BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE: ParaGard IUD Products Liability Litigation	MDL No. 2974 Oral Argument Requested

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR TRANSFER OF ACTIONS TO THE CENTRAL DISTRICT OF CALIFORNIA PURSUANT TO 28 U.S.C. §1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

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Defendants, Teva Pharmaceuticals USA, Inc., Teva Women's Health, Inc., Teva Women's Health, LLC, Teva Branded Pharmaceutical Products R&D, Inc., The Cooper Companies, Inc., and CooperSurgical, Inc. ("Defendants"), jointly submit this Response in Opposition to the Motion to Transfer Actions to the Central District of California pursuant to 28 U.S.C. §1407 for Coordinated or Consolidated Pretrial Proceedings ("Motion") filed by Latiesha Traylor ("Movant") (MDL No. 2974, (Doc. No. 1.)) For the reasons set forth herein, Defendants respectfully request that the Judicial Panel on Multidistrict Litigation ("JPML" or "Panel") deny Movant's Motion actions involving the ParaGard T 380A Intrauterine Copper Contraceptive ("ParaGard").

I. INTRODUCTION

The ParaGard T-380A intrauterine device ("ParaGard") is a copper containing non-hormonal contraceptive originally approved by the federal Food and Drug Administration (FDA) in 1984. Movant and the other plaintiffs in the cases that are the subject of the transfer motion allege personal injury from embedment of an arm of a ParaGard in the myometrium (muscle) tissue of their uterus and breakage of the arm during removal. Some plaintiffs assert that surgical removal of the arm was required.

ParaGard must be placed and removed by a healthcare professional ("HCPs"). Every plaintiff whose case is subject of the transfer motion had their ParaGard placed during a time when the ParaGard FDA-approved labeling directed to HCPs contained instructions about: (1) proper placement and removal, (2) warnings about the risk of embedment of ParaGard in the myometrium, (3) that ParaGard may break and embedment and breakage, or breakage in the myometrium may make removal difficult, and (4) that surgical removal may be necessary. The ParaGard labeling also instructed those HCPs to discuss the Patient Information part of the FDA-approved labeling with their patients. The Patient Information that the HCP was to discuss with

patients contained warning information about difficult removals, that ParaGard may be hard to remove because it is stuck in the uterus, and that surgical removal may be needed.

All plaintiffs are from jurisdictions that apply the learned intermediary doctrine. As the Panel is aware, the learned intermediary doctrine focuses on warnings directed to physicians and other HCPs. As discussed in more detail below, two district courts have held the warnings in the ParaGard labeling for HCPs regarding embedment and breakage of ParaGard and the possibility of surgical removal are adequate as a matter of law and dismissed claims based on a failure to warn theory. Importantly, both cases were summary judgment decisions after fact and expert discovery had been conducted and closed. The plaintiff in the first of those cases was represented by Movant's counsel. No district court has held to the contrary.

Defendants understand the Panel's role is not make merits determinations - such as whether plaintiffs' have a viable failure-to-warn claim. Defendants, however, respectfully submit that Movant's contentions about the need for broad-based coordinated discovery should be evaluated in the context of those decisions that found ParaGard's warnings sufficient as a matter of law. That is in addition to the fact that plaintiffs from at least two states (Michigan and Texas) cannot pursue a failure-to-warn claim at all. *See* Mich. Comp. Laws § 600.2946(5); Texas Civil Practices and Remedies §82.007.

Similarly, to the extent plaintiffs actually intend to pursue a manufacturing defect theory, the discovery they say they seek is individualized. Defendants assert there has been a quality and consistency of manufacturing and quality assurance process that eliminates any possibility of a causal defect. There also is a common causation hurdle plaintiffs cannot overcome. Further, it has been recognized that a manufacturing defect claim cannot be based on a plaintiff experiencing a known and warned-of possible side effect. *See, e.g.*, *Yates v. Ortho-McNeil-Janssen Pharm.,*

Inc., 808 F.3d 281, 301-02 (6th Cir. 2015). In prior cases, however, Movant's counsel has requested discovery on manufacturing lots and attempted to assert a manufacturing defect on the basis of documents specific to a manufacturing lot. As a result, discovery sought by plaintiffs, even if permitted, will be different in those cases, and no commonality will exist because there will be different manufacturing lots at issue. Defendants also know from prior cases that some plaintiffs will not have lot numbers for the ParaGard they allegedly had placed, introducing yet another individual variable in any manufacturing defect claim plaintiffs attempt to pursue.

Movant's arguments for transfer and consolidation fare no better with respect to her design defect theory. As an initial matter, any change to the design of ParaGard plaintiffs may propose relative to their embedment and breakage claims would have to be approved by FDA before it could be implemented. Accordingly, any design defect claim based on implementation of that design would be preempted. *See Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 483-484 (2013) (holding drug design defect claims are preempted because legally a drug may not be changed without FDA's prior approval); *PLIVA, Inc. v. Mensing,* 564 U.S. 604, 623-624 (2011) (changes requiring FDA permission prior to implementation are preempted). Again, Defendants recognize the Panel will not be making that determination, but Defendants submit the Panel should consider these threshold legal principles when evaluating Movant's assertions about the need for coordinated discovery in pursuit of a purported design defect claim.

ParaGard has been sold in the United States for over 30 years. Each ParaGard had to be placed. Each ParaGard had to be removed. The first embedment and breakage case was brought by Movant's counsel in July, 2014. Prior to that date, millions of ParaGards had been placed and removed under FDA-approved labeling that warned about embedment, breakage and the possible need for surgical removal. Since Movant's counsel brought the first lawsuit, two district courts

have found the ParaGard labeling adequate as a matter of law, and two district courts and one circuit court have held that summary judgment was appropriate on a manufacturing defect claim. ParaGard is a mature product and embedment and breakage cases such as those Movant seeks to have consolidated in an MDL, have been litigated to conclusion without liability.

The cases that are the subject of the Motion all have been filed since March, 2018, more than thirty-three years after ParaGard was approved by FDA. Of the 55 cases on the Schedule of Actions attached to the Motion, 75% were filed in 2020; 55% of the cases have been filed since September 1, 2020. Prior to May 11, 2020, all of the cases on the Schedule were filed by Movant's counsel. This is about attorney advertising and an uptick in that advertising promoted by Movant's counsel, not a genuine mass tort. *See* Exhibit 1, A-C. It portends a model that plays out in MDLs in which cases are filed and added to the MDL not because they are meritorious, but rather because cases can easily be filed, escape individual scrutiny and artificially inflate case counts for settlement. *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.,* MDL Doc. No. 2004, 4:08-md-2004, 2016 WL 4705827, *1 (M.D. Ga. Sept. 7, 2016) ("the evolution of the [multidistrict litigation] process toward providing an alternative dispute resolution forum for global settlements has produced incentives for the filing of cases that otherwise would not be filed if they had to stand on their own merit as a stand-alone action."). Relatedly, the MDL proceeding, established for the purpose of managing cases efficiently so as to achieve judicial economy, "becomes populated with non-meritorious cases that must nevertheless be managed by the transferee judge." *Id*. Defendants request that the Panel allow the individual cases to proceed in their respective courts where they will be subject to individual scrutiny. To the extent there is any efficiency to be achieved by coordinated discovery, there are other mechanisms available.

If the Panel nonetheless decides to grant the Motion and transfer the cases, it should be to

a judge experienced with MDLs and/or IUD litigation, who will efficiently manage the cases, and be willing to make decisions that subject cases to the correct level of scrutiny, take into account the history of ParaGard cases, and limit the scope and expense of discovery to the matters that are truly at issue.

II. BACKGROUND

A. The Defendants

Movant treats the "Defendants" as a homogenous group (from whom plaintiffs will seek discovery) and broadly alleges wrongdoing relating to "the development, testing, manufacture, marketing, and sale of ParaGard." (Memorandum in Support ("Memo.") (Doc. No. 1-1) p. 8). In fact, the underlying actions name *different* kinds of defendants and the complaints allege *different* legal theories challenging *different* conduct occurring at *different* times.

There are three separate groups of Defendants. First, there are those Defendants who held the ParaGard New Drug Application ("NDA") and have manufactured and sold ParaGard. The NDA holders were (1) Teva Women's Health, Inc. ("TWH, Inc.") (formerly Duramed Pharmaceuticals, Inc.), which held the ParaGard NDA from November 10, 1995 to August 11, 2017; (2) Teva Women's Health, LLC ("TWH, LLC"), which held the ParaGard from August 12, 2017 to November 1, 2017; and (3) CooperSurgical, Inc. ("CooperSurgical"), which purchased the NDA on November 2, 2017, and thereafter manufactured and sold ParaGard.

The second group of Defendants are parent companies, indirect, or otherwise, of the NDA holders. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is an indirect parent of TWH, LLC, and was an indirect parent of TWH, Inc. Defendant The Cooper Companies, Inc. ("Cooper"), is the parent of CooperSurgical. Cooper is a holding company that does not manufacture or sell any products including ParaGard.

