IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE INJECTAFER PRODUCTS LIABILITY LITIGATION **This Document Relates To:** **CROCKETT v. LUITPOLD PHARMA., INC., NO. 2:19-cv-00276;** **KRUEGER v. LUITPOLD PHARMA., INC., NO. 2:19-cv-00984.**	**NO. 2:19-CV-00276-WB** **HON. WENDY BEETLESTONE**

DEFENDANTS AMERICAN REGENT, INC., DAIICHI SANKYO, INC., DAIICHI SANKYO US HOLDINGS, INC., AND VIFOR (INTERNATIONAL) AG'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO CONSOLIDATE CASES FOR TRIAL

Pursuant to the Court's June 28, 2021 Order (Doc. 203), Defendants American Regent, Inc. ("ARI"), Daiichi Sankyo, Inc. ("DSI"), Daiichi Sankyo US Holdings, Inc. ("DSUSH") and Vifor (International) AG ("Vifor") (together, "Defendants")[1] file this opposition to Plaintiffs' Motion for Rule 42 Consolidation (Doc. 205) ("Plfs.' Mot.") seeking a joint trial of the *Crockett* and *Krueger* cases.

I. INTRODUCTION

Jointly trying *Crockett* and *Krueger* would substantially prejudice Defendants, confuse the jury, and risk a result that may make judgment in both cases vulnerable to reversal and retrial.

[1] The American Regent, Inc. entity named as a defendant in the respective Third Amended Complaints ("TACs") of Ms. Crockett (Doc. 44, No 2:19-cv-00276-WB) and Ms. Krueger (Doc. 83, No. 2:19-CV-00984) was a wholly-owned subsidiary of Luitpold Pharmaceuticals, Inc. and no longer exists. To streamline its business, Luitpold Pharmaceuticals, Inc. merged this entity into itself on December 31, 2018. Thereafter, the surviving entity was renamed American Regent, Inc. In this response, "ARI" refers to the new surviving entity, the former Luitpold Pharmaceuticals, Inc., and the former American Regent, Inc.

Especially in the very first trial in this litigation, these downsides outweigh any efficiencies to be achieved by trial consolidation. The risk of jury confusion and prejudice to defendants is particularly high in prescription drug cases which involve products that have inherent risks and highly individualized decision-making of learned intermediaries. Even more so than with other products, juries cannot fairly assess the merits of injury claims involving prescription drugs in a vacuum, untethered to case-specific evidence. In fact, Plaintiffs highlighted the critical importance of case-specific evidence—and the special significance of the first trial—in their alternative proposal that *Krueger* jump ahead of the earlier filed *Crockett* to take the first single-plaintiff trial slot. (June 23, 2021 Pls.' Letter, attached as Ex. 1, at 5 (emphasis added).) Consolidation is not appropriate because there will be a substantial divergence in the witnesses, case-specific experts, and liability evidence in the *Crockett* and *Krueger* trials.

Each of these cases will involve witnesses and issues specific to each Plaintiff such as: (1) the decision-making that went into each prescribing physician's prescription of Injectafer, including the knowledge of each of the prescribing physicians about the general underlying medical conditions and Injectafer; (2) the content of the FDA-approved labeling at the time of each Plaintiff's administration of Injectafer; (3) the medical condition of each Plaintiff that lead to the prescription; (4) the timing of administration relative to each Plaintiff's alleged onset of symptoms; (5) each Plaintiff's prior medical history and the presence of other medical conditions that could give rise to the symptoms Plaintiff alleges independent of Injectafer; (6) each Plaintiff's alleged symptoms, their timing, course and treatment; (7) the damages alleged as a result; and (8) the different fact and expert witnesses to address these issues, which are different for each Plaintiff. Every one of those issues turns on proof specific to each individual Plaintiff. Indeed, it is precisely the critical nature of *case-specific* witnesses, which will make a consolidated trial meshing

unrelated case-specific issues more confusing for jurors, the Court and parties. Consolidating the two cases for trial would give Plaintiffs the opportunity to focus on the case they perceive to be stronger and diminish the jury's ability to judge each case on its own merit—or lack of merit.

Crockett and *Krueger* also differ in other critical ways affecting the admissibility and significance of liability evidence in each case. For example, a scientific study on which Plaintiffs rely to show Defendants' putative knowledge of and failure to warn adequately about the injury they allege was published *before* Ms. Krueger's Injectafer prescription but *after* Ms. Crockett's. Additionally, wording in the Injectafer labeling that Plaintiffs say "grossly mischaracterize[d]" the risk of their claimed injury was changed *after* Ms. Crockett's prescription, which should be inadmissible in her case that the jury would nonetheless learn of if her case is tried with Ms. Krueger's. (*Krueger* TAC ¶ 77; *Crockett* TAC ¶ 81.)

