

**COMMONWEALTH OF KENTUCKY
PIKE CIRCUIT COURT
DIVISION I
CIVIL ACTION NO. 16-CI-00907**

SARANDA WOLFORD

v.

PLAINTIFF

**BAYER CORPORATION, BAYER
HEALTHCARE LLC, BAYER ESSURE INC.
(F/K/A CONCEPTUS, INC.), BAYER
HEALTHCARE PHARMACEUTICALS INC.,
And PIKEVILLE MEDICAL CENTER, INC.**

DEFENDANTS

*******CONSOLIDATED FOR DISCOVERY PURPOSES WITH*******

**COMMONWEALTH OF KENTUCKY
PIKE CIRCUIT COURT
DIVISION I
CIVIL ACTION NO. 17-CI-002299**

**FRANKIE NEWSOME,
KIMBERLY HOWELL,
STACEY VARNEY**

v.

PLAINTIFFS

**BAYER CORPORATION, BAYER
HEALTHCARE LLC, BAYER ESSURE INC.
(F/K/A CONCEPTUS, INC.), BAYER
HEALTHCARE PHARMACEUTICALS INC.,
And PIKEVILLE MEDICAL CENTER, INC.**

DEFENDANTS

**FINDINGS OF FACT, CONCLUSIONS OF LAW AND
DISCOVERY ORDER OVERRULING BAYER'S BURDEN OBJECTIONS**

This matter came before the Court on the Bayer Defendants' Objections to the November 22, 2019 Order from the Special Master Commissioner. Based upon the record, this Court makes the following findings of fact and conclusions of law, and enters the following Order:

I. FINDINGS OF FACT

A. PROCEDURAL BACKGROUND.

1. On June 6, 2018, the Protocol Order for Production of Documents and Electronically Stored Information (hereafter "ESI Order")¹ was entered by this court.
2. On September 11, 2018, the Qualified Protective Order (hereafter "PO")² was entered.
3. On November 14, 2018, Plaintiffs served their discovery requests ("Ps' Requests")³ pursuant to CR 33.01(2) and 34.02(2).
4. On December 21, 2018, Bayer produced their Systems Disclosure (hereafter "Bayer's 1st Systems Disclosure").⁴
5. On April 1, 2019, Plaintiffs filed their First Motion to Compel ("Ps' 1st MTC"). Plaintiffs addressed three major areas of deficiency in this motion, including: 1. Bayer's Custodial Disclosure; 2. Bayer's failure to disclose or produce Discrete Document Collections; and 3. Bayer's failure to produce the "Conceptus-era" documents. Plaintiffs allege that Bayer failed to specifically answer any of Ps' Requests. Bayer has produced documents in this case already produced in other jurisdictions, maintaining that such documents adequately answer Ps' Requests.
6. On April 25, 2019, Bayer filed its Response in Opposition to Ps' 1st MTC. Bayer claimed that responding to Ps' Requests would impose an unreasonable and costly burden. Bayer submitted the April 24, 2019 Declaration of Julian Ackert,⁵ an ESI expert witness, in support of its objections.

¹ Attached as Exhibit 1A to Plaintiffs' Brief Opposing Bayer's Burden Objections (hereafter called "Ps' Brief").

² Attached as Exhibit 1B to Ps' Brief.

³ Plaintiffs' First Set of Interrogatories and Requests for Production of Documents and Things to the Bayer Defendants ("Ps' Requests").

⁴ Attached as Exhibit 1C to Ps' Brief.

⁵ Attached as Exhibit 1D to Ps' Brief and hereafter called "Ackert 4-24-19 Decl."

