IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., and
MERCK SHARP & DOHME LLC,

Plaintiffs,

v.

XAVIER BECERRA, U.S. Secretary of Health & Human Services, *et al.*

Defendants.

Civ. No. 1:23-01615 (CKK)

PLAINTIFFS' MOTION TO GOVERN FURTHER PROCEEDINGS

Plaintiffs respectfully move for an order to govern proceedings in this case following the amendment of the complaint to add Merck Sharp & Dohme LLC (MSD) as a second plaintiff. Despite their consent to an amendment that merely adds a subsidiary as a party and makes no other changes, Defendants insist that the amended complaint requires many additional months to re-brief the pending summary judgment motions, one of which is already fully briefed. But the amendment has no substantive effect on those motions; it merely moots a procedural objection to simplify the parties' dispute. Neither the law nor common sense supports Defendants' effort to stall resolution of this time-sensitive case. When pressed, Defendants failed to state a single reason why they need any more time to supplement the briefing, let alone completely re-do it. That is because no such reason exists. The Court should reject what is plainly a delay tactic.

1. On June 6, 2023, Plaintiff Merck & Co., Inc. (Merck) filed this action seeking declaratory and injunctive relief against Defendants (the Government). ECF 1.

2. The parties agreed that Merck's complaint presented legal questions about the constitutionality of a federal statute, which could properly be resolved through dispositive motions, without the need for discovery. The parties accordingly negotiated and proposed a schedule for cross-motions for summary judgment that would allow all issues to be fully briefed by November

21, 2023, thus avoiding the need for Merck to seek preliminary relief. The parties also requested that the Court dispense with the Government's obligation to file an Answer. ECF 13. This Court approved the briefing schedule and agreed that the Government need not file an Answer. ECF 14.

3. Consistent with the scheduling order, Merck filed its motion for summary judgment on July 11, 2023. ECF 23. Also consistent with the scheduling order, the Government filed its opposition and cross-motion two months later, on September 11, 2023. *See* ECF 24.

4. In its opposition and cross-motion, the Government defended the constitutionality of the statute. It also argued that Merck lacks prudential standing because, under guidance that Defendant CMS issued *after* Merck filed its complaint, the proper plaintiff is supposedly a wholly owned Merck subsidiary—namely, MSD. *See* ECF 24-1 at 18–22.

5. In its opposition-reply filed today, Merck explains why that prudential objection is misguided for a host of reasons. ECF 52, Part I.A. But, to streamline the issues this Court needs to resolve, Merck also filed an amended complaint that merely adds MSD as a second plaintiff. ECF 51. The Government consented in writing to that amended complaint. *See* Exh. A; Fed. R. Civ. P. 15(a)(2); *see also, e.g.*, *Mullaney v. Anderson*, 342 U.S. 415, 416–17 (1952) (allowing addition of plaintiffs to cure asserted standing defect, even on appeal).

6. MSD respectfully joins in Merck's previously filed motion for summary judgment and statement of undisputed facts, and asks the Court to treat that motion as filed on behalf of both Plaintiffs. Doing so would impose no prejudice on the Government, because the constitutionality of the statute does not depend on the plaintiff's identity. Nothing in the merits analysis is affected by this addition. And the Government has conceded that MSD has prudential standing even if Merck does not. *See* ECF 24-1 at 19. Briefing on Merck's summary judgment motion is complete; there is no reason for MSD to file duplicative briefs on the identical claims.

7. There is no need for the Government to repeat its cross-motion, either, just because a second plaintiff has now joined the same two claims challenging the statute's constitutionality. As to the merits, nothing in the Government's cross-motion depends on whether the plaintiff is Merck or MSD. And again, the Government has admitted that MSD would be a proper plaintiff to assert these very claims. Plaintiffs therefore request that the Court treat the Government's cross-motion as seeking judgment as to MSD in addition to Merck. Both Plaintiffs joined the opposition to that motion earlier today. The Government has until November 21 for its reply, per the agreed-on schedule. Notably, that deadline—33 days from now—gives the Government *more time* than the usual 14 days to respond to an amended complaint. *See* Fed. R. Civ. P. 15(a)(3).