Plaintiffs want these cases consolidated precisely to allow them to obscure and minimize the crucial case-specific issues, as well as potentially conflate the facts from one claim to the other. Merely instructing jurors to compartmentalize and selectively disregard evidence is a wholly inadequate fix. Jurors' inability or unwillingness to separate and selectively consider evidence plaintiff-by-plaintiff significantly increases the likelihood they will unconstitutionally award punitive damages to one plaintiff based on harm to another. Further, data on single- versus multi-plaintiff trials in mass tort litigation show that consolidation disproportionately benefits plaintiffs, resulting in more and higher plaintiffs' verdicts. **Indeed, Plaintiffs cite no cases in which a court consolidated the first trial in a prescription drug products liability case.** Consolidation of the first two trials in this pharmaceutical product liability litigation will be an outlier. And a verdict in either or both Plaintiffs' favor will not have the intended effect of helping to resolve the docket.

Plaintiffs invoke efficiency and a pandemic-related backlog. But they fail to grapple with the practical realities of a joint trial, or persuasively explain why purported marginal gains in efficiency – which would markedly increase the chance that any judgment for Plaintiffs would be subject to reversal on appeal – warrant tilting the playing field in their favor in the very first Injectafer trial. Defendants respectfully ask the Court to deny Plaintiffs' motion.

II. FACTS AND PROCEDURAL HISTORY

Plaintiffs sue for personal injuries allegedly caused by the prescription medication Injectafer, an iron replacement product administered intravenously, and indicated for the treatment of iron deficiency in adults who have intolerance to or an unsatisfactory response to oral iron or who have non-dialysis dependent chronic kidney disease. (*Krueger* TAC ¶ 50; *Crockett* TAC ¶¶ 59, 113.) The United States Food and Drug Administration ("FDA") approved Injectafer in 2013 and it remains on the market today. (*Krueger* TAC ¶¶ 60, 64; *Crockett* TAC ¶¶56, 77.) Plaintiffs allege they developed severe levels of hypophosphatemia ("HPP"), or low blood phosphorus, from taking Injectafer as prescribed to treat iron deficiency anemia. Before approving Injectafer, the FDA was aware of the risk of HPP, and the Injectafer label has always informed physicians of the condition as a potential adverse reaction. (*E.g. Krueger* TAC ¶¶ 77–78; *Crockett* TAC ¶¶ 77-79.) Although the Injectafer labeling always has warned about HPP, Plaintiffs assert that the FDA-approved labels inadequately warned physicians of "Severe HPP" or "clinically important hypophosphatemia." (*Krueger* TAC ¶ 78; *Crockett* TAC ¶79.) Both Plaintiffs plead causes of action for negligence, negligent failure to warn, negligent design defect, negligent misrepresentation, and fraud. (*Krueger* TAC ¶¶ 100–173; *Crockett* TAC ¶¶102-169.)

Crockett and *Krueger* are among 84 related cases consolidated by agreement and with approval of the Court for pretrial purposes only. (*See* Apr. 6, 2021 Order (Doc. 186, No. 2:19-cv-

00276).) When Plaintiffs sought consolidation pursuant to Federal Rule 42, Defendants made plain any agreement to consolidate would be for pretrial discovery purposes only. At the April 29, 2021 telephonic status conference, the Court asked the parties to submit proposed trial dates for *each* one of the four Group 1 cases. The parties submitted a joint letter to the Court proposing four sets of separate *Daubert* hearings and trials dates for the four Group 1 cases (May 13, 2021 Joint Letter), for which they requested that the Court set aside four separate trial dates. Consolidating cases for trial was never raised by Plaintiffs' counsel. After one of the Group 1 cases was dismissed, the parties notified the Court that the fourth set of dates was no longer needed, and also requested additional time to propose the sequence of cases for the three trial dates that had already been requested for the remaining three Group 1 cases, including *Crockett* and *Krueger*. (May 21, 2021 Joint Letter regarding Group 1 trial dates, attached as Ex. 2.)

On June 23, 2021, Plaintiffs submitted a letter brief asking the Court,[2] for the first time, to consolidate *Crockett* and *Krueger* for the first trial in the litigation, or, alternatively, that it set the later-filed *Krueger* for trial first. (Ex. 1.) At a telephonic status conference on June 28, 2021, the Court indicated it was disposed to try *Crockett* and *Krueger* jointly and permitted briefing from the parties.

[2] Defendants initially proposed the order of the trials should be *Crockett*, *Atkinson*, *Krueger*, which was the order in which they were filed. The parties exchanged several emails regarding Defendants' proposal before Plaintiffs actually proposed a consolidated trial or, in the alternative, that the order of the trials should be *Krueger*, *Crockett*, and *Atkinson*. Defendants responded that that a consolidated trial was not a proper suggestion since the parties' joint motion for consolidation was—by agreement—to establish consolidated proceedings *for pretrial purposes only*, and the issue before the Court to be addressed by the Parties was the assignment of each Group 1 cases to the three jointly proposed and agreed upon trial dates. Defendants recognize that it is certainly the Court's prerogative to determine cases can be consolidated for trial, but Defendants thought this explanation was necessary in light of footnote 1 on page 2 of Plaintiffs' motion.