7. On May 13, 2019, Plaintiffs filed a counter-Affidavit⁶ from their ESI Expert, Mark Lanterman.
8. On May 28, 2019, Bayer filed their Response to Mr. Lanterman's Affidavit by serving another Declaration from Julian Ackert.⁷
9. On June 28, 2019, the Special Master Commissioner, Pierce Hamblin, entered his Order ("June SM Order"),⁸ which defined the scope of discovery and outlined specific requests for Bayer to answer.
10. On July 15, 2019, Bayer filed its Exceptions to the June SM Order, again claiming an unreasonable burden if forced to comply with the June SM Order.
11. This Court held a hearing on Bayer's Exceptions on September 9, 2019.
12. On October 17, 2019, this Court entered an Order Overruling Bayer's Exceptions.⁹
13. On November 22, 2019, the Special Master entered an Order establishing a timeline for compliance with his June SM Order within 45 days.¹⁰
14. On December 2, 2019, Bayer filed Objections to the Special Master Commissioner's November 22, 2019 Order.
15. On December 16, 2019, Bayer filed another Declaration of Julian Ackert¹¹ as Supplemental Authority to its Exceptions to the November SM Order. On December 17, 2019, this Court held a hearing on Bayer's Exceptions entering an Order¹² regarding the same, as follows:
 - The 45-day deadline required by the Nov. 22 SM Order remained in place regarding disclosure of all information that informed the cost/burden analysis and conclusions of the Defendants' ESI expert, Julian Ackert, including but not limited to data maps, data systems, and storage of data. All other deadlines established by the Special Master in his November SM Order were suspended;
 - The court ordered that Julian Ackert be made available for a deposition regarding his cost/burden analysis and conclusions;

⁶ Filed under seal on May 13, 2019, the Lanterman Affidavit was attached to Ps' Brief as Exhibit 1E (pursuant to Plaintiffs' Motion to File Under Seal Select Exhibits to Plaintiffs' Brief Opposing Bayer's Burden Objections ("Ps' Mtn. to Seal").

⁷ Attached as Exhibit 1F to Ps' Brief and hereafter called "Ackert 5-28-19 Decl."

⁸ Attached as Exhibit 1G to Ps' Brief.

⁹ Attached as Exhibit 1H to Ps' Brief.

¹⁰ Attached as Exhibit 1I to Ps' Brief.

¹¹ Attached as Exhibit 1J to Ps' Brief, hereafter called "Ackert 12-16-19 Decl."

¹² Attached as Exhibit 1K to Ps' Brief.

- Plaintiffs were to file expert opinions of their ESI Expert, Mr. Lanterman;
 - Plaintiffs' ESI expert, Mr. Lanterman, was also ordered to be presented for his deposition; and,
 - An evidentiary hearing on arguments related to cost and burden was set for March 18, 2020.
16. On January 31, 2020, the "Bayer Defendants' Submission of Information Regarding Systems and Data Sources" ("Bayer's 2nd Systems Disclosure")¹³ was served on Plaintiffs' counsel and "Defendants' Submission Regarding Information that Informed the Conclusions of Defendants' Expert Witness Julian Ackert" was filed.¹⁴
17. On February 26, 2020, Plaintiffs served Plaintiffs' Deficiency Notice re: Systems and Data Sources Disclosure on Bayer.¹⁵ The letter drafted by Plaintiffs' counsel was in excess of 50 pages.
18. The Deposition of Julian Ackert was held on March 10, 2020.¹⁶
19. On March 12, 2020, Bayer filed a Notice of Supplemental Authority in Support of Bayer's Pending Objections, attaching the Affidavit of Christian Savine.¹⁷
20. The Deposition of Mark Lanterman was held on June 23 and 25, 2020.¹⁸
21. On July 7, 2020, a hearing originally scheduled for March 10, 2020 but re-scheduled due to the Covid-19 crisis was held electronically by this Court via ZOOM. A transcript of this hearing was filed with the Court on July 24, 2020 and is part of the record reviewed.

¹³ Attached as Exhibit 1L to Ps' Brief pursuant to Ps' Mtn. to Seal.

¹⁴ Attached as Exhibit 1M to Ps' Brief.

¹⁵ Attached as Exhibit 1N (without exhibits) to Ps' Brief, hereafter called "Deficiency Letter."

¹⁶ The full transcript of the March 10, 2020 deposition of Julian Ackert ("Ackert Dep.") is attached as Exhibit 1P to Ps' Brief with some exhibits to the deposition filed separately under seal.

¹⁷ Hereafter called "Savine Affidavit," attached as Exhibit 1Q to Ps' Brief.

¹⁸ The June 23 & 25 Deposition of Mark Lanterman ("Lanterman Dep.") is attached as Exhibit 1S (without exhibits) to Ps' Brief. The original Lanterman Deposition with all exhibits was mailed to this court for filing from the court reporter, as described in Plaintiffs' June 29, 2020 Notice of Filing.