8. The Government's position is as follows: "Defendants consent to the filing of an amended complaint. The filing of an amended complaint, however, necessarily overtakes the previous complaint and the parties' previous motions for summary judgment. Accordingly, Defendants do not consent to a continuation of briefing on those motions which were filed with respect to an inoperative complaint (and in Plaintiffs' case, by different parties). As Defendants explained to Plaintiffs, Defendants are open to reaching agreement on a sensible schedule for further proceedings, but any delays that now result from the filing of an amended complaint are attributable to Plaintiffs' failure to identify the proper parties to bring this lawsuit."

9. The parties' correspondence is attached as Exhibit A. Although the Government fails to identify any substantive reason why further briefing is required, it insists on restarting the briefing from scratch—and further claims that other obligations now preclude it from completing that briefing until *months* beyond the agreed date of November 21, 2023. The Government is wrong on the law, and it will suffer no prejudice from adhering to the schedule it jointly proposed, whereas starting over would impede the Court's ability to render a timely ruling.

10. First, although an amended complaint supersedes an original complaint, that does not mean the amendment automatically wipes out all pending motions. "To hold otherwise would be to exalt form over substance." Wright & Miller, FEDERAL PRAC. & PROC. § 1476. Courts thus routinely recognize that an amended complaint *does not* moot or supersede a pending dispositive motion—whether under Rule 12 or Rule 56—except insofar as the amendment actually affects the substantive arguments in that motion.[1] And that is especially true with respect to "[s]ummary judgment motions," which "are not directed at pleadings, but at claims." *United Sec. Fin. Corp. v. First Mariner Bank*, 2017 WL 3309690, at *5 (D. Utah Aug. 2, 2017).

[1] As to motions to dismiss, *see, e.g.*, *MSA Prod., Inc. v. Nifty Home Prod., Inc.*, 883 F. Supp. 2d 535, 539 (D.N.J. 2012) ("The filing of an amended pleading does not render a motion to dismiss moot"); *Jordan v. City of Philadelphia*, 66 F. Supp. 2d 638, 641 (E.D. Pa. 1999) (similar); *Duran v. United States*, 2021 WL 10338166, at *1 n.1 (S.D. Tex. Nov. 24, 2021) ("Whether an amended complaint moots a motion to dismiss is discretionary and … the court simply may consider the motion as being addressed to the amended pleading."); *Bouknight v. KW Assocs., LLC*, 2016 WL 3344336, at *1 n.2 (D.S.C. June 16, 2016) ("the Second Amended Complaint does not moot Defendants' motion to dismiss"); *Country Mut. Ins. Co. v. Med. Weight Loss Ctrs., LLC*, 2019 WL 2251201, at *2 (E.D. Mo. Feb. 8, 2019) (similar); *Tower Ins. Co. v. Edwards Zubizarreta P'ship*, 2011 WL 5509989, at *1 n.2 (N.D. Tex. Nov. 10, 2011) (similar); *Baker v. USD 229 Blue Valley*, 2020 WL 1233731, at *5 n.8 (D. Kan. Mar. 13, 2020) (similar); *Pettaway v. Nat'l Recovery Sols., LLC*, 2019 WL 13243083, at *3 (S.D.N.Y. May 20, 2019) (similar); *see also Montgomery v. Flandreau Santee Sioux Tribe*, 2006 WL 482479, at *1 (D.S.D. Feb. 27, 2006) (amended complaint "does not moot the motions filed" where amendment merely added plaintiffs).