Finally, the last "group" actually is one Defendant, Teva Branded Pharmaceutical Products

R&D, Inc. ("Teva Branded"), which is named in seven actions.[1] Teva Branded, an indirect, wholly-owned subsidiary of Teva USA, "was formed in 2009 … and is engaged in research and development of new products. Teva Branded had nothing whatsoever to do with the research and development of the ParaGard IUD" and never manufactured or sold ParaGard. *See Reith v. Teva Pharmaceuticals USA, Inc.*, Civil Action Nos. 18-3987, 18-3992, 2019 WL 1382624, *3 (E.D. Pa. Mar. 27, 2019).[2]

B. ParaGard History

Contrary to the Factual Background set forth by Movant (Memo. p.1), the ParaGard T 380A Intrauterine Contraceptive was developed in the 1970s by The Population Council. The Population Council submitted New Drug Application 18-680 ("NDA") to FDA on September 4, 1981, and resubmitted it on January 19, 1983, pursuant to § 505(b) of the federal Food, Drug, and Cosmetic Act. FDA approved the NDA on November 15, 1984. ParaGard is regulated by FDA as a drug. *See* 21 C.F.R. §310.502(a)(8).

On November 9, 2005, Duramed Pharmaceuticals, Inc., a subsidiary of Barr Pharmaceuticals Inc. ("Duramed"), acquired FEI Women's Health, LLC, which had earlier acquired the ParaGard NDA from The Population Council. Thereafter, Duramed manufactured and sold ParaGard. On December 23, 2008, as a result of a corporate transaction between its parent and Teva USA's indirect parent, Duramed became an indirect wholly-owned subsidiary of Teva USA. In September 2009, Duramed changed its name to TWH, Inc.

On August 11, 2017, Defendant Teva Women's Health, LLC was formed under Delaware

[1] *See e.g.*, *Benotch v. Teva Pharmaceuticals, USA, Inc., et al*., 2:20-cv-01296-PP (E.D. Wis.)

[2] In Movant's case, Teva Branded was dismissed as fraudulently joined to defeat diversity jurisdiction. *See Traylor v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 18-3991 (E.D. Pa. March 28, 2019) (Doc. No. 42)

law. TWH, Inc., subsequently converted into Teva Women's Health, LLC, and ceased to exist. TWH, LLC, held the ParaGard NDA, manufactured and sold ParaGard from August 11, 2017, until November 1, 2017, when it sold certain ParaGard assets to CooperSurgical, Inc., pursuant to an Asset Purchase Agreement.

III. ARGUMENT

A. Plaintiffs have failed to show that MDL coordination is warranted.

Movant has failed to meet her burden to establish that coordination is proper. *See In re: Best Buy Co., Inc., California Song-Beverly Credit Card Act Litig.*, 804 F. Supp. 2d 1376, 1379 (J.P.M.L. 2011). The Panel should not order transfer unless the moving party establishes three elements. First, the moving party must establish existence of common questions of fact. *See* 15 Charles A. Wright *et al.*, Federal Practice and Procedure: Jurisdiction and Related Matters § 3863, at 380 (2007) (citing 28 U.S.C. § 1407). However, commonality of questions of fact is seldom "sufficient, by itself, to justify granting the motion to transfer." *Id*. Second, the moving party must establish that MDL coordination will "serve the convenience of the parties and witnesses." *Id*. at 407. Third, the moving party must establish "that the just and efficient conduct of the actions will be served" by transfer and coordination. *Id*. at 413. Movant has not established any of those requirements; accordingly, her Motion must be denied.

1. Plaintiffs' indiscriminate naming of Defendants precludes common questions of fact.

The Actions which Movant seeks to consolidate have different arrays of Defendants. Defendants, TWH, Inc., TWH, LLC, and CooperSurgical (after November 1, 2017), each held (or holds) the ParaGard NDA and manufactured and sold ParaGard in the United States at different times. Defendant, Teva Branded, which was not involved in the manufacture or sale of ParaGard, is also named in a few cases. Defendants, Teva USA and Cooper, parent corporations of those

Defendants which held the NDA and manufactured and sold ParaGard, are also named in a number of Actions.[3]

In some of these Actions, all Defendants are named.[4] In other actions, there is a different makeup of what plaintiff colloquially refers to as the "Teva Defendants." (Memo. p. 2).[5] There are a handful of cases in which CooperSurgical, Inc., and Cooper are not named as Defendants.[6] There are also cases, like Movant's, in which CooperSurgical is a Defendant, but not Cooper.[7] Finally, there is one case in which the "Cooper Defendants" have been dismissed with prejudice on a motion for judgment on the pleadings.[8] While Movant alleges these Actions arise out of the same or similar alleged wrongful conduct, involve the resolution of the same or similar questions of fact and law, and that discovery will be substantially similar, the array of differing Defendants in these Actions, in and of itself, demonstrates that is not the case. In denying a recent request for MDL coordination in a multi-defendant case, this Panel reasoned that "[t]he variance in named defendants virtually ensures that a significant amount of the discovery will be defendant-specific."

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[3] *See, e.g.*, *Barrett v. Teva Pharmaceuticals USA, Inc*., 5:20-cv-00442-BO, (E.D. N.C.)

[4] *See, e.g.*, *Melendez v. Teva Pharmaceuticals USA, Inc.,* 1:20-cv-06683-LJL, (S.D. N.Y.)

[5] *Compare Spence v. Teva Pharmaceuticals USA, Inc.,* 1:20-cv-03667-ELR, (N.D. Ga.) and *Perez v. Teva Pharmaceuticals USA, Inc.,* 2:20-cv-00212, (S.D. Texas).

[6] *See, e.g.*, *Williams-Holley v. Teva Pharmaceuticals USA, Inc.,* 2:20-cv-04210-JLG-CMV, (S.D. Ohio.)

[7] In Movant's case, Judge Bartle also dismissed Cooper and Teva USA as fraudulently joined to defeat removal, holding liability could not attach because they did not manufacture or sell Movant's ParaGard. *Traylor v. Teva Pharmaceuticals USA, Inc.*, (Doc. No. 42); *see also Reith v. Teva Pharmaceuticals USA, Inc.*, 2019 WL 1382624, *3, *4-5 (E.D. Pa. Mar. 27, 2019). Similar orders were entered in the *Riley* and *Halperin* cases.

[8] *Barcelo v. Teva Pharmaceuticals U.S.A., Inc.*, No. 4:20-cv-00017, 2020 WL 1666116 (S.D. Texas Apr. 2, 2020).

See In re Cordarone, 2016 WL 3101841, at *2.

2. Any discovery that is warranted in the Actions is individualized and case-specific questions of fact overwhelm any purported commonality among the Actions.

If "a highly individualized inquiry is necessary to determine whether any particular plaintiff" was injured as a result of the defendants' actions, then coordination is not warranted. *In re Lipitor Mktg, Sales Practices & Prods. Liab. Litig.*, 959 F. Supp. 2d 1375, 1376 (J.P.M.L. 2013); *see also In re Electrolux Dryer Prods. Liab. Litig.*, 978 F. Supp. 2d 1376 (J.P.M.L. 2013) (denying motion to create MDL because individualized facts would predominate over common factual issues); *In re Wells Fargo Bank, N.A., Mtg. Corp. Force-Placed Hazard Ins. Litig*., 959 F. Supp. 2d 1363, 1364 (J.P.M.L. 2013) (denying motion to create MDL because "individualized discovery and legal issues still will be substantial"). The record here reveals highly individualized factual questions precluding MDL coordination.

As shown above, these product liability actions do not involve one defendant or even one group of defendants. Nonetheless, Movant claims the "Teva Defendants" failed to "adequately communicate and/or warn consumers, the FDA and/or doctors and the medical community" of purported "newly acquired evidence," that Movant alleges to be "the propensity [of ParaGard] to break upon removal." (Memo. pp. 2-3). Movant also contends that the cases are closely related in that "they share the same Defendants, the same basic theory of liability, and the same basic factual allegations." (*Id*., p. 4). Because ParaGard is manufactured in different lots, the issue of "whether the ParaGard lots at issue contained manufacturing defects" - which Movant incorrectly contends is a common question of fact (Memo. p. 4) - is individualized as to each plaintiff. Movant's contentions cannot be reconciled with the adequacy of the label, the individualized nature of any manufacturing defect claim, and the wide array of Defendants named in these cases.

The common issue relative to plaintiffs' failure-to-warn claims is that the ParaGard label's

clear warnings about the possibility of embedment, breakage and difficult removals (including possible surgery) have been found by two federal district courts to be adequate as a matter of law in granting summary judgment because those risks were expressly warned about in the label. *See Ideus v. Teva Pharmaceuticals USA, Inc*., 361 F. Supp. 3d 938, 948 (D. Neb. 2019), *app. argued*, No. 19-1361 (8th Cir. Sept. 23, 2020); *Estrada v. Teva Pharmaceuticals USA, Inc*., Case No. 14-CV-1875-AJB-AGS, p. 28 (S.D. Cal. 2017) (to be submitted under motion to seal). Both decisions were entered after extensive discovery was completed on a purported failure-to-warn claim. The discovery in *Estrada* was conducted by Movant's counsel and was from a district court in Movant's home state. Moreover, no court has found that the warnings are inadequate *or that there is a question of fact regarding the adequacy of the warnings*. Movant's contention that discovery is needed on fact questions relative to the adequacy of the ParaGard warnings has absolutely no basis in fact or law and Defendants should not have to bear the costs of the ill-conceived and unneeded coordinated discovery Movant proposes.

Similarly, the purported common issues regarding any design defect claim do not justify discovery, coordinated or otherwise. A design defect claim such as by Movant is preempted *See, e.g., Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139-1140 (8th Cir. 2014) (holding federal law preempts state law claims that would require the manufacturer to redesign its drug); *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281 (6th Cir. 2015) (holding plaintiff's "design defect claim is clearly preempted by federal law"). Similarly, the manufacturing defect claims alleged by plaintiffs fail because they cannot be based on a plaintiff experiencing a known and warned-of possible side effect. *Yates,* 808 F.3d at 301-02. Those legal roadblocks obviate any need to consider the factual commonality Movant alleges design or manufacturing defect claims share.