B. FINDINGS OF FACT.

Based on the pleadings and the record summarized above, the depositions, evidence and expert opinions filed, the briefs filed, and the oral arguments of counsel presented on July 7, 2020, this Court finds as follows:

1. The ESI Order and PO were entered over two years ago. Ps' Requests were served one year and eight months ago, and the June SM Order was entered over a year ago. Since October 2019, when this Court ruled on Bayer's Exceptions to the June SM Order, much clarity has emerged for the Court regarding Bayer's efforts to conform to its orders and obligations pursuant to the Kentucky Rules of Evidence and Procedure. To date, Bayer has failed to fully respond to Ps' Requests, specifically those discovery requests ordered to be answered by the Special Master in his June SM Order.

2. The parties retained ESI Experts who provided testimony on Bayer's discovery burden. Bayer retained Julian Ackert, and Plaintiffs retained Mark Lanterman. The testimony of these experts has been reviewed by this court.

3. Mr. Ackert was retained to opine on Bayer's burden to review Conceptus-era¹⁹ data for privilege and confidentiality, based on Bayer's representation to him that the corpus of Conceptus-era data was 10 terabytes ("TB") in size.²⁰ This was the only fact Bayer provided Mr. Ackert for him to rely upon when forming his opinions.

4. Mr. Ackert testified that Bayer did not retain him to form opinions of Bayer's actual burden in this case,²¹ and that his opinions were not based on the specific rulings of the June SM

¹⁹ Conceptus was the original innovator of Essure, obtaining FDA approval for and marketing Essure between January 1, 1997 through 2013 (the "Conceptus Era"), when Bayer acquired Conceptus.

²⁰ Ackert Dep. at 23:1-20; Ackert 12-16-19 Decl., ¶ 16.

²¹ Ackert Dep. at 198:18-200:24.

Order.²² Therefore, Mr. Ackert's opinions regarding Bayer's burden were based on hypothetical numbers, not real Essure-related costs and burdens.

5. Bayer did not give Mr. Ackert information regarding the amount or type of data subject to review or any detailed information about the systems upon which that data resides, nor did it give him information about its preservation or collection efforts, the review platforms it utilizes, its process for conducting review in this case, the specific orders as stated in the June SM Order and this Court's October 17 2020 Order, the actual scope of custodians, costs associated with document review and production in other Essure jurisdictions, or the permissible redactions and other review-related provisions stated in the PO.²³ Mr. Ackert opined that "data is data" and that there is no need to know the type of data because "industry accepted measures"²⁴ provide a reliable basis for estimating²⁵ the cost of review. He defined the industry as "the electronic discovery industry," although he did not "believe there's a governing body for the electronic discovery industry that would prepare metrics..."²⁶ He also testified that he could not recall any publication that supported his estimates, nor did he rely on any specific peer reviewed publication.²⁷

6. Without this information, Mr. Ackert assumed all 10 TB of Conceptus-era data were subject to collection, review, logging and production,²⁸ and he opined that even if Bayer were to use "Technology Assisted Review" or "TAR" to "cull out" responsive documents, there would still be a two-part "manual review" of all responsive data for privilege and redactions, which he

²² *Id.* at 233:4-234:2.

²³ *Id.* at 24:17-27:19, 28:4-32:4, 35:12-36:9, 51:3-55:16, 69:1-70:2, 72:11-13, 125:17-129:23, 135:5-10, 142:10-142:13 and 186:16-195:13.

²⁴ *Id.* at 82:12-83:5, 83:6-16, 84:19-85:7-12, 86:11-87:13, 92:8-96:9, 183:4-7, 232:23-233:3.

²⁵ *Id.* at 82:12-83:5, 183:4-7.

²⁶ *Id.* at 87:17-88:3.

²⁷ *Id.* at 203:5-24.

²⁸ Ackert 4-24-19 Decl. ¶ 9; Ackert Dep. 23:3-9, 66:12-20, 74:4-25, 124:25-125:6, 129:13-23.

estimated would cost \$38-\$46 million, taking two years to complete. He estimated that 70% of the 10 TB corpus of Conceptus-era data would be responsive to TAR and thus subject to the two-part manual review. This Court finds that Bayer did not inform Mr. Ackert of the orders entered by the Special Master and this Court requiring the use of TAR, therefore this Court disregards his opinions. This Court finds that Bayer has submitted no evidence which legitimizes the claim that it would cost millions of dollars to search and produce the data.

