evidence has prejudiced Abbott. Among other things, the spoliation has robbed Abbott of its ability to counter the liability and damages claims from the vast majority of states (*id.* at 14), and has deprived Abbott of contemporaneous emails and documents directly relevant to AWP policy issues, cross-subsidization, and awareness of so-called “mega spreads,” (*id.* at 10-18). Such information is unquestionably relevant to Abbott’s defenses and the quantum of any potential liability.

Despite this clear record, should the Court have outstanding questions regarding the appropriate way to redress the Government's spoliation, or should it wish to reserve judgment, the Court could order the Government to show cause why sanctions for spoliation should not be imposed, and set a hearing.²⁹

B. The Court Should Deny Damage Recovery Relating to Any Alleged False Claim Where the Government Has Spoliated Underlying Payment Data.

The Court should first impose a sanction that forbids recovery of any damages on alleged “false claims” for which the key underlying payment data has been spoliated. As Abbott will detail in its summary judgment papers, it is effectively impossible to calculate causation and damages without the underlying claims data and/or pricing arrays. Abbott should not be forced to do so, or be forced to rebut the Government's speculative causation and damages models that it has concocted in the absence of real evidence. *See Beatrice Foods Co. v. New Eng. Printing & Lithographing Co.*, 899 F.2d 1171, 1175 (Fed. Cir. 1990) (holding that where the “uncertainty in the damages calculation is the direct result of [the Government's] procedures,” that “[f]undamental principles of justice require [courts] to throw any risk of uncertainty upon the wrongdoer rather than upon the injured party”).

As such, the Court should eliminate damages for all Medicaid claims where the Government expert's damage calculation does not use detailed claims data (from the state) for that particular claim. Likewise, the Court should eliminate damages on Medicare claims where

²⁹ Indeed, should the Court determine the Government's spoliation was in bad faith, or that the available factual record is inadequate for a fair adjudication of this case, an appropriate sanction would be termination of the case. *See, e.g., Micron Tech., Inc.*, 255 F.R.D. at 150-51; *Plasse v. Tyco Elecs. Corp.*, 448 F. Supp. 2d 302, 308 (D. Mass. 2006); *Computer Assocs. Int'l, Inc. v. Am. Fundware, Inc.*, 133 F.R.D. 166, 169-70 (D. Colo. 1990); *Wm. T. Thompson Co. v. Gen. Nutrition Corp.*, 593 F. Supp. 1443, 1455-57 (C.D. Cal. 1984). Alternatively, the Court might well conclude that the prejudice and due process concerns presented by the Government's spoliation prohibits its complaint from relating back to Ven-A-Care's under seal complaints. *See* Dkt. No. 5143 at 13 (March 13, 2008 Mem. and Order) (“Abbott insists that the exception I suggested in Dey for cases in which ‘egregious delay may be sufficiently prejudicial to trigger due process concerns,’ *Dey*, 498 F. Supp. 2d at 399, should apply to prevent relation-back of the government's complaint in this case. *On the current record*, I do not find sufficient prejudice to prohibit relation-back.”) (emphasis added). Allowing the Government to relate back to an under seal complaint which it did not treat as triggering its document preservation obligations is particularly unfair to Abbott.

the Government's expert does not have or utilize the pricing array that computed the median AWP potentially used to pay the claim in the first instance. The Government can hardly complain if such damages are denied, when (at best) it decided damages attributable to those claims were not important enough to warrant preservation of the underlying payment data.

C. The Court Should Require Competent and Sufficient Evidence of Fraud on a State-By-State Basis, And Shift to the Plaintiff the Burden of Negating "Government Knowledge."

The Government's spoliation has resulted in an evidentiary patchwork where some states have provided relevant evidence, while others have provided nearly nothing. The Court should require Plaintiffs to show *actual evidence of fraud* on a state-by-state basis, and forbid the Government from trying to analogize any favorable evidence from some states as proof of liability in other states, where evidence has been spoliated. *See, e.g., Testa*, 144 F.3d at 177-78 (allowing adverse inference as a spoliation sanction); *Blinzler*, 81 F.3d at 1159 (same).

This sanction is particularly appropriate given the Government's litigating position and the evidence adduced during fact discovery. State and federal officials have repeatedly disagreed with core propositions of Plaintiffs' claims. For example, these officials have testified that (1) "AWP" referred to undiscounted prices in the compendia which they knew did not equal or approximate acquisition costs for generics; (2) they knew they were paying a margin on ingredient costs, often to compensate for inadequate dispensing and administration fees; and (3) they were not misled about AWPs. (*See, e.g., slides 3-4, 5-9, 11-17, infra.*) Rather than reassess the validity of their fraud allegations, however, Plaintiffs have instead ignored or sought to bury this evidence. Indeed, Plaintiffs' initial trial strategy was to put on no evidence from the states, much less take discovery from them. (*See Ex. VVV at 2.*)

Plaintiffs' attempt to avoid evidence contrary to their preordained conclusions, by spoliation or otherwise, is improper. Comprehensive state-by-state evidence should be required.