To the extent there are issues for discovery at all, and Defendants contends there are not,

they are highly individualized. Notwithstanding that breakage during removal of an embedded arm is a labeled event, discovery conducted in *Estrada* was about the specific manufacturing lot for a ParaGard IUD, i.e., individualized discovery directed at specific facts about that manufacturing lot. Plaintiffs in the Actions had ParaGards from different manufacturing lots placed. Some of the plaintiffs do not have lot numbers, which differentiates them from other plaintiffs relative to the discovery Movant says plaintiffs want to conduct. Notably, summary judgment was granted on the manufacturing defect claim in *Estrada* after the discovery was conducted (*slip op*. at 13-20); *see also*, *Dalton v. Teva North America*, 891 F.3d 687, 691-92 (7th Cir. 2018)(upholding summary judgment on manufacturing defect claim).

It is axiomatic that Movant and the other plaintiffs must prove causation. Although, for the reasons stated above, Defendants do not think causation should be reached on any of plaintiffs' claims, to the extent they are, and discovery is conducted, it is individualized, not common. For example, putting aside the speculative nature of a claim that an embedded arm broke because of a manufacturing defect, as opposed to breaking because it is known that embedded arms may break during removal, any discovery will be based on that specific ParaGard IUD and the specifics of a plaintiff's circumstances and event.

Similarly, as part of her causation burden, Movant is required to prove that her prescribing physician would not have prescribed and placed Movant's ParaGard if different warnings had been given in order to prevail on a failure-to-warn claim. *Motus v. Pfizer Inc.,* 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001). It is beyond dispute that plaintiffs in the other Actions have the same individualized requirement. *See, e.g., Brinkley*, 772 F.3d at 1138.

Movant's assertions, regardless of their lack of merit, reinforce the individual nature of discovery plaintiffs seek to conduct when they suggest they need to conduct discovery on

"whether Defendants negligently, recklessly or intentionally misrepresented the risk," and "whether defendants knowingly, recklessly, or negligently concealed from physicians and/or consumers." (Memo. p. 6-7). Discovery regarding the injury and damages claimed by each plaintiff will necessarily be plaintiff specific.

In short, the discovery is individualized and patient and prescriber specific. As such, an MDL would be ill-suited to address so many individualized questions. *See, e.g., In re Abbott Labs., Inc. Similac Prods. Liab. Litig.*, 763 F. Supp. 2d 1376 (J.P.M.L. 2011) ("individual facts contained in these actions will predominate over any alleged common fact questions"); *In re Qualitest Birth Control Prods. Liab. Litig.*, 38 F. Supp. 3d 1388, 1389 (J.P.M.L. 2014) ("It appears that individualized facts…will predominate over the common factual issues alleged by plaintiffs."). Core, operative facts must be adduced through the depositions of each individual plaintiff, compilation of each plaintiff's medical records, and the depositions of prescribing and treating physicians, or other health care providers. That discovery is uniquely individualized. MDL coordination will not eliminate the need for this individualized work, nor permit it to be completed more economically, efficiently, or conveniently.

3. Plaintiffs have failed to demonstrate that an MDL would enhance convenience, economy, or efficiency.

Movant strains to set forth how MDL coordination would enhance convenience, economy or efficiency. (Memo. pp. 7-10). She contends "pretrial transfer will undoubtedly ease the burdens on all involved." (*Id*., p. 7). But, as explained above, all plaintiffs' failure to warn claims involve the same labeling already found to be adequate as a matter of law and individualized discovery would overwhelmingly dominate each plaintiff's case. There is nothing convenient, efficient, or economical about placing in one arbitrary location a group of plaintiffs suing different and varied Defendants over their use of product which allegedly injured them.

"The Panel has often stated that centralization under Section 1407 "should be the last solution after considered review of all other options," including "coordination among the parties and the various transferor courts." *In re: Gerber Probiotic Prods. Mktg. and Sales Pracs. Litig.*, 899 F. Supp. 2d 1378, 1379-80 (J.P.M.L. 2012) (internal citation omitted). Voluntary cooperation is a preferable "[a]lternative[] to transfer...that may minimize whatever possibilities could arise of duplicative discovery." *In re Table Saw Prods. Liab. Litig.*, 641 F. Supp. 2d 1384, 1384-85 (J.P.M.L. 2009); s*ee also In re: Rite Aid Corp. Wage and Hour Empl. Pracs. Litig.*, 655 F. Supp. 2d 1376, 1377 (J.P.M.L. 2009) (denying request for an MDL and noting "[c]ooperation among counsel and the parties is particularly appropriate here, where plaintiffs in four of the six actions encompassed by the motion share counsel.") Even assuming that there would be some "common discovery," those considerations undermine Movant's motion.

Movant here is represented by counsel from at least two plaintiff firms. *See, e.g.*, Motion, p. 3 (Sanders Phillips Grossman, LLC); *see also*, Notice of Appearance of Tobias L. Millrood, PogustMillrood, (MDL Doc. No. 9, appearing for Movant). These counsel individually or jointly represent at least 40 of the 55 individual cases included in the motion. They already are coordinating in this litigation, and there is no reason they could not continue to do so for any discovery purportedly common to multiple cases. Similarly, Defendants can coordinate among the various cases to achieve efficiencies, economy, and convenience that MDL coordination cannot provide. Plaintiffs have offered no reason why cooperation among coordinating counsel for all parties is not a more efficient, cost-effective, and easier method of achieving the intended benefits of coordination.

To the extent any common questions exist, they can be handled efficiently through informal discovery coordination and cooperation, without allowing any superficially common questions to

hijack the litigation. And to Movant's contention that "[d]iscovery conducted in each of these Actions will be substantially similar and it will involve the same documents and witnesses" (Motion p. 2) or that "counsel for plaintiffs will invariably seek discovery from the same Defendants and witnesses relating to the development, testing, manufacture, marketing, and sale of ParaGard" (Memo. p. 8), the Panel has observed in similar circumstances that "[n]otices of deposition can be filed in all related actions; the parties can stipulate that any discovery relevant to more than one action can be used in all those actions; or the involved courts may direct the parties to coordinate their pretrial activities." *In re Trans Union LLC Fair Credit Reporting Act (FCRA) Litig.*, 923 F. Supp. 2d 1374, 1375 (J.P.M.L. 2013).

Finally, although Movant asserts "it is likely that hundreds of other actions will be filed in jurisdictions throughout the United States" (Memo. p. 1), the Panel has made clear that it is "disinclined to take into account the mere possibility of future filings in [its] centralization calculus." *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 959 F. Supp. 2d 1375, 1376 (J.P.M.L. 2013). Movant may point to additional cases that have been filed since she filed her motion, many of them by Movant's counsel in an apparent continuation of a process that began approximately sixty days before the motion to transfer was filed. It is part of the pattern of filing cases in a manner that allows them to escape individual scrutiny. As demonstrated above, when ParaGard cases have been subject to individual scrutiny, they have been dismissed. The "common questions" and "common discovery" asserted by Movant are illusory. Movant's motion is simply a tactical ploy to avoid individual scrutiny of cases and use the MDL process as an improper and unfair form of alternative dispute resolution. It should be denied.

B. If the Actions are Transferred, They Should be Transferred to Hon. Cathy Seibel in the Southern District of New York

If the Panel decides to grant the Movant's Motion, the actions should be sent to a venue that is convenient and a judge experienced with MDLs and/or IUD litigation, who will efficiently manage the cases, and be willing to make decisions that subject cases to the correct level of scrutiny, take into account the history of ParaGard cases, and limit the scope and expense of discovery to the matters that are truly at issue. The assignment to the Hon. Cathy Seibel and the United States District Court for the Southern District of New York would be the appropriate choice. The Southern District of New York has handled numerous complex MDL proceedings. In fact, according to the JPML website, there are 17 MDLs currently pending in the Southern District. As the Panel has therefore acknowledged, the Southern District has demonstrated the resources to handle MDLs. *See In re Comp. of Managerial, Prof'l & Technical Emp. Antitrust Litig.*, 206 F.Supp. 2d 1374, 1375 (J.P.M.L. 2002) (assigning MDL to an "accessible, urban district[] equipped with the resources that [a] complex docket is likely to require"); *In re: Nickelodeon Consumers Privacy Litig.*, 949 F. Supp. 2d 1377, 1378 (J.P.M.L. 2013) (same).

The location of the parties and witnesses is a factor the Panel long has identified as an important consideration. *See, e.g.*, *In re Upjohn Co. Antibiotic "Cleocin" Prods. Liab. Litig.,* 450 F. Supp. 1169 (J.P.M.L. 1978). The Southern District of New York (where six cases are currently pending), is convenient to the litigants and their counsel. Defendants who held (or hold) the ParaGard NDA, that is, those who manufactured and sold ParaGard, are/were located in Cincinnati, Ohio (TWH, Inc., and TWH, LLC) and Trumbull, Connecticut (CooperSurgical), reasonably close to White Plains, New York, where Judge Seibel is located. Teva USA is located in Parsippany, New Jersey, Teva Branded is located in West Chester Pennsylvania. The facility where ParaGard is and has been manufactured is in Buffalo, New York. *See, e.g.*, *In re Mirena IUD Prods. Liab. Litig.*, 938 F. Supp. 2d 1355, 1358 (J.P.M.L 2013) ("we have selected the

Southern District of New York. Bayer Healthcare LLC is located in New York and other Bayer corporate affiliates are located nearby in New Jersey, Connecticut, and Pennsylvania. Thus, the primary witnesses and documentary evidence … likely will be located in New York and the surrounding area. This district also will be easily accessible for this nationwide litigation.")

