

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION**

)	Misc. Action No. 1:10mc00001
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)	
IN RE SUBPOENAS)	<u>MEMORANDUM OPINION</u>
)	
)	By: Samuel G. Wilson
)	United States District Judge

This is a motion by the United States to compel compliance with two subpoenas issued to Abbott Laboratories (“Abbott”) pursuant to 18 U.S.C. § 3486, which authorizes the Attorney General or his designee to issue subpoenas “in any investigation relating to any act or activity involving a federal health care offense.” Abbott refused to comply on the ground that the subpoenas are unreasonable and unduly burdensome. The United States has agreed to limit the scope of the subpoenas. The court has concluded that, as limited, the subpoenas are sufficiently limited in scope, relevant in purpose, and specific in directive so that compliance will not be unreasonably burdensome. Accordingly, the court enforces them as limited.

I.

Abbott is a publicly traded manufacturer of pharmaceuticals, medical devices, and nutritional products. It operates in over 100 countries, has nearly 72,000 employees, and annual sales of nearly \$30 billion. In 1982, the Food and Drug Administration (“FDA”) approved Abbott’s new drug Depakote for the treatment of bipolar disorder, epileptic seizures, and migraines. The United States is investigating Abbott for a number of potential federal violations arising out of Abbott’s impermissible off-label marketing of Depakote as a treatment for agitation and aggression in the elderly, and health care fraud arising out of that allegedly improper use. Earlier, the government issued a number of subpoenas, and the parties were able

to resolve their differences without the court's intervention. Abbott has since refused to comply with two subpoenas it claims are unduly burdensome. Those subpoenas seek all e-mails sent or received by thirteen individuals from 1996 through 2008. The government has offered to limit those subpoenas to the e-mails of only three people (William Dempsey, Miles White, and Jeffrey Leiden) relating to Depakote and off-label marketing of other FDA approved drugs. Abbot can satisfy the subpoena by producing (1) the "live e-mails" sent or received by each of the three individuals relating to Depakote and off-label marketing of other FDA approved drugs and, (2) the e-mails of each of those individuals relating to Depakote and off-label marketing of other FDA approved drugs retrieved from a single snapshot from "backup tapes" for each of the years 2002 through 2008. According to Abbott, this will require Abbott to restore 53 (out of 32,300) backup tapes¹ that were preserved for other litigation. Abbott estimates that it will cost "roughly \$750" for each backup tape, "approximately \$10,000 to establish the back-up environment, . . . any engineering required to access the data or troubleshoot" at the rate of \$240 per hour, and "anywhere from \$350-\$650" for each gigabyte of restored data to place it in reviewable format (with each tape containing "5-10 gigabytes of data potentially responsive to the subpoenas for e-mails").

II.

Abbott maintains that it is prohibitively expensive to restore the yearly, snapshot e-mails of the three individuals, despite the fact that the requested records were necessarily retained for other litigation. This requires the court to determine whether the subpoenas are "sufficiently

¹ The court notes that Abbott has submitted an affidavit which confirms that the tapes in question are all located in the same facility near the corporate headquarters, and all have been identified successfully. (See Abbott Declaration 2-4.)

limited in scope, relevant in purpose, and specific in directive so that compliance will not be unreasonably burdensome.” See v. City of Seattle, 387 U.S. 541, 544 (1967). The court concludes that the subpoenas, as limited by the government, are not unreasonably burdensome, and the court will enforce them.

The Fourth Amendment imposes a reasonableness standard on subpoenas. See In Re Subpoena Duces Tecum, 228 F.3d 341 (4th Cir. 2000). To satisfy the reasonableness standard, a subpoena must be issued for a legitimate and authorized governmental purpose, and it must be relevant to the inquiry. Id. at 349. The “legitimate and authorized governmental purpose prohibits the government from ‘engaging in arbitrary fishing expeditions’ and from ‘selecting targets of investigation out of malice or an intent to harass.’” Id. (citing United States v. R Enters., Inc., 498 U.S. 292, 299 (1991)). The court will not enforce a subpoena that is “far too sweeping” or not “suitably specific and properly limited in scope,” if the person served has sought but has not received a reasonable accommodation from the government narrowing the scope of that subpoena. Id. (internal citations omitted). In summary, to be reasonable under the Fourth Amendment, an investigative subpoena must be:

- (1) authorized for a legitimate governmental purpose;
- (2) limited in scope to reasonably relate to and further its purpose;
- (3) sufficiently specific so that a lack of specificity does not render compliance unreasonably burdensome; and
- (4) not overly broad for the purpose of the inquiry as to be oppressive

Id. at 349. However, the recipient of an investigative subpoena has the burden of proving that the subpoena, as limited, is unreasonable. See Oklahoma Press Publ’g Co. v. Walling, 327 U.S. 186, 218 (1946). Abbott has failed to meet that burden.

