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Defendants Can't Be Held To Impossible Discovery Standards

By **Michelle Hart Yeary** (October 30, 2018, 3:15 PM EDT)


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In a classic case of overreaching, plaintiffs in the Abilify multidistrict litigation sought sanctions against the defendant, Bristol-Myers Squibb Co., for not preserving emails dating between 2002 and 2006 — more than a decade before the start of the litigation. We have a hard time even contemplating what a duty to preserve that covered those emails would begin to look like. Fortunately, so did the court.

Not for lack of argument by the plaintiffs. They tried everything from industry-wide events to FDA requirements to alleged breach of a pharmacovigilance agreement between the defendants. But this "everything plus the kitchen sink" approach couldn't mask the lack of merit in any of their arguments.

Before 2007, the defendant had a document retention policy of 60 days for emails.[1] The plaintiffs argued that destruction of email before that time constituted spoliation, and warranted sanctions against the defendant — a question that is governed by Federal Rule of Civil Procedure 37(e). Sanctions for failure to preserve electronically stored information, or ESI, are permissible when ESI should have been preserved "in the anticipation or conduct of the litigation," the ESI was lost or destroyed due to the party's failure to take reasonable steps to preserve and the ESI cannot be restored or replaced. All of those conditions must be met — making the only question for the court in this case whether the defendant had a duty to preserve emails from 2002 to 2006. It did not.

The court cited Eleventh Circuit precedent that the duty to preserve doesn't arise until "litigation is pending or reasonably foreseeable."[2] So the plaintiffs' first argument was that the defendant should have reasonably anticipated the litigation long before the first lawsuit was filed in 2016. The plaintiffs argued that the duty to preserve can be triggered by "industry-wide events, regardless of the status of individual litigation."[3]

But this theory is too outward-focused. The industry-wide events the plaintiffs were relying on are scientific literature, other lawsuits and adverse event reports. The early literature pertains to other drugs in the same class as Abilify, and the question of whether that literature was sufficient to place the defendant on notice of the risk of compulsive gambling is a "hotly contested issue in the case"[4] — making it a

> quantum leap to conclude that [defendant] had a duty to preserve all of its emails ... simply because there may have been some scientific literature published in the late 1990's and early 2000's that addressed [the class of] drugs and a possible link to compulsive gambling.[5]

Adverse events in clinical trials were similarly insufficient to place the defendant on notice of possible litigation.[6] Other litigation about different drugs was also insufficient to put the defendant on notice that it too would be sued a decade later.

> The Court is not aware of any case law, which requires a drug manufacturer to preserve all of its documents where the manufacturer has not received any notice of the potential threat of litigation other than simply knowledge that there was other litigation involving a different drug prescribed for different conditions that may fall within the very broad category of dopaminergic drugs. Such an overly broad view of the duty of preservation would impose on every drug manufacturer a duty to preserve all of its documents, without regard to subject matter or time frame. That is at odds with the requirement that a party must preserve documents when it reasonably anticipates litigation.[7]

The plaintiffs' last industry-wide argument was that the defendant should have put a legal hold in place based on a subpoena from the U.S. Department of Justice in an investigation concerning off-label promotion of Abilify. The court quickly pointed out that that investigation did not involve the safety or compulsive gambling information at issue in the MDL, but more importantly a demand from the DOJ at best triggers a duty to preserve that runs to the DOJ. That duty cannot be shifted to be owed to these plaintiffs in a separate action.[8]

Disregarding all of these external events to focus on the case specifics, the plaintiffs' counsel didn't start advertising for plaintiffs until 2013, and didn't threaten litigation until 2014.[9] So, in looking at the action of these plaintiffs, the earliest the defendant could have anticipated litigation was 2014.[10]

We're not done yet. The plaintiffs tried another duty-shifting argument, this time with the U.S. Food and Drug Administration. Drug manufacturers are required to preserve adverse event data, including correspondence, for 10 years. The plaintiffs latched on to the "correspondence" language to argue that there must have been AE-related emails that were deleted. But even if true, "failure to comply with a regulatory obligation does not create a duty to preserve for purposes of a spoliation motion."[11] The "obligation ... runs to the FDA and not the plaintiffs in this case."[12] The emails at issue were gone a decade before the defendant owed an obligation to the plaintiffs, as opposed to the FDA.

The plaintiffs' last attempt to find an earlier trigger was to point to the pharmacovigilance agreement between the defendant and another manufacturer. The agreement required both parties to keep and make available to each other all of their adverse event information, and the language once again included correspondence.[13] There was no allegation that any manufacturer did not properly maintain their adverse event data, only that if the agreement included correspondence then there "must have been" relevant correspondence in the deleted emails. But putting aside the plaintiffs' obvious twisting of the true meaning of the agreement:

> The more fundamental problem with Plaintiff's argument is that Plaintiffs as non-parties to the Pharmacovigilance Agreement cannot enforce the obligations in the agreement to their benefit.[14]

The plaintiffs attempted to rely on state law to make their case, but (1) Rule 37(e) prohibits reliance on state law to create a basis for discovery sanctions and (2) even under Florida law, the plaintiff has to be a party to the contract to use its breach as a basis for spoliation.[15]

Because the defendant had "no inkling" in 2004 that potential claimants like the plaintiffs even existed, there is no evidence that the auto-delete document policy in effect at that time was anything other than an ordinary business policy. Simply stated, the defendants were not acting in bad faith.[16] Even more simply stated, defendants can't be held to the standard of Carnac the Magnificent.

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[1] In re Abilify (Aripiprazole) Prods. Liab. Litig., 2018 U.S. Dist. LEXIS 172536 at *3 (N.D. Fla. Oct. 5, 2018).

[2] Id. at *5.

[3] Id. at *7.

[4] Id. at *10.

[5] Id.

[6] Id. at *12.

[7] Id. at *11 ("reasonable anticipation" is more than "mere possibility").

[8] Id. at *13-14.

[9] Id. at *8.

[10] Id.

[11] Id. at *15-16.

[12] Id. at *16.

[13] Id. at *19.

[14] Id.

[15] Id. at *21.

[16] Id. at *23-24.