Defendants' counsel is located in Cincinnati, Ohio, far closer to the Southern District of New York than movant's suggested venues of the Central District of California or Western District of Missouri. Counsel for Movant, who have filed the majority of the cases listed in the Schedule of Cases accompanying the Motion, are located in Philadelphia (Mr. Millrood) and California (Ms. Welling and Mr. Clark) (their firm also has offices in New York (Garden City, Manhattan, and Mineola), among others.)

Judge Seibel is an experienced jurist and she presided over *In Re Mirena IUD Prods. Liab. Litig.*, MDL No. 2434 ("Judge Cathy Seibel is … an experienced transferee judge who we are confident will steer this litigation on a prudent course.") *In Re Mirena,* 938 F. Supp. 2d at 1358. She has previously demonstrated the knowledge, skill, and experience to efficiently manage pharmaceutical products liability litigation. It is well-settled that "the availability of an experienced and capable judge familiar with the litigation is one of the more important factors in selecting a transferee forum…." *In re Ampicillin Antitrust Litig.*, 315 F. Supp. 317, 319 (J.P.M.L. 1970). The Panel has previously seen the wisdom of centralizing cases before a judge with prior MDL experience over the same or similar class of products. *See e.g.*, *In re Pella Corp. Architect and Designed Series Windows Mktg., Sales Practices & Prods. Liab. Litig*., 996 F. Supp. 2d 1380, 1382-83 (J.P.M.L. 2014) (transferee judge's experience involving allegedly defective windows "is likely to benefit the parties here"). Judge Seibel does not have a current MDL.

Alternatively, assignment to the Hon. James S. Moody, Jr., and the United States District

Court for the Middle District of Florida would be appropriate. Judge Moody is an experienced jurist having received his commission in July, 2000. Judge Moody also has demonstrated the knowledge, skill, and experience to efficiently manage pharmaceutical products liability litigation and was chosen by this panel and presided over *In re Accutane (Isotretinoin) Prods. Liab. Litig.,* MDL 1626. Currently, there are two actions pending in the Middle District of Florida,[9] one of which is before Judge Moody.

The middle District of Florida currently has only three pending MDL's, none of which has more than 55 actions in it. See, https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-October-15-2020.pdf (last accessed October 21, 2020). The most recent United States District Court – Judicial Caseload Profile, published in June, 2020, lists the Middle District of Florida as No. 32 in terms of pending cases and the number of filings for the 12-month period ending June 30, 2020 as only 10,544. Located on the eastern seaboard, the Middle District of Florida, is relatively convenient to the parties and is located in an area with an abundance of hotels, taxis, rental cars, and other necessary litigation resources.

As described in more detail below, California is not an appropriate venue, but if the Panel decides to transfer the Actions to California, Defendants respectfully submit that the Hon. Anthony J. Battaglia of the Southern District of California is a more logical choice because of his experience with ParaGard cases. Judge Battaglia presided over *Estrada*, and *Luma v. Teva Pharmaceuticals USA, Inc., et al*., Case No. 3:17-cv-01655-AJB-AGS, both of which were filed by Movant's counsel. *See, In re Ampicillin Antitrust Litig.*, 315 F. Supp. at 319 ("the availability of an experienced and capable judge familiar with the litigation is one of the more important factors in

[9] *Tredway v. Teva Pharmaceuticals USA, Inc. et al.*, Case No. 8:20-cv-02087; *Lepine v. Teva Pharmaceuticals USA Inc., et al.,* Case no. 8:20-cv-02002.

selecting a transferee forum…."). Judge Battaglia has also demonstrated the ability to manage complex MDL cases and currently presides over MDL-2452, *In re: Incretin-Based Therapies Prods. Liab. Litig.*

C. Transfer should not be to the districts proposed by Movant.

Defendants agree there is "no one jurisdiction where the litigation is further advanced than another" in the Actions addressed by the Motion. (Memo. p. 11). There is no venue that has a common connection to the cases that have been filed. Movant contends that the Central District of California is the "most suitable" venue for the pretrial proceedings of the ParaGard Litigation because there "are currently four related actions filed in the Central District of California pending before the Hon. John A. Kronstadt." (*Id*.) That is a curious position to take. Movant, and each of the other plaintiffs in that group of "related actions" (*Riley*, *Halperin*, and *Wenger*), chose to commence each of their actions, not in the Central District of California, or even in a federal court, but in the Philadelphia County Court of Common Pleas. (*See* Docket sheets attached as Exhibit 2.) When Defendants removed those actions to the Eastern District of Pennsylvania, each plaintiff unsuccessfully moved to remand. Thereafter, each of the California plaintiffs (Movant, *Halperin*, and *Riley*) unsuccessfully opposed motions to transfer to the Central District of California, where each plaintiff resides and received her care and treatment.

Movant next wrongly contends that the Central District of California "is certainly a convenient forum" (Memo. p. 11), because one Defendant, Cooper (a holding company that has not held the NDA and has never manufactured or sold ParaGard), is based in California. That is another curious contention. Cooper was dismissed by Judge Bartle in the Eastern District of Pennsylvania from Movant's case, and also from Ms. Halperin's and Ms. Riley's cases, because it was fraudulently joined to destroy diversity. *See* n.7. The last plaintiff in that group, Ms. Wenger, didn't even name Cooper as a Defendant in her Action. *Wenger v. Teva Pharmaceuticals USA,*

Inc., et al., Case No. 2:20-cv-07550 (C.D. Cal.). Movant's actions, and those of her counsel, demonstrate that the Central District of California is not the most suitable venue for the MDL.

Los Angeles is not geographically convenient nor is it the location where most witnesses and documents are located. None of the Defendants who held (or hold) the ParaGard NDA or who manufactured and sold ParaGard, are headquartered in California. The only witnesses who will likely be located in or near the Central District of California are the few plaintiffs who reside there (who originally chose to commence their Actions in the Philadelphia County Court of Common Pleas) and other case-specific witnesses.

Movant alternatively requests that the Panel transfer the cases to the Northern District of Georgia or Movant's third choice, the Western District of Missouri. As noted above, the fact that there are, subject to the Motion, four cases actually commenced in the Northern District of Georgia and three cases actually commenced in the Western District of Missouri is not a relevant factor. Notably, those jurisdictions were similarly bypassed by Movant's counsel who previously filed in the Philadelphia County Court of Common Pleas cases involving plaintiffs residing in the Northern District of Georgia[10] and the Western District of Missouri.[11] The remaining Actions which were originally filed in the Western District of Missouri and the Northern District of Georgia, were all filed within three weeks of the filing of the Motion. Neither venue is proximate to any of the Defendants, the Western District of Missouri even less so, and the judges suggested by Movant in the Northern District of Georgia do not have any MDL experience.[12] Defendants further dispute

[10] *See, e.g., Duncan v. Teva Pharmaceuticals USA, Inc., et al*., Case No. 2:20-cv-04902-HB.

[11] *See, e.g*., *Burrell v. Teva Pharmaceuticals USA, Inc.*, et al., Case No. 4:20-cv-00687 (W.D. Mo.)

[12] Should the Panel decide to transfer these cases to the Northern District of Georgia, which Defendants respectfully state is not an appropriate forum, Defendants submit that the Hon.

that the Northern District of Georgia is convenient. Although Atlanta is home to the world's largest airport, long travel delays in and out of that airport are well-known, a factor of importance for a venue that has no connection to the litigation.

IV. CONCLUSION

Movant has not satisfied the requirements for transfer and consolidation or coordination under 28 U.S.C. §1407. If the Panel nevertheless determines that MDL consolidation or coordination is appropriate, then transfer should be to the Hon. Cathy Seibel in the Southern District of New York or, in the alternative, the Hon. James S. Moody, Jr., in the Middle District of Florida. Should the panel determine that transfer to California or the Northern District of Georgia is appropriate, then transfer should be to the Hon. Anthony J. Battaglia in the Southern District of California or the Hon. Timothy C. Batten, Sr., respectively.

October 23, 2020

Respectfully submitted,

[redacted]

Timothy C. Batten, Sr. would more appropriate for this MDL. Judge Batten has demonstrated the skill and experience needed to properly manage MDL litigation as he did in *In re: Delta/AirTran Baggage Fee Antitrust MDL* (MDL No. 2089). Judge Batten also does not currently have an MDL.