III. ARGUMENT

A. Plaintiffs have the burden to justify consolidation.

Rule 42 authorizes courts to consolidate actions, including for trial, if they involve a common question of law or fact. Fed. R. Civ. P. 42(a). But while the existence of common issues is a threshold requirement, "their mere presence does not compel consolidation." *Farahmand v. Rumsfeld*, No. CIV.A. 02-1236, 2002 WL 31630709, at *1 (E.D. Pa. Nov. 20, 2002). Rather, in exercising its discretion on the matter of consolidation, a court should weigh any benefits of efficiency against the potential for confusion and prejudice. *Id.* at *2 (citing, *inter alia*, *In re Consolidated Parlodel Litig.* ("*In re Parlodel*"), 182 F.R.D. 441, 444 (D.N.J. 1998)); *see also* 9A Wright & Miller, *Fed. Prac. & Proc.*, § 2383 (3d ed. 2010) (consolidation for trial unwarranted if it "will lead to confusion or prejudice in the effective management or trial of one or more of the cases"). Consolidation under Rule 42 is "a matter of 'convenience and economy in administration,'" and is not intended to "change the rights of the parties." *Pac-West Distrib. NV LLC v. AFAB Indus. Serv., Inc.*, No. 19-3584, 2020 WL 4470447, at *9 (E.D. Pa. Aug. 4, 2020) (denying motion to consolidate cases that would "add[] a notable layer of complication, claims, and facts") (citing *In re TMI Litig.*, 193 F.3d 613, 724 (3d Cir. 1999)). Thus, goals of convenience and economy "must yield to a paramount concern for a fair and impartial trial." *In re Parlodel*, 182 F.R.D. at 444 (citation omitted).

Plaintiffs seek consolidation and they have the burden to show why its benefits outweigh the dangers of jury confusion and prejudice to Defendants.[3] *Farahmand*, 2002 WL 31630709 at *1. They have not met that burden. Rather, the "paramount concern for a fair trial" outweighs

[3] Defendants do not dispute that a court may consolidate cases, even *sua sponte*. (*See* Pls.' Mot., Dkt. 205, at 2, 4.)

whatever convenience and economy that jointly trying *Crockett* and *Krueger* would achieve. *In re Parlodel*, 182 F.R.D. at 444.

B. Early consolidated trials in coordinated litigation magnify the prejudice to defendants.

The trial at issue will likely be the first Injectafer trial anywhere. Courts and commentators have recognized that caution is warranted before consolidating cases for trial early in mass tort litigation. "If there are few prior verdicts, judgments, or settlements, additional information may be needed to determine whether aggregation is appropriate." Federal Judicial Center, Manual for Complex Litig. ("Manual"), § 22.314 at 359 (4th ed. 2004); *see also, e.g.*, *In re Levaquin Prods. Liab. Litig.*, No 08-1943, 2009 WL 5030772, at *3 (D. Minn. Dec. 14, 2009) (denying motion to consolidate as premature where "the exact factual and legal contours" of the plaintiffs' claims were "still undefined," and the merits had "not been tested in trial, in dispositive motions, or through some out-of-court resolution"). This Court declined to find that a class action was a superior means of adjudicating multiple tobacco cases based on similar reasoning:

> If there existed a prior track record of trials in these types of cases, the Court would be able to make a more accurate determination as to judicial efficiency. The Court could refer to the actual issues and problems that arise in these cases, instead of being forced to speculate as to what these issues and problems may be.

Arch v. Am. Tobacco Co., Inc., 175 F.R.D. 469, 495 (E.D. Pa. 1995) (citing *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 749–50 (5th Cir. 1996)); *see also In re Parlodel*, 182 F.R.D. at 445 (finding that the analysis of predominance in class action cases applies in the context of consolidation) (citing *Hasman v. G.D. Searle & Co.*, 106 F.R.D. 459, 461 (E.D. Mich. 1985)).

Although this coordinated litigation is not an MDL or a putative class action, and it does not involve hundreds or thousands of cases as in many mass torts, it shares some features with these types of litigation, such as coordinated procedures and discovery. Also, the Court has ordered the parties to meet and confer regarding a process for selecting "a bellwether pool of Consolidated

Cases." (May 17, 2021 Order (Doc. 196) at ¶ 8.) A bellwether case "is a test case," designed to "produce representative verdicts and settlements" from which the parties can "gauge the strength of the common MDL claims to determine if a global resolution of the MDL is possible." *In re: Tylenol (Acetaminophen) Mktg., Sales Practices and Prod. Liab. Litig.*, No 2:13-md-02436, 2016 WL 4056026, at * (E.D. Pa. Jul. 27, 2016) (citing Manual §§ 16–21)). And while *Crockett* and *Krueger* are not bellwether plaintiffs[4], the first trials in coordinated litigation inevitably will function to some extent as "test cases" for the others, defining the "the exact factual and legal contours" of the claims and defenses. *In re Levaquin Prods. Liab. Litig.*, 2009 WL 5030772 at *3.