Here, Abbott does not contest that the subpoenas were authorized for a legitimate governmental purpose, but it does contest the relevance of e-mails relating to off-label marketing

of all FDA approved drugs (other than Depakote), and it contends that it would be unreasonably burdensome for it to comply. The court rejects those challenges.

First, as to relevance, Abbott itself recognizes that the off-label marketing of Depakote is highly relevant to the government's investigation. The same also appears to be true as to the off-label marketing of other drugs. The government has indicated that it has evidence that the off-label marketing of other FDA approved drugs may have followed a similar pattern to the off-label marketing of Depakote.² If this is so, the off-label marketing of these other drugs may raise the same related health care fraud issues that the marketing of Depakote raises.³

Second, the court does not credit Abbott's argument that the two subpoenas are unduly burdensome. Essentially, Abbott (a company with nearly \$30 billion in annual sales) argues that it is unduly burdensome to produce snapshot e-mails for a limited period of time for three specifically identified individuals out of a work force of approximately 72,000, even though Abbott has been required to maintain those e-mails for other litigation. Although it is understandable that prudence and the wish to avoid the appearance of obstructive conduct may result in excessive document retention and that some retained documents may, by nature, be difficult to retrieve, it is difficult to see why that should be true for the e-mails here. As the court

² The government proffered that an Abbott employee who "had been with Abbott for years" had stated that she only "knew of one drug during that entire time period that she marketed exclusively on-label or within the law." (Hearing, 2/12/10 at 13.)

³ Nothing in this court's opinion is intended to imply anything concerning the actual merits of the government's investigation or to imply that off-label marketing necessarily equates to health care fraud. Rather, the court has simply concluded that because "the DOJ's subpoena power in investigating federal health care offenses is meant to be broad," Doe v. United States, 253 F.3d 256, 267 (6th Cir. 2001), and the subpoenaed documents here are "reasonably relevant" to an authorized investigation, see United States v. Morton Salt Co., 338 U.S. 632, 652 (1950), and compliance is not unduly burdensome, Abbott must comply.

views it, if retrieving the e-mails the government requests is as difficult as Abbott conveys, then the fault lies not so much with an overly broad governmental request as it does with Abbott's policy or practice of retaining documents (documents Abbott has been required to retain for litigation purposes) in a format that shrouds them in practical obscurity. Accordingly, the court concludes that the subpoenas as limited by the government, are not unduly burdensome and that Abbott must comply.

III.

For the reasons stated, the court will order Abbott to produce live e-mails and snapshot e-mails retrieved from the backup tapes (related to Depakote and the off-label marketing of other FDA approved drugs)⁴ for the following persons: William Dempsey, Miles White, and Jeffrey Leiden.⁵

ENTER: This 10th day of March, 2010.

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⁴ Abbott seems to claim that it is unduly burdensome to formulate search terms relating to the off-label marketing of other FDA approved drugs. The alternative is for Abbott to comply with the subpoenas by supplying all the e-mail's for each of the three persons for the ordered time period.

⁵ The court notes that one of these three individuals, Jeffrey Leiden, is not identified in either of the challenged subpoenas, so the court's enforcement order includes only the other two. If Abbott does not consent to the inclusion of the third, the government may issue a subpoena in conformity with this opinion, and the court will enforce it without further argument.

ABINGDON DIVISION

IN RE SUBPOENAS) **Misc. Action No. 1:10mc00001**
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) **ORDER**
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) **By: Samuel G. Wilson**
) **United States District Judge**

In accordance with the accompanying memorandum opinion entered on this date, it is hereby **ORDERED** and **ADJUDGED** that the United States' motion to compel compliance with subpoenas 2007R01115-0029 and 2007R01115-0030 is **GRANTED** subject to the limiting conditions set forth below.

Abbott Laboratories shall, within **Twenty-one (21)** days of the date of this order:

Provide, in native form, all e-mails relating to Depakote and the off-label marketing of other FDA approved drugs, sent to or from **William Dempsey** and **Miles White**. The e-mails shall include all live e-mails to or from the named individuals relating to Depakote and the off-label marketing of other FDA approved drugs , as well as all e-mails to or from the named individuals relating to Depakote and the off-label marketing of other FDA approved drugs restored from the March mid-month backup tapes in each of the years 2002 through 2008.⁶

ENTER: This 10th day of March, 2010.

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⁶ As noted in the accompanying memorandum opinion, the government also seeks the e-mails sent to or from Jeffrey Leiden for the same time period. If Abbott does not consent to this additional request, the government may issue a new subpoena, and the court will enforce it in conformity with the court's memorandum opinion.