7. This Court entered an Order on October 17, 2019, adopting the June SM Order, which states on pages 18-19, ¶ 9 that Bayer shall use TAR to aid in identifying potentially privileged documents. Bayer did not inform Mr. Ackert of these Orders, the Court's requirement that the parties use technology to lessen their discovery burden, or the requirement that Bayer recommend a reasonable search protocol.

8. This Court finds that Bayer did not provide Julian Ackert with adequate facts upon which to opine on its discovery burden in this case, and therefore the opinions of Julian Ackert are not persuasive. The Court finds that the opinions of Mark Lanterman are persuasive.

9. This Court finds Mr. Lanterman's testimony persuasive that the type of data and how it resides on a system must be known to understand Bayer's discovery burden here. Mr. Lanterman testified that Bayer's attempt to describe the Conceptus-era data systems in their systems disclosures was inadequate, and this Court finds his testimony credible. Mr. Lanterman also reviewed the Deficiency Letter sent by Plaintiffs' counsel to Bayer²⁹ and agreed that the information sought by Plaintiffs about Bayer's data and sources of ESI would be useful to help narrow Bayer's discovery burden.³⁰

²⁹ Exhibit 1N to Ps' Brief.

³⁰ Lanterman 6/25 Dep. at 60:21-68:12.

10. Mr. Lanterman testified that there are not generally accepted “industry measures” allowing estimation of cost for privilege review and redactions based solely on the size of Conceptus-era data. Bayer did not provide any evidentiary support that Mr. Ackert’s estimates are accepted by the industry, so this Court finds Mr. Lanterman’s opinions persuasive on this point.

11. The Court agrees with Mr. Lanterman that the use of TAR will significantly reduce Bayer’s burden in this case. This court agrees with Mr. Lanterman and Mr. Ackert³¹ that Bayer has not disclosed information for the parties to design a reasonable search protocol using TAR.

12. Bayer has not provided enough information to Plaintiffs about its custodians, discrete document collections, the Conceptus-era data, or the systems where such ESI was or is stored for the parties to narrow Bayer’s burden. Nor has Bayer disclosed efforts, such as data collection, performed in other Essure jurisdictions nationally that could serve to reduce its burden here; thus, this Court finds:

- a. The true scope of information potentially responsive to the June SM Order in the 10 TBs (or 11.1 TBs per Mr. Savine’s affidavit) of Conceptus-era data is unknown;
- b. The true scope of responsive data containing potentially privileged or confidential information is unknown; and
- c. Bayer’s true burden to search Conceptus-era data for responsiveness and privileged or confidential information is unknown.

13. After a minimum of four years of litigation here and six years of Essure litigation nationwide, Bayer should have identified custodians and sources of responsive information to comply with its obligations to search for and preserve relevant data properly requested by an opposing party. By this time, Plaintiffs should have real numbers and specific answers about the Conceptus-era documents, and not just hypothetical opinions.

³¹ Ackert Dep. at 175:15-176:20.

14. However, as Mr. Lanterman recognized, Bayer's 2nd Systems Disclosure³² shows that it still has not identified and contacted the former Conceptus employees or other Conceptus-era custodians it believes are likely to have knowledge about the information requested, meaning that it either has failed to comply with the obligations quoted above, or failed to reveal its efforts to contact Conceptus-era custodians to this Court.³³

II. DISCOVERY ORDER - CONCLUSIONS OF LAW.

1. The discovery process in this Commonwealth is a liberal one meant to simplify issues and reduce the element of surprise, thereby "achiev[ing] a balanced search for the truth, which in turn helps to ensure that trials are fair ..." *Clephas v. Garlock, Inc.*, 168 S.W.3d 389, 393 (Ky. App. 2004) (internal citation omitted). Our civil rules allow discovery "regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action," and "it is not ground for objection that the information sought will be inadmissible at trial if the information sought appears reasonable calculated to lead to the discovery of admissible evidence." CR 26.02(1). Discovery "is allowable if there is a reasonable possibility that the information sought may provide a lead to other evidence that will be admissible." *Ewing v. May*, 705 S.W.2d 910,912 (Ky. 1986).