Whether early trials are single-plaintiff or multi-plaintiff matters in coordinated litigation because, simply put, consolidation benefits plaintiffs at the expense of defendants.[5] *See Castano v. Am. Tobacco Co.*, 84 F.3d 734, 746 (5th Cir. 1996) (stating that aggregation of cases "makes it more likely that a defendant will be found liable and results in significantly higher damage awards").

On this point, Plaintiffs do not meaningfully dispute that consolidation prejudices defendants—they instead tout "significant efficiencies" compared to the "very few complications" of a consolidated trial which "pale in comparison." (Pls.' Mot., Dkt. 205, at 6, 9.) They also cite

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[4] The Parties agreed to, and the Court ordered, that the Group 1 cases are not part of the bellwether cases. *See* Apr. 6, 2021 Order (Doc. 186, No. 2:19-cv-00276), at top of page 2.

[5] For example, in an analysis of 66 single-plaintiff trials conducted by MDL judges between 2009 and 2019, the authors found that 42 (63.6 percent) of verdicts were for defendants and 24 (36.5 percent) were for plaintiffs. John Beisner, Jessica Miller, Nina Rose, and Jordan Schwarz, *Trials and Tribulations, Contending with Bellwether and Multi-Plaintiff Trials in MDL Proceedings*, U.S. Chamber Institute for Legal Reform (Oct. 2019) at 8. By contrast, of seven multi-plaintiff trials tried to verdict in the same time period (involving 32 plaintiffs in total), 78.1 percent resulted in a plaintiffs' verdict and only 21.9 percent resulted in a defense verdict. *Id.* at 8–9. What's more, in *none* of the multi-plaintiff trials did the jury find in favor of some plaintiffs but not others. *Id.* at 9, 9–12 (discussing outcomes of each multi-plaintiff case in detail). This data confirms the plaintiffs-side advantage of consolidation noted by courts and commentators.

an unpublished order in which the Northern District of Florida consolidated three cases for the first trial in the 3M combat earplugs products liability MDL. (Pls.' Mot., Dkt. 2015, at 7–8: Ex. A (citing and attaching Order, *In re 3M Combat Arms Earplug Prod. Liab. Litig. ("In re 3M")*, Case No. 3:19md2885 (Dec. 30, 2020).) But the 3M earplug MDL did not involve the unique issues raised by prescription drug cases involving learned intermediaries. In fact, the court later rejected the defendants' argument that the military, which supplied the earplugs, constituted a sophisticated intermediary, expressly contrasting it with "physicians [who] through specialized education and experience, *are generally in the best position to evaluate the potential risks and benefits of a particular drug or medical device and to advise their patients accordingly*." *In re 3M*, No. 3:19md2885, 2021 WL 2476651, at *1–3 (N.D. Fla. June 17, 2021) (emphasis added). Federal courts also have declined to consolidate prescription drug cases for trial because they raise highly individualized issues that increase the risk of jury confusion and prejudice to defendants. *See* cases cited *infra* at p 9-11, 14-15.

Similarly, "[t]he majority of courts to address joinder in the context of drug liability cases have found that basing joinder merely on the fact that the plaintiffs ingested the same drug and sustained injuries as a result thereof is insufficient to satisfy Rule 20(a)'s [same transaction/occurrence] requirement." *Cumba v. Merck & Co., Inc.*, 2009 WL 1351462, at *1 (D.N.J. May 12, 2009) (Cavanaugh, J.); *accord, e.g.*, *McGrew v. Howmedica Osteonics Corp.*, 2015 WL 159367, at *2-3 (S.D. Ill. Jan. 13, 2015) (Yandle, S.) ("In the medical products liability context, 'medical and legal causation present formidable obstacles under Rule 20.'" (citation omitted)); *Hill v. Eli Lilly & Co.*, 2015 WL 5714647, at *6-8 (S.D. Ind. Sept. 29, 2015) (Magnus-Stinson, J.) ("keeping with the consistent reluctance of federal courts to treat products liability claims as arising from the same transaction or occurrence merely because they relate to the same

medicine," plaintiffs' "claims do not arise from a common transaction or occurrence" and "common questions of law or fact are [] eclipsed by the individualized issues that dominate Plaintiffs' claims, as such claims "likely . . . turn on," among other things, "whether each Plaintiff's medical provider . . . conveyed [defendant's] warning to their patient"); *In re Accutane Prod. Liab. Litig. MDL No. 1626*, 2012 WL 4513339, at *1 (M.D. Fla. Sept. 20, 2012) (Moody, J.) ("highly individualized facts" and differences of "each individual" plaintiff's case have led many "federal courts" to "hold that product liability cases are generally inappropriate for multi-plaintiff joinder") (collecting cases); *Wyeth-Ayerst Labs. v. Caldwell*, 905 So.2d 1205, 1209 (Miss. 2005) (reversing denial of motion to sever, stating "plaintiffs may not simply allege injuries stemming from the same drug manufacturer" for joinder and, instead, "must also show, among other things, how they were exposed to those drugs, which" would require "introducing evidence of [plaintiffs'] unrelated interactions with various doctors); *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So.2d 31, 48 (Miss. 2004) (joinder of plaintiffs "prescribed [a drug] by different physicians in different amounts for different ailments" was improper); *Prempro Prods. Liab. Litig.*, 417 F. Supp. 2d 1058, 1060 (E.D. Ark. 2006) (Wilson, J.) (joinder improper when "[t]he only thing common among Plaintiffs is that they took an HRT drug" and they "were prescribed different [] drugs from different doctors, for different lengths of time, in different amounts, and suffered different injuries"); *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d 563, 651-54 (S.D. Tex. 2005) (Jack, J.) (recognizing joinder of plaintiffs who were merely prescribed the same allegedly defective drug is improper); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, 294 F. Supp. 2d 667, 678-79 (E.D. Pa. 2003) (Bartle, J.) (emphasizing that plaintiffs "were prescribed different diet drugs by different doctors at different times," and "[o]ur decision comports with those of other courts, who have similarly found misjoinder where the only connection among plaintiffs is their