As to Rule 56 motions, *see, e.g.*, *Alaska Excursion Cruises, Inc. v. United States*, 603 F. Supp. 541, 548 (D.D.C. 1984) (allowing amendment but still deciding "legal issues presented by the heretofore filed motions for summary judgment"); *TAS Distr. Co. v. Cummins, Inc.*, 676 F. Supp. 2d 719, 720 (C.D. Cal. 2009) (amended complaint did not moot summary judgment motion since count was "substantively identical"); *Peterson v. Medtronic, Inc.*, 2020 WL 6999225, at *3 n.1 (W.D. Tenn. Sept. 30, 2020) (similar); *Jones v. Mnuchin*, 2020 WL 3237516, at *1 n.3 (S.D. Ga. June 15, 2020) (similar); *McCall v. FedEx Corp.*, 2018 WL 1565607, at *2 (S.D. Ohio Mar. 30, 2018) ("The filing of an amended complaint does not render the pending motion for summary judgment moot unless the motion pertained to claims that were removed in the Amended Complaint."); *Barrett v. Pioneer Nat. Res. USA, Inc.*, 2017 WL 10591359, at *2 (D. Colo. Nov. 29, 2017) (similar); *Kirk v. IRS*, 1998 WL 681457, at *1 (D. Ariz. Aug. 17, 1998) (court has "discretion to consider a motion for summary judgment" filed pre-amendment); *Scott v. Wollney*, 2021 WL 4202169, at *4 (N.D. Tex. Aug. 28, 2021) (amended complaint did not moot "pending motions for summary judgment because the claims addressed by their motions remain the same").

11. Particularly when the only amendment is to add a plaintiff, the litigation need not be upended. *See, e.g.*, *Enyart v. Karnes*, 2010 WL 4823061, at *2 n.5 (S.D. Ohio Nov. 12, 2010) ("Because plaintiff's anticipated amended complaint only adds new parties that do not change the substantive allegations against defendant[,] … the anticipated amended complaint will not moot [defendant's] pending motion for summary judgment."). To the contrary, the Court "may *at any time*, on just terms, add or drop a party." Fed. R. Civ. P. 21 (emphasis added).

12. Second, it is clear here that the pending motions are substantively unaffected by the addition of MSD as a plaintiff. Again, the sole question in this case is whether the new drug "negotiation" program is facially unconstitutional. The nature of the challenge does not depend in any way on whether it is asserted by the parent or subsidiary. MSD would file exactly the same brief Merck already filed. On the merits, the Government too would file the same opposition and cross-motion; it cannot (and did not, in its correspondence with counsel) identify any way in which its substantive arguments would differ.

13. The only difference relates to the prudential standing objection, which applies to Merck but by all accounts is cured by MSD's addition. The Government's brief was only 35 pages (out of a total of 55 that were allowed), which means it did not omit any arguments as a result of including its five-page prudential standing objection. And, contrary to the Government's claim, this prudential standing hiccup is not Merck's fault. For one thing, the objection is without merit; Merck chose to amend simply to streamline the dispute and moot the need for the Court to address this procedural issue. *Supra* ¶ 5. For another, the objection allegedly arises from agency guidance that did not issue until two months *after* Merck filed its action. ECF 24-1 at 19. Thus, if anything, it is *the Government's* "maneuvers designed to insulate" its action "from review by this Court [that] must be viewed with a critical eye." *Knox v. SEIU*, 567 U.S. 298, 307 (2012).

14. There is accordingly no reason to wipe the slate clean and thereby delay resolution of this case. The Government will suffer no prejudice from allowing MSD to join Merck's pending motions. Its formalistic insistence on restarting the briefing from scratch thus appears to be solely an attempt to back out of the negotiated briefing schedule and delay adjudication of the merits. That is not only unwarranted—it is irresponsible. As the Government itself emphasizes, the Medicare "negotiation" program is a very significant public policy measure. *See* ECF 24-1 at 11–18. It presents serious constitutional questions that have been raised by a host of lawsuits around the country, with appellate litigation likely to follow. While this is not emergency litigation, it is plainly time sensitive. And Merck teed up these issues in a way that allows sufficient time for meaningful briefing and adjudication before the Program takes effect. The Government's approach would only force Merck to seek expedited preliminary relief, which benefits nobody.