If it does not exist, Plaintiffs should bear the failure to meet their affirmative burden of proof on both liability and damages. Even where Plaintiffs can produce some favorable evidence, the spoliation of other evidence potentially relevant to Abbott’s defenses should be remedied.

In particular, assuming *arguendo* that Plaintiffs are able to prove or provide state-by-state evidence of fraud (proof of which is largely lacking in the record), and the Court believes a “government knowledge” defense turns on whether the “government kn[ew] of, and approve[d], the particulars of a claim for payment before that claim was presented” (*In re Pharm. Indus. Avg. Wholesale Price Litig.*, 254 F.R.D. 35, 41 (D. Mass. 2008) (internal quotation marks omitted), a reasonable sanction for the Government’s rampant spoliation is to shift the burden on that question to the Government. The Government should have to prove that state and federal governments, including their legislatures, did not—*years after being made aware of spreads and fraud allegations concerning the subject drugs*—knowingly pay claims on terms that Plaintiffs now label false and fraudulent. See *Tenet Healthsystem Desert, Inc. v. Fortis Ins. Co.*, 520 F. Supp. 2d 1184, 1198 (C.D. Cal. 2007) (Court has “the power to draw an adverse inference from the destruction of relevant evidence and the power to shift the burden of proof to the party that destroyed the evidence.”).³⁰ After all, a “primary harm caused by [the Government’s] spoliation is the difficulty [Abbott] now face[s] in demonstrating” that the Medicaid and Medicare programs knowingly paid drug spreads to providers that the Government now seeks to recover from Abbott. *Arista Records, LLC v. Usenet.com Inc.*, --- F. Supp. 2d ---, 2009 WL 185992, at *26 (S.D.N.Y. Jan. 26, 2009). In short, Abbott should not have the burden of proving a defense which relies on evidence the Government has largely destroyed.

³⁰ See also *Welsh v. United States*, 844 F.2d 1239, 1245-46 (6th Cir. 1988), *overruled on other grounds by Adkins v. Wolever*, 554 F.3d 650 (6th Cir. 2009) (shifting burden due to spoliation, that “the burden of proof lies where the pleadings place it, unless reasons of probability, policy, or fairness dictate otherwise”); *Gen. Atomic Co. v. Exxon Nuclear Co.*, 90 F.R.D. 290, 308-09 (S.D. Cal. 1981) (holding, as a sanction for spoliation, that “counterclaim defendants shall have the burden to prove the non-existence of the . . . allegations”).

Indeed, such a sanction is particularly appropriate given the gross imbalance of power which the FCA already gives to the Government. This Court has previously recognized the potential for serious due process concerns for extended seal periods. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 498 F. Supp. 2d at 399. Here, the Government’s spoliation, combined with the extended eleven-year seal period, raises such concerns; indeed, “the very integrity of the litigation process has been impugned.” *Micron Tech., Inc.*, 255 F.R.D. at 151. Only significant spoliation sanctions will serve as a deterrent; otherwise, the Government would be rewarded for its spoliation and encourage the pursuit of such misconduct as a litigation strategy in future FCA cases. *See West*, 167 F.3d at 779.

D. Monetary Sanctions Are Also Appropriate.

Finally, the Court has the power to award fees and costs as a response to spoliation, including against the Government. *See MOSAID Techs. Inc. v. Samsung Elecs. Co.*, 348 F. Supp. 2d 332, 334, 339 (D.N.J. 2004) (holding fees and costs to be “an appropriate, additional sanction”); *United Med. Supply*, 77 Fed. Cl. at 264 n.7, 275-76 (requiring Government to “reimburse plaintiff for any additional discovery-related costs, including attorney’s fees, that were incurred . . . pursuing this spoliation matter”). An award of attorneys’ fees and costs related to both this motion and Abbott’s earlier spoliation motion (Dkt. No. 4711) is appropriate.

CONCLUSION

The Court should hold that the Government has spoliated evidence in this case relevant to Abbott’s defenses, and impose appropriate sanctions, as described above.

Dated: June 4, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SANCTIONS RELATED TO THE GOVERNMENT'S SPOILIATION OF EVIDENCE to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 4th day of June, 2009.

/s/ David S. Torborg
David S. Torborg