use of certain pharmaceuticals"); *In re Baycol Prods. Litig.*, 2003 WL 22341303, at *4 (D. Minn. 2003) (Davis, J.) (plaintiffs' claims based on "the fact that plaintiffs were residents of the same state . . . who alleged claims . . . based on injuries suffered as a result of ingesting [defendant's drug], without more, did not satisfy the joinder requirements of Rule 20); *In re Baycol Prods. Litig.*, 2002 WL 32155269, at *2 (D. Minn. July 5, 2002) (Davis, J.) (denying joinder in pharmaceutical drug case based on, among other factors, the "many differences between the unique histories of each plaintiff"); *In re Rezulin Prods. Liab. Litig.*, 168 F. Supp. 2d 136, 145-47 (S.D.N.Y. 2001) (Kaplan, J.) (joinder of plaintiffs receiving the same pharmaceutical drug was inappropriate, as (among other factors) "[t]hey do not allege that they received [defendants' drug] from the same source or that they were exposed to [defendants' drug] for similar periods of time").

Plaintiffs cite no cases in which a court consolidated the first trial in a prescription drug products liability case – presumably they would have if one existed. The undersigned counsel in their many years of experience defending pharmaceutical cases are not aware of a multi-plaintiff trial being set first in a coordinated or consolidated litigation. Plaintiffs cite several asbestos cases, but the distinctions between asbestos and FDA-approved prescription drugs aside, asbestos already was viewed as a "mature" mass tort over thirty years ago. *See, e.g.*, Francis E. McGovern, *Resolving Mature Mass Tort Litigation*, 69 B.U. L. Rev. 659 (1989). Plaintiffs primarily rely on a prescription device case, *Campbell v. Boston Scientific Corp.*, 882 F.3d 70 (4th Cir. 2018), in which the Fourth Circuit found no abuse of discretion in consolidating four prescription device (pelvic mesh) cases for trial. But pelvic mesh litigation against Boston Scientific was not new—there had already been three single-plaintiff state court trials. *See* Ex. 3, *Albright v. Boston Sci. Corp.*, No. 12-0909, Dkt. 118 (Mass. Sup. Ct. July 29, 2014); Ex. 4, *Cardenas v. Boston Sci. Corp.*, No. 12-2912, Dkt. 110 (Mass. Sup. Ct. Sept. 4, 2014); Ex. 5,

Salazar v. Boston Sci. Corp., No. DC-12-14349-D (Tex. Dist. Ct. Sept. 8, 2014). The same is true in the other prescription device cases Plaintiffs cite.[6] *See* Ex. 6, *Seeno v. Mentor Corp.*, No. RF06264787 (Cal. Sup. Ct. Dec. 15, 2008); Ex. 7, *Herlihy-Paoli v. DePuy Ortho. Inc.*, No. 3:12-cv-04975 (N.D. Tex. Oct. 23, 2014); Ex. 8, *Nicholson v. Biomet*, No. 18-cv-3057, Dkt. 419 (N.D. Iowa Nov. 23, 2020); Ex. 9, *Bayes v. Biomet*, No. 4:13-cv-00800, Dkt. 363 (E.D. Mo. Nov. 24, 2020).

Plaintiffs also do not dispute that early trials in coordinated litigation have special significance. In fact, they implicitly acknowledge the point in their alternative proposal that the Court try the purportedly "best-suited" case first. (Ex. 1 at 5.) Their alternative argument has it backwards—the importance of the first trial weighs against letting one side choose a preferred case out-of-order. It also illustrates why consolidation of the first trial is inadvisable.