15. Notably, in a related case, the parties (including the Government) filed a joint motion asking the District of Delaware to rule by March 1, 2024, to avoid the need for preliminary relief. *See AstraZeneca Pharms., LP v. Becerra*, No. 1:23-cv-931, Dkt. 15 (D. Del. Sept. 19, 2023). The court adopted that "Target Decision Date." *Id.* at ¶ 6. Plaintiffs here respectfully suggest that the same "target date" would be appropriate for this action—the first action to be filed challenging the IRA—but that goal would become untenable if all briefing had to begin afresh.

16. For these reasons, Plaintiffs respectfully request that the Court (i) allow MSD to join Merck's fully briefed motion for summary judgment; (ii) treat the Government's cross-motion for summary judgment as directed to MSD as well as Merck; (iii) maintain the agreed-on deadline of November 21, 2023, for the Government's reply in support of its cross-motion; and (iv) dispense with the Government's obligation to file an Answer to the Amended Complaint.

17. In the alternative, if the Court determines that all motions and briefs must be refiled, Plaintiffs request that the deadlines be set as follows: (i) Plaintiffs' motion for summary judgment: October 26, 2023; (ii) Government's opposition / cross-motion: October 30, 2023; (iii) Plaintiffs' opposition / reply: November 1, 2023; and (iv) Government's reply: November 21, 2023. The Government should not need more time than that to refile the same brief with a new caption, and it already knows from today's filing exactly what Plaintiffs will say in their opposition.

CONCLUSION

For the foregoing reasons, the Court should grant the relief set forth above in Paragraph 16, or in the alternative, the relief set forth in Paragraph 17.

Dated: October 19, 2023

Respectfully submitted,

/s/ Yaakov M. Roth
Yaakov M. Roth (D.C. Bar 995090)
Megan Lacy Owen (D.C. Bar 1007688)
Brinton Lucas (D.C. Bar 1015185)
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Counsel for Plaintiffs

EXHIBIT A

From: Sverdlov, Alexander V. <Alexander.V.Sverdlov@usdoj.gov>
Sent: Thursday, September 21, 2023 12:48 PM
To: Roth, Yaakov M. <yroth@JonesDay.com>; Pezzi, Stephen (CIV) <Stephen.Pezzi@usdoj.gov>; Coogle, Christine L. (CIV) <Christine.L.Coogle@usdoj.gov>
Cc: Lucas, Brinton <blucas@jonesday.com>; Owen, Megan L. <mlacyowen@jonesday.com>
Subject: RE: Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

Hi Yaakov,

Our default position would be that, upon the filing of a new complaint, the parties restart summary judgment briefing. Given our other IRA cases, however, we could not consent to a schedule that has us filing a reply brief in support of our motion before February, at the earliest. If you are amenable to something along those lines, we are happy to discuss specific dates. Otherwise, we ask that you represent our position to the Court in its entirety as stated in my prior email.

Best,
Aleks

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From: Roth, Yaakov M. <yroth@JonesDay.com>
Sent: Thursday, September 21, 2023 11:26 AM
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Cc: Lucas, Brinton <blucas@jonesday.com>; Owen, Megan L. <mlacyowen@jonesday.com>
Subject: [EXTERNAL] RE: Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

OK, but I'd still like to hear your specific proposal—if we can work it out without burdening the court, that seems preferable. You have rejected our proposal but have not specified how you'd like this to play out procedurally. Can you propose something?

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Sent: Thursday, September 21, 2023 11:23 AM
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Cc: Lucas, Brinton <blucas@jonesday.com>; Owen, Megan L. <mlacyowen@jonesday.com>
Subject: RE: Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

Yaakov,

I recognize that Plaintiffs in the Young case had sought summary judgment in the alternative before the amendment, but the government had not yet responded or filed its own motion. We are not trying to make things any more complicated than they need to be and are certainly not being discourteous—we consented to your request to amend the complaint and just have a disagreement with you about a procedural point, as parties sometimes do. We provided you both our explanation and our position to facilitate you filing a motion to obtain the relief that you seem to want. We are confident that, if you file such a motion, the court will provide us guidance soon.