2. Bayer has objected to the discovery at issue here based on burden. A party raising a burden objection has the burden of showing why the discovery should not be answered. A responding party "must show specifically how each discovery request is burdensome and oppressive by submitting affidavits or offering evidence revealing the nature of the burden." *In re Heparin Prods. Liab. Litig.*, 273 F.R.D. 399, 410-411, 2011 U.S. Dist. LEXIS 17503, *35-36, 2011 WL 197967 (N.D. Ohio January 24, 2011) (internal citations omitted). "The mere statement

³² Bayer's 2nd Systems Disclosure, at 7, attached as Exhibit 1L to Ps' Brief (emphasis added).

³³ See Lanterman 6/25 Dep. at 42:1-24.

by a party that an interrogatory or request for production is overly broad, burdensome, oppressive and irrelevant is not adequate to voice a successful objection.” *Id.* “At the very least, where a party claims burdensomeness, it must explain why that is so.” *Id.*

3. Litigation, however, always involves burdens and costs. Discovery may be limited, “for good cause shown,” because of *undue* or *unreasonable* burden or expense. *See* CR 26.03. This Court is tasked with exercising discretion to “manag[e] discovery in light of the unique factors present in any particular case,” this case being no exception. *Commonwealth v. Wingate*, 460 S.W.3d 843, 849 (Ky. 2015).

4. After having afforded the Bayer Defendants multiple occasions to present persuasive evidence that conforming to the June SM Order would present an unreasonable burden, Bayer has failed to do so. Thus, the Court stands by its original conclusions in its Order entered on October 16, 2019, quoted as follows:

Bayer's Exception stating that the June SM Order puts a disproportionate burden on Bayer is overruled based on the findings of the Special Master and the lack of convincing credible evidence presented by Bayer that production of clearly relevant information would place upon it a disproportionate burden. The Court finds the affidavits presented by Plaintiffs in this regard especially convincing.

5. This Court found above that Bayer failed to inform Mr. Ackert of facts that would allow him to form opinions of Bayer's actual burden, so his opinions are based on insufficient information and therefore are not persuasive. *Goodyear Tire & Rubber Co. v. Thompson*, 11 S.W.3d 575, 581 (Ky. 2000). Since Bayer did not provide Mr. Ackert with facts about their actual discovery burden in this case, his testimony is not helpful to this Court and does not meet the criteria of KRE 702(3), which requires that the expert witness applies “principles and methods reliably to the facts of the case.”

6. The Court's October 16, 2019 Order cited *Wal-Mart Stores, Inc. v. Dickinson*, 29 S.W.3d 796, 804 (Ky. 2000) outlining the obligations of a party responding to discovery requests. "Inherent in the duty created by CR 34.02 is the duty to search for and ascertain whether the requested documents exist and, if they do, where they are located." *Id.* at 804. The *Wal-Mart* Court went on to explain:

Therefore, we hold that a person--regardless of whether that person is opposing counsel--signing a response to a request for production, which is made pursuant to CR 34.01, holds him or herself out as having personal knowledge of the answers given and is subject to deposition for the limited purpose of exploring his or her actual knowledge of the answers given including, but not limited to, the methods employed to search for the documents requested and the scope of that search. And, of course, the inquiry into the mechanics of the search must be relevant.

Id.

7. This Court concludes that Bayer had a duty to search for the discovery requested, find it and reveal it to the other side who requested it. As stated above in this Court's findings of fact, Bayer presented no evidence that it tried to find and preserve evidence to satisfy the June SM Order.

8. This Court recognizes that the discovery issues involved in this case are complex and will result in the production of a substantial amount of documents. However, the discovery obligation of Bayer has been extensively briefed and argued and this Court has issued its Orders and will not revisit or alter its previous Orders. To the extent that Bayer is seeking a modification to these Discovery Orders, their motion is denied.

9. The Court is mindful that the parties need clear guidelines and identifiable goals to complete these discovery obligations. The Court deems that the parties would benefit from a staggered deadline for compliance to simplify issues and allow the parties to better focus their efforts on the discovery required in this case. It is noted that the Special Master attempted to obtain

from Bayer their assistance in establishing a timeline for production of the Ordered discovery and that Bayer stated they could not provide any assistance because they intended to file a writ with the Court of Appeals and any timeline would be meaningless. This Court will set deadlines for Bayer.