C. Case-specific issues in *Crockett* and *Krueger* weigh against consolidation.

The risk that consolidation will deprive the defendant of a fair trial is enhanced when "the evidence in one case is not relevant to the issues in the other" and thus will "create a likelihood of prejudice by confusing the issues." *Garanin v. City of Scranton*, Civil No. 3:19-CV-1275, 2019 WL 6875541, at *23 (M.D. Pa. Dec. 17, 2019) (quoting *Liberty Lincoln Mercury, Inc. v. Ford Mktg Corp.*, 149 F.R.D. 65, 81 (D.N.J. 1993) (internal quotation marks omitted)); *see also* Manual for Complex Litigation, Fourth, § 11.631 ("Unless common evidence predominates, consolidated trials may confuse the jury rather than promote efficiency."). Jury instructions on what evidence

[6] *See also Frankum v. Boston Sci. Corp.*, No. 1:15-cv-00091, 2015 WL 3832187 (W.D.N.C. June 22, 2015); *In re DuPuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11-md-2244, 2016 WL 10719395 (N.D. Tex. Jan. 8, 2016); *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, No. 4:08-md-2004, 2010 WL 797273 (M.D. Ga. Mar. 3, 2010); *Laughlin v. Biomet, Inc.*, No. ELH-14-1645, 2020 WL 1307397 (D. Md. Mar. 18, 2020).

is relevant to what Plaintiff and for what issues accomplish little when individual issues predominate. *See Malcolm v. Nat'l Gypsum Co.*, 995 F.2d 346, 349, 352 (2d Cir. 1993) (noting that the "jury was instructed on several occasions to consider each case separately and each juror was given a notebook for this purpose" but concluding that "the sheer breadth of the evidence made these precautions feckless in preventing jury confusion"); *Cain v. Armstrong World Indus.*, 785 F. Supp. 1448, 1455 (S.D. Ala. 1992) ("It is evident (unfortunately, in hindsight) that despite all the precautionary measures taken by the Court (e.g., juror notebooks, *cautionary instructions before, during and after the presentation of evidence*, special interrogatory forms) the joint trial of such a large number of differing cases both confused and prejudiced the jury." (emphasis added)).

The danger of jury confusion and prejudice to Defendants that jointly trying *Crockett* and *Krueger* would create outweighs considerations of economy and convenience in these cases for three reasons.

1. Prescription drug cases inherently require highly individualized analysis.

Prescription drug products liability cases require very individualized inquiry because they involve highly-regulated products with inherent risks that are accessible only through learned intermediaries who exercise professional judgment in prescribing them. Under Pennsylvania law, a prescription drug manufacturer must provide adequate warnings to the learned intermediary/prescribing physician, not the patient. *See Icollingo v. Ewing*, 282 A.2d 206, 288 (Pa. 1971); *Hahn v. Richter*, 673 A.2d 888, 890–91 (Pa. 1996); PA-JICIV 23.10. The extensive FDA approval process for such drugs reflects the complexity of the risk-benefit analysis—and highlights the critical importance of evidence concerning each learned intermediary. *See In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 143 (3d. Cir. 2017) ("A drug manufacturer seeking to market a new drug 'must submit a New Drug Application [NDA] to the federal Food

and Drug Administration (FDA) … and undergo a long, comprehensive, and costly testing process") (quoting *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013).) By contrast, the medical devices at issue in the cases on which Plaintiffs rely involve a less complex risk-benefit analysis, as reflected in the 510(k) "substantial equivalence" regulatory process that does not require clinical trials. *See Campbell*, 882 F.3d at 73.

Numerous courts have denied trial consolidation in prescription drug cases because they involve such individualized issues.[7] *See, e.g.*, In *re Parlodel*, 182 F.R.D. at 443–46 (denying trial consolidation and stating "consolidation may be inappropriate where individual issues predominate," such as "diverse medical histories," "different "injuries," "particular representations made by [defendants] to [each plaintiff's] particular treating physician," "geographic and temporal differences in [defendants'] marketing," and other "evidence of [defendants'] marketing practices [that] will be specific to each Plaintiff"); *Sherman v. Novartis Pharma. Corp.*, Nos. 2:14-cv-173-FtM-29DNF, 2:14-cv-205-FtM-29DNF, 2014 WL 4252275, at *1 (M.D. Fla. Aug. 28, 2014) (denying trial consolidation because "ultimately the damages at issue are unique" to each plaintiff); *Bowles v. Novartis Pharma. Corp.*, No. 3:12-cv-145, 2013 WL 663040, at *1-2 (S.D. Ohio Feb. 25, 2013) (denying trial consolidation because plaintiff-specific factors made consolidation

[7] In the Philadelphia Court of Common Pleas, General Court Regulation 2013-01 (which the Court issued after consideration of the views of the entire bar) precludes consolidation of mass tort cases: "Consolidation of mass tort cases shall not occur absent an agreement of all parties, except in the asbestos program in accordance with the protocols set forth herein below." (Ex. 10 (General Court Regulation 2013-01); Ex. 11 (Jan. 6, 2017 Order noting that the terms of General Court Regulation No. 2013-01 "shall remain in full force and effect").) For this reason, the Pennsylvania asbestos cases cited by Plaintiffs should not be considered by the Court as persuasive authority.

inappropriate, such as treatment "by different doctors," plaintiffs' "different risk factors," and the timing of plaintiffs' prescriptions).[8]

2. A joint trial of *Crockett* and *Krueger* would hamper the jury's ability to fairly consider each Plaintiff's claims on their own merits.