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: ParaGard IUD Products Liability Litigation	MDL No. 2974

PROOF OF SERVICE

In compliance with Rule 4.1(a) of the Rules of Procedure for the United States Judicial Panel on Multidistrict Litigation, I hereby certify that a copy of the foregoing Defendants' Response In Opposition To Plaintiffs' Motion For Transfer Of Actions To The Central District of California Pursuant To 28 U.S.C § 1407 For Coordinated Or Consolidated Pretrial Proceedings and this Certificate of Service were served via ECF notification on October 23, 2020 to the following:

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D. Minnesota, No. 0:20-cv-02080
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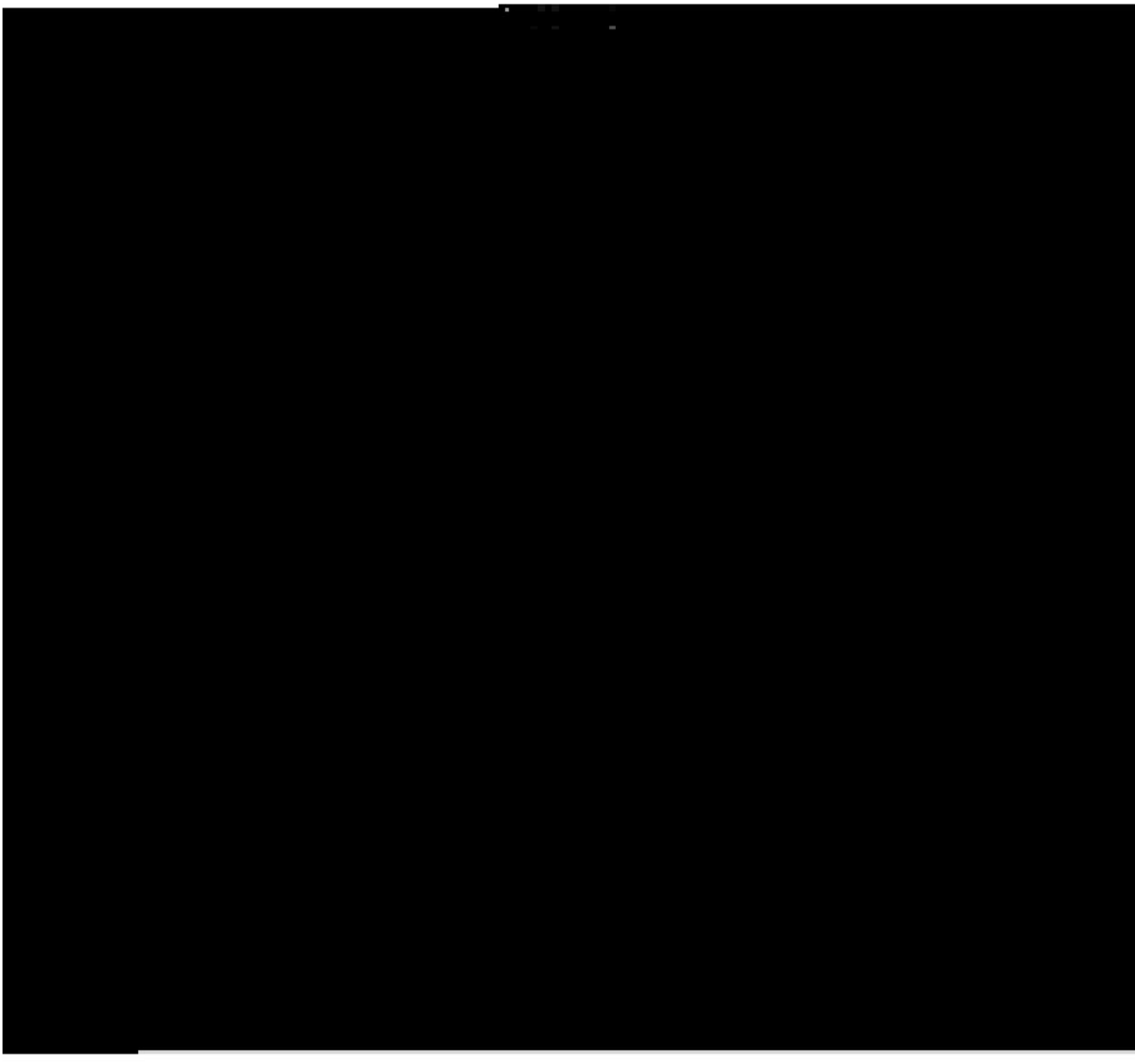

