

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

DONNA EMLEY,)	
DENNIS EMLEY,)	
)	
Plaintiffs,)	
)	
v.)	No. 1:17-cv-02350-SEB-TAB
)	
WAL-MART STORES, INC.,)	
L.N.K. INTERNATIONAL, INC.,)	
L. PERRIGO COMPANY,)	
)	
Defendants.)	

SCHEDULING ORDER ON PLAINTIFFS’ MOTION FOR SANCTIONS

This matter arises from Plaintiff Donna Emley’s injuries allegedly resulting from her ingestion of Equate acetaminophen, manufactured by Defendants L. Perrigo Company (“Perrigo”) and L.N.K. International (“L.N.K.”) and sold by Defendant Wal-Mart Stores, Inc. (“Wal-Mart”). At the forefront of the parties’ dispute is whether Defendants should have included a skin reaction warning on the labeling of their acetaminophen products pursuant to state products liability laws. On June 27, 2019, we denied Defendants’ motions for summary judgment on the basis of preemption, rejecting Defendants’ averments that they were “impossibly preempted” by federal law from complying with state law labeling requirements prior to the issuance of FDA guidance in November 2014 (the “Guidance”).¹ [Dkt. 199]. The factual question persists as to

¹ The Guidance stated that the FDA “does not intend to object to the marketing of products containing the following warning language:”

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

whether it was reasonable for defendants to omit the skin reaction warning from their products' labels.

On January 17, 2020, Plaintiffs Donna and Dennis Emley filed their Motion for Sanctions against Defendant Perrigo "based upon Perrigo's substantial and prejudicial abuse of discovery[.]" [Dkt. 327]. Plaintiffs' motion, in short, details the following chronology of alleged discovery transgressions.

On April 25, 2018, Plaintiffs received Perrigo's responses to Plaintiffs' first requests for production, in which they sought all documents (including e-mails) reflecting any communications within Perrigo, or between Perrigo and others, relevant to Perrigo's decision to change its acetaminophen label to include the disputed skin reaction warning. Perrigo produced no emails responsive to Plaintiffs' request. Claiming to have found this "highly unusual," Plaintiffs sent a Rule 37-1 letter requesting supplemental responses. In response, Perrigo confirmed that it had previously produced all relevant documents.

On July 9, 2018, Defendant Wal-Mart produced numerous e-mails regarding the modification of the Equate acetaminophen label. Many of these emails included Perrigo employees, yet, according to Plaintiffs, Perrigo itself had not disclosed them as requested. Counsel for Perrigo indicated that the nondisclosure was inadvertent, assuring Plaintiffs that an exhaustive search would be conducted to ensure that all relevant communications

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- Skin reddening
 - Blisters
 - Rash

If a skin reaction occurs, stop use and seek medical help right away.

were disclosed. The parties thereafter resolved this issue among themselves and moved on with the litigation.

However, in or around October 2019, Plaintiffs' counsel, while reviewing discovery documents received in a separate matter involving similar facts but different manufacturers, located two additional e-mails on which Perrigo employees' names were included. The e-mails were dated as received in August 2013, which, from Plaintiffs' perspectives, establishes that the FDA extended an opportunity to Perrigo to participate in a coordinated voluntary label change process to include the skin reaction warning. According to Plaintiffs, these emails directly undercut the preemption defense pursued by Perrigo throughout this litigation—namely, that Perrigo could not legally have altered its label prior to the FDA's Guidance issued in 2014. This defense has been included in Perrigo's summary judgment motion, its petition to certify our summary judgment order for interlocutory appeal, and its pending motion to reconsider our order denying certification. Plaintiffs also assert that the recently discovered emails undermine Perrigo's factual defense that it reasonably feared FDA's enforcement action against it if it voluntarily changed its acetaminophen label.

Plaintiffs believe these e-mails were intentionally concealed by Perrigo because they would be detrimental to both Perrigo's factual and legal defenses. Compounding Plaintiffs' concerns is the deposition testimony of Perrigo's corporate representative, Valerie Gallagher, who, despite her name appearing on the newly discovered emails, has testified that Perrigo could not have voluntarily changed its product's label prior to the issuance of the FDA Guidance in 2014. Plaintiffs' concerns extend to include the opinion

of one of Perrigo's regulatory compliance experts, Dr. Andrea Leonard-Segal, whose analysis apparently relied on Ms. Gallagher's deposition testimony as well as the purported nonexistence of any notice from the FDA that voluntary changes would be permitted prior to its 2014 Guidance.

We are informed that the parties have met and conferred on this issue on multiple occasions, including with the assistance of Magistrate Judge Baker on January 13, 2020, but have been unable to reach a resolution that is satisfactory to all parties. According to Plaintiffs, Perrigo has acknowledged that "the subject e-mails should have been located through the agreed upon ESI [electronically stored information] search, and also that the e-mails are discoverable and highly relevant to their defenses." Plaintiffs also note that the emails should have been retained pursuant to Perrigo's own retention policy; in fact, other emails from the relevant timeframe were produced.

Plaintiffs request that the Court impose "the most severe sanctions," including entry of a default judgment against Perrigo or an order striking Perrigo's answer. Alternatively, Plaintiffs request the following: that Valerie Gallagher be produced in the capacity of Perrigo's corporate representative for a second deposition; the Perrigo representatives whose names appear on the subject e-mails conduct a thorough search of all their e-mail programs (past and present) in an effort to locate any and all additional relevant e-mails, including the subject e-mails and responses thereto, and produce all e-mails uncovered through this renewed search to Plaintiffs (and certify under oath that the search has been completed and detail the actions taken to effectuate the search); Dr. Andrea Leonard-Segal be excluded from testifying as an expert in this; Perrigo pay all

costs and fees incurred by Plaintiffs due to its concealment of the emails (including those incurred in preparing for Ms. Gallagher and Dr. Leonard-Segal's depositions); and a spoliation charge be given to the jury at trial. Plaintiffs have expressly stated that they prefer that their Motion for Sanctions not interfere with or require a postponement of the upcoming March 2, 2020 trial, asking that we "reserve ruling on any issues that would delay the trial of the case."

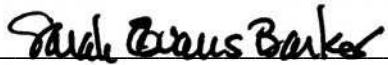
In light of the apparent materiality of the allegedly concealed (or at least not disclosed) e-mails and the time exigencies associated with the upcoming trial, the Court hereby imposes the following schedule:

- 1) Valerie Gallagher shall be produced to testify in her capacity as corporate representative for Perrigo for a second supplemental deposition at the earliest feasible date prior to the February 18, 2020 final pretrial conference.
- 2) No later than February 1, 2020, Valerie Gallagher, AJ Shannon, David Mason, Heidi Horn, and Devon Morgan shall undertake another search of their e-mail programs (past and present) to locate all relevant e-mails, including the recently uncovered e-mails and responses thereto, and shall immediately produce to Plaintiffs all e-mails located, certifying under oath by affidavit the actions taken to conduct the search and that their search has been completed.
- 3) When and as Perrigo produces any newly discovered e-mails to Plaintiffs, it shall provide such e-mails, in addition those underlying Plaintiffs' Motion for Sanctions, to its expert, Dr. Leonard-Segal, to allow her to amend her expert report in light of the new materials.

Plaintiff's Motion for Sanctions [Dkt. 327] in all other respects is **stayed** pending completion of the trial, except for the requests that Perrigo's answer be stricken or a default judgment entered against Perrigo, which we **deny**.

IT IS SO ORDERED.

Date: 1/24/2020



SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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