Plaintiffs assert that consolidating *Crockett* and *Krueger* for the first Injectafer trial would cause minimal jury confusion and prejudice to Defendants because the two cases "are 'based largely on the same facts,'" and "share *substantial* overlap" in relevant evidence. (*See* Pls.' Mot., Dkt. 205, at 4 (emphasis in original), 5 (citing *Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304, 1314 (11th Cir. 2017))).[9] But just as in other prescription drug cases, the case-specific issues in

[8] *See also, e.g.*, *Dopson-Troutt v. Novartis Pharma. Corp.*, No. 8:06-CV-1708-T-24-EAJ, 2012 WL 7659710, at *1 (M.D. Fla. Oct. 16, 2012) (denying trial consolidation because "the benefits of consolidation do not override the substantial risk of prejudice and confusion where, as here, individualized questions of law and fact predominate"); *Michael v. Wyeth, LLC*, No. 2:04-0435, 2011 WL 1527581, at *2-3 (S.D. W.Va. Apr. 20, 2011) (denying trial consolidation because the "the factors weighing in favor of consolidation for trial are overborne by 'risks of prejudice and possible confusion,' such as "unique medical and famikliy history[ies]," "varying doses," "different doctors, at different times, based on different sources of information about [] risks and benefits," taking the drug "for different lengths of time," and "different pre-existing risk factors") (citation omitted)); *Janssen Pharma, Inc. v. Bailey*, 878 So.2d 31, 48 (Miss. 2004) (reversing judgment in 10-plaintiff consolidated trial, finding "little doubt" consolidating trials unfairly prejudiced the defendant by overwhelming the jury with testimony and "creating a confusion of the issues," including claims involving different temporal scopes, pre-existing conditions, and ages of plaintiffs).

[9] Plaintiffs also contend that a consolidated trial would save the Court and the parties three weeks of time by having one consolidated five-week trial versus two separate plaintiff trials in eight weeks. Defendants believe the single plaintiff trials can be conducted much more quickly, particularly the second trial, which will follow the rulings of the first, thus negating Plaintiffs' claimed time savings. Moreover, any potential time saved ignores that consolidation under these circumstances would be subject to review on appeal and potential retrial if consolidation were deemed improper.

Crockett and *Krueger* are of greater significance and create a potential for unfair prejudice and juror confusion that outweigh considerations of judicial economy and convenience.

For example, the evidence will show that Ms. Crockett tried but was unable to tolerate an alternative injectable treatment for her iron deficiency, a fact that affected her physician's decision to prescribe Injectafer. *See, e.g.*, Ex. 12, Dr. Go Dep., at 75:19-76:3. In fact, her prescriber testified that, even knowing what he knows now, he *still* would have prescribed Injectafer for her based on her unique needs and medical history. Ex. 13, Dr. Go Dep., at 78:10-25. The jury should hear this testimony unadulterated by the differing—and wholly irrelevant—testimony of Ms. Krueger's health care providers. Plaintiffs cannot credibly argue that differing testimony by the prescribing physicians is merely one of the "slight differences in individual causation" that are of minor importance as compared to the ostensibly common issues. (*See* Pls.' Mot., Dkt. 205, at 8–9.) Their insistence (in their alternative proposal) that *Krueger* is the "best-suited" for the first trial because the physicians will testify in person refutes any such argument. And it illustrates why diluting the videotaped testimony of Ms. Crockett's prescriber by pairing it with the irrelevant testimony of a different prescriber for Ms. Krueger gives Plaintiffs an unfair strategic advantage. That the *Krueger* testimony will be live only increases the advantage—and the prejudice to Defendants.

Other key evidence will differ between the two cases. After Ms. Crockett's Injectafer prescription and alleged injury in 2017, but before Ms. Krueger's in 2018, the results of a large randomized, double-blind clinical trial performed at the request of the FDA addressing ferric carboxymaltose (the active chemical in Injectafer) and evaluating hypophosphatemia was published. (Ex. 14, N. Franklin Adkinson, *et al.*, *Comparative safety of intravenous ferumoxytol versus ferric carboxymaltose in iron deficiency anemia: A randomized trial*, Am. J. Hematol. 2018, 93:683–90.) While the study may be admissible on the issue of general causation in cases arising

before its publication, like *Crockett*, it and other post-2017 scientific articles should not be admissible in *Crockett* to support claims that Defendants "fraudulently concealed and intentionally omitted" material information from Ms. Crockett's prescribing physician, or engaged in intentional, malicious, or grossly negligent conduct that caused harm to Ms. Crockett. (*See Crockett* TAC ¶¶ 156, 168.)[10] Yet instructing the jury to consider evidence for a limited purpose only in one case but for any purpose in another, asks jurors to do the near-impossible.