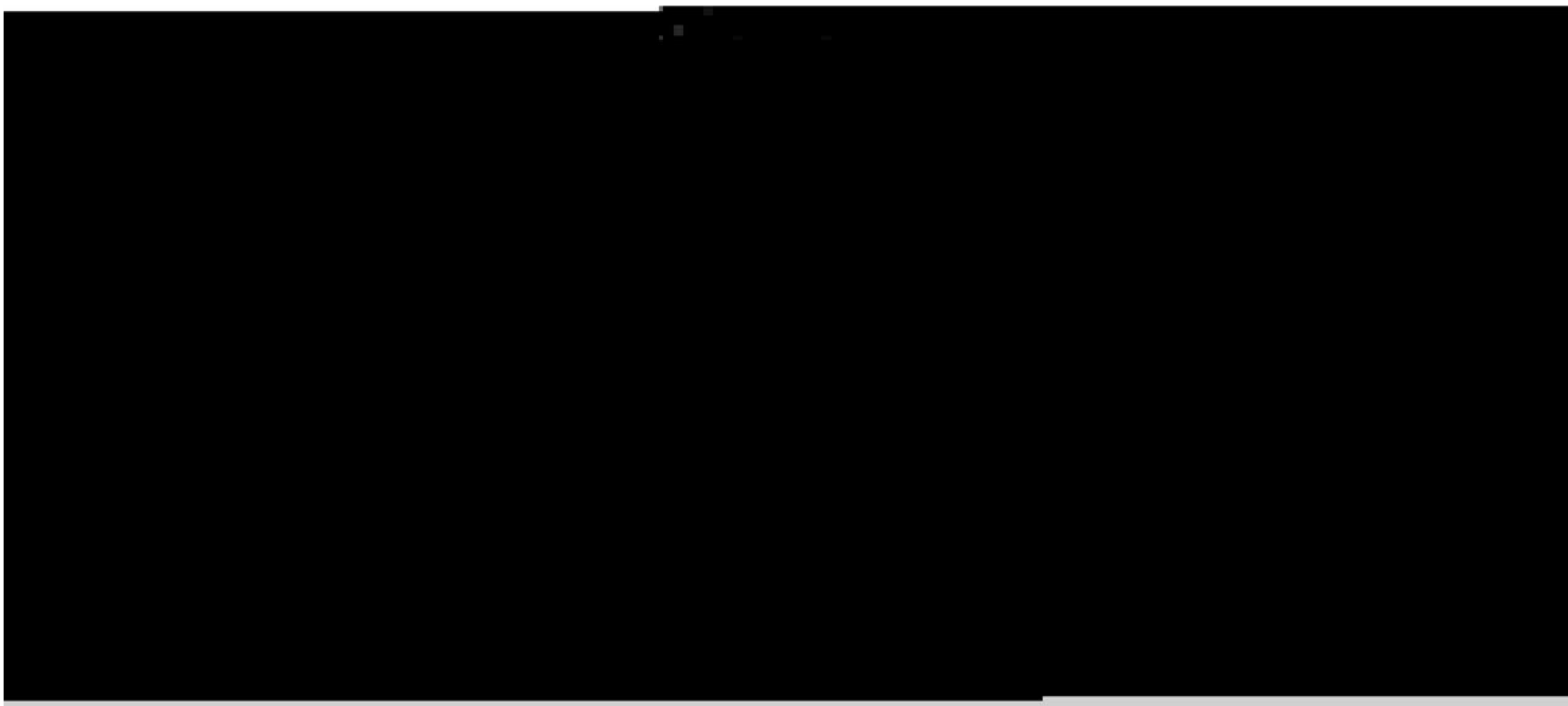

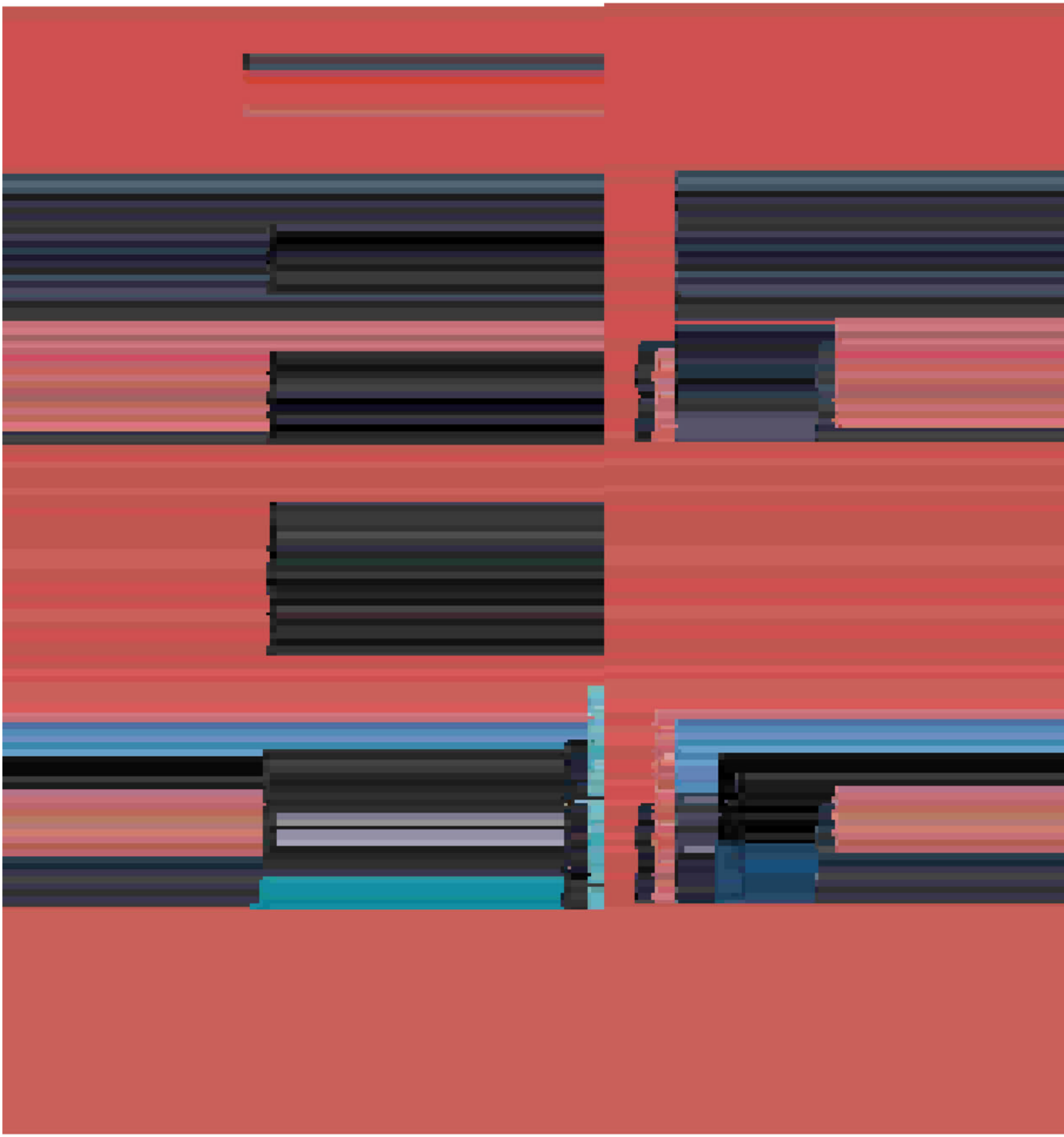

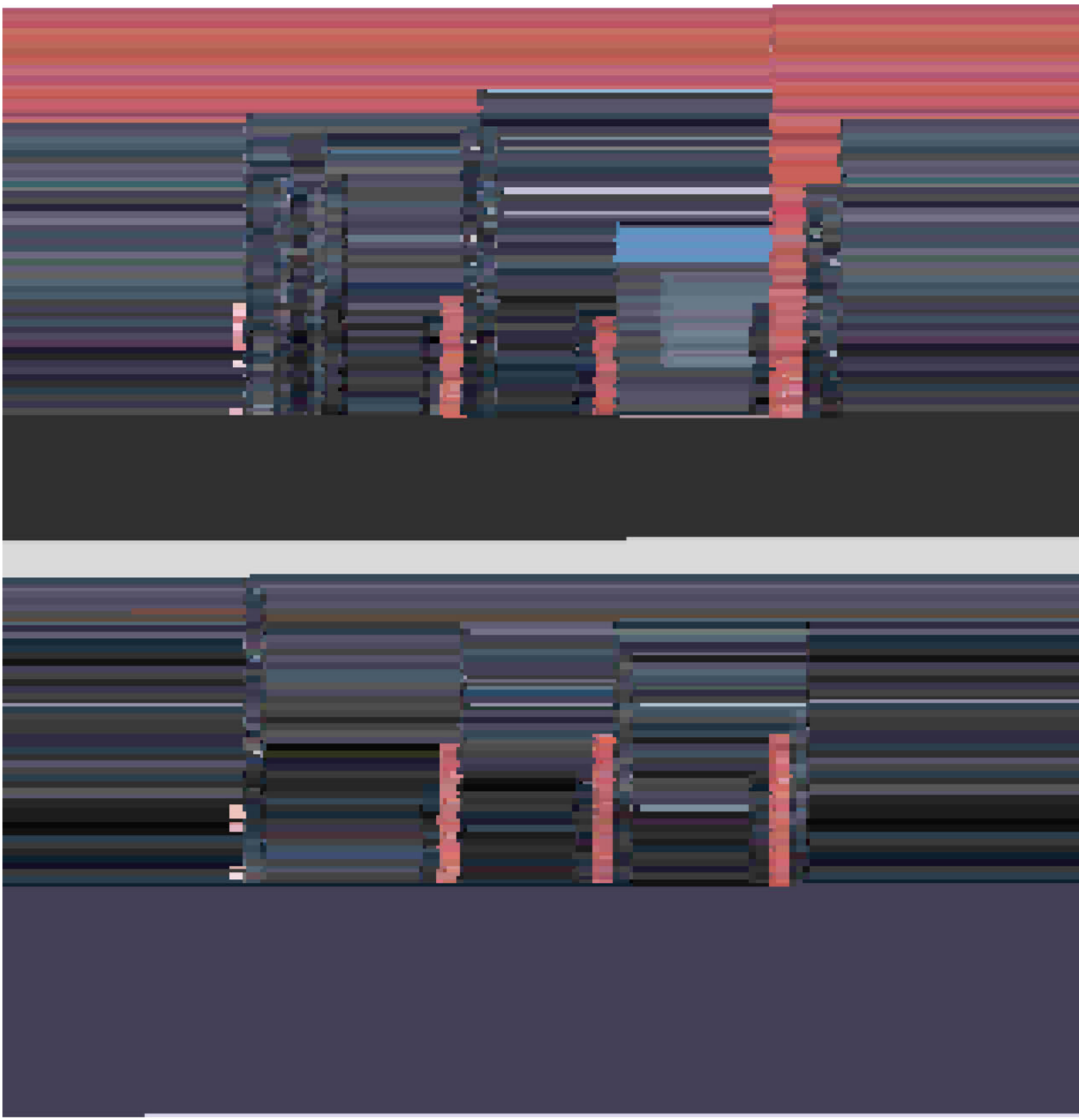

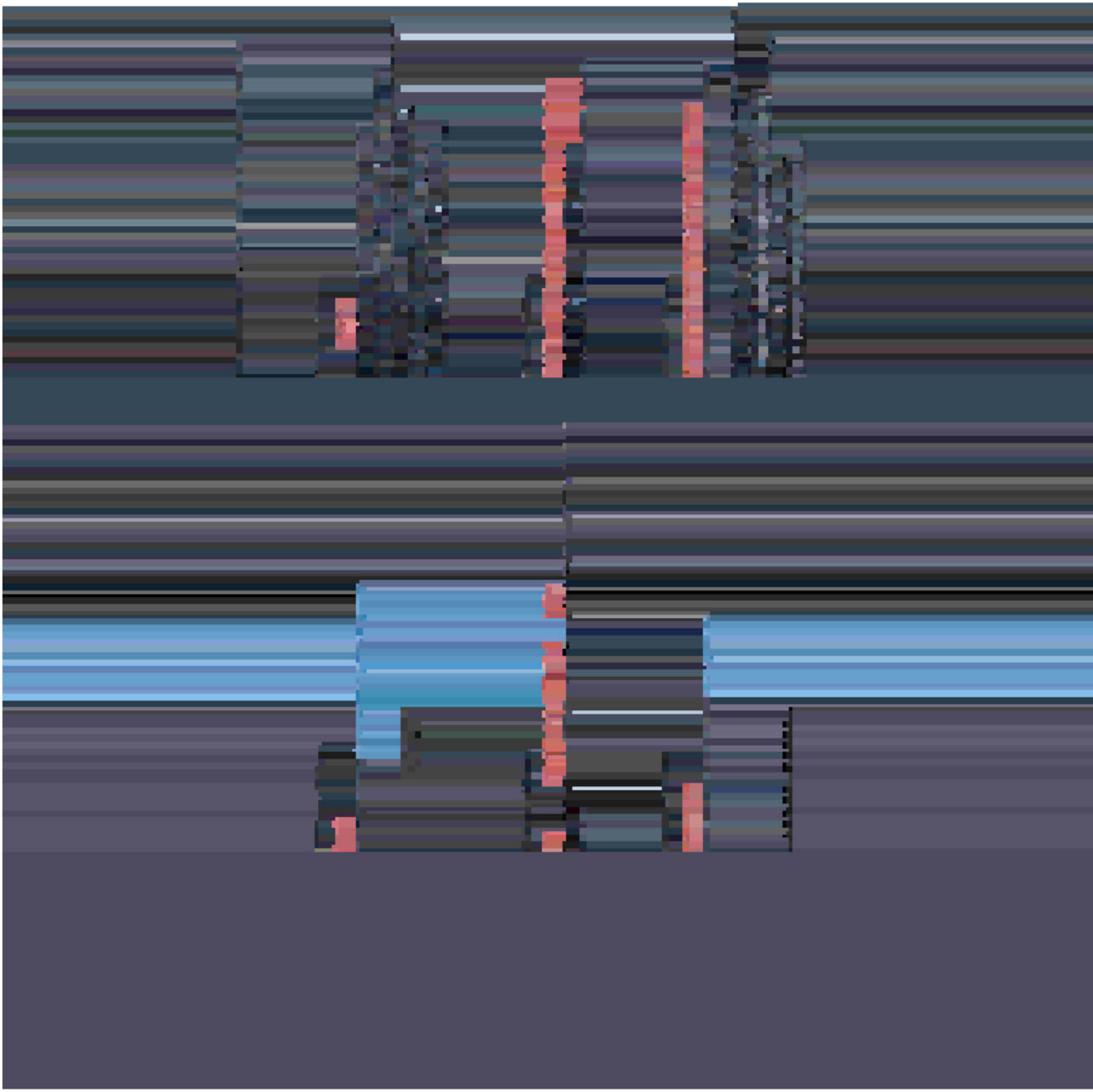