Best,
Aleks

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Cc: Lucas, Brinton <blucas@jonesday.com>; Owen, Megan L. <mlacyowen@jonesday.com>
Subject: [EXTERNAL] RE: Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

Aleks,

You're not correct about the Young v. EPA case. Take a look at the docket. The dispositive motion was filed first; then the amended complaint adding the new party; and the new party simply joined the prior motion by way of the uncontested joinder notice that I sent you. Nobody, including DOJ, had any issue with that. There is no reason it has to be any more complicated than that here either. Since there are no substantive changes to the claims, the previous briefs can be brought into technical "conformance" through a simple, one-sentence notice to the court. Other than

delay for its own sake, what is the basis for restarting the process when the claims and arguments are exactly the same? I'm still not sure exactly what you're proposing—you want us to refile a new MSJ, identical but for the caption, and then you'd file a new opposition and cross-motion, identical but for dropping Part I? I fail to see what possible legitimate interest that serves, and I find it particularly discourteous given that we gave you as much time as you asked for in the negotiated schedule.

Thanks,
Yaakov

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Sent: Thursday, September 21, 2023 10:40 AM
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Cc: Lucas, Brinton <blucas@jonesday.com>; Owen, Megan L. <mlacyowen@jonesday.com>
Subject: RE: Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

Hi Yaakov,

Thanks for the flag. We think the circumstances of the case Brett identified are sufficiently different from what we have here that your proposed approach to the schedule will not work. Among other reasons, as we understand it, in that case the amendment came before any party filed a dispositive motion. Here, by contrast, when both sides have already cross-moved on the basis of the prior complaint we think some other kind of procedure would be required—namely, an order amending the existing schedule or otherwise bringing the briefs into conformance with the new complaint. Absent such relief from the Court, we would view the previous complaint and the pending motions as having been completely obviated; our only obligation under those circumstances would be to respond to the new complaint as required by Rule 15(a)(3).

As a practical matter, we understand that you may not want to restart the case in this way or to delay summary judgment briefing. And, given our scheduling obligations in the other IRA cases, I suspect we are likely to have a disagreement about how fast we could restart summary-judgment briefing in this case. That said, we are certainly open to reaching agreement on a sensible schedule for further proceedings, if you are amenable to an approach that sufficiently accounts for our other deadlines.

I understand from your prior emails that you likely do not want to proceed in this way—and instead want to continue on the current briefing schedule without regard to the fact that a new complaint has been filed. For the reasons explained above, we cannot consent to this approach. Accordingly, we think the best course in that circumstance would be for you to file some kind of motion with the court proposing that approach along with your amended complaint. If you do file such a motion, please reflect our position as follows, which we hope will obviate us from needing to file an actual opposition brief on this scheduling issue:

> "Defendants consent to the filing of an amended complaint. The filing of an amended complaint, however, necessarily overtakes the previous complaint and the parties' previous motions for summary judgment. Accordingly, Defendants do not consent to a continuation of briefing on those motions which were filed with respect to an inoperative complaint (and in Plaintiffs' case, by different parties). As Defendants explained to Plaintiffs, Defendants are open to reaching agreement on a sensible schedule for further proceedings, but any delays that now result from the filing of an amended complaint are attributable to Plaintiffs' failure to identify the proper parties to bring this lawsuit."

In sum, we consent to the filing of an amended complaint. But if you simply file an amended complaint without obtaining any additional relief, we plan to respond to the amended complaint in the manner contemplated by FRCP 15(a)(3).

Best,
Aleks

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From: Roth, Yaakov M. <yroth@JonesDay.com>
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Cc: Lucas, Brinton <blucas@jonesday.com>; Owen, Megan L. <mlacyowen@jonesday.com>
Subject: [EXTERNAL] RE: Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

Aleks, in case it helps, Brett Shumate told me that he had this happen recently in another DDC case involving DOJ, and they simply filed a notice (attached) by which the new plaintiff joined the previously filed MSJ. Neither DOJ nor the court took issue with that joinder. It seems to me like something similar would be the simplest path for us, but again, please let me know if you have a different preference.