In addition, the wording of a portion of the Injectafer labeling changed—to remove the word "asymptomatic" in connection with reductions in blood phosphorous—between Ms. Krueger's and Ms. Crockett's prescriptions. (*See Krueger* TAC ¶ 76 (referencing label change).) Plaintiffs reference the word "asymptomatic" seven times in their Complaints and cite it as proof that Defendants "grossly mischaracterize[d]" the risk of hypophosphatemia. (*Krueger* TAC ¶¶ 76-77, 79, 141, 159, 163; *Crockett* TAC ¶¶ 80-81, 83, 137, 155, 159.) But the label change should not be admissible in *Crockett* under Rule 407, which "instructs that evidence of a remedial measure taken subsequent to an injury, that would have made the injury less likely to occur, cannot be admitted to prove negligence, culpable conduct, defect, or the need for a warning or instruction." *Sikklelee v. Precision Airmotive Corp.*, --- F. Supp.3d ---, No. 4:07-CV-00886, 2021 WL 780817, at *26 (M.D. Pa. Mar. 1, 2021) (citing Fed. R. Evid. 407). Defendants dispute that the word "asymptomatic" significantly changed the information provided in the earlier label, but that is not the point. Plaintiffs bear the burden on a motion for consolidation, and their own Complaints signal

[10] Defendants in no way concede that Plaintiffs have legally sufficient evidence to proceed on any of their claims, including for fraud and punitive damages. For purposes of this motion, however, Plaintiffs bear the burden to show that their claims as pled may be jointly tried without undue confusion and prejudice to Defendants.

their intent to highlight a label change that should not be admissible in one of the cases they propose to try jointly.

In sum, prescription drug cases generally, and these two cases specifically, are ill-suited for consolidation. Plaintiffs fail to cite a single prescription drug case in which the court granted a motion to consolidate cases for trial. Merely repeating their own allegations as proof of commonality does not persuasively show that common issues and evidence will predominate over case-specific issues in these two cases. (*See* Pls.' Mot., Dkt 205, at 4–5.) Plaintiffs have not met their burden and should not obtain the strategic advantage of consolidating *Crockett* and *Krueger* to the prejudice of Defendants.

3. A joint trial of punitive damage claims risks violating due process.

Plaintiffs lack legally sufficient evidence supporting their claims for punitive damages, and Defendants will oppose submitting punitive damages to the jury. But if the jury is permitted to consider such damages, consolidating the claims of two unrelated plaintiffs raises the specter of a due process violation requiring reversal. In *Phillip Morris USA v. Williams*, the Supreme Court held that the Due Process Clause prohibits a jury from using "a punitive damages verdict to punish a defendant directly on account of harms it is alleged to have visited on nonparties." 549 U.S. 346, 355 (2007); *see also State Farm Mut. Auto. Ins. v. Campbell*, 538 U.S. 408 (2003); *BMW of North America, Inc. v. Gore*, 517 U.S. 599 (1996). In other words, a jury may not punish a defendant for wrongful conduct in the abstract; that conduct must be causally linked to the harm suffered by the plaintiff.

Tying allegedly "egregious" conduct to a given plaintiff's harm is an inherently individualized inquiry—as Plaintiffs' own allegations confirm. (*E.g.*, *Crockett* TAC ¶ 156 (alleging that Defendants made fraudulent representations to her prescribing physician, Dr. Go.)

Jointly trying cases in which case specific issues – particularly concerning causation – predominate negatively impacts the jury's ability to make this individualized inquiry. Courts "cannot authorize procedures that create an unreasonable and unnecessary risk" of jury confusion resulting in improper punitive damages awards. *Williams*, 549 U.S. at 347. The risk of a due process violation is an additional reason to deny consolidation, especially in the first Injectafer trial.

Defendants are not arguing there is a *per se* rule prohibiting consolidation when plaintiffs seek punitive damages. Some courts in medical device cases have found that jury instructions are adequate to address the due process concerns. *See, e.g., Campbell*, 882 F.3d at 76, (affirming compensatory and punitive damages awards in consolidated trial and stating that trial judge "bent over backwards" to avoid jury confusion). Prescription drug cases, however, involve a unique set of case-specific issues, as discussed above. Those issues raise the due process stakes and weigh against consolidation here. *Cf. McCoy v. Biomet Orthopedics, LLC*, Nos. ELH-12-1436, ELH-19-607, 2019 WL 6324558, at *7–8 (D. Md. Nov. 25, 2019) (rejecting argument that "due process forecloses consolidation" of punitive damages claims in medical device cases but denying consolidation because case-specific distinctions raised a "significant risk" that "spillover evidence" would prejudice the defendant).

In sum, when cases hinge on case-specific evidence – as Plaintiffs admitted these do by arguing that the trial availability of case-specific witnesses should determine trial order – there is a real chance that consolidation of punitive damages claims will lead to a due process violation and a verdict vulnerable to reversal.

IV. CONCLUSION

For the foregoing reasons, Defendants ask the Court to deny Plaintiffs' motion for trial consolidation.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Heather C. Giordanella, certify that on this 7th day of July, 2021, a true and correct copy of Defendants American Regent, Inc., Daiichi Sankyo, Inc., Daiichi Sankyo US Holdings, Inc., and Vifor (International) AG's Response In Opposition To Plaintiffs' Motion To Consolidate Cases For Trial was served via the Court's electronic filing system upon all counsel of record.

/s/ Heather C. Giordanella
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