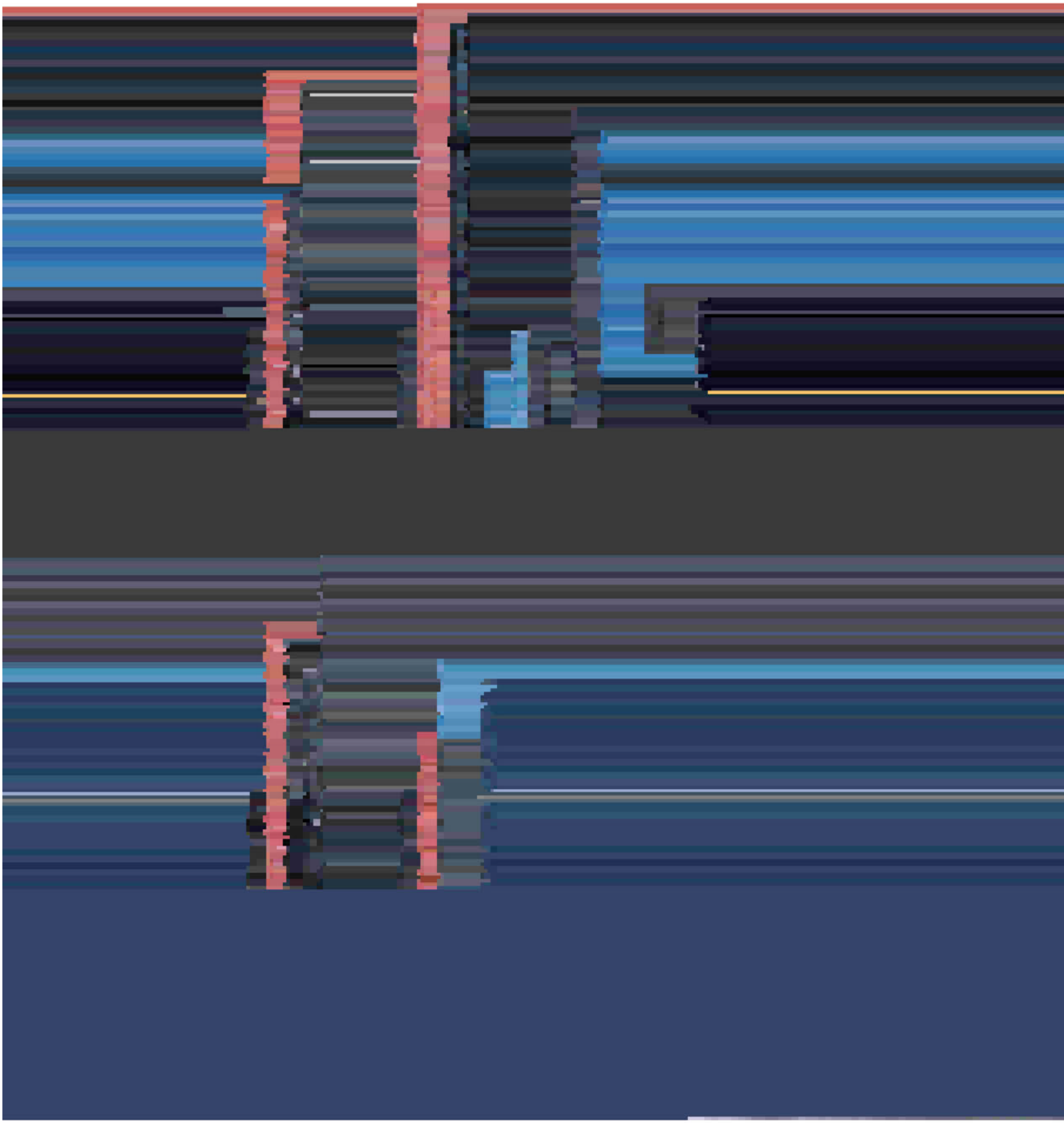

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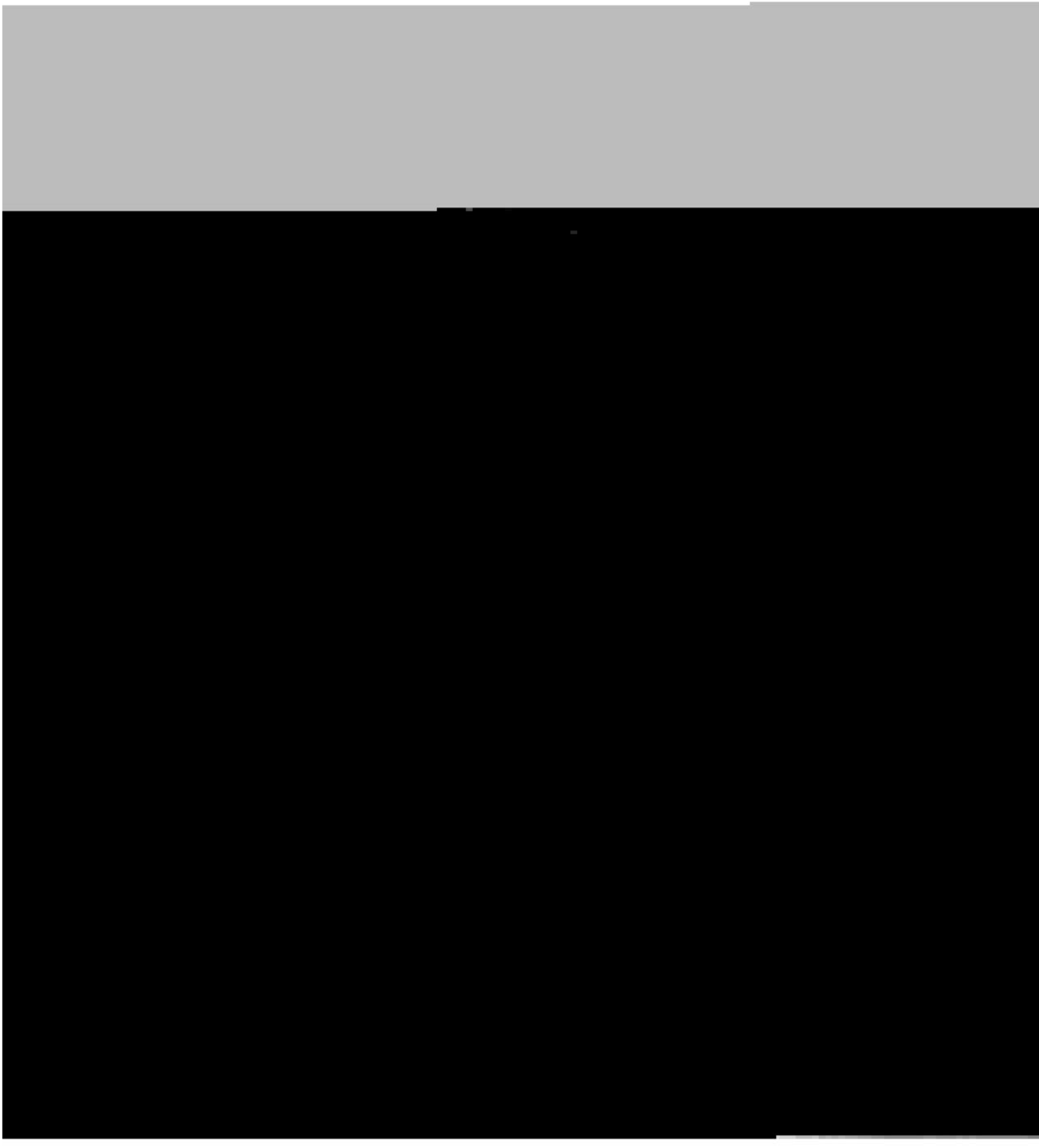