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Subject: RE: Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

I get the formal point, but aside from the standing objection, I don't see that anything substantive would change about the claims or arguments. So I would think the parties could just agree to stand on the existing cross-motions notwithstanding the addition of the new party. I've done that before when amended complaints were filed after MTD briefing. From my perspective, this could be spelled out in a letter or notice, but I am open to alternative procedures if you have any in mind.

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Subject: RE: Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

Hi Yaakov,

Thanks for the clarification—that's helpful. It seems to us that, as a formal matter, any amended complaint would by necessity overtake the previously-filed motions for summary judgment. By definition, those motions are seeking relief with respect to the claims in the initial complaint and with respect to the original parties, and so would be rendered inoperative by the filing of a new complaint. There are, naturally, various procedural ways to address the mismatch, some of which may have a bigger effect on the briefing schedule than others. Hence our question about what kind of procedures you might have in mind.

Best,
Aleks

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From: Roth, Yaakov M. <yroth@JonesDay.com>
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Subject: [EXTERNAL] RE: Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

Thanks, Aleks. Yes, I'd imagine adding MSD to the caption, and adding a sentence in the Parties section to the effect that MSD is a wholly owned Merck subsidiary that holds the NDA for the drugs at issue. I don't see any reason why that would impact the MSJ briefing or schedule, but please let me know if you disagree.

--Yaakov

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Cc: Lucas, Brinton <blucas@jonesday.com>; Owen, Megan L. <mlacyowen@jonesday.com>
Subject: RE: Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

Hi Yaakov,

Thanks for flagging the issue. We think there is a good likelihood that we can reach agreement on the path forward. However, before we consent to any proposal we would like to have a better sense of how you think this amendment would impact the schedule in the case.

Are we correct to assume that the only change to the complaint you are proposing would be to add MSD as a Plaintiff, and to make whatever minimal conforming changes are necessary to effectuate that change to the caption? If so, how do you envision that amendment affecting the current MSJ briefing?

Best,
Aleks

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From: Roth, Yaakov M. <yroth@JonesDay.com>
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Cc: Lucas, Brinton <blucas@jonesday.com>; Owen, Megan L. <mlacyowen@jonesday.com>
Subject: [EXTERNAL] Merck & Co., Inc. v. Becerra et al. (DDC No. 23-cv-1615)

Dear Counsel,

Hope all is well. Although we don't agree with the standing objection raised in your brief last week, we plan to amend our complaint to add Merck Sharp & Dohme LLC (MSD) as a second plaintiff and thereby moot the objection. We think we can still amend as of right under FRCP 15(a)(1) given that your standing argument sounds in Rule 12(b)(1), but to avoid any doubt we would appreciate your written consent to the amendment. (We note that, at oral argument on Friday, Steve flagged amendment as a way of dealing with a similar issue in the Chamber case.) Otherwise, our alternative is to file a second action with MSD as the plaintiff and then seek to consolidate the two actions—that seems like more work for everyone to get to the same place. So, kindly let us know if Defendants will consent under FRCP 15(a)(2) to an amendment adding MSD as a plaintiff.

Thanks,
Yaakov

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., and
MERCK SHARP & DOHME LLC,

Plaintiffs,

v.

XAVIER BECERRA, U.S. Secretary of Health & Human Services, *et al.*

Defendants.

Civ. No. 1:23-01615 (CKK)

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION TO GOVERN FURTHER PROCEEDINGS

Good cause appearing, the Court hereby ORDERS:

1. Plaintiff Merck Sharp & Dohme LLC (MSD) is permitted to join the motion for summary judgment filed by Plaintiff Merck & Co., Inc. (Merck).

2. Defendants' combined cross-motion for summary judgment and opposition to Plaintiffs' motion is treated as directed to both Merck and MSD.

3. Defendants shall file a reply in support of their cross-motion by November 21, 2023, consistent with this Court's June 28, 2023 scheduling order.

4. Defendants need not file an Answer to the Amended Complaint.

SO ORDERED.

_____

HONORABLE COLLEEN KOLLAR-KOTELLY
UNITED STATES DISTRICT JUDGE