10. This Court has determined that certain discrete documents are available for immediate production notwithstanding the issues related to electronic search methods, which is a separate issue. The Court further notes that information regarding the way the electronic information is stored is necessary to comply with this Court's order and resolve the issues between the parties regarding Technology Assisted Review.

WHEREFORE, IT IS ORDERED that Bayer's Objections that it is unreasonably or disproportionately burdened by the discovery orders entered in this case are **OVERRULED**. This Court further refers to its October 17, 2019 Order, wherein Bayer's objections to the scope of discovery in Kentucky as stated by the June SM Order and Bayer's continued objections to the ESI Order and PO were and hereby are again overruled.

IT IS FURTHER ORDERED that Bayer's production obligation shall be staggered into stages in order to simplify matters and ensure efficient production of discrete documents and information necessary to reach the next stages with regarding to the TAR, to wit:

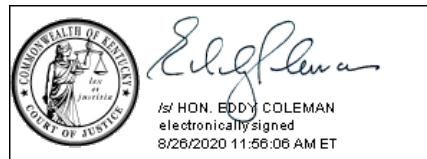
1. Within 20 days of the date of this Order, Bayer will produce to the Plaintiffs, all documents which have been previously produced in other Essure cases including, but not limited, to those filed in California and Pennsylvania.
2. Within 30 days of the date of this Order, Bayer will identify the appropriate custodians and identify their job title based on the following areas:
 - a. Custodians responsible for clinical trials and all actions taken to obtain approval

- from the FDA for the Essure Device.
- b. Custodians responsible for continued regulatory compliance for the Essure Device, including, but not limited to post-market surveillance.
 - c. Custodians responsible for receiving and investigating adverse events related to the Essure device.
 - d. Custodians responsible for the sales and marketing of the Essure device to physicians and patients. This shall be interpreted to include physician training on the Essure device.
 - e. Custodians responsible for being and/or working with “opinion leaders” to inform physicians and patients regarding the Essure device, its safety and efficacy.
 - f. Custodians responsible for ensuring that good manufacturing processes were followed in the production of the Essure device.
 - g. The Court does not deem Bayer to be in compliance with this Order by merely reiterating the custodians which have been named in other litigation. The Court expects Bayer to identify relevant custodians based on the parameters set forth herein.
 - h. For each custodian, Bayer is not required to provide biographical information at this time. The Court will revisit the necessity for biographical information on a case by case basis.
 - i. This order related to custodians shall be interpreted to include custodians for Bayer’s subsidiaries (i.e. Conceptus) related to the Essure device. Bayer will denote which custodians are Conceptus and which are Bayer.

3. The prior system disclosures by Bayer necessitated the Plaintiffs submitting a 50 page deficiency. Within 30 days of the date of this Order, Bayer will provide sufficient information related to Bayer's electronically stored information including but not limited to:
 - a. The location of the electronically stored information;
 - b. The data systems and/or software programs used to store the electronically stored information;
 - c. The means by which the electronically stored information may be searched (i.e. search terms, predictive coding, etc.)
 - d. It is the intent of this Court that the information provided by Bayer regarding electronically stored information be in sufficient detail for Plaintiffs and their consultants to determine whether Bayer is proposing an accurate comprehensive plan for Technology Assisted Review.
 - e. It is further the intent of this Court that this disclosure include the electronically stored information of Bayer's subsidiaries, (i.e. Conceptus).
4. Within 60 days of the date of this Order, Bayer will produce all 100,000+ adverse event reports it has received related to the Essure device, regardless of the source of the adverse events (including but not limited to MedWatch, Physician reports, FDA reports, Patient reports, etc.). These documents should be provided in an electronic format. Protected Health Information (PHI) shall be redacted in accordance with the Qualified Protective Order. For this initial production, Bayer is not required to produce any other information as set forth in the subparts of Plaintiff's RFPOD No. 15 if said information is not on the face of the adverse event itself. Once Bayer has produced the

adverse events in accordance with this Order, the Court will revisit the relevancy of further information related to these adverse events.

- 5. There will be a status conference on 5th day of November 2020 at 10:00 am to review the steps Bayer’s has taken to comply with this Order and to set timelines for the remaining discovery obligations of Bayer pursuant to the ESI Protocol and the Special Master Discovery Order dated June 28, 2019. This status conference will be held on Zoom using the Court’s Zoom account.



HON. EDDY COLEMAN
 JUDGE, PIKE CIRCUIT COURT

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