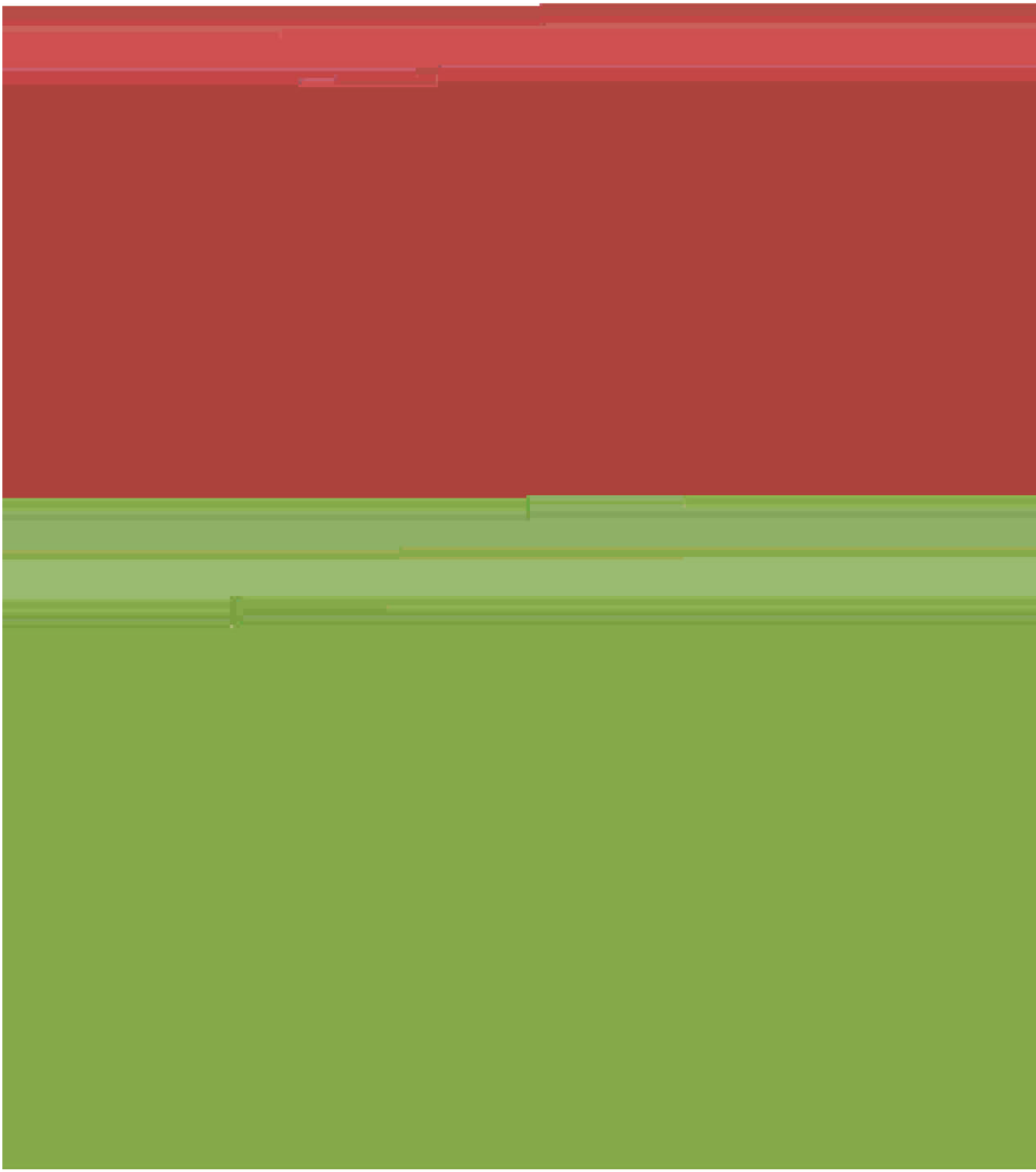

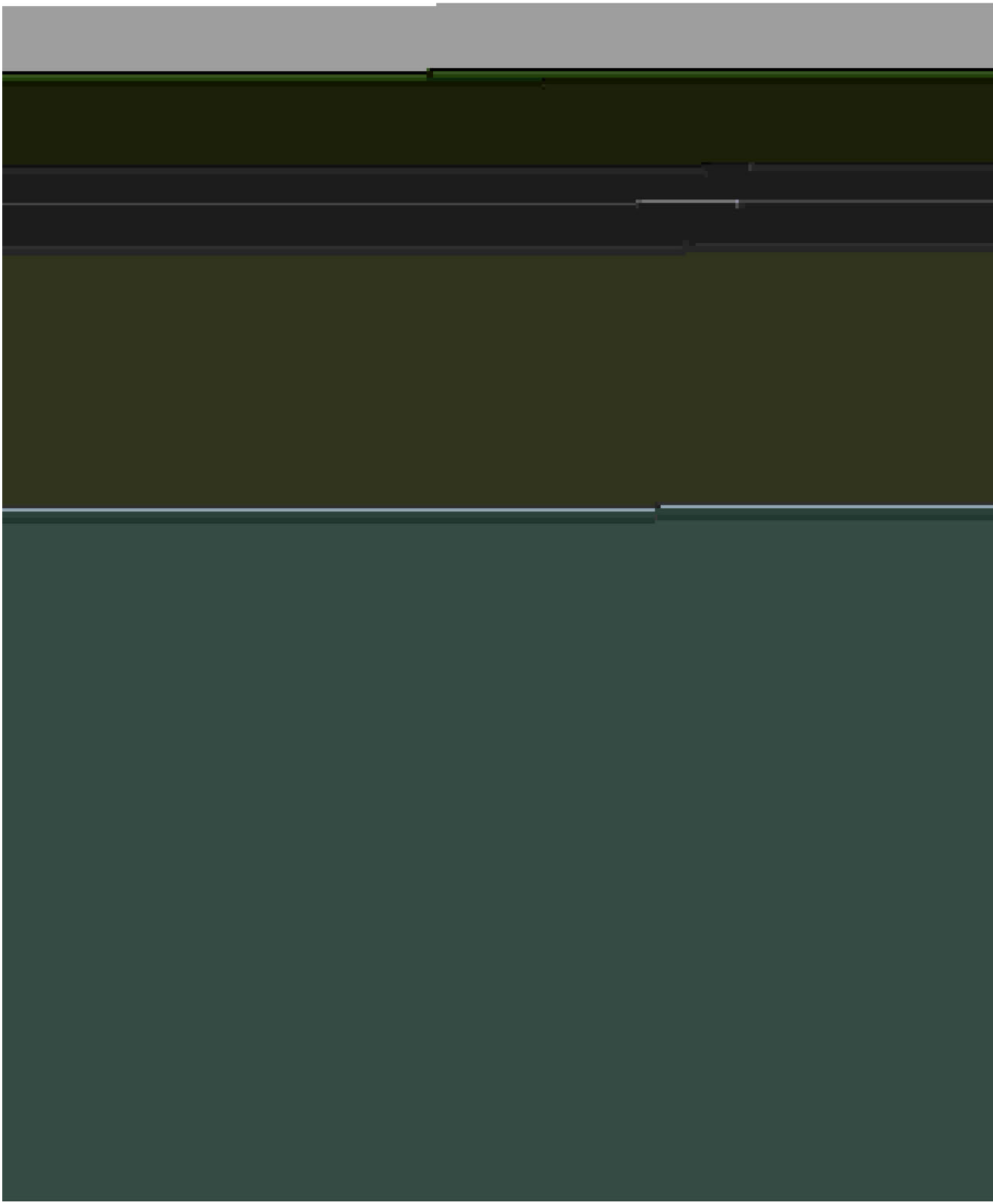

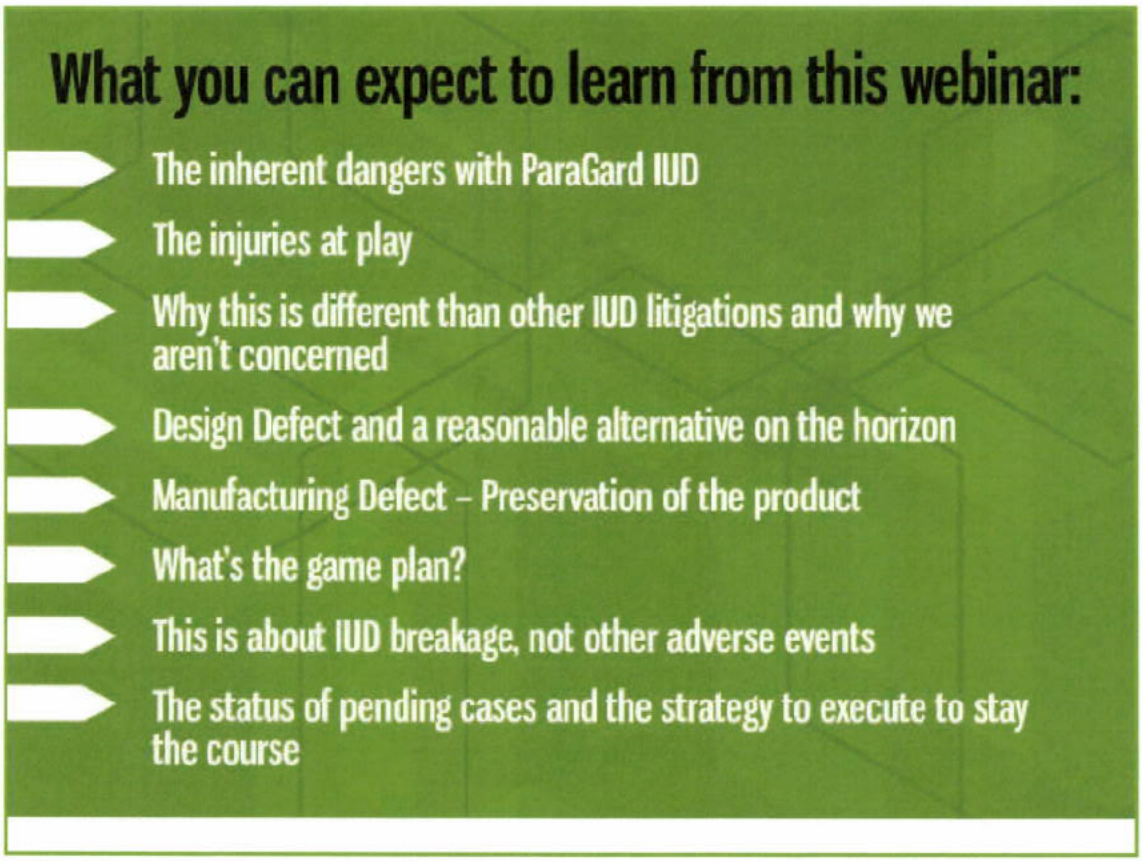
What you can expect to learn from this webinar:
The inherent dangers with ParaGard IUD
The injuries at play
Why this is different than other IUD litigations and why we aren't concerned
Design Defect and a reasonable alternative on the horizon
Manufacturing Defect – Preservation of the product
What's the game plan?
This is about IUD breakage, not other adverse events
The status of pending cases and the strategy to